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

FORM 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2018

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 FOR THE TRANSITION PERIOD FROM TO**

Commission File Number 001-38624

Vaccinex, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**16-1603202**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
1895 Mount Hope Avenue Rochester, NY	**14620**
(Address of principal executive offices)	(Zip Code)

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

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

Title of each class	Name of each exchange on which registered
Common Stock, par value $0.0001 per share	Nasdaq Global Market

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the Registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. YES ☐ NO ☒

Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. YES ☐ NO ☒

Indicate by check mark whether the Registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. YES ☒ NO ☐

Indicate by check mark whether the Registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the Registrant was required to submit such files). YES ☒ NO ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405) is not contained herein, and will not be contained, to the best of Registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
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. ☐

Indicate by check mark whether the Registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). YES ☐ NO ☒

As of March 13, 2019, the registrant had 11,475,749 shares of common stock, $0.0001 par value per share, outstanding.

Portions of the Registrant's Definitive Proxy Statement for its 2019 Annual Meeting of Stockholders (the "Proxy Statement"), to be filed within 120 days of the registrant's fiscal year ended December 31, 2018, are incorporated by reference in Part III of this Annual Report on Form 10-K. Except with respect to information specifically incorporated by reference in this Form 10-K, the Proxy Statement is not deemed to be filed as part of this Form 10-K.

SPECIAL NOTE REGARDING FORWARD LOOKING STATEMENTS

This Annual Report on Form 10-K contains, and our officers and representatives may from time to time make, forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act, which statements involve substantial risks and uncertainties. All statements contained in this Annual Report on Form 10-K other than statements of historical fact, including statements regarding our future results of operations and financial position, our business strategy and plans, and our objectives for future operations, are forward-looking statements. The words "may," "will," "should," "expects," "plans," "anticipates," "believes," "estimates," "predicts," "potential," "intends," "continue" and similar expressions that convey uncertainty of future events or outcomes are intended to identify forward-looking statements. Forward-looking statements included in this Annual Report on Form 10-K include, but are not limited to, statements regarding:

- our estimates regarding our expenses, future revenues, anticipated capital requirements and our needs for additional financing;
- the implementation of our business model and strategic plans for our business and technology;
- the timing and success of the commencement, progress and receipt of data from any of our preclinical and clinical trials;
- our expectations regarding the potential safety, efficacy or clinical utility of our product candidates;
- the expected results of any clinical trial and the impact on the likelihood or timing of any regulatory approval;
- the difficulties in obtaining and maintaining regulatory approval of our product candidates;
- the rate and degree of market acceptance of any of our product candidates;
- the success of competing therapies and products that are or become available;
- regulatory developments in the United States and foreign countries;
- current and future legislation regarding the healthcare system;
- the scope of protection we establish and maintain for intellectual property rights covering our technology;
- developments relating to our competitors and our industry;
- our failure to recruit or retain key scientific or management personnel or to retain our executive officers;
- the performance of third parties, including collaborators, contract research organizations and third-party manufacturers;
- the development of our commercialization capabilities, including the need to develop or obtain additional capabilities; and
- our use of the proceeds from our recent initial public offering.

These statements are only current predictions and are subject to known and unknown risks, uncertainties and other factors that may cause our or our industry's actual results, levels of activity, performance or achievements to be materially different from those anticipated by the forward-looking statements. We discuss many of these risks in greater detail in the risk factors in Part I, Item 1A and elsewhere in this Annual Report on Form 10-K. You should not rely upon forward-looking statements as predictions of future events.

Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance or achievements. Except as required by law, after the date of this Annual Report on Form 10-K, we are under no duty to update or revise any of the forward-looking statements, whether as a result of new information, future events or otherwise.

References in this Annual Report on Form 10-K to the "Company," "we," "our," or "us" mean Vaccinex, Inc. and its subsidiaries except where the context otherwise requires.

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PART I

BUSINESS

Overview

We are a clinical-stage biotechnology 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. We believe we are the leader in the field of SEMA4D biology and that we are the only company targeting SEMA4D as a potential treatment for cancer, neurodegenerative diseases, or autoimmune disorders. SEMA4D is an extracellular signaling molecule that regulates the migration of immune and inflammatory cells to sites of injury, cancer or infection. We are leveraging our SEMA4D antibody platform and our extensive knowledge of SEMA4D biology to develop our lead product candidate, VX15, which we believe utilizes novel mechanisms of action. In June 2018, the U.S. Adopted Name Council approved the use of pepinemab as the adopted name for VX15. We are focused on the development of pepinemab for the treatment of non-small cell lung cancer, or NSCLC, osteosarcoma, melanoma and Huntington's disease. We have developed multiple proprietary platform technologies and are developing product candidates to address serious diseases or conditions that have a substantial impact on day-to-day functioning and for which treatment is not addressed adequately by available therapies. We employ our proprietary platform technologies, including through our work with our academic collaborators, to identify potential product candidates for sustained expansion of our internal product pipeline and to facilitate strategic development and commercial partnerships.

Our lead platform technologies include our SEMA4D antibody platform and our ActivMAb antibody discovery platform.

- ***Our SEMA4D antibody platform*** is the application of our extensive knowledge of SEMA4D biology to develop our lead product candidate pepinemab for the treatment of various indications, including cancer and neuroinflammatory and neurodegenerative diseases. Pepinemab's mechanisms of action block the SEMA4D signal and activate innate physiological mechanisms to respond to tumors or tissue injury. We have demonstrated in animal models in preclinical studies that the biological activities associated with an antibody blockade of SEMA4D can promote immune cell infiltration into tumors and the repair or prevention of neurological damage in neuroinflammatory and neurodegenerative diseases.
- ***Our ActivMAb® antibody discovery platform*** is a proprietary human antibody discovery platform based on a novel method for expressing large and diverse libraries of high affinity, full-length human monoclonal antibodies on the surface of vaccinia, a mammalian virus. We believe our ActivMAb technology offers (i) rapid generation of high affinity, full-length, human monoclonal antibodies synthesized and naturally modified in mammalian cells, (ii) expression and selection of antibodies that easily and predictably transition to manufacturing in mammalian lines, and (iii) an innovative and efficient method for selecting antibodies against multi-pass membrane proteins, an important class of pharmacological targets. Our product candidate VX5 was generated by our ActivMAb platform and is currently in preclinical development for the treatment of MS and potentially for other autoimmune disorders. We intend to continue to utilize our ActivMAb platform to identify additional product candidates for our own pipeline development and for strategic collaborations.

In addition, we and our academic collaborators are using our Natural Killer T, or NKT, vaccine platform to discover product candidates that target and extend the activity of NKT cells. NKT cells work directly to kill certain types of parasites and cells, including tumor cells and virus-infected cells. We are applying our agonists to direct NKT cells to the site of tumors, potentially enhancing tumor-specific immunity through recruitment and activation of cytotoxic T cells, or CTL, and antibody-armed natural killer, or NK, cells that will work to eradicate the tumor.

Vaccinex Product Pipeline

Our lead product candidate pepinemab is currently in clinical development for the treatment of NSCLC, osteosarcoma, melanoma and Huntington's disease, through our efforts or through Investigator Sponsored Trials, or ISTs. Our additional product candidates VX5 and VX25 are in earlier stages of development and were generated using our ActivMAb and NKT vaccine platforms, respectively. VX5 is a human antibody to CXCL13, a molecule that regulates the formation of immune tissues, and is currently in preclinical development for the treatment of MS and potentially for other autoimmune disorders. VX25, a bi-specific NKT cell stimulator, is being evaluated in various preclinical cancer models and seeks to address challenges for the therapeutic application of NKT cell stimulation for cancer immunotherapy. We believe our multiple platform technologies position us well for continued pipeline expansion and partnership opportunities going forward.

Pepinemab

Pepinemab is a humanized monoclonal antibody that binds and blocks the signaling activity of SEMA4D. We are advancing pepinemab with what we believe to be novel mechanisms of action for the treatment of cancer and certain neurodegenerative diseases, including Huntington's disease. As of December 31, 2018, 452 patients have been treated or enrolled in seven Phase 1 clinical trials and two Phase 2 clinical trials of pepinemab in separate indications.

Cancer – NSCLC, Osteosarcoma and Melanoma

Pepinemab is currently being studied as a treatment for advanced solid tumors, including NSCLC, osteosarcoma, and melanoma. We have demonstrated in preclinical tumor models that SEMA4D regulates infiltration of immune precursor cells into tumor tissue. Our preclinical data suggest that blocking SEMA4D promotes infiltration of immune cells that can eradicate the tumor. We have also demonstrated in preclinical models the potential for synergy between pepinemab and a checkpoint inhibitor when used in combination. We completed a Phase 1 clinical trial of pepinemab as a single-agent cancer therapy and released top-line data in October 2014. Pepinemab was well tolerated in this clinical trial. In October 2017 in collaboration with Merck KGaA, we initiated the CLASSICAL–Lung clinical trial, a Phase 1b/2 clinical trial of pepinemab in combination with avelumab, an inhibitor of the PD-1/PD-L1 checkpoint pathway, in patients with NSCLC who have not previously been treated with immunotherapy. In July 2018, an additional cohort was added to the CLASSICAL – Lung study to include patients who failed prior immunotherapy. In February 2018, The Children's Oncology Group, or COG, with financial support of the National Cancer Institute, initiated a Phase 1/2 clinical trial of pepinemab as a single agent in pediatric patients with recurrent, relapsed, or refractory solid tumors, including osteosarcoma. In June 2018, a Phase 1 IST of pepinemab in combination with *Yervoy*® or with *Opdivo*® began at the UCLA Jonsson Comprehensive Cancer Center in patients with advanced melanoma who have progressed on prior anti-PD-1/PD-L1 based therapies.

Huntington's Disease

We are studying pepinemab as a treatment for Huntington's disease, which is a neurodegenerative genetic disorder that typically manifests in mid-adult life. Our study of pepinemab in Huntington's disease is based on our prior research of neurodegenerative disease mechanisms, where we demonstrated in preclinical models that SEMA4D triggers activation of both microglia and astrocytes, the innate inflammatory cells of the central nervous system, or CNS. The chronic activation of microglia and astrocytes has been implicated as an important disease mechanism in Huntington's disease, progressive MS, and other neurodegenerative disorders. We initiated the SIGNAL study, a Phase 2 clinical trial, in July 2015 in early manifest and late prodromal Huntington's disease patients. This clinical trial builds upon preclinical studies in an animal model of Huntington's disease and safety data from a Phase 1 dose-escalation clinical trial of pepinemab in MS patients that we completed in November 2014. The SIGNAL study has an adaptive design, and interim analysis of Cohort A data for 36 randomized patients was completed in April 2017. On the basis of this data, the design of the Cohort B study was modified. Enrollment in Cohort B was completed in December 2018 and includes a total of 265 subjects in two cohorts: 179 patients in group 1 (B1) who have early manifest disease, and 86 in group 2 (B2) who are late prodromal. All subjects are randomized to receive monthly infusions of either pepinemab or placebo for 18 months in double-blind fashion without crossover. The estimated primary completion date for the SIGNAL Phase 2 trial is the second half of 2020. The FDA has granted both Orphan Drug designation and Fast Track designation to pepinemab for Huntington's disease.

VX5

We discovered VX5 using our ActivMAb platform. VX5 is a human antibody to CXCL13, a molecule that regulates the formation of immune tissues, and is currently in preclinical development for the treatment of MS and potentially for other autoimmune disorders. In preclinical studies, anti-CXCL13 antibodies, such as VX5, have been shown to reduce CXCL13-induced B cell and T helper cell migration, which contributes to inflammatory and autoimmune responses. Therapeutic administration of anti-CXCL13 antibody has also been demonstrated to prevent disease progression in mouse models of MS and rheumatoid arthritis.

VX25

VX25 is an investigational, bi-specific molecule based on our NKT vaccine platform. VX25 aims to address two major challenges for the therapeutic application of NKT cell stimulation for cancer immunotherapy: (i) the activation of NKT cells without inducing tolerance, or the natural resistance to a second cycle of activation by a strong agonist; and (ii) the efficient targeting of NKT cells to the site of tumors. We and our academic collaborators have designed molecules that incorporate a potent NKT-activating glycolipid in one arm and a tumor-targeting antibody fragment in a second arm. These constructs are being evaluated in various preclinical cancer models.

Our Strategy

Our goal is to efficiently discover and cost-effectively develop targeted biotherapeutics that will provide safe, substantial and sustained benefits to patients with serious diseases and unmet medical needs. The principal elements of our business strategy are to:

- ***Develop pepinemab in combination with checkpoint inhibitors as a therapy for patients with NSCLC***. We have initiated the CLASSICAL–Lung clinical trial, a Phase 1b/2 clinical trial of pepinemab in combination with avelumab, an inhibitor of the PD-1/PD-L1 checkpoint pathway in patients with NSCLC**.** Enrollment was initiated in October 2017, and the primary completion date is anticipated in the fourth quarter of 2019.
- ***Develop pepinemab as a therapy in Huntington's disease***. We initiated the SIGNAL study, a Phase 2 multi-center, randomized, double-blind, placebo-controlled clinical trial in subjects with late prodromal and early manifest Huntington's disease in July 2015. The SIGNAL study has an adaptive design, and interim analysis of Cohort A data for 36 randomized patients was completed in April 2017. On the basis of this data, the design of the Cohort B study was modified, and became fully enrolled in December 2018 with a total of 265 subjects. The estimated primary completion date is the third quarter of 2020.
- ***Apply our SEMA4D antibody platform to treat serious diseases with unmet needs, including additional neurodegenerative disease and cancer indications***. We plan to build on the development work in Huntington's disease to pursue treatments, potentially in collaboration with strategic partners, for additional neurodegenerative diseases, including progressive MS and Alzheimer's disease. We also plan to pursue the application of our SEMA4D antibody platform to a variety of other cancers, including sarcoma, melanoma, colorectal, ovarian, breast, renal, gastric and bladder cancers.
- ***Leverage our existing SEMA4D collaborations and establish new partnerships***. We plan to build on our current research collaborations and establish new partnerships with pharmaceutical companies to explore various applications of our SEMA4D technology and continue to study pepinemab in combination with other cancer immunotherapies in development.

Utilize our ActivMAb antibody discovery platform to identify human antibodies for our own pipeline development and for strategic collaborations. As demonstrated by the selection of VX5 for the treatment of MS and potentially for other autoimmune disorders, we plan to utilize our ActivMAb platform to select additional product candidates for development or partnership. We currently have active agreements for antibody selection, including with Merck Sharp & Dohme Corp. and Surface Oncology, Inc, or Surface Oncology. As illustrated below, each of our two major platforms, SEMA4D and ActivMAb, is the subject of multiple existing research collaborations. We are actively engaged in discussions regarding additional collaborations.

Partner/Collaborator	Purpose of Relationship
SEMA4D / pepinemab	
Ares Trading S.A. (Merck KGaA, Darmstadt Germany)	Phase 1b/2 clinical trial of pepinemab in combination with avelumab, a checkpoint inhibitor, in two cohorts of (i) patients with NSCLC who have not previously been treated with immunotherapy and (ii) patients who have failed previous immunotherapy.
The Children's Hospital of Philadelphia, on behalf of Children's Oncology Group	Phase 1/2 IST of pepinemab as a single agent in pediatric patients with recurrent, relapsed, or refractory solid tumors, including osteosarcoma.
Emory University	Three separate Phase 1 IST "window of opportunity" studies evaluating pepinemab as a single agent and in combination with ipilimumab or nivolumab in pre-surgical melanoma, head and neck, and colorectal or pancreatic cancer patients.
Huntington Study Group	General CRO-related services for Phase 2 clinical trial of pepinemab in early-stage and late prodromal Huntington's disease patients.
UCLA Jonsson Comprehensive Cancer Center	Phase 1 IST of pepinemab in combination with *Yervoy* and *Opdivo* in patients with melanoma whose tumors have progressed following treatment with any anti-PD-1/PD-L1 antibody.
ActivMAb	
Catalent Pharma Solutions, LLC	Selection of an antibody to a cancer membrane target suitable for construction of an antibody drug conjugate employing proprietary Catalent technology.
Merck Sharp & Dohme Corp.	Testing of vaccinia strain Modified Vaccinia Ankara with genetic sequences designed by us.
Surface Oncology, Inc.	Identification and selection of antibodies against two target antigens using our proprietary technology.

Background on the Immune System and Antibodies

The immune system is a powerful mechanism to defend and protect the body from pathogens, such as viruses, parasites and bacteria, and provides surveillance against cancers, by recognizing and responding to their characteristic antigens. The power of the immune system can, however, also present dangers, as misdirected immune responses can cause devastating autoimmune diseases. To address these issues, the immune system has evolved to encompass two interacting arms, an aggressive arm that serves to eradicate infection and has the potential to kill tumors and a regulatory arm that serves to limit the magnitude and duration of immune responses. The balance of activity between these two arms has evolved to allow effective responses to the numerous pathogens in our environment, the primary threat to the integrity of organisms. This balance is, however, not necessarily well calibrated to respond to weaker antigenic challenges such as those of tumors that differ in relatively subtle ways from our normal tissues to which we are generally tolerant. Advances in our understanding of these regulatory mechanisms and our ability to develop drugs that modulate their effects, such as checkpoint inhibitors, has enabled important advances in immunotherapy and the treatment of cancer. We believe our SEMA4D antibody platform offers what we believe to be novel mechanisms of immune modulation that could further enhance the beneficial effects of immunotherapy in cancer.

Key interacting elements of the immune system that play a role in either aggressive or regulatory responses include:

- *B* lymphocytes, or B cells, which are a type of white blood cell that produce antibodies in response to foreign antigens in the body. Activated B cells can produce factors that either enhance or limit immune responses.
- T lymphocytes, or T cells, which are a type of white blood cell generally divided into three subsets:
  - T helper cells, which secrete specialized factors that activate other cells, such as B cells, to fight off infection;
  - CTL, which directly kill certain types of parasites and cells, including tumor cells and virus-infected cells, and
  - Regulatory T cells, or Tregs, which can limit the activity of other immune cells.
- Dendritic cells, which capture and present antigens to T lymphocytes in the lymphoid organs where an immune response is initiated. Some dendritic cell subsets activate, and others suppress immune responses.
- Macrophages, some subsets, such as M1 type macrophage, help to regulate immune response by essentially picking up and ingesting foreign materials and presenting these antigens to activate other antigen-specific cells of the immune system, such as T cells and B cells. Other macrophage subsets, such as M2 type macrophage, are immunoregulatory and tolerogenic–that is, they can incapacitate other immune cells.
- NK cells, which directly destroy certain types of tumors or cells infected with viruses.
- NKT cells, which can both directly destroy target cells and recruit and activate other immune effector cells to the site of tumor or infection.

The immune system protects the body through various mechanisms that recognize and eliminate bacteria, viruses and other pathogens, and abnormal cells such as cancer cells. These mechanisms initiate a series of signals resulting in stimulation of the immune system in response to pathogenic or abnormal cells. The activities of the immune system are undertaken by its two components: the innate immune system and the adaptive immune system.

The role of the innate immune system is to provide a rapid, non-specific response to a pathogen or abnormal cells in the body and to facilitate activation of the adaptive immune system. The innate immune system consists of specialized cells such as macrophages, dendritic cells, monocytes and NKT cells. When the body recognizes a pathogen, it activates these specialized cells of the innate immune system, resulting in a cascade of signaling events that cause the production of proteins to fight the infection caused by the pathogen.

In contrast to the innate immune system, the adaptive immune system provides a pathogen-specific response to an infection. The adaptive immune system does this through the recognition by specific receptors expressed on B cells and T cells of specific proteins, called antigens, which are part of the pathogen or abnormal cell. Signals produced by the innate immune system facilitate this process. Upon recognition of an antigen, which could come from pathogens or from cancer cells, the adaptive immune system produces antibodies and antigen-specific immune cells that specifically detect and destroy cells that express the antigen. T cells and B cells (and the antibodies derived from the mature B cell) of this adaptive immune system respond to the many antigenic differences between pathogens and human cells or to small structural differences that, for example, distinguish a cancer cell from a normal cell.

Monoclonal antibodies are proteins manufactured in cell lines that can bind to specific substances in the body, including cancer cells and molecules that regulate immune responses. Monoclonal antibodies can be used alone to enhance immune responses or to direct NK cells to tumors or to carry drugs, toxins or radioactive substances directly to the cancer cells. Therapeutic monoclonal antibodies are typically derived from genes encoding specific natural antibodies and are produced by introducing those genes into specially adapted mammalian manufacturing cell lines. The antibody's ability to bind specifically to a target or antigen is also referred to as its specificity. Using this mechanism, antibodies can tag foreign substances for attack by other immune system cells or neutralize the targets directly. In treating diseases such as cancer, researchers either find antigens specific to cancer cells, create antibodies that bind those antigens to use the body's immune system to destroy the cancer cells or target immune regulatory mechanisms to increase the magnitude and duration of protective immune responses.

Our SEMA4D Antibody Platform

Overview

Our SEMA4D antibody platform is the application of our extensive knowledge of SEMA4D biology to develop our lead product candidate pepinemab for the treatment of various indications, including to promote immune cell infiltration into tumors as well as to inhibit neuroinflammatory and neurodegenerative diseases. Pepinemab, a molecule that blocks the signaling activity of SEMA4D, is currently in development for the treatment of NSCLC, osteosarcoma and Huntington's disease. We intend to use our SEMA4D platform to address additional cancer indications and neurodegenerative diseases in the future.

Pepinemab

Pepinemab is a humanized monoclonal antibody that binds and blocks the signaling activity of SEMA4D, which is an extracellular signaling molecule that regulates the migration of immune and inflammatory cells to sites of injury, cancer or infection. SEMA4D signals through the plexin-B1, or PLXNB1, receptor expressed on many precursor cells. The PLXNB1 receptor molecule can activate the R-Ras protein, which regulates adhesion to the extracellular matrix. Binding of SEMA4D to PLXNB1 can also either activate or inactivate RhoA protein and its effect on ROCK-kinase, which regulates the cell cytoskeleton. These two activities, cell adhesion and cytoskeletal reorganization, control the migration of precursor cells. Precursor cells play an important role in maintaining health and repairing tissue damage in the adult organism by migrating to a target location in the body where they can differentiate into mature functional cells. In the case of an immune precursor cell, the mature cell can engage in protective activity against a tumor or infection. Other precursor cells are dedicated to repairing tissue damage, such as precursor cells that can remyelinate nerve axons at a demyelinated lesion. Depending on the nature of a precursor cell and its natural signaling cascade, a precursor cell will respond to SEMA4D by being attracted or repelled. However, the fundamental biology of activation and migration of precursor cells to a target location in the body where they can differentiate into mature functional cells is the same across multiple types of tissues.

As a result, pepinemab's ability to affect SEMA4D's regulation of precursor cells may be relevant to multiple disease indications. In cancer, we believe pepinemab will promote the infiltration of immune precursor cells into the tumor. In Huntington's disease, we believe pepinemab will mobilize precursor cells that repair damage to myelin and neurons and prevent chronic activation of inflammatory cells of the brain, microglia and astrocytes, which is implicated in neurodegenerative diseases.

We have performed numerous preclinical studies in animal disease models to investigate the mechanisms of action of the anti-SEMA4D antibody. Pepinemab is a humanized version of our antibody used in preclinical studies. The mouse antibody that we use in our pre-clinical studies and the humanized antibody we use in our clinical trials are closely related and have very similar properties, including specificity and affinity. As a result, they are both referred to as pepinemab in our preclinical studies and in the clinical trials described in this Annual Report.

Collaboration and IST Agreements

Merck KGaA

In October 2016, we entered into a clinical trial collaboration and supply agreement with Merck KGaA through its subsidiary Ares Trading S.A. to test pepinemab in combination with avelumab checkpoint inhibitor in NSCLC patients whose tumors have progressed on or following chemotherapy, which is the CLASSICAL–Lung clinical trial. Subsequently, the collaboration initiated an additional cohort of the study in July 2018 to include patients who have failed prior immunotherapy. We are the investigational new drug application, or IND, sponsor of this study and Merck KGaA shares in the cost of the trial. Either party may elect to extend the collaboration to one additional cancer indication under certain circumstances. The agreement does not convey rights or a license to Merck KGaA to either manufacture or sell pepinemab. The agreement also does not convey rights or a license to us to either manufacture or sell avelumab, a Merck KGaA compound. All clinical data, including raw data and results, generated under this

agreement will be jointly owned by us and Merck KGaA. The agreement continues in full force until completion of all of the obligations of the parties under the agreement. Either party may terminate the agreement upon uncured material breach, good faith belief that safety issues give rise to imminent danger to patients, if a regulator takes action that prevents the party from supplying its compound for purposes of the study, or if it determines to discontinue development of its compound for material safety, medical, scientific, legal or regulatory reasons. Merck may terminate the agreement upon written notice for our failure to adequately respond to notice of Merck's good faith belief that avelumab is being used in an unsafe manner in the trial.

UCLA Jonsson Comprehensive Cancer Center

In June 2018, we entered into an Investigator Sponsored Clinical Trial Agreement, or ISTA, with the University of California Los Angeles Jonsson Comprehensive Cancer Center. We provide pepinemab drug and financial support for a Phase 1 IST of pepinemab in combination with *Yervoy* and with *Opdivo* in two cohorts of patients with melanoma whose tumors have progressed following treatment with any anti-PD-1/PD-L1 antibody. The *Yervoy* and *Opdivo* checkpoint inhibitors are provided by Bristol-Myers Squibb under a separate agreement with UCLA. The Cancer Center owns the clinical data generated from this IST, and we have the right to access and use this data for any lawful purpose. We provide funding for site clinical operations and clinical laboratory testing of patient samples at Covance Central Labs. The estimated primary completion date for this IST is the first half of 2021.

Children's Oncology Group

In December 2017, we entered into an agreement for an IST with Children's Hospital of Philadelphia, or CHOP, on behalf of COG, to provide pepinemab for a Phase1/2 clinical trial to study pepinemab as a single agent in treating younger patients with recurrent, relapsed, or refractory solid tumors, including osteosarcoma. We provide pepinemab drug and limited funding for clinical laboratory testing of patient samples, but all other clinical trial expenses are funded by the National Cancer Institute, or the NCI, through a grant to COG. CHOP, on behalf of COG, owns the clinical data developed or obtained in connection with this IST, except that we will own data developed by or obtained from us or on our behalf and that Vaccinex and CHOP, on behalf of COG, will jointly own certain pharmacokinetic and pharmacodynamic data and biomarker analysis data. We possess an exclusive right under the agreement to purchase any of the data owned by CHOP. No license rights to pepinemab are conveyed to CHOP, COG or the NCI by this agreement.

Emory

We have entered into three IST agreements with Emory University to provide pepinemab and financial support for three separate investigator sponsored clinical trials: (1) a Phase 1 clinical trial evaluating pepinemab as a single agent and in combination with ipilimumab or nivolumab in pre-surgical patients with resectable pancreatic or colorectal cancer; (2) a Phase 1 clinical trial evaluating pepinemab as a single agent and in combination with ipilimumab or nivolumab in pre-surgical patients with resectable head and neck cancer; and (3) a Phase 1 clinical trial evaluating pepinemab as a single agent and in combination with ipilimumab or nivolumab in pre-surgical patients with resectable melanoma. All three studies will evaluate the effect of the regimens on the immune profile in the tumor microenvironment and in peripheral blood. These trials are "window of opportunity" studies in which patients receive treatment between their cancer diagnosis and surgical resection. To support these studies, we are providing pepinemab and combination antibodies for neoadjuvant administration and limited financial support for site clinical operations prior to resection and clinical laboratory testing of patient samples. Emory University will own the clinical data resulting from these ISTs, and we will have the right to access and use this data for any lawful purpose. No license rights to pepinemab are conveyed to Emory University by these agreements.

Huntington Study Group (SIGNAL)

In March 2015, we entered into a Clinical Trial Management Agreement with The Huntington Study Group, or HSG, to provide general CRO-related services for the SIGNAL study in Huntington's disease, including management of subcontractors involved in the clinical trial, at approximately 30 clinical sites in the United States and Canada, each covered by a standard clinical trial agreement between us, as IND sponsor, HSG and the clinical site. Payments are on a fee for service basis. We will retain ownership of all clinical data generated from this agreement, while HSG and its subcontractors, including the clinical sites, will have the right to use limited data generated from the study for internal educational and non-commercial purposes. No license rights to pepinemab are conveyed to HSG by this agreement.

Pepinemab in Cancer

Overview

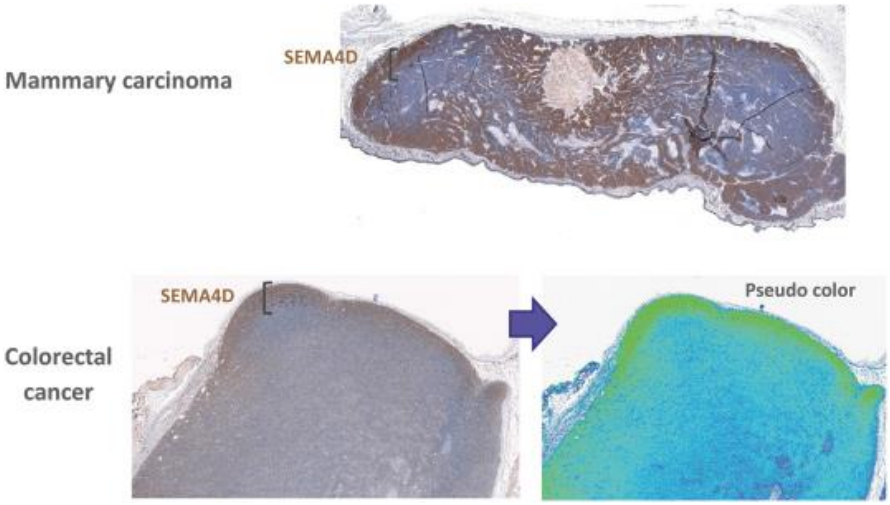
We are studying pepinemab as a treatment for advanced solid tumors, including NSCLC. Our preclinical data suggest that blocking of SEMA4D promotes infiltration of immune cells that can eradicate the tumor. We completed a Phase 1 clinical trial of pepinemab as a single-agent cancer therapy and released top-line data in October 2014. We initiated the CLASSICAL–Lung clinical

trial of pepinemab in combination with avelumab, a checkpoint inhibitor of the PD-1/PD-L1 pathway, in October 2017 in patients with NSCLC who have not been previously treated with immunotherapy and in patients who have failed prior immunotherapy.

The Role of SEMA4D in Cancer

As illustrated in Figure 1, we have demonstrated in preclinical research that many tumors express a high concentration of SEMA4D at the invasive tumor margin, the growing edge of the tumor, creating an apparent barrier.

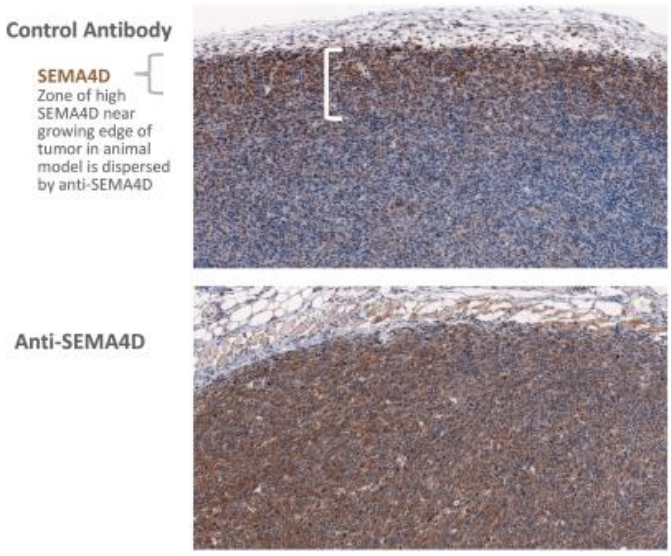
Figure 1. SEMA4D Expression Concentrated at Tumor Growing Edge



Low magnification images show intense SEMA4D staining at the invasive tumor margins (brackets) of colorectal and breast tumors in mice.

In preclinical studies, we have also determined that treating tumor-bearing animals with anti-SEMA4D antibody leads to breakdown of this gradient of SEMA4D expression as shown in Figure 2. This made it possible to determine whether the SEMA4D “barrier” inhibits infiltration of tumoricidal immune precursor cells into tumors.

Figure 2. Pepinemab Breaks Down SEMA4D Barrier in Colon26 Tumor



As illustrated in Figure 3, treating tumor-bearing animals with anti-SEMA4D results in enhanced infiltration of CD8+ T cells into the tumor. Figure 4 shows that this enhanced infiltration results in a statistically significant increase in both the total number of CD3+ T cells and CD8+ T cells and in tumor-specific CTL among tumor-infiltrating lymphocytes, or TIL, recovered from the mice treated with anti-SEMA4D antibody as compared to mice treated with a control antibody.

Figure 3. Anti-SEMA4D Antibody Increases Cytotoxic T Cells in Tumor

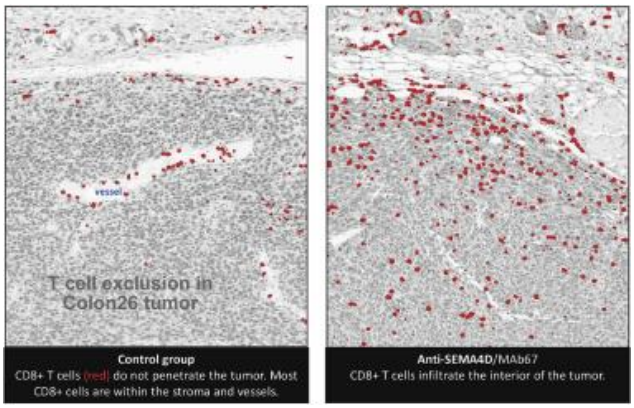
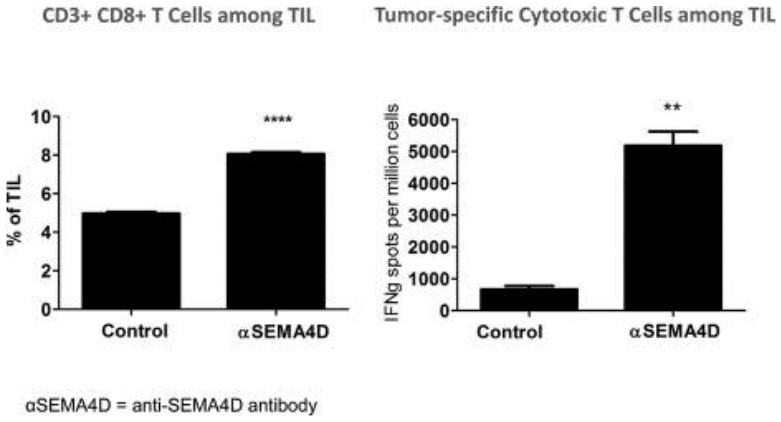
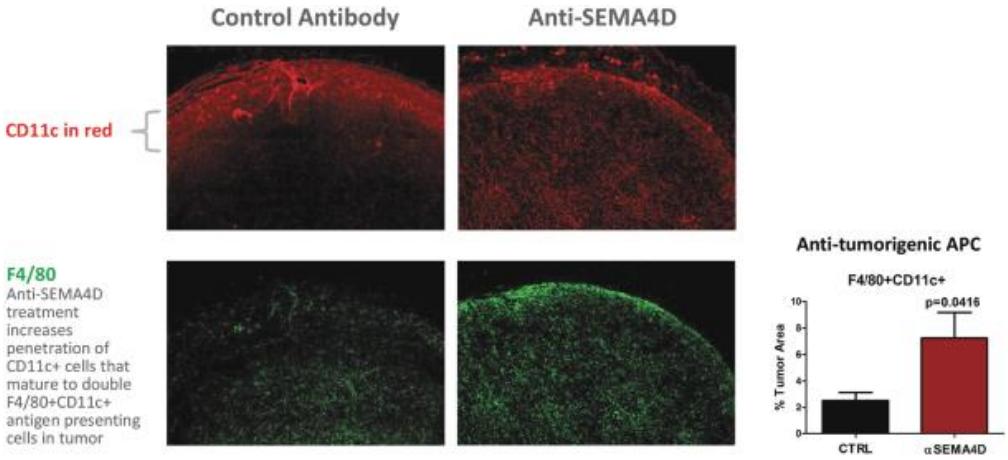


Figure 4. Anti-SEMA4D Antibody Enhances Tumor-specific Cytotoxic TIL



In addition to increased infiltration of T cells, infiltration of other functionally important immune cells, including cells expressing the CD11c marker and the F4/80 marker of antigen presenting cells, or APC, are also increased as illustrated in Figure 5.

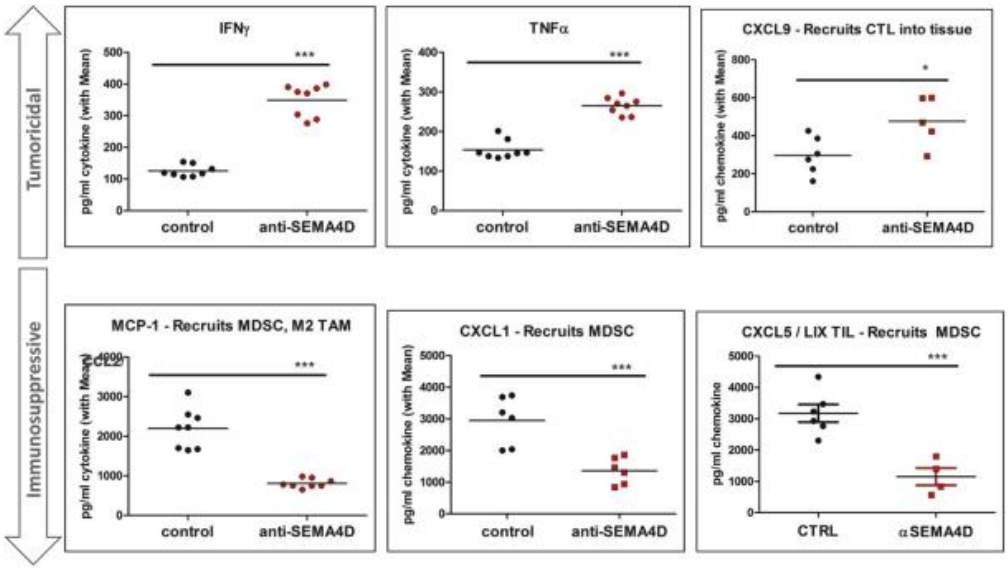
Figure 5. SEMA4D Gradient at Invasive Tumor Margin Regulates Migration and Maturation of Antigen Presenting Cells



Anti-SEMA4D treatment enhances infiltration of pro-inflammatory cells and reduced immunosuppressive cells.

Importantly, as illustrated in Figure 6, the change in cell populations induced by anti-SEMA4D treatment enhances secretion of tumoricidal cytokines (IFN g, TNF a) and chemokines (CXCL9) that recruit activated CTL while simultaneously reducing secretion of molecules that promote infiltration of immunosuppressive cells (MCP-1, CXCL1, CCL17). This results in increased APC and CTL that can give rise to tumoricidal effects and reduces cells such as regulatory T cells, or Treg, Myeloid Derived Suppressor Cells, or MDSC, and M2 type Tumor Associated Macrophage, or TAM, that express the characteristic CD206 marker (Figure 5). Neutralizing SEMA4D with anti-SEMA4D antibody, therefore, results in greater immune infiltration as illustrated in Figures 3, 4 and 5 and has the potential to give rise to greater tumor destruction. This is consistent with the Phase 1 clinical trial of pepinemab as a single-agent cancer therapy in patients with solid tumors (e.g., colorectal, breast, lung, renal and bladder cancers) in which patients with higher levels of circulating B and T cells were observed to have longer progression-free survival. We believe the level of circulating B and T cells is a surrogate marker for residual immune competence in these heavily pre-treated patients.

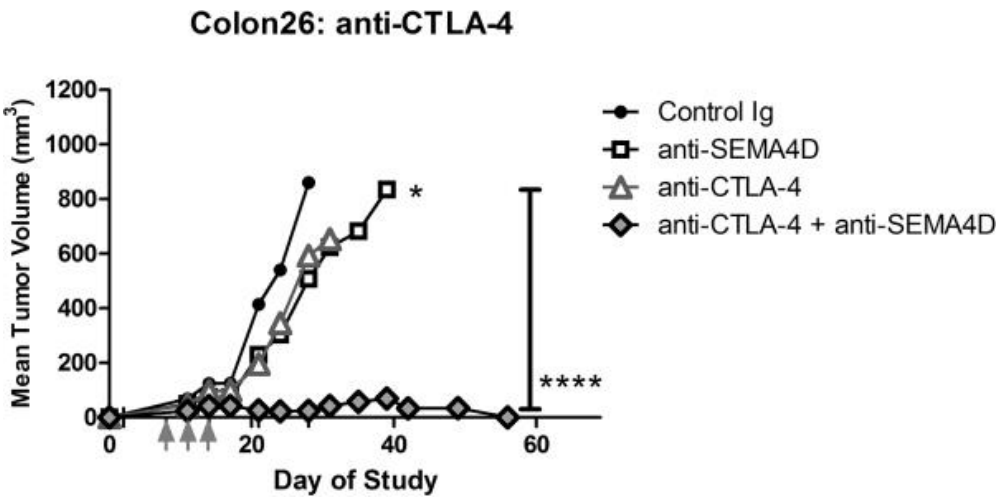
Figure 6. Anti-SEMA4D Treatment Shifts the Balance of Cytokines and Chemokines in the Tumor Microenvironment



Anti-SEMA4D treatment enhances secretion of tumoricidal Th1 cytokines (IFN γ, TNF α) and chemokines (CXCL9) that recruit activated cytotoxic T lymphocytes (CTL), while reducing chemokines that promote infiltration of immunosuppressive cells (MCP-1, CXCL1, CCL17).

As illustrated in Figures 7A and B, we have also demonstrated in mouse models of colorectal and head and neck cancer that the pepinemab antibody amplifies the benefits of other treatments that increase anti-tumor immunity in peripheral lymphoid tissues, including, in particular, the checkpoint inhibitors anti-CTLA-4 and anti-LAG3. Five separate studies performed by us showed tumor regression in on average approximately 80% and as high as 100% of mice in the colorectal tumor model (Figure 7A). We understand this synergy as the combined effect of an agent, anti-CTLA-4, that allows increased expansion of tumor-specific T cells in tumor draining lymph nodes and anti-SEMA4D that increases infiltration of these expanded T cells into tumor. Similar benefits are seen in the head and neck cancer model and in a colon cancer model in combination with anti-LAG3 (Figure 7B).

Figure 7A. Combination Treatment with Anti-CTLA-4 and Anti-SEMA4D in a Colorectal Tumor

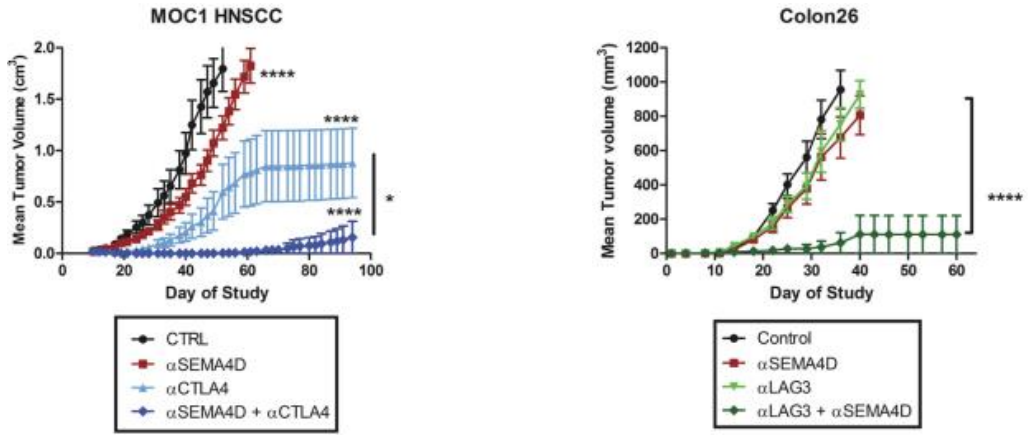


Single agent treatments (anti-SEMA4D and anti-CTLA-4) induce a modest inhibition of tumor growth but act synergistically in combination (anti-CTLA-4 + SEMA4D) to cause tumor regressions.

Figure 7B. Anti-SEMA4D Antibody Enhances Activity of Immune Checkpoint Antibodies: Combination with anti-CTLA-4 and with anti-LAG3 in Preclinical Cancer Models

anti-CTLA-4 Combination with Pepinemab in Head & Neck Cancer
(collaboration with NIH)

anti-LAG3 Combination with Pepinemab in Colon Cancer
(collaboration with TESARO)



The Unmet Medical Need for Cancer

Cancer is a leading cause of death worldwide, and according to the World Health Organization it accounted for 8.8 million deaths globally in 2015. Cancer follows only heart disease as the leading killer in the U.S. The American Cancer Society estimates that a total of 15.5 million Americans with a history of cancer were alive as of January 1, 2016, and this number is expected to grow to 20.3 million by 2026. An estimated 1.7 million Americans will be diagnosed with cancer and 609,640 are expected to die from the disease in 2018.

Current Approaches to Cancer Treatment

Standard treatment regimens for cancer vary widely by tumor type and location as well as by stage of the cancer, health of the patient and several other factors. Multiple treatment options include surgery, radiation, chemotherapy and administration of other anticancer agents. A cancer patient often receives treatment with a combination of these methods. For patients with localized disease, surgery and radiation therapy are particularly effective. Systemic drug therapies are generally used by physicians in patients who have cancer that has spread beyond the primary site or cannot otherwise be treated through surgery. The goal of these therapies is to damage and kill cancer cells or to interfere with the molecular and cellular processes that control the development, growth and survival of cancer cells. In many cases, drug therapy entails the administration of several different drugs in combination. Over the past several decades, drug therapy has evolved from non-specific drugs that kill both healthy and cancerous cells, to drugs that target specific biological activities related to cancer.

Immunotherapy is one of the most promising therapeutic approaches for cancer because it has the potential to be targeted, is generally lower in toxicity compared to chemotherapy, and can potentially improve survival in end-stage disease. The anti-cancer immune response may lead to the restoration of immune surveillance, which has the potential to contain the metastatic process and limit future relapse or tumor escape. Immunotherapy could bring patients closer to a curative treatment, something that has not been achieved with other targeted oncology therapeutics.

Among the most promising immunotherapy approaches to activating antitumor immunity is the blockade of immune checkpoints. Immune checkpoints refer to inhibitory pathways hardwired into the immune system that are crucial for maintaining and modulating the magnitude and duration of immune responses to minimize collateral tissue damage. Scientists have observed that

tumors co-opt certain immune-checkpoint pathways as a major mechanism of immune resistance, particularly against T cells that are specific for tumor antigens and otherwise would attack the tumor. Research has demonstrated that because many of the immune checkpoints are initiated by the interaction between ligands and their specific receptors, many of these immune checkpoints can be readily blocked by antibodies that neutralize ligands or block receptors. Anti-CTLA-4 antibodies are antibodies to the cytotoxic T-lymphocyte-associated antigen 4 and Yervoy was the first of this class of immunotherapies to achieve approval by the FDA. Programmed cell death protein 1, or PD-1, is another immune checkpoint pathway currently being targeted with immunotherapies. Merck's anti-PD-1 drug Keytruda ® (pembrolizumab) is approved for use for the treatment of patients with advanced or unresectable melanoma who are no longer responding to first-line therapy, and Opdivo is approved for patients with melanoma who no longer respond to other drugs and for patients with advanced (metastatic) squamous NSCLC with progression on or after platinum-based chemotherapy. Keytruda has also received approval as first-line therapy in NSCLC patients with high PD-L1 expression and in May 2017 was approved for use combination with chemotherapy in patients with metastatic non-squamous NSCLC and as second line therapy in patients with greater than 1% PD-L1 expression. Both Opdivo and Keytruda have also received approvals for certain populations of patients with squamous cell carcinoma of head and neck, urothelial cancer and Hodgkin's lymphoma. Other checkpoint inhibitors targeting PD-L1 have also received approvals for certain patient populations with specific cancer indication: Genentech's Tecentriq ® (atezolizumab) in urothelial cancer and NSCLC; Bavencio® in Merkel cell and urothelial cancer; and AstraZeneca's Imfinzi ® (durvalumab) in urothelial cancer and as maintenance therapy in unresectable Stage III NSCLC following chemoradiation therapy.

Currently, there are several hundred clinical trials of anti-PD-1, the receptor, and anti-PD-L1, the matching ligand, many of which may selectively enroll patients with tumors that express the programmed death ligand 1, or PD-L1, due to a greater expected response rate in such patients than those with PD-L1 negative tumors. However, even though PD-L1 positive patients respond better than PD-L1 negative patients, the anticipated response rate of PD-L1 positive patients is generally low, at approximately 20%, with the exception of melanoma and bladder cancers, where response rates can be as high as 35% to 40%. Therefore, we believe it is important to identify combination therapies that could result in greater response rates in more tumor types.

Our Approach to a Combination Therapy in Cancer

Preclinical research into pepinemab has demonstrated in animal models that expression of SEMA4D by cancerous cells and by other tumor associated immune cells is common to a wide variety of tumor types, and that SEMA4D expression in tumors can enhance tumor growth, survival and metastatic potential. We are pursuing the development of pepinemab as a therapeutic for cancer because of its potential to neutralize these effects of SEMA4D.

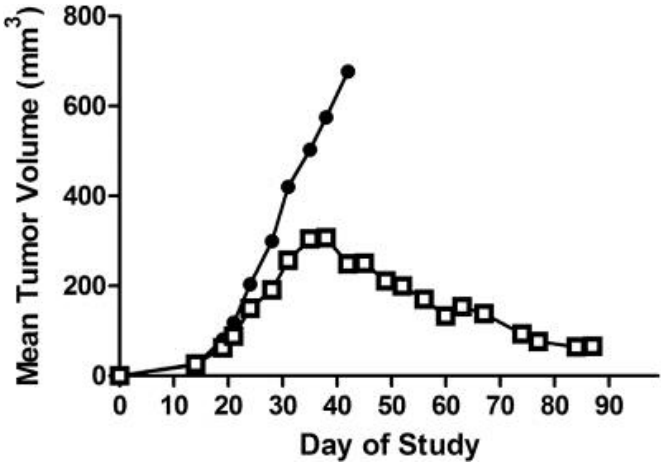
We believe that the combination of pepinemab with immunotherapeutic drugs could prove beneficial. Many immunotherapeutic drugs act by inhibiting negative feedback that limits the magnitude or duration of immune responses, e.g., checkpoint inhibitors such as anti-PD-1, or act by directly inducing greater tumor-specific immune activity, e.g., co-stimulator activities or cancer vaccines. Pepinemab has a different immunotherapeutic mechanism of action in cancer. It promotes infiltration of immune cells into a tumor and, as such, we believe could enhance the activity of other agents that increases peripheral immune responses. This is the basis for several of our preclinical and clinical collaborations.

In preclinical studies, we determined that pepinemab in combination with the CTLA-4 checkpoint inhibitor can greatly enhance the immune response to tumors by amplifying the benefits of such checkpoint inhibitor. In preclinical tumor models, anti-SEMA4D demonstrated synergy in combination with anti-CTLA-4 for inhibition of tumor growth and increased frequency of complete tumor regression. Based on our preclinical studies, it appears that pepinemab removes the barrier presented by SEMA4D to infiltration into the tumor of immune cells expanded by blockade of CTLA-4. Pepinemab does not itself expand immune response but has a profound influence on the traffic of tumor-specific immune cells and, therefore, the cells' ability to target tumor cells.

Notwithstanding the promise of checkpoint inhibitors, we believe there are still challenges with treatments that are currently approved and in development. The response rate to anti-CTLA-4 is higher in melanoma than in most other tumor types. Combination with pepinemab could increase response rates in cancers that respond poorly to checkpoint inhibitors as single agents. Moreover, we believe that the use of pepinemab in combination with anti-CTLA-4 can address some of the reported toxicity of high doses of anti-CTLA-4 (at 10 and 3 mg/kg). At the approved dose of 3 mg/kg in metastatic melanoma, Yervoy is associated with significant toxicity. We believe that higher doses of anti-CTLA-4 are being administered than would otherwise be required in the presence of the activity of an anti-SEMA4D antibody. We have observed in preclinical models that SEMA4D produced in tumors obstructs infiltration of tumor-inhibiting immune cells into the tumor environment. Clinical studies by Bristol-Myers Squibb have demonstrated that Yervoy toxicity is dose related, and, therefore, if it were possible to reduce the dose, then it would be expected that toxicity could be significantly reduced. Our preclinical studies suggest synergy between pepinemab and anti-CTLA-4 can be effective at lower doses of anti-CTLA-4 (equivalent to 0.3 or 1.0 mg/kg in humans), potentially resulting in reduced toxicity as well as increased efficacy.

In addition to the immune-mediated mechanism of action of pepinemab described above, there is an independent mechanism of action relevant to certain tumors that express both the plexin-B1 receptor for SEMA4D and an oncogenic membrane receptor kinase, ErbB-2 or MET. We and others have shown that the crosslinking of membrane associated PLXNB1 receptors by SEMA4D can transactivate the two oncogenic membrane receptor kinases, ErbB-2 and MET. ErbB-2 is also known as human epidermal growth factor receptor 2, or HER2, the target of the immunotherapy Herceptin ® (trastuzumab). ErbB-2 and MET membrane receptor kinases are oncogene products, which when transactivated are known to play an important role in the development and progression of certain types of cancers. Both SEMA4D and its PLXNB1 receptor are over-expressed in a wide array of tumor types, such as breast, lung, colorectal, pancreatic, ovarian, head and neck cancer and sarcoma. SEMA4D is also produced by inflammatory cells present in certain tumor microenvironments and has been shown in genetic studies to be a key oncongenic factor in osteosarcoma. As illustrated in Figure 8, we have demonstrated in animal models in preclinical research that blocking SEMA4D from crosslinking its PLXNB1 receptor by treatment with pepinemab induces regression of a PLXNB1/ErbB-2 double positive tumor even when administered as a single agent. We believe that this single agent activity may be attributed to pepinemab's neutralization of SEMA4D to block its interaction with its PLXNB1 receptor and prevent transactivation of ErbB-2 in combination with the immune enhancing effects of pepinemab. We believe pepinemab represents a new potential therapeutic strategy for treatment of HER2+ breast and ovarian cancers either as a single agent or in combination with anti-HER2 antibodies (e.g. trastuzumab).

Figure 8. Treatment of PLXNB1 and ErbB-2 Double Positive Mammary Carcinoma with Anti-SEMA4D Delays Tumor Growth



The single agent efficacy of anti-SEMA4D in a PLXNB1 and ErbB-2 double positive tumor contrasts with the limited single agent efficacy in a colorectal cancer. This may be attributed to the dual effect of anti-SEMA4D in blocking the oncogenic ErbB-2 pathway as well as promoting immune infiltration into the tumor.

Clinical Development of Pepinemab in Cancer

Early Studies and Preclinical Data

We and others have shown in preclinical studies that SEMA4D protein is highly expressed in the majority of the solid tumors evaluated, including gastrointestinal, head and neck, breast, lung, ovarian, skin, pancreatic, urogenital and sarcoma, including osteosarcoma. The results of these studies reveal that the majority of tumors sampled have moderate to high SEMA4D expression levels. Thus, a potential therapy involving SEMA4D molecule signaling may be applicable to many forms of cancer. We also found that the plexin-B1 receptor, the highest affinity receptor for SEMA4D, was broadly expressed in a range of tumor types.

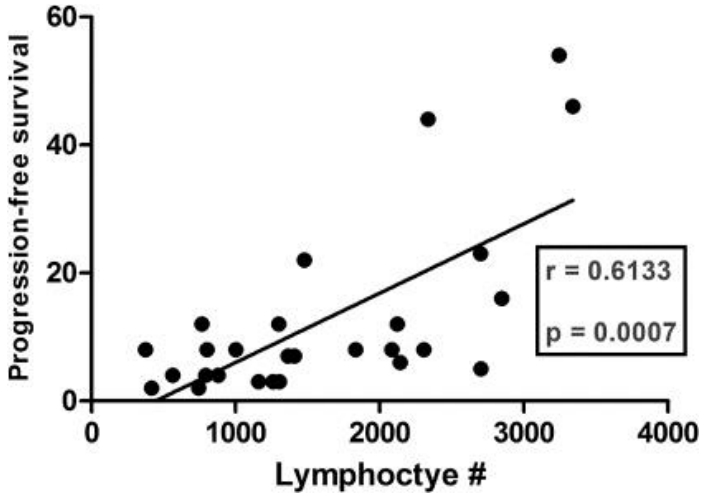
We conducted preclinical studies evaluating pepinemab in conjunction with checkpoint inhibitors similar to the anti-PD-1 antibody nivolumab, and the anti-CTLA-4 antibody ipilimumab. These studies generated preclinical data suggesting that the pepinemab antibody can act synergistically with anti-PD-1 and anti-CTLA-4 antibodies. Anti-CTLA-4 is believed to be active in draining lymph nodes of the tumor, where it acts to enhance expansion of tumor-specific T cells, as well as in the tumor environment. Expanded T cells from draining lymph nodes must penetrate into the tumor to be effective. Anti-PD-1 is thought to act predominantly to block interaction between PD-1 positive tumor-associated T cells and tumor cells induced to express the PD-L1 ligand. Pepinemab

has been shown in preclinical studies to promote infiltration of immune cells into a tumor and, as such, we believe that combining pepinemab with either of these checkpoint inhibitors could enhance their activity to increase immune responses in tumors.

Completed Phase 1 Clinical Trials

In October 2014, we completed a two-center, open-label, multiple-dose, dose-escalation, non-randomized, Phase 1 safety and tolerability clinical trial of intravenous pepinemab in adult patients with advanced solid tumors, such as colorectal, breast, lung, renal and bladder cancers. As illustrated in Figure 9, it was observed that some patients had relatively greater benefit from pepinemab treatment as demonstrated by extended progression-free survival. This was directly correlated to the level of circulating immune cells, a surrogate marker of immune competence. This is consistent with our understanding of the immune-mediated mechanism of action of pepinemab which enhances immune cell traffic and tumor infiltration but does not alone increase the level of circulating immune cells. Our scientific rationale for combining pepinemab with an immunomodulatory therapy is to increase the number of patients who have a sufficiently strong immune response that they can benefit from the ability of pepinemab to direct these immune cells into the tumor.

Figure 9. Correlation of Immune Cell Number versus Duration of Progression-Free Survival.



In October 2014, we reported final results of our Phase 1 clinical trial of pepinemab in patients with solid tumors. In this clinical trial, 460 doses of pepinemab were administered to 42 patients as weekly intravenous infusions at concentrations ranging from 0.3 to 20 mg/kg. Pepinemab was well tolerated through 20 mg/kg, the highest dose tested. Patients with elevated levels of circulating lymphocytes were observed to have had longer progression-free survival when treated with pepinemab, and one of these patients had a partial response with tumor shrinkage. There were 15 serious adverse events in 12 patients all of which were unrelated to the treatment as determined by independent review. One pancreatic cancer patient developed a dose-limiting toxicity, or DLT, involving elevated liver enzymes concurrent with disease progression (metastasis to liver). The most frequent treatment-related adverse events included grade 1/2 nausea and fatigue.

Pepinemab appeared to be well tolerated in this study, as well as in a separate Phase 1 clinical trial of single-ascending doses up to 20 mg/kg in 50 patients with MS in which no DLTs were observed. Furthermore, in both short and longer term preclinical animal toxicology studies in monkeys and rodents, the pepinemab was well tolerated at weekly doses up to 200 mg/kg administered over six months.

Ongoing and Planned Phase 1b/2 Clinical Trials

Non-Small Cell Lung Cancer (NSCLC)

Based on safety data obtained in a Phase 1 clinical trial with pepinemab administered as a monotherapy in patients with solid tumors, we initiated the CLASSICAL–Lung Phase1b/2 clinical trial in NSCLC patients who have not previously been treated with immunotherapy and in patients who have failed prior immunotherapy to evaluate pepinemab as a combination therapy with avelumab, a checkpoint inhibitor targeting the PD-1/PD-L1 blocking pathway. The Phase 1b dose escalation stage of the trial in NSCLC patients not previously treated with immunotherapy was completed in October 2018. No concerning safety signals were identified. The most

frequent related adverse events were grades 1 or 2 fatigue, pyrexia, or chills; no grade 3 AE occurred in more than one subject. One dose-limiting toxicity, a grade 3 pulmonary embolism, occurred but resolved, and did not recur in that same subject nor in additional cohort subjects. As of December 31, 2018, disease was controlled in 90% of patients treated for at least 2 months. Merck KGaA will share in the cost and data generated in this study but will not receive a license to manufacture or sell pepinemab. The CLASSICAL–Lung clinical trial has an open-label design. The estimated primary completion date of this clinical trial is the second half of 2019.

In the Phase 1b dose escalation portion of the study, 12 immunotherapy naïve patients were treated with escalating doses of pepinemab at 5, 10 and 20 mg/kg in combination with 10 mg/kg of avelumab every two weeks until confirmed disease progression, unacceptable toxicity, or the subject withdraws consent for further treatment. The primary objective in Phase 1b was to evaluate safety and tolerability of the recommended Phase 2 dose, or RP2D, of pepinemab administered in combination with 10 mg/kg avelumab every two weeks. A secondary objective is to obtain a preliminary estimate of efficacy using objective response, duration of response and progression-free survival in accordance with Response Evaluation Criteria in Solid Tumors, or RECIST, 1.1. An RP2D of 10mg/kg of pepinemab is being used in combination with 10mg/kg avelumab, both administered every two weeks, in the Phase 2 expansion stage of the CLASSICAL – Lung trial. We plan to enroll a total of 50 subjects in each of two cohorts in the Phase 2 expansion phase: 22 subjects in one cohort in which patients are immunotherapy naïve and 28 subjects in a second cohort whose tumors have progressed during or following an initial treatment with immunotherapy.

Osteosarcoma

In February 2018, COG with financial support of the NCI, initiated a Phase 1 clinical trial of pepinemab as a single agent in pediatric patients with recurrent, relapsed, or refractory solid tumors, including osteosarcoma. This study is based on the finding that SEMA4D is a key oncogenic factor in this type of cancer.

It is contemplated that the study will enroll 36 patients to be treated with pepinemab at 20 mg/kg every two weeks until either confirmed disease progression or unacceptable toxicity. The primary objectives of this Phase 1 clinical trial are to define and describe the toxicities of pepinemab administered on this schedule and to characterize the pharmacokinetics of pepinemab in pediatric patients with recurrent or refractory cancer. Eighteen subjects have been recruited to the study as of December 31, 2018.

Melanoma

In June 2018, an IST of pepinemab in combination with *Yervoy* and in combination with *Opdivo* began at the UCLA Jonsson Comprehensive Cancer Center in patients with advanced melanoma who have progressed on prior anti-PD-1/PD-L1 based therapies.

It is contemplated that the study will enroll up to 60 patients to be treated with escalating doses of pepinemab at 10 and 20 mg/kg in combination with 480 mg/kg of nivolumab every 4 weeks or with pepinemab at 10 and 20 mg/kg in combination with 3 mg/kg of ipilimumab every 3 weeks for 4 cycles and then continuing with pepinemab alone every four weeks until, in all cases, confirmed disease progression, unacceptable toxicity, or the subject withdraws consent for further treatment or requires another form of antineoplastic therapy as determined by the investigator. In some cases, subjects may continue study treatment despite apparent disease progression based on iRECIST guidelines, provided there are no new or worsening symptoms and no change in performance status. The primary objectives are to determine (i) the safety and tolerability of the combination of pepinemab with nivolumab, or ipilimumab, in melanoma patients who have progressed on anti-PD-1/PD-L1 based checkpoint inhibitors; and (ii) the recommended phase 2 dose and schedule of the combination of pepinemab with nivolumab, or ipilimumab. Secondary objectives are to (x) define the adverse event profile for the agent combinations and determine attribution (i.e., drug related adverse events); (y) evaluate clinical response of patients treated with maximum tolerated dose or maximum administered dose of the combination of anti-SEMA4D with nivolumab, or ipilimumab by objective response rate as determined by RECIST 1.1 criteria; and (z) evaluate whether adding anti-SEMA4D to PD-1 or CTLA-4 blockade can increase T-cell infiltration into tumors and whether change in T-cell infiltration is associated with response. As of December 31, 2018, there were a total of four subjects enrolled in the study. The estimated primary completion date of this IST is the second half of 2020.

Pepinemab in Huntington's Disease

Overview

We are studying pepinemab as a treatment for Huntington's disease, which is a neurodegenerative genetic disorder that typically manifests in mid-adult life. Our study of pepinemab in Huntington's disease is based on our prior research of neurodegenerative disease mechanisms, where we demonstrated in preclinical models that SEMA4D triggers activation of both microglia and astrocytes, the innate inflammatory cells of the CNS, and that such activation can be reduced or prevented by treatment with pepinemab The chronic activation of microglia and astrocytes has been implicated as an important disease mechanism in Huntington's disease,

progressive MS, and other neurodegenerative disorders. The FDA has granted both Orphan Drug designation and Fast Track designation to pepinemab for Huntington's disease.

We completed a Phase 1 dose-escalation clinical trial of pepinemab in MS patients in November 2014. We initiated the Phase 2 SIGNAL study of pepinemab in early-stage and prodromal Huntington's disease patients in July 2015 to assess the safety, tolerability, pharmacokinetics and efficacy of intravenously administered pepinemab.

The Role of SEMA4D in Neurodegenerative Disease

SEMA4D plays a crucial role in neuroinflammatory and neurodegenerative diseases through at least three independent mechanisms: (i) inducing the activation of innate inflammatory cells of the CNS, including both microglia and astrocytes, which are associated with long term damage to nervous tissue; (ii) inhibiting migration and differentiation of precursor cells that have the ability to repair demyelinated lesions; and (iii) inducing the breakdown of the tight junctions between endothelial cells that seal the blood-brain barrier and prevent degradation of the cellular and molecular environment of the brain.

Chronic activation of microglia is associated with neuroinflammatory and neurodegenerative disease. We have demonstrated in preclinical studies that SEMA4D activates microglia at the site of demyelinated lesions. We have also demonstrated that SEMA4D inhibits the migration of oligodendrocyte precursor cells, which are capable of repairing damage to demyelinated lesions.

As demonstrated in Figure 10, spinal cord sections were stained for expression of a characteristic marker of oligodendrocyte precursor cells known as NKx2.2. It was observed that oligodendrocyte precursor cells are randomly distributed and do not migrate to the site of demyelinated lesion in control animals (red stained cells in left panel) and are, therefore, unable to repair damage. SEMA4D appears to inhibit migration of these precursors because they migrate when animals are treated with pepinemab (right panel). In contrast, SEMA4D promotes activation of microglia at the site of lesions. We have also demonstrated in preclinical models that the activation of microglia is mediated by SEMA4D because activation is inhibited upon treatment with pepinemab. As illustrated below, in Figures 10 and 11, the left panel represents sections of spinal cord from animals treated with control antibody and the right panel represents similar sections from animals treated with pepinemab. In Figure 10, the sections are stained for NKx2.2 (red), a marker of oligodendrocyte precursors, while in Figure 11, the sections are stained for Iba1 (brown), a marker of microglial activation.

Figure 10. Pepinemab Promotes Migration of Oligodendrocyte Precursor Cells

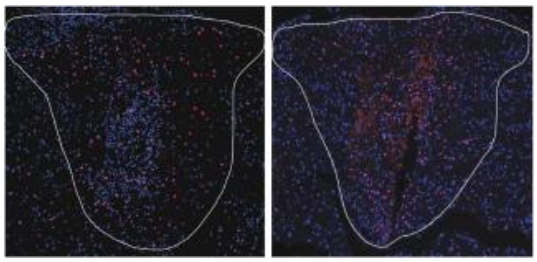
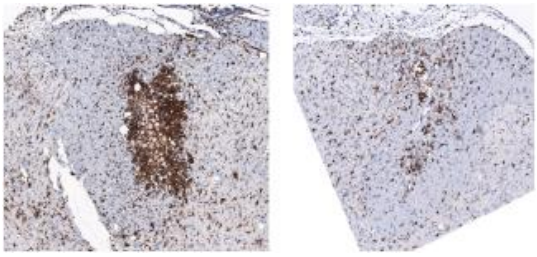


Figure 11. Pepinemab Inhibits Activation of Microglia



In addition to microglia, the second major type of innate inflammatory cells of the CNS is the astrocyte. Astrocytes comprise approximately half the cells of the brain. A single astrocyte makes numerous connections to other cells through cytoplasmic extensions. These connections allow astrocytes to provide trophic support in the form of growth factors and nutrients to neurons and other brain cells. Among other important astrocyte functions, the interaction of astrocytes with endothelial cells is required to induce tight junctions and form the blood-brain barrier. The blood vessels that feed the brain are covered with a specialized extension of the astrocyte. In addition, astrocytes are responsible for reabsorbing approximately 80% of the free excitatory transmitter, typically

glutamate, released at nerve synapses. This is believed to be an important function to reduce the danger of excitotoxicity induced by high concentrations of excitatory transmitter that can lead to loss of function and degeneration of post-synaptic neurons. Astrocyte activation is common to a number of different neurodegenerative diseases, including Huntington's disease and progressive MS. When astrocytes are activated, their cytoskeletons partially collapse, and they lose cell contacts. This can cause loss of trophic support and increased concentrations of excitotoxic transmitters leading to neurodegenerative effects. We observed that astrocytes express high levels of receptors for SEMA4D. To determine the effect of SEMA4D signaling on astrocytes, we isolated purified rat astrocytes in culture and investigated the effect of adding recombinant SEMA4D. Quantitative measure of the level of polymerized actin, or F-actin, demonstrated that SEMA4D signaling through receptors on astrocytes results in a statistically significant loss of F-actin, which in turn results in partial collapse of cytoskeleton and corresponding loss of cell contacts. We have therefore concluded that SEMA4D is an important factor for activation of both astrocytes and microglia.

The Unmet Medical Need for Huntington's Disease

Huntington's disease is a neurodegenerative genetic disorder that typically manifests in mid-adult life. People with Huntington's disease experience profound neurodegeneration predominantly in the basal ganglia and cortex, which are brain areas critically involved in motor control and cognitive function. Individuals afflicted with Huntington's disease develop involuntary movements, known as chorea, as well as significant cognitive and psychiatric problems. The gene inheritance is based on a single mutated autosomal dominant gene. Therefore, an individual with one mutated copy of the gene inherited from either parent will develop the disease. In general, if an individual has the disease, each of his or her children is at 50% risk of inheritance. The disease often manifests in mid-adult life, and as a result, an individual may have already raised a family and unwittingly passed on the mutated gene prior to diagnosis. Thus, each diagnosis may affect more than just one person with devastating impact on the family. To date, treatment is largely directed towards management of symptoms and improving quality of life without much potential for disease modification.

Individuals at risk of Huntington's disease can be identified by a simple genetic test. There is, therefore, an opportunity for preventative therapy in this devastating inherited disease. We believe a therapeutic that can promote remyelination and repair of damaged nerves and protect against breakdown of the blood-brain barrier while simultaneously reducing inflammation would represent a powerful and comprehensive approach toward preventing or delaying disease onset.

There is no known cure for Huntington's disease. According to the Huntington's Disease Society of America, there are over 30,000 people in the United States who have been clinically diagnosed with Huntington's disease and an additional 250,000 people that are at risk of inheriting the mutated Huntington's disease allele from their parents. Less than 5% of at-risk individuals pursue predictive genetic testing, due to a lack of effective treatments. However, because there is a 50% chance of inheriting the mutated allele, roughly 125,000 people from the at-risk pool will ultimately develop Huntington's disease. The development of a disease-modifying therapy could encourage at-risk patients to seek out testing.

Current Approaches to the Treatment of Huntington's Disease

Despite extensive medical research into the pathogenesis of Huntington's disease, little progress has been made in developing disease-modifying treatment. Treatment is mainly limited to palliative measures, which evolve as the disease advances. Sometimes, medications to treat some symptoms generate side effects that worsen other symptoms, which complicate the overall treatment regimen and necessitates regular reviews of medications by physicians and updates to the treatment protocol.

To treat movement disorders, clinicians often prescribe antichoreic drugs, such as tetrabenazine or Teva's Austedo ® (deutetrabenazine), or neuroleptics. Tetrabenazine and Austedo are specifically approved by the FDA to reduce the involuntary jerking and writhing movements associated with Huntington's disease. However, tetrabenazine carries serious side effects, including worsening or triggering depression, insomnia, drowsiness, nausea and restlessness. Austedo, a deuterated form of the drug, was approved in April 2017 and may have reduced side effects. Commonly used neuroleptics include Haldol ® (haloperidol) and clozapine, which can suppress unwanted movements but can also worsen involuntary contractions and muscle rigidity. Other drugs prescribed to alleviate motor symptoms include anti-seizure medications such as Klonopin® (clonazepam) and anti-anxiety drugs like Valium ® (diazepam), although these drugs alter consciousness and carry risks of dependence and abuse.

For psychiatric symptoms, clinicians prescribe antidepressants, antipsychotics, or mood-stabilizing drugs depending on the severity and particular constellation of symptoms for each patient. The antidepressants commonly used in treating Huntington's disease patients are serotonin reuptake inhibitors, such as Lexapro ® (escitalopram), Prozac ® (fluoxetine), or Zoloft ® (sertraline). Antipsychotics may also be used to suppress violent outbursts, agitation, and other symptoms of mood disorders or psychosis. Mood-stabilizing drugs can treat bipolar symptoms when they are present, including lithium and anticonvulsants, such as valproic acid and lamotrigine. These drugs can cause weight gain, tremors, or gastrointestinal symptoms. To supplement medications, psychotherapy can help Huntington's disease patients cope and manage behavioral problems while also fostering communication with family members.

Our Approach to Huntington's Disease

We are studying pepinemab for the treatment of early-stage Huntington's disease as well as preventative treatment of prodromal (pre-manifest) subjects, a target population of individuals who have not yet reached the point of clinical diagnosis but are known to carry the dominant Huntington's disease mutation. We believe SEMA4D impacts the pathology of Huntington's disease through multiple mechanisms, making SEMA4D a promising target for therapeutic development in this disease. Our primary goal is to develop a treatment that will prevent or delay the progress of, or reduce the symptoms of, the disease in early manifest patients. In patients with prodromal disease, we will seek to prevent or delay disease onset and will employ clinically validated biomarkers as endpoints in our Phase 2 clinical trial because diagnostic endpoints are not available for preventative therapy. The potential biomarkers include imaging markers, cognitive tests and quantitative motor assessments that have been shown in two large observational studies to progress, including during the 10 years just prior to disease onset. The FDA standard for an approvable biomarker is that the biomarker should be "reasonably likely to predict clinical benefit." We believe that an effective way to meet this standard for the prodromal population would be to demonstrate that clinical outcomes are correlated with a biomarker in manifest disease and that the same biomarker is associated with treatment in pre-manifest disease. It is for this reason that our Phase 2 SIGNAL study in Huntington's disease includes assessments of both clinical/functional endpoints and imaging biomarkers in both the early manifest and late prodromal populations.

Investigators have developed an algorithm that relates the projected age of disease onset directly to the age of a patient and inversely to the length of the mutation in the *Huntingtin* gene. It is, therefore, possible to initiate preventative therapy during a span of years that are expected to precede disease diagnosis and during which time we believe the available biomarkers may undergo meaningful changes in the prodromal population.

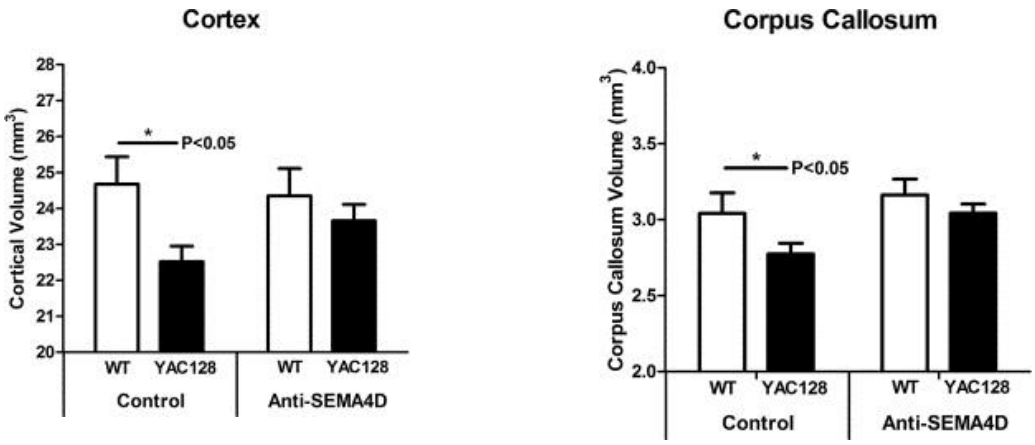
Clinical Development of Pepinemab in Neurodegenerative Indications

Early Studies and Preclinical Data

We have conducted preclinical studies evaluating the pepinemab antibody as a therapeutic agent for multiple neurological indications. We examined pepinemab in a transgenic mouse model of Huntington's disease, finding that weekly pepinemab administration prevented brain degeneration in areas affected by Huntington's disease. pepinemab-treated mice also exhibited improvements in a range of behavioral and cognitive tests, but not motor tests. We also examined changes induced by pepinemab in a mouse model of MS, observing substantial reductions in neuroinflammatory processes and a sparing of myelin degradation. These preclinical results were important proof-of-concept steps necessary to move forward with clinical trials in multiple neurological indications.

Huntington's disease is based on a single mutated gene, and there are transgenic animals that express this gene and reproduce many of the characteristics of the human disease. We and our academic collaborators evaluated the pepinemab antibody as a potential preventative therapy for Huntington's disease patients in the yeast artificial chromosome, or YAC, transgenic mouse model that expresses full-length mutated human Huntingtin gene, or YAC128, and reproduces many of the characteristic signs and symptoms of Huntington's disease. Starting at six weeks of age, YAC128 and normal wild type, or WT, control mice received either pepinemab or isotype-control antibodies weekly for 47 weeks. Before the mice reached 12 months of age, behavioral assessments and tissue analyses were performed to determine any benefits from treatment with the pepinemab antibody. As illustrated below in Figure 12, the results demonstrated a significant reduction in the loss of cortical and white matter volume in the brain of the transgenic animals. Loss of brain volume is a characteristic neuropathology in these animals that is also observed in both Huntington's disease and progressive MS patients.

Figure 12. Pepinemab Treatment Significantly Inhibits Cortical and Corpus Callosum Degeneration in Brains of YAC128 Mice

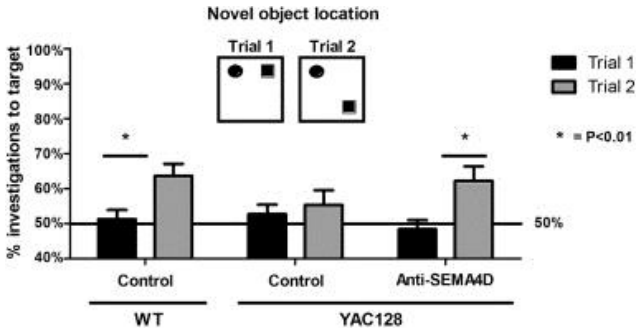


Cortical (grey matter) volume and Corpus Callosum (white matter) volume were determined in transgenic (YAC128) and WT control mice that had been treated with either control or pepinemab antibody from six weeks of age until sacrifice at 12 months. Open bars are normal mice, closed bars are YAC128 mutant mice.

The mice were evaluated in an open-field activity test, which measures the presence of anxiety-like behavior as reflected in their tendency to avoid open space in the center of their cage. Control YAC128 transgenic mice had both a significantly reduced number of entries into the center and spent less time in the center. pepinemab-treated YAC128 mice had no significant difference in center entries from WT control mice, suggesting that pepinemab can reduce anxiety-like behavior. The study found similar results using total time spent in the cage center as its behavioral measure.

In another cognitive test, investigators found that pepinemab antibody treatment improved spatial memory in a novel object location test in the YAC128 mouse model of Huntington's disease. Mice are naturally curious and if an object is placed in their cage, they will investigate it through nose probes, or "sniffing." As demonstrated in Trial 1 in Figure 13, if two different shaped objects are placed at one end of the cage, they investigate both equally because both objects are novel. As demonstrated in Trial 2 in Figure 13, if the mouse is removed and one of the objects is relocated to the opposite end of the cage, then when the same mouse is reintroduced, it will preferentially investigate the object in the now novel location. This is illustrated in the WT control group of Figure 13, where the ratio of investigating the two different objects is represented by the white bars for Trial 1 and by the grey bars for Trial 2. However, as illustrated in YAC128 control group, if this same sequence of trials is performed with YAC128 mice, the ratio of investigating the two different objects is indistinguishable in Trial 1 and Trial 2. This suggests that these mice do not remember which location is old and which location is novel. In contrast, as illustrated in YAC128 anti-SEMA4D group, if YAC128 mice have been treated with pepinemab, then these mice show a memory trial performance indistinguishable from WT control mice. The data suggest that pepinemab may improve the working spatial memory deficits that are found in some neurological disorders such as Huntington's disease and Alzheimer's disease.

Figure 13. Pepinemab May Improve Spatial Memory in the YAC128 Mouse Model



Control WT mice preferentially explore an object in a novel location, while untreated YAC128 mice do not. Treatment of YAC128 with pepinemab antibody preserved this WT behavior.

Completed Phase 1 Clinical Trial

The safety and tolerability of pepinemab was initially assessed in a Phase 1 dose-escalation clinical trial in MS patients. In November 2014, we completed a multi-center, double-blind, placebo controlled, single-ascending dose Phase 1 safety and tolerability clinical trial of intravenous pepinemab in 50 adult patients with MS. Pepinemab was well tolerated in this Phase 1 clinical trial. No dose-limiting toxicity was found in five cohorts with doses ranging from 1 to 20 mg/kg. Only one serious adverse event has been reported and was deemed unrelated to the study treatment. This same clinical trial also provided quantitative data that allowed us to estimate the half-life of the pepinemab antibody in patients as approximately 20 days. We believe this extended half-life will allow us to treat subjects once a month. This is desirable because prodromal subjects with active work lives would not wish to disrupt their schedule with clinic visits that are more frequent than once a month. We selected Huntington's disease as our initial indication for pepinemab because of the unmet need in the indication, as well as well-characterized natural history and biomarkers, and nearly 100% diagnostic precision based on presence of mutations. The data from the Phase 1 MS safety clinical trial has contributed to the safety database to enable initiation of a Phase 2 clinical trial in Huntington's disease.

Phase 2 Clinical Trial

Our SIGNAL study is designed to assess the safety and efficacy of pepinemab in early-stage and prodromal Huntington's disease patients. The SIGNAL study is a randomized, double-blind, placebo-controlled Phase 2 clinical trial evaluating the safety, tolerability, pharmacokinetics, and efficacy of intravenously administered pepinemab. We initiated the clinical trial in July 2015. We engaged a contract research organization specializing in Huntington's disease, HSG, to assist in site selection and trial management. Our clinical trial is structured as an adaptive design with an initial Cohort A of 36 patients treated monthly for six months with either pepinemab or placebo in a 1:1 ratio. At the end of six months, the placebo group crossed over to pepinemab so that all subjects were treated with the drug until month 12. Enrollment in Cohort B was completed in December 2018 and includes a total of 265 subjects in two cohorts: 179 patients in group 1 (B1) who have early manifest disease, and 86 in group 2 (B2) who are late prodromal. All subjects are randomized 1:1 to receive monthly infusions of either pepinemab or placebo for 18 months in double-blind fashion without crossover. Endpoints for this clinical trial include a cognitive assessment battery, and a quantitative motor assessment battery, each developed for Huntington's disease, as well as imaging by MRI and PET in a subset of patients. Two PET ligands will be employed: FDG-PET, which is expected to reflect effects on astrocyte activation, and TSPO-PET (PBR28), which is expected to reflect effects on microglial activation. These measures may provide confirmation of target engagement for two key mechanisms of action of pepinemab. The estimated primary completion date, which is the date on which the last participant in a clinical study was examined or received an intervention to collect final data for the primary outcome measure, for the SIGNAL study is the second half of 2020.

Figure 14 shows graphical representations of changes in MRI volume as a percentage of baseline over the full 11-month treatment period for the regions of frontal and parietal lobes that showed the largest consistent treatment effects. The pepinemab-treated group (blue line) appears to be stabilized relative to the loss of MRI volume observed in the first six months by the placebo group (red line), which also appears to stabilize following cross-over to pepinemab at the end of six months. The data indicate that the delayed start does not catch up with early treatment in terms of preservation of MRI volume within this time frame, suggesting a benefit to early treatment.

Figure 14. MRI: Mean Change from Baseline in Regions of Frontal and Parietal Cortex
Pepinemab Treatment vs. Placebo

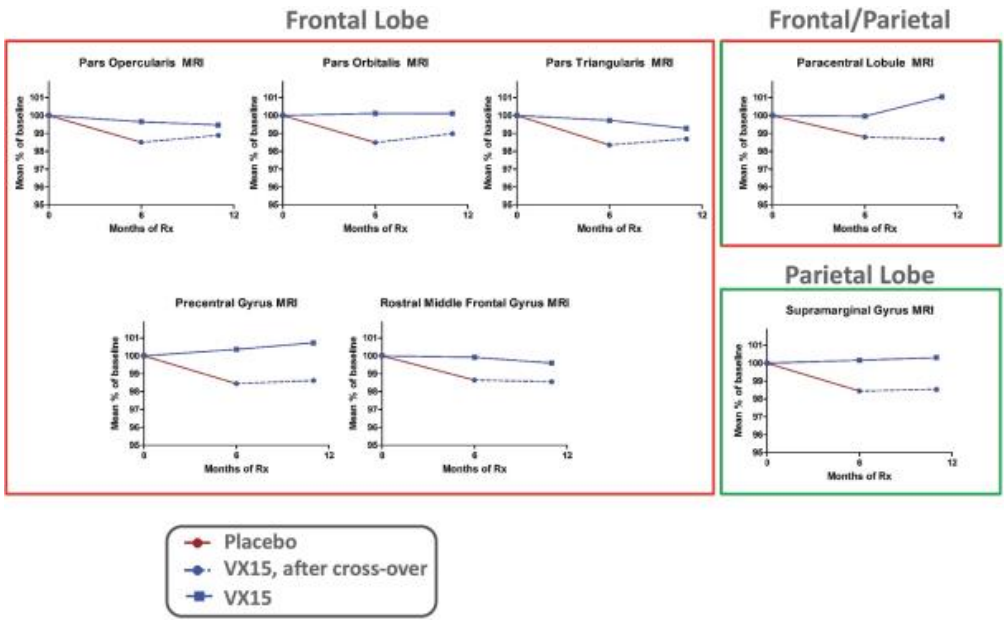


Figure 15 shows graphical representations of changes in FDG-PET signal as a percentage of baseline over the full 11-month treatment period for the regions of frontal and parietal lobes that showed the largest consistent treatment effects. The pepinemab-treated group (blue line) shows an initial increase in metabolic activity (FDG-PET signal) during the first six months, which in six of the nine regions, as indicated by an asterisk (*), is statistically significant with a p-value of less than 0.05, followed by the more stabilizing effect of continuing treatment relative to the loss of metabolic activity observed in the first six months of the placebo group (red line). The placebo group also shows a sharp increase in metabolic activity following cross-over to pepinemab at the end of six months, which parallels in magnitude and significance the change seen following the initial six months of treatment in the pepinemab-treated group. Statistical significance means that a result is unlikely to have occurred by chance, and the p-value is the probability that the difference between two data sets was due to chance. The smaller the p-value, the more likely the differences are not due to chance alone. In drug development, preclinical study and clinical trial results are generally considered statistically significant when the probability of the results occurring by chance, rather than from the effect of the drug candidate, is sufficiently low. The FDA generally considers a p-value of less than or equal to 0.05 to be statistically significant.

Figure 15. FDG-PET: Mean Change from Baseline in Regions of Frontal and Parietal Cortex
Pepinemab Treatment vs. Placebo

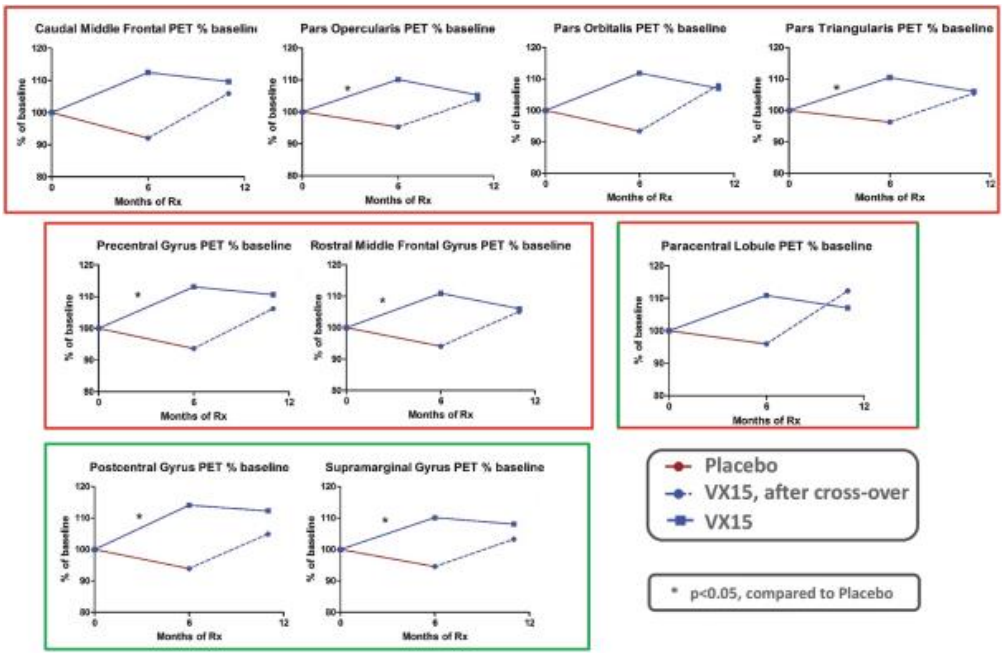


Figure 15 indicates statistically significant changes in FDG-PET uptake for six of nine regions and a consistent trend of increase in volumetric MRI in multiple cortical regions.

Our ActivMAb Antibody Discovery Platform

Overview

ActivMAb is a proprietary human antibody discovery platform based on a novel method for expressing large and diverse libraries of high affinity, full-length human monoclonal antibodies on the surface of the vaccinia virus. The vaccinia virus is a mammalian virus that enables synthesis and selection of fully human monoclonal antibodies in mammalian cells where they undergo the post-translational modifications that distinguish mammalian cells from either bacteria or yeast. We believe our ActivMAb technology offers several advantages over selection platforms that utilize bacterial or yeast expression vectors:

- rapid generation of high affinity, full-length, human monoclonal antibodies synthesized and naturally modified in mammalian cells;
- expression and selection of antibodies that easily and predictably transition to manufacturing in mammalian lines; and
- efficient selection of antibodies against multi-pass membrane proteins, an important class of pharmaceutical targets.

By leveraging the advantages of our ActivMAb platform over alternative bacterial and yeast-based technologies, we believe we can build a significant pipeline of therapeutics antibodies in multiple disease indications through both our own internal discovery efforts and through collaborations. Our product candidate VX5 was generated by our ActivMAb platform, and is a high-affinity, human IgG1 antibody to CXCL13, a chemokine that induces development of lymphoid tissue. VX5 has initiated IND-directed development for the treatment of MS and potentially for other autoimmune disorders.

Our Approach to Antibody Discovery

Our ActivMAb platform uses a novel method for synthesizing and naturally modifying fully human monoclonal antibodies on the surface of the vaccinia virus. Traditionally, the most common methods for selecting fully human antibodies have been through immunization of immunoglobulin transgenic mice, which has the disadvantage of tolerance to the many target determinants that are common to both mice and humans (approximately 90%), or through use of in vitro libraries synthesized and expressed in either bacterial or yeast cultures. While library-based methods of antibody selection avoid the problem of tolerance, the selected antibodies are synthesized in an environment that differs from the mammalian cells in which they will ultimately be manufactured and their properties in that environment are not always predictable. By expressing antibodies on a virus that infects mammalian cells, our antibodies undergo the normal range of modifications characteristic of such cells. We believe that these antibodies can more predictably transition to manufacturing in mammalian cell lines that are commonly used to produce commercial quantities of therapeutic antibodies.

Monoclonal antibodies were first produced in mice and although these were relatively easy to generate, mouse antibodies have significant drawbacks as targeted therapeutics in patients. The major drawback is that a mouse monoclonal antibody is recognized by the human immune system as a foreign target and therefore, the immune system attacks the antibody, rendering it useless against its intended target. Many advances have been made to genetically engineer and humanize monoclonal antibodies. In addition, full-length human antibodies can be created employing a limited number of alternative technologies, such as our ActivMAb platform.

Our ActivMAb platform is designed to include complementary DNA, or cDNAs, of interest in recombinant vaccinia viruses and to enable high-throughput screening of antibodies with desirable properties that are expressed on the viral surface. The vaccinia virus is an enveloped virus, which means that its protein capsid is protected by a cell membrane. The viral envelope typically expresses several viral surface glycoproteins, which are key components that define how the virus interacts with its host organism. These viruses have been engineered to efficiently express full-length IgG antibodies on the envelope surface permitting for recognition of desired target antigens. In effect, the technology enables the equivalent of phage display in mammalian cells. This is intended to have the dual advantage of allowing expression of full-length functional antibodies and reflecting the post-translational modifications of protein expression that distinguish mammalian cells from bacteria and yeast. The platform can aid in de novo antibody selection, optimization of antibody affinity, or conversion of a non-human antibody into a panel of fully human antibodies.

We believe antibodies selected for development through ActivMAb will be efficiently expressed because both discovery and eventual clinical and commercial manufacturing are in similar types of mammalian cells.

Importantly, our technology also allows multi-pass membrane proteins to be expressed on the vaccinia virus envelope, a setting in which very few other proteins are expressed but which supports the natural configuration of such targets. This makes it possible to efficiently select antibodies against this important class of pharmaceutical targets without the complication of numerous false positives that would occur in their normal setting of a naturally complex cell membrane.

VX5 for Autoimmune Disease

VX5 is our first product candidate generated from our ActivMAb platform. VX5 is a human antibody to CXCL13, a molecule that regulates the formation of immune tissues, and has initiated IND-directed development for the treatment of MS and potentially for other autoimmune disorders.

During a normal immune response, the interaction of CXCL13 and its receptor CXCR5 on B cells and follicular helper T cells directs those cells to primary follicles in lymph nodes and the spleen and induces germinal center formation and lymphoid organogenesis. In a chronically inflamed environment, ectopic lymphoid follicles form within affected tissues. Over-expression of CXCL13 in these tertiary lymphoid organs, accompanied by deregulation of regulatory interactions among immune cells, enables survival of autoreactive B cells and the generation of high affinity antibodies that contribute to development of autoimmune diseases, such as rheumatoid arthritis and MS.

In preclinical studies, anti-CXCL13 antibodies such as VX5 have been shown to prevent CXCL13 from interacting with its CXCR5 receptor, resulting in interference with B cell and T helper cell migration into inflamed tissues and ultimately the reduction of inflammatory and autoimmune responses. Therapeutic administration of anti-CXCL13 has been demonstrated to prevent disease progression in mouse models of rheumatoid arthritis and MS.

Discovery Collaborations with Third Parties

General Terms of Master Agreements

We have offered the ActivMAb platform as a discovery tool to third parties since 2014. We enter into separate master agreements with each client that generally provide for one or more target molecules for antibody selection. The client provides sufficient quantities of antigens for use in each program, and we use our ActivMAb platform to select human monoclonal antibodies against the antigen that substantially comply with the applicable program requirements set forth in the master agreement. Pursuant to each agreement, we may receive a technology access fee and research payments and are eligible to receive a success fee.

Following our delivery of a selected antibody, the client will obtain a non-exclusive, worldwide, royalty-free, limited-purpose license to use the selected antibody for research and testing purposes. Additionally, each client generally has an exclusive option to obtain an exclusive product license to develop and commercialize each selected antibody. If the client enters into a product license with respect to a particular antibody, it may, in the case of a proprietary target or in consideration for certain payments, preclude us, for a certain time period, from undertaking or performing any activities, services or programs to identify or develop any antibodies to an antigen that is the subject of the product license.

Pursuant to these agreements, we will own (i) all inventions and know-how discovered, developed, made, conceived or generated in the course of or as a direct result of the activities conducted under a discovery program that relate to the construction of immunoglobulin gene libraries or the process for the selection of monoclonal antibodies from such libraries and (ii) any and all antibodies generated under the discovery programs.

In addition to an upfront technology access fee, we are generally eligible to receive additional research support and performance payments with respect to each discovery program under the master agreement. In addition, if the client exercises its option to obtain an exclusive product license to develop and commercialize selected antibodies, we would be eligible to receive milestone payments and low single-digit royalties on future net sales of products commercialized by client.

Multi-Pass Membrane Protein Research

A novel recent development of our ActivMAb platform is the ability to efficiently select antibodies against multi-pass membrane proteins. Multi-pass membrane proteins, which constitute the largest and most diverse group of membrane receptors in eukaryotes, are an important class of targets for pharmaceutical products. Many small molecule drugs target multi-pass membrane proteins, but it has been difficult to select antibodies against them because natural cellular membranes are a complex environment with many different proteins and specific multi-pass proteins cannot be purified away from the membrane without denaturing. We have invented fusion protein technology to enable the direct incorporation of multi-pass membrane proteins such as G protein-coupled receptors, or GPCRs, and ion channels into the viral membrane. This method is rapid, does not require any detergents or refolding, and can be applied to multiple different cell types in order to maximize protein expression. Antigen-expressing virus can be readily purified and used for antibody selection by using this method.

We have entered into collaboration agreements with respect to GPCR drug targets. For example, in September 2017, we entered into a research agreement with Merck to demonstrate functional expression of two different multi-pass membrane proteins on the vaccinia envelope as a proof of concept study, and in the fourth quarter of 2018 entered a second agreement with Merck to test these antigen particles in an antibody discovery campaign. In addition, in November 2017, we entered into an agreement with Surface Oncology to select an antibody against two target antigens, including an undisclosed human multi-pass membrane protein. We expect delivery of the selected antibodies in the second quarter of 2019.

Catalent Pharma Solutions

In October 2017, we entered into an agreement with Catalent to select an antibody to a cancer membrane target suitable for construction of an antibody drug conjugate, or ADC, employing proprietary Catalent technology. Pursuant to the agreement, we will license a Vaccinex-optimized antibody candidate to Catalent for construction of the ADC, testing for efficacy in an animal tumor model, and manufacture for evaluation of tolerability in rodents and cynmologous monkeys. The ADC will be jointly owned by us and Catalent. We have agreed pursuant to the agreement to discuss in good faith a business relationship to promote and market the ADC.

We believe that other biotechnology or pharmaceutical companies may be interested in the opportunity to efficiently select and express specific antibodies required for drug development against novel target antigens. As collaborations with our ActivMAb platform progress, we will seek to increase our economic return and explore opportunities to enter into discovery and co-development arrangements.

Our NKT Vaccine Platform

Our NKT vaccine platform uses agonists that we and our academic collaborators have designed to target and extend the activity of NKT cells, which work directly to kill certain types of parasites and cells, including tumor cells and virus-infected cells. Our NKT platform targets cancer, where we believe the agonists we have developed can minimize or prevent the response paralysis of NKT cells that normally follows stimulation by a strong agonist. We believe these agonists should prolong the activity of NKT cells and help to mobilize and maintain the overall immune response.

NKT cells serve as master regulators of the immune system. NKT cells secrete soluble molecules, cytokines and chemokines that trigger downstream activation of both innate and adaptive immune cells, including antigen presenting dendritic cells, antibody producing B cells, NK cells and T cells, while inhibiting myeloid derived suppressor cells. This cascade of events lowers the barrier for the induction of adaptive immune responses, thereby generating more effective responses. NKT cell activity in patients can be limited as a result of a low local concentration of NKT cells. These cells also frequently fail to respond or develop tolerance following just one round of stimulation by their agonists, which prevents continued stimulation and function. We are applying our agonists to direct NKT cells to the site of antigen presentation to enhance localized immune responses.

We direct NKT cells to the site of an antigen or tumor by administering a fusion protein created through the fusing of two genes that code for different proteins, in this case, a tumor antigen-specific antibody fragment and a molecular complex that efficiently activate NKT cells. The use of a soluble NKT cell-activating complex, as opposed to activation by antigen presenting cells, has been shown to avoid or reduce the tolerance that is typically present after the initial stimulation by agonists.

We have recently developed a means of covalent linkage that is far more stable and effective for NKT cell activation, which resolved a key problem of dissociation of the two components, CD1d and a glycolipid ligand, of the NKT-activating molecular complex when administered in vivo. A patent application has been filed to protect this proprietary technology.

VX25

VX25 is an investigational, bi-specific molecule based on our NKT vaccine platform. VX25 aims to address two major challenges for the therapeutic application of NKT cell stimulation for cancer immunotherapy: (i) the activation of NKT cells without inducing tolerance, or the natural resistance to a second cycle of activation by a strong agonist; and (ii) the efficient targeting of NKT cells to the site of tumors. We and our academic collaborators have designed molecules that incorporate a potent NKT-activating glycolipid in one arm and a tumor-targeting antibody fragment in a second arm. These constructs are being evaluated in various preclinical cancer models.

BVX20 for Multiple Sclerosis

BVX20, an investigational, novel, humanized monoclonal antibody that we selected, is under development by Biocon Limited, or Biocon, a pharmaceutical company based in India pursuant to an agreement entered into with Biocon in October 2009. BVX20 targets the CD20 antigen, which is expressed on both normal and malignant B cells, and the development pathway for BVX20 is currently focused on use in the treatment of patients with relapsing remitting or progressive MS.

Upon Biocon's completion of initial development of BVX20, we are entitled to elect to participate in the further development and commercialization of BVX20 with Biocon. If Biocon continues with clinical development and we choose not to participate, we are entitled to low single digit royalties under the agreement. The agreement is effective until the expiration of all payment obligations under the agreement, or the expiration of each party's obligations under any manufacturing and supply agreement and/or third-party licensing agreement. Either party may terminate the agreement in the event of bankruptcy or an uncured material breach by the other party. Under the terms of the agreement, we also granted Biocon a fully paid-up, royalty-free and exclusive license to our intellectual property to manufacture clinical and commercial supplies of BVX20.

Biocon initiated a Phase 1 clinical trial in India in patients with NHL. However, in March 2016, we mutually agreed with Biocon not to further pursue Phase 1 clinical trials in India for NHL. Biocon now plans to initiate a new Phase 1 clinical trial for the development of BVX20 in MS in the United States.

Manufacturing

We currently do not own or operate manufacturing facilities. We currently have no plans to build our own clinical or commercial scale manufacturing capabilities. We rely, and expect to continue to rely, on third-party contract manufacturing organizations, or CMOs, for the manufacture of our product candidates for clinical trials. Catalent is responsible for the manufacturing

of pepinemab for use in clinical trials, and we use other third-party CMOs for other aspects of the manufacturing process. We may elect to pursue other CMOs for manufacturing clinical supplies for later-stage trials and for commercialization.

Commercialization

We have not established sales, marketing or product distribution operations. We generally expect to retain some commercial rights in the United States for our product candidates for which we may receive marketing approvals. We expect to utilize a variety of types of collaboration, distribution and other marketing arrangements with one or more third parties to commercialize pepinemab, upon approval, and any other products that we develop and obtain approval for in markets outside the United States.

Competition

The biotechnology and pharmaceutical industries are characterized by continuing technological advancement and significant competition. While we believe our product candidates, technology, knowledge, experience and scientific resources provide us with competitive advantages, we face competition from major pharmaceutical and biotechnology companies, academic institutions, governmental agencies and public and private research institutions, among others. We believe we are the only company targeting SEMA4D as a potential treatment for neurodegenerative diseases, cancer or autoimmune disorders.

To the extent we are successful in developing pepinemab, we believe we would compete with products that utilize a different mechanism of action, particularly with respect to Huntington's disease because to date there are no marketed preventative therapeutic treatments for Huntington's disease. Yervoy, which targets the CTLA-4 protein, was the first immunomodulating monoclonal antibody to receive FDA approval. Recently, the FDA has also approved Keytruda and Opdivo for immunotherapy of melanoma and NSCLC, as well as other selected cancer indications. Other antibodies targeting PD-1 or PDL-1, including Tecentriq, Bavencio and Imfinzi, are also in clinical development and have received FDA approval for some cancer indications. These monoclonal antibodies may have been initially tested for specific selected indications, but their broad effects on the immune system as a whole make them potentially relevant across a wide range of solid tumors. We believe the differentiated mechanisms of action of pepinemab provide an opportunity to pursue combination therapy with one or more of these competing technologies. Given the known toxicity of immunotherapy, we believe the evidence from three clinical studies to date that pepinemab is well tolerated as a single agent makes it a potentially attractive candidate for combination therapy.

Any product candidates we successfully develop and commercialize may compete with existing therapies and new therapies that may become available in the future. Key product features that would affect our ability to effectively compete with other therapeutics include the efficacy, safety and convenience of our products. Similarly, our ActivMAb antibody discovery platform technology will also compete with marketed or future discovery platforms or alternative technologies on the basis of effectiveness, convenience and cost, among other factors. The level of generic competition and the availability of reimbursement from government and other third-party payors will also significantly affect the pricing and competitiveness of our products. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we enter the market. They may also obtain patent protection or other intellectual property rights that limit our ability to develop or commercialize our product candidates or platform technologies.

Many of the companies against which we may compete have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These companies also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

Intellectual Property

Overview

Our intellectual property is critical to our business and we strive to protect our technology, including by obtaining and maintaining patent protection in the United States and certain other countries for our platform technologies, product candidates, novel biological discoveries, and other inventions that are important to our business. We pursue broad patent protection for our platform technologies and for our product candidates. We initially pursue patent protection for compositions of matter, methods of use including various treatment indications, and methods of making. Throughout the innovation process, we seek to identify additional means of obtaining patent protection that would potentially enhance our commercial success, including obtaining patent protection for additional methods of use such as additional medical indications for our product candidates, and refinements and improvements of our platform technologies. We also rely on trade secrets relating to our discovery platform technology and product candidates and seek to

protect and maintain the confidentiality of proprietary information to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection.

Our success may also depend on our ability to obtain rights to intellectual property held by third parties that may be necessary or useful to our business. We generally obtain rights to third-party intellectual property through exclusive or non-exclusive licenses. If we are not able to obtain rights to intellectual property held by third parties that are necessary or useful to our business, our business could be harmed, possibly materially harmed.

The patent positions of biotechnology companies like ours, however, are generally uncertain and involve complex legal, scientific and factual questions. In addition, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Consequently, we may not obtain or maintain adequate patent protection for any of our product candidates or platform technologies. We cannot predict whether the patent applications we are currently pursuing will issue as patents in any particular jurisdiction, or whether the claims of any issued patents will provide sufficient protection from competitors. Any patents that we hold may be challenged, circumvented or invalidated by third parties. In such an event, it would have a material and adverse effect on our business and financial condition. For a more comprehensive discussion of the risks related to our intellectual property, please see "Risk Factors–Risks Related to Our Intellectual Property."

The patent portfolios for our platform technologies and our three most advanced product candidates are summarized below:

SEMA4D Antibody Platform and Pepinemab

Our intellectual property portfolio for our SEMA4D antibody platform and pepinemab includes several issued United States and foreign patents as well as pending U.S. and foreign patent applications encompassing compositions of matter for pepinemab, methods of use and methods of making. We wholly own rights to several families of patents and patent applications related to the SEMA4D antibody platform and pepinemab that will expire or are projected to expire between 2030 and 2038. The "Smith II" patent family discloses and claims a group of antibodies and encoding polynucleotides that includes the pepinemab antibody, as well as methods of making and using the antibodies. This family has a projected expiration date of May 2030. The Smith II family includes granted patents in the United States (four patents), Australia, China, Eurasia (validated in Russia, Armenia, Azerbaijan, Belarus, Kirgizstan, Kazakhstan, Moldova, Tajiksistan, and Turkmenistan), Europe (validated in Austria, Belgium, Czech Republic, Germany, Denmark, Finland, Spain, France, Ireland, the United Kingdom, Italy, Luxembourg, the Netherlands, Norway, Poland, Portugal, Sweden, and Switzerland), Israel, Japan (two patents), South Korea, Mexico (two patents), New Zealand (two patents), Singapore, and South Africa, and pending in Australia, Brazil, Canada, China, India, South Korea, Thailand, the United States and Vietnam. We also wholly own ten additional pepinemab-related patent families. These are directed to: (i) methods of modifying blood brain barrier permeability and treating neuroinflammatory disorders (projected expiration of October 2032; granted in Australia, Eurasia (validated in Russia), Japan, Mexico, Europe (validated in Austria, Belgium, Switzerland, Germany, Denmark, Spain, Finland, France, the United Kingdom, Italy, Luxembourg, the Netherlands, Norway, Portugal, and Sweden), New Zealand, South Africa, and Singapore, and pending in the United States, Brazil, Canada, China, Israel, South Korea, Thailand, and Vietnam (two applications)); (ii) methods of treating cancer and inhibiting angiogenesis using a combination of an anti-SEMA4D antibody and a VEGF inhibitor (projected expiration of December 2032; granted in the United States and pending in Canada); (iii) compositions comprising the pepinemab epitope on SEMA4D and related products such as a nucleic acid encoding the epitope, and methods of producing the polypeptide epitope (projected expiration of March 2033; granted in Australia, the United States, New Zealand, and South Africa, and pending in Canada); (iv) methods of promoting neurogenesis and treating stroke (projected expiration of May 2033; granted in Australia, Eurasia (validated in Russia), Japan, Mexico, New Zealand, and Singapore, and pending in the United States, Brazil, Canada, China, Europe, Israel, South Korea, Thailand and South Africa); (v) methods of treating cancer using a combination of a SEMA4D antagonist and an immune modulator (projected expiration of June 2034; granted in the United States (two patents), and pending in the United States, Australia, Brazil, Canada, China, Eurasia, Europe, Israel, India, Japan, New Zealand South Korea, Mexico, South Africa, Singapore, and Thailand); (vi) methods of inhibiting the growth of atherosclerotic plaques, inhibiting neovascularization and treating atherosclerosis (projected expiration of October 2034; granted in the United States and New Zealand, and pending in New Zealand, Australia, Brazil, Canada, China, Eurasia, Europe, Israel, Japan, South Korea, Mexico, Singapore, South Africa, and Thailand); (vii) methods of treating neurodegenerative disorders such as Huntington's disease (projected expiration of October 2034; granted in the United States (two patents) and New Zealand, and pending in the United States, New Zealand, Australia, Brazil, Canada, China, Eurasia, Europe, Israel, Japan, South Korea, Mexico, Singapore (two applications), South Africa, and Thailand); (viii) methods for early detection of glial cell activation in subjects having, suspected of having, or at risk of developing a neurodegenerative or neuroinflammatory disease such as Huntington's disease, and determining whether such subjects would benefit from treatment a SEMA4D antagonist (projected expiration of February 2038, international application under the Patent Cooperation Treaty, or the PCT, filed February 22, 2018); (ix) methods of treating cancer using a combination of a SEMA4D antagonist and an epigenetic modulator (projected expiration of March 2038, international application under the PCT filed March 14, 2018); and (x) a fully-human anti-SEMA4D antibody VX18 (projected expiration May 2038, international application under the PCT filed May 4, 2018).

In addition to the patents and applications wholly owned by us, our SEMA4D antibody platform patent portfolio also includes patents and applications exclusively licensed from third parties, including Institut National de la Santé et de la Recherche Médicale (INSERM) and the Tokyo Medical and Dental University of Japan.

The portfolio includes a patent family exclusively licensed to us by INSERM that has a projected expiration date of February 2024 and includes a Canadian patent and a European patent that both generically claim use of an anti-SEMA4D antibody to treat neuroinflammatory disorders such as MS. We have also exclusively licensed a family of applications directed to compositions and methods for treating osteoporosis and other bone-related diseases from the Tokyo Medical and Dental University of Japan. This family is granted in Australia, China, Europe (validated in Austria, Belgium, Switzerland, Germany, Denmark, Finland, France, the United Kingdom, Ireland, Italy, the Netherlands, Norway, Sweden, Spain, and Portugal), Japan, Mexico, New Zealand, Singapore and the United States, and is pending in Brazil, Canada, India, and South Korea. The application family has a projected expiration date of May 2032.

ActivMAb Antibody Discovery Platform

Our ActivMAb platform is encompassed by a patent family wholly owned by us, as well as granted U.S. and foreign patents in families that are exclusively licensed to us by the University of Rochester. These patent families broadly encompass the process and methods of use of the ActivMAb platform.

University of Rochester License Agreement. In connection with the formation of our company in 2001, a 1998 license agreement with the University of Rochester, or the Rochester Agreement, was assigned to us. Under the Rochester Agreement, the University of Rochester granted an exclusive, worldwide, sublicensable license to commercialize patents used in the discovery of antibodies. These patents are relevant to our ActivMAb antibody discovery platform. Under the Rochester Agreement, we are obligated to pay the University of Rochester low single-digit royalties on sales of products covered by the patents licensed to us under the Rochester Agreement as well as an annual license maintenance fee creditable in part against the royalties. In addition, with respect to the first product covered by the patents licensed to us under the Rochester Agreement, we are obligated to pay the University of Rochester milestone payments in de minimis amounts upon (i) the submission of the first IND application, (ii) the approval of the first IND application and (iii) the filing of the first 510(k) filing for a diagnostic. However, because the Rochester Agreement relates to our ActivMAb antibody discovery platform, while we intend to use these patents in our business, we do not intend to directly sell products covered by the patents licensed to us under the Rochester Agreement. The term of the University of Rochester license runs until the end of the enforceable term of any patents issued. The Rochester Agreement may also be terminated upon material breach or terminated by us upon 90 days' prior written notice to the University of Rochester.

ActivMAb Platform Patents. Three patent families covering the ActivMAb platform are wholly owned by us. The first family discloses and claims aspects of the technology as currently practiced that are improved over the in-licensed patent family discussed below. Pending claims in this family include product claims directed to fusion proteins, recombinant libraries, host cells and kits, as well as claims directed to methods of constructing libraries and methods of selecting antibodies possessing a desired specificity. This family has a projected expiration date of March 2033 in the United States and April 2033 in all other jurisdictions. This application family is granted in the United States (two patents), Australia, China, Europe (to be validated in Austria, Belgium, Denmark, Finland, France, Germany, Ireland, Italy, Luxembourg, Netherlands, Norway, Poland, Portugal, Spain, Sweden, Switzerland, and the United Kingdom), Eurasia (validated in Russia), and New Zealand, and is pending in the United States, Canada, Israel, Japan, South Korea, and Singapore. The second family discloses and claims compositions and methods for displaying multi-pass membrane proteins in native conformation on vaccinia virus extracellular virions to enable selection of antibodies binding to these proteins in our ActivMAb platform. This application has a projected expiration date of April 2037, and is pending in the United States, Australia, Brazil, Canada, China, Europe, India, Israel, Japan, South Korea, Mexico, New Zealand, Russia, Singapore, and South Africa. The third family discloses and claims methods for increasing the number of independent poxvirus genomes in our antibody libraries. This application has a projected expiration date of July 2037, and is pending in the United States, Australia, Brazil, Canada, China, Europe, India, Israel, Japan, South Korea, Mexico, New Zealand, Russia, Singapore, and South Africa.

A patent family licensed from the University of Rochester is directed to methods of producing and identifying immunoglobulin molecules in eukaryotic cells, as well as kits for the selection of antigen-specific recombinant immunoglobulins. This family has a projected expiration date of November 2021 in foreign countries and January and March 2025 in the United States. Patents are granted in this family in Australia (two patents), Canada, China, Europe (validated in Austria, Belgium, Switzerland, the United Kingdom, and Germany), Japan and the United States.

VX5

Our patent portfolio covering VX5 includes a family exclusively licensed from the University of Rochester that contains two U.S. patents and one Canadian patent with projected expiration dates in April 2025 in Canada and October 2025 and November 2026

in the United States. This family includes claims directed to methods of treating MS and rheumatoid arthritis, as well as methods of inhibiting inflammation or reducing ongoing inflammation using anti-CXCL13 antibodies.

The portfolio further includes three VX5-related patent families wholly owned by us. The first, directed to the VX5 composition and related methods, has a projected expiration date of September 2031. This family is granted in Australia, China, Europe (validated in Belgium, Switzerland, Germany, Denmark, Finland, France, the United Kingdom, Ireland, the Netherlands, Norway, and Sweden), Japan, Mexico, New Zealand, Singapore, South Korea, and the United States, and is pending in the United States, Brazil, Canada, and India. The application includes claims directed to antibodies, nucleic acids, vectors, cells and polypeptides, as well as methods for neutralizing CXCL13, and methods of treating autoimmune diseases or inflammatory diseases. The second family, directed to methods of treatment of B cell-mediated inflammatory diseases, *e.g.*, Sjogren's syndrome, has a projected expiration date of March 2033. This family is granted in the United States, Australia, China, Europe (validated in German, France, and the United Kingdom), Japan, and New Zealand, and is pending in Canada, India, and South Korea. The third family, directed to methods for increasing mucosal IgA levels, has a projected expiration date of January 2034. It is granted in the United States and Japan, allowed, in Australia, and is pending in Canada, China, Europe, South Korea, and New Zealand.

NKT Vaccine Platform

Our patent portfolio covering our NKT vaccine platform includes three families exclusively licensed from the Albert Einstein College of Medicine, or Einstein, and one co-owned by Einstein and us, as well as two families wholly owned by us. The families include granted patents and pending applications with projected expiration dates extending from September 2023 through February 2034.

The NKT vaccine portfolio includes three families owned or co-owned by Einstein. The first family, assigned to Einstein and exclusively licensed to us, has a projected expiration date of June 2026 in the United States and August 2025 in the remaining jurisdictions. This family has granted patents in Australia, Canada, China, Europe (validated in Germany, France, and the United Kingdom), Israel, India, Japan (two patents), South Korea, New Zealand and the United States (two patents). Claims in this first family are directed to various ceramide-like glycolipid compositions, methods of evaluating a compound for its ability to activate an NKT cell, and methods of treating or preventing an autoimmune disease, cancer or an infection. The second family, co-assigned to Einstein and us and exclusively licensed to us, has a priority date of February 2013 and a projected expiration date of March 2033 in the United States and February 2034 in all other jurisdictions. This family is granted in the United States (two patents) and Australia, is allowed in Europe, and is pending in Japan, China, Canada, South Korea, and New Zealand. Claims in this second family are directed to compositions that include modified ceramide-like glycolipids with photoreactive groups to allow covalent linkage of the glycolipid to CD1d in bispecific fusion constructs, and also includes methods of disease treatment. An additional related family directed to bacterial vaccines is assigned to Einstein and exclusively licensed to us. This family, projected to expire in January 2030, is granted in Australia, China, Europe (validated in Austria, Belgium, Denmark, Finland, France, German, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and Liechtenstein, and the United Kingdom), India, Japan, New Zealand, and the United States, is allowed in Japan and South Korea, and is pending in Canada and China. This family includes claims directed to compositions including ceramide-like glycolipid-modified bacteria, methods of treating or preventing disease using the modified bacteria, and methods of modulating a CD8 T-cell response to bacille Calmette-Guérin, or BCG, using the modified bacteria. Two NKT vaccine-related families are wholly owned by us. One has a projected expiration date of September 2023, and is granted in the United States, Europe (validated in Germany, France, and the United Kingdom) and Canada. This family includes composition claims directed to CD1d molecules fused to antibodies or fragments thereof targeted to specific antigens, and methods of treatment such as inducing anti-tumor responses, preventing or treating autoimmunity or inflammatory diseases, and methods of preventing or treating an infectious disease. The second has a projected expiration date of February 2028, is granted in the United States, Australia Europe (validated in Germany, France, and the United Kingdom), and Japan, is allowed in Canada, and is pending in the United States. This family includes claims directed to antigen-loaded CD1d molecules, as well as methods of modulating immune responses, methods of treating and/or preventing diseases, and methods of inhibiting an anergic effect of a ceramide-like glycolipid antigen on NKT cell activity.

Patent Protection

The term of individual patents depends on the legal term of the patents in the countries in which they are obtained. In countries in which we file, the patent term is at least 20 years from the filing date of a non-provisional patent application, assuming all maintenance fees and annuities are paid. The patent term in the United States may be extended beyond the 20-year term based on U.S. Patent and Trademark Office, or USPTO, delay. In various jurisdictions, the patent exclusivity covering a specific product can be extended in certain circumstances to account for delays in regulatory approval.

For example, in the United States the term of a patent that covers an FDA-approved product or a method of using or manufacturing the product may also be eligible for extension, which permits patent term restoration as compensation for the patent

term lost during product development and the FDA regulatory review process. Patent term extension, which can be applied to only a single patent and is effective only with regard to the approved product, can be available when the approval is the first permitted commercial marketing or use of the active ingredient. The length of the patent term extension is related to the length of time the drug is under development and then regulatory review and cannot extend the term of a patent more than 14 years from the date of product approval. Similar supplemental protection provisions are available in Europe and other foreign jurisdictions to extend the term of a patent that covers an approved drug. In the future, if and when our products receive FDA approval, we expect to apply for patent term extensions on patents covering those products, where applicable. We plan to seek patent term extensions to any of our issued patents in any jurisdiction where these are available; however, there is no guarantee that the applicable authorities, including the USPTO and the FDA in the United States, will agree with our assessment of whether such extensions should be granted, and if granted, the length of such extensions.

Trade Secret Protection

We also rely on trade secret protection for our confidential and proprietary information. Although we take steps to protect our proprietary information and trade secrets, including through contractual means with our employees and consultants, third parties may independently develop substantially equivalent proprietary information and techniques, or otherwise gain access to our trade secrets, or disclose our technology. Thus, we may not be able to meaningfully protect our trade secrets. It is our policy to require our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with us. These agreements provide that all confidential information concerning our business or financial affairs developed or made known to the individual during the course of the individual's relationship with us is to be kept confidential and not disclosed to third parties except in specific circumstances. Our agreements with employees also provide that all inventions conceived by the employee in the course of employment with us or from the employee's use of our confidential information are our exclusive property.

Government Regulation and Product Approval

United States Government Regulation

In the United States, the FDA regulates our current product candidates as biological products, or biologics, under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, and related regulations. Biologics are also subject to other federal, state and local statutes and regulations. The FDA and comparable regulatory agencies in state and local jurisdictions impose substantial requirements upon, among other things, the testing, development, manufacture, quality control, safety, purity, potency, labeling, storage, distribution, record keeping and reporting, approval, import and export, advertising and promotion, and postmarket surveillance of biologics. Although our product candidates are subject to these requirements, the ActivMAb and NKT platforms we utilize to develop our product candidates are not themselves subject to FDA regulation.

The FDA's policies may change, and additional laws and regulations may be enacted that could prevent or delay further development or regulatory approval of any product candidates, product or manufacturing changes, additional disease indications, or label changes. We cannot predict the likelihood, nature or extent of government regulation that might arise from future legislative or administrative action.

Failure to comply with applicable statutory and regulatory requirements at any time during the product development process, approval process or after approval may subject a sponsor to administrative or judicial enforcement actions. These actions could include the suspension or termination of clinical trials by the FDA, the FDA's refusal to approve pending applications or supplemental applications, withdrawal of an approval, warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, import detention, injunctions, fines, civil penalties or criminal prosecution. Any such administrative or judicial action could have a material adverse effect on us.

Although this discussion focuses on regulation in the United States, we anticipate seeking approval for and marketing of our product candidates in other countries, either independently or with collaborators. Generally, our product candidates will be subject to regulation in other countries that is similar in nature and scope as those imposed in the United States, although there can be important differences. In Europe, for example, some significant aspects of regulation are addressed in a centralized way through the European Medicines Agency, but country-specific regulation remains essential in many respects.

Biologics Development Process

Before a biologic may be marketed or sold in the United States, a sponsor generally must conduct nonclinical laboratory and animal tests; submit an IND application, which must become effective before clinical trials may begin; conduct adequate and well-controlled human clinical trials to establish the safety, purity and potency of the proposed biologic for its intended use or uses;

undergo pre-approval inspection of manufacturing facilities and sometimes clinical trial sites; and obtain FDA approval of a Biologics License Application, or BLA. The testing and approval process requires substantial time and financial resources, and we cannot be certain that any approvals for our product candidates will be granted on a timely basis, if at all.

Preclinical Testing. Before testing any compound in human subjects, a sponsor must develop extensive preclinical data. Preclinical testing generally includes laboratory evaluation of product chemistry and formulation, as well as toxicological and pharmacological studies in several animal species to assess the quality and safety of the product. Certain animal studies must be performed in compliance with the FDA's Good Laboratory Practice regulations, or GLP, and the United States Department of Agriculture's Animal Welfare Act and related regulations.

IND Application. Prior to commencing the first clinical trial in humans in the United States, an IND must be submitted to the FDA, and the IND must become effective. A sponsor must submit information, including preclinical testing results, to the FDA as part of the IND and the FDA must evaluate whether there is an adequate basis for testing the drug in humans. The IND automatically becomes effective 30 days after receipt by the FDA unless the FDA within the 30-day time period raises concerns or questions about the submitted data or the conduct of the proposed clinical trial and places the IND on clinical hold. In such case, the IND sponsor must resolve any outstanding concerns with the FDA before the clinical trial may begin. A separate submission to the IND must be made for each successive clinical trial to be conducted during product development. Further, an independent Institutional Review Board, or IRB, for each site proposing to conduct the clinical trial must review and approve the protocol and informed consent form for any clinical trial before it commences at that site. Informed consent must also be obtained from each study subject. Regulatory authorities, an IRB, a data safety monitoring board or the trial sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the study subjects are being exposed to an unacceptable health risk.

Clinical Trials. For purposes of developing product candidates for BLA approval, human clinical trials are typically conducted in phases that may overlap:

- Phase 1 – The investigational biologic is initially given to a small group of healthy human subjects or patients and tested for safety, dosage tolerance, reactivity, absorption, metabolism, distribution and excretion. These trials may also yield early evidence of effectiveness. During Phase 1 clinical trials, sufficient information about the safety of the investigational new drug must be obtained to permit the design of well-controlled and scientifically valid Phase 2 clinical trials.
- Phase 2 – Studies are conducted in a limited number of patients to identify possible adverse effects and safety risks, to initially assess the efficacy of the investigational product for the particular indication or indications sought within the target disease or condition and to determine dosage tolerance and optimal dosage. Multiple Phase 2 clinical trials may be conducted by the sponsor to obtain information prior to beginning larger and more expensive Phase 3 clinical trials.
- Phase 3 – When Phase 2 evaluations show that an investigational product may have a promising benefit-risk profile, Phase 3 clinical trials are undertaken at multiple clinical trial sites to establish statistically significant evidence of the safety, purity, and potency of the investigational biologic for the proposed use and the proposed dosing regimen, and to provide an adequate basis for product labeling and ultimately, for review and potential approval by the FDA.

All clinical trials must be conducted in accordance with Good Clinical Practice requirements, or GCPs, which establish standards for conducting, recording data from, and reporting the results of, clinical trials. GCPs are intended to assure that the data and reported results are credible and accurate, and that the rights, safety, and well-being of study participants are protected. A study sponsor is also required to submit to the National Institutes of Health, or NIH, for public posting on NIH's clinical trial website, www.clinicaltrials.gov, certain details about applicable clinical trials and clinical trial results.

Our planned clinical trials for our product candidates may not begin or be completed on schedule, if at all. Clinical trials can be delayed for a variety of reasons, including delays in:

- obtaining regulatory authorization to commence a study;
- reaching agreement with clinical trial sites and their subsequent performance in conducting accurate and reliable studies on a timely basis;
- obtaining IRB approval to conduct a study at a prospective site;
- recruiting patients to participate in a study; and
- supply of the investigational product and related materials.

Success in early stage clinical trials does not ensure success in later stage clinical trials. Data obtained from clinical trials are not always conclusive and may be susceptible to varying interpretations, which could delay, limit or prevent regulatory approval.

The BLA Process

BLA Submission and Review. In order to obtain approval to market a biologic in the United States, a BLA must be submitted to the FDA that provides data establishing to the FDA's satisfaction the safety, purity and potency of the investigational product for the proposed indication(s). Each BLA submission requires a substantial user fee payment unless a waiver or exemption applies. The application includes all relevant data available from pertinent nonclinical studies and clinical trials, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product's chemistry, manufacturing, controls and proposed packaging and labeling, among other things. Data may come from company-sponsored studies as well as from a number of alternative sources, including studies initiated by investigators and literature.

The FDA will initially review the BLA for completeness before accepting it for filing. Under the FDA's procedures, the agency has 60 days from its receipt of a BLA to determine whether the application will be accepted for filing based on the agency's threshold determination that the application is sufficiently complete to permit substantive review. If it determines that the application does not meet this initial standard, the FDA may refuse to file the application and request additional information, in which case the application must be resubmitted with the requested information, and review of the application is delayed. After the BLA is accepted for filing, the FDA reviews the BLA to determine, among other things, whether the proposed product is safe, pure and potent, which includes determining whether it is effective for its intended use, and whether the product is being manufactured in accordance with current Good Manufacturing Practices, or cGMPs, to assure and preserve the product's identity, strength, quality, potency and purity. The FDA may refer applications for novel products or products that present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved and, if so, under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions and usually has followed such recommendations.

During the approval process, the FDA also will determine whether a Risk Evaluation and Mitigation Strategy, or REMS, is necessary to assure the safe use of the biologic. A REMS may include various elements depending on what the FDA considers necessary for the safe use of the biologic, ranging from a medication guide or patient package insert to limitations on who may prescribe or dispense the biologic. If the FDA concludes that a REMS is needed, the BLA sponsor must submit a proposed REMS and the FDA will not approve the BLA without a REMS that the agency has determined is acceptable.

Certain applications for approval must include an assessment, generally based on clinical trial data, of the safety and effectiveness of the biological product in relevant pediatric populations. Under certain circumstances, the FDA may waive or defer the requirement for a pediatric assessment, either at the sponsor's request or by the agency's initiative.

FDA performance goals generally provide for action on a BLA within 10 months of filing, which (as discussed above) typically occurs within 60 days of submission, but that action date can be and frequently is extended in certain circumstances. For example, the review process is often significantly extended by FDA requests for additional information or clarification. A sponsor may apply to restore a portion of patent term lost during product development and FDA review of a BLA if approval of the application is the first permitted commercial marketing or use of a biologic containing the active ingredient. The patent term restoration period is generally one-half the time between the effective date of the IND and the date of submission of the BLA, plus the time between the date of submission of the BLA and the date of FDA approval of the product. The maximum period of restoration is five years, and the patent cannot be extended to more than 14 years from the date of FDA approval of the product. Only one patent claiming each approved product is eligible for restoration and the patent holder must apply for restoration within 60 days of approval. The USPTO, in consultation with the FDA, reviews and approves the application for patent term restoration.

For investigational products that are intended to treat serious diseases, certain mechanisms may expedite the development and FDA approval process. For example, the FDA may grant Priority Review designation to a product that could provide significant improvement in the treatment, diagnosis, or prevention of a serious condition. Priority Review sets the target date for FDA action on the application at six months from filing of the BLA, rather than the standard 10 months. Priority Review designation does not, however, change the standard for approval or the quality of evidence necessary to support approval. Another potential approach is Fast Track designation, which a sponsor can request at any time during the development process to facilitate development and expedite review of a product intended to treat a serious condition and fill an unmet medical need. Fast Track designation involves early and frequent communication between the FDA and the sponsor (e.g., about clinical trial design), and also allows rolling review, under which a sponsor may submit sections of its BLA for FDA review on an ongoing basis, rather than waiting to submit the BLA when the entire application is complete, each of which may lead to earlier BLA submission and approval. Breakthrough Therapy designation is another approach that is intended to expedite development and review of a product that is intended to treat a serious condition and where preliminary clinical evidence indicates that the product may demonstrate substantial improvement over available therapy on a clinically significant endpoint. Breakthrough Therapy designation provides all of the features of Fast Track designation, as well as the opportunity to obtain early and intensive guidance from the FDA for an efficient drug development program and a commitment to involve senior agency personnel in providing this guidance. A fourth approach is Accelerated Approval, which is available for a drug intended to treat a serious condition that fills an unmet need. FDA may grant accelerated approval based on such drug's effect on a surrogate endpoint or an intermediate clinical endpoint that is reasonably likely to predict clinical benefit, subject to the requirement that the sponsor conduct postmarketing confirmatory trials to verify the clinical benefit.

If the FDA determines that a BLA does not meet the regulatory standard for approval, it will issue a Complete Response letter to communicate that the agency will not approve the BLA in its current form and to inform the sponsor of changes the sponsor must make or additional clinical, nonclinical or manufacturing data the sponsor must provide before the FDA can approve the application, with no implication regarding the ultimate approvability of the application. If a Complete Response letter is issued, the sponsor may resubmit the BLA, addressing the deficiencies identified in the letter or withdraw the application.

Before approving a BLA, the FDA will inspect the facilities at which the product is manufactured. The FDA will not approve the product unless the agency determines that the manufacturing processes and facilities are in compliance with cGMP and are adequate to assure consistent production of the product within required specifications. Additionally, before approving a BLA, the FDA may inspect one or more clinical sites to assure compliance with GCP. If it determines that the application, manufacturing process or manufacturing facilities are not acceptable, the FDA typically will outline the deficiencies and often will request additional testing or information. This may significantly delay further review of the application. If the FDA finds that a clinical site did not conduct the clinical trial in accordance with GCP, the FDA may determine that the data generated by the clinical site should be excluded from analyses provided in the BLA. Additionally, notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

The testing and approval process for a biologic requires substantial time, effort and financial resources and this process may take several years to complete. The FDA may not grant approval on a timely basis, or at all. We may encounter difficulties or unanticipated costs in our efforts to secure necessary governmental approvals, which could delay or preclude us from marketing our products.

Even if a product candidate receives regulatory approval, the approval may be limited to specific disease states, patient populations and dosages, or might contain significant limitations on use in the form of warnings, precautions or contraindications, or in the form of a REMS, restrictions on distribution, or postmarketing study requirements. Further, even after regulatory approval is obtained, later discovery of previously unknown problems with a product may result in restrictions on the product or even complete withdrawal of the product from the market. In addition, we cannot predict what adverse regulations may arise from future governmental action.

Postmarketing Commitments. The FDA may require, or companies may pursue, additional clinical trials after a product is approved. These so-called Phase 4 clinical trials may be a condition to be satisfied for continuing drug approval. The results of Phase 4 clinical trials can, among other things, be intended to confirm the effectiveness of a product candidate that received Accelerated Approval, or to provide important safety information. In addition, the FDA has express statutory authority to require sponsors to conduct postmarket studies to specifically address safety issues identified by the agency.

Orphan Drug Exclusivity. The Orphan Drug Act provides incentives for the development of drugs and biological products intended to treat rare diseases or conditions, which generally are diseases or conditions affecting fewer than 200,000 individuals in the United States. If a sponsor demonstrates that a drug or biologic is intended to treat a rare disease or condition, the FDA may grant orphan drug designation to the product for that use. The benefits of orphan drug designation include research and development tax credits and exemption from the application user fees. A drug or biologic that is approved for the orphan designated indication generally is granted seven years of orphan drug exclusivity. During that period, the FDA generally may not approve any other application for the same product (for biologics, that means a product with the same principal molecular structural features) for the same use, although there are exceptions, most notably when the later product is shown to be clinically superior to the product with exclusivity.

Post-Approval Requirements

If and when approved, any product candidates manufactured or distributed by us or on our behalf will be subject to continuing regulation by the FDA, including requirements for record-keeping, reporting of adverse experiences, submitting annual reports, and reporting biological product deviations. Also, post-approval modifications to a licensed biologic, such as changes in indications, labeling, or manufacturing processes or facilities, may require a sponsor to develop additional data or conduct additional preclinical studies or clinical trials, to be submitted in a new or supplemental BLA, which would require FDA review and approval.

Good Manufacturing Practice. Manufacturers are required to register their facilities with the FDA and certain state agencies, and are subject to periodic inspections by the FDA and certain state agencies for compliance with cGMP, which relate to among other things organization of personnel, buildings and facilities, equipment, control of components and drug product containers and closures, production and process controls, packaging and labeling controls, holding and distribution, laboratory controls, quality control and quality assurance procedures, and records and reports. We cannot be certain that we or our present or future third-party manufacturers and suppliers will be able to comply with all cGMP and other applicable regulatory requirements. If we or our present or future suppliers are not able to comply with these requirements, the FDA may, among other things, halt our clinical trials, refuse to approve a BLA or other application, force us to recall a drug from distribution, shut down manufacturing operations or withdraw approval of a

BLA. Noncompliance with cGMP or other applicable FDA requirements can also result in other sanctions, including issuance of warning letters, fines, civil and criminal penalties, seizures, operating restrictions, and injunctive action.

Advertising and Promotion. The FDA and other federal and state agencies regulate the labeling, marketing, advertising and promotion of biologics. A biologic cannot be commercially promoted before it is approved. After approval, promotion of a biologic must be consistent with the labeling approved by the FDA. Although doctors may prescribe a product approved by the FDA for any use based on their professional judgment, a company may not promote its approved product for uses not approved by the FDA. Under certain conditions, however, a company may engage in non-promotional, balanced communication regarding an unapproved use. Any claims that a company makes in advertising or promotion about a product's approved uses must be adequately substantiated and effectiveness claims must be appropriately balanced with safety information. Failure to comply with these and other requirements may result in, among other consequences, untitled or warning letters, corrective advertising requirements, injunctions, potential civil and criminal penalties, criminal prosecution, and agreements with governmental agencies that materially restrict the manner in which a company promotes or distributes its products. Government regulators other than FDA, including the Department of Justice and the Office of the Inspector General of the Department of Health and Human Services, as well as state authorities, have scrutinized the promotion and marketing of drugs and biologics.

Biologics Price Competition and Innovation Act of 2009

The Biologics Price Competition and Innovation Act of 2009, or BPCIA, amended the Public Health Service Act to create a new licensure framework for biosimilar products. The BPCIA sets criteria for determining that a product is biosimilar to an already-licensed biologic, or reference product, and establishes a process by which an abbreviated BLA for a biosimilar product is submitted, reviewed and approved. In certain circumstances, the BPCIA provides periods of exclusivity that protect a reference product from biosimilar competition. If applicable, the exclusivities prevent the FDA from accepting a biosimilar application for review until four years after the date of first licensure of the reference product, and from approving the biosimilar until 12 years after the reference product's approval. Additionally, the BPCIA establishes procedures by which the biosimilar applicant provides information about its application and product to the reference product sponsor, and by which information about potentially relevant patents is shared and litigation over patents may proceed in advance of approval. The BPCIA also provides a period of exclusivity for the first biosimilar to be determined by the FDA to be interchangeable with the reference product.

In addition, the BPCIA incorporates by reference many provisions of section 505A of the Federal Food, Drug, and Cosmetic Act, such that if a sponsor conducts pediatric studies for a biologic that fairly respond to a written request from FDA, the 12-year exclusivity period will be deemed to be 12 1⁄2 years, and the 4-year period will be deemed to be 4 1⁄2 years.

The contours of the BPCIA are still being defined by the FDA through a variety of means, including issuance of guidance documents and decisions the agency has made in the course of considering and approving specific biosimilar applications. FDA may promulgate regulations to implement provisions of the BPCIA, as well. FDA's interpretation of the BPCIA, as well as court decisions in lawsuits regarding provisions of the BPCIA, may significantly affect the impact of the statute on both reference product and biosimilar sponsors. For example, the Supreme Court has held that, notwithstanding language in the statute that a biosimilar applicant "shall provide" certain information to the reference product sponsor, the information exchange is not mandatory.

Coverage and Reimbursement

In both domestic and foreign markets, sales of any product candidates for which we may receive regulatory approval will depend in part upon the availability of coverage and reimbursement from third-party payors. Such third-party payors include governmental healthcare programs, such as Medicare and Medicaid, private health insurers and managed care organizations and other entities. Coverage decisions may depend upon clinical and economic standards that disfavor new drug products when more established or lower cost therapeutic alternatives are already available or subsequently become available. Assuming coverage is granted, the reimbursement rates paid for covered products might not be adequate for us to sell on a profitable basis. Even if favorable coverage status and adequate reimbursement rates are attained, less favorable coverage policies and reimbursement rates may be implemented in the future. The marketability of any products for which we may receive regulatory approval for commercial sale may suffer if governmental healthcare programs and other third-party payors fail to provide coverage and adequate reimbursement to allow us to sell such products on a competitive and profitable basis. For example, under these circumstances, physicians may limit how much or under what circumstances they will prescribe or administer, and patients may decline to purchase, such products. This, in turn, could affect our ability to successfully commercialize our products and impact our profitability, results of operations, financial condition, and future success.

If we successfully commercialize any of our products, we may participate in the Medicaid Drug Rebate program. Participation is required for federal funds to be available for our covered outpatient drugs under Medicaid and, if applicable, Medicare Part B. Under the Medicaid Drug Rebate Program, we would be required to pay a rebate to each state Medicaid program for our covered outpatient

drugs that are dispensed to Medicaid beneficiaries and paid for by a state Medicaid program as a condition of having federal funds being made available to the states for our drugs under Medicaid and, if applicable, Part B of the Medicare program.

Federal law requires that any company that participates in the Medicaid Drug Rebate Program also participate in the Public Health Service's 340B drug pricing program in order for federal funds to be available for the manufacturer's drugs under Medicaid and Medicare Part B. The 340B drug pricing program requires participating manufacturers to agree to charge statutorily-defined covered entities no more than the 340B "ceiling price" for the manufacturer's covered outpatient drugs. These 340B covered entities include a variety of community health clinics and other entities that receive health services grants from the Public Health Service, as well as hospitals that serve a disproportionate share of low-income patients.

In addition, in order to be eligible to have its products paid for with federal funds under the Medicaid and Medicare Part B programs and purchased by certain federal agencies and grantees, a manufacturer also must participate in the U.S. Department of Veterans Affairs, or VA, Federal Supply Schedule, or FSS, pricing program. Under this program, the manufacturer is obligated to make its innovator and single source products available for procurement on an FSS contract and charge a price to four federal agencies, DoD Public Health Service and U.S. Coast Guard, that is no higher than the statutory Federal Ceiling Price. Moreover, pursuant to regulations issued by the DoD Defense Health Agency to implement Section 703 of the National Defense Authorization Act for Fiscal Year 2008, manufacturers are required to provide rebates on utilization of their innovator and single source products that are dispensed to TRICARE beneficiaries by TRICARE network retail pharmacies. The requirements under the 340B, FSS, and TRICARE programs could reduce the revenue we may generate from any products that are commercialized in the future and could adversely affect our business and operating results.

The market for any product candidates for which we may receive regulatory approval will depend significantly on the degree to which these products are listed on third-party payors' drug formularies or lists of medications for which third-party payors provide coverage and reimbursement. The industry competition to be included on such formularies often leads to downward pricing pressures on pharmaceutical companies. Also, third-party payors may refuse to include a particular branded drug on their formularies or otherwise restrict patient access to a branded drug when a less costly generic equivalent or another alternative is available. In addition, because each third-party payor individually approves coverage and reimbursement levels, obtaining coverage and adequate reimbursement is a time-consuming and costly process. We may be required to provide scientific and clinical support for the use of any product to each third-party payor separately with no assurance that approval will be obtained, and we may need to conduct expensive pharmacoeconomic studies in order to demonstrate the cost-effectiveness of our products. We cannot be certain that our product candidates will be considered cost-effective by third-party payors. This process could delay the market acceptance of any product candidates for which we may receive approval and could have a negative effect on our future revenues and operating results.

Federal and State Fraud and Abuse and Data Privacy and Security Laws and Regulations

In addition to FDA restrictions on marketing of pharmaceutical products, federal and state fraud and abuse laws restrict business practices in the pharmaceutical industry, and our marketing, sales, and distribution of any products for which we obtain marketing approval will be subject to scrutiny and enforcement under one or more federal or state health care fraud and abuse laws and regulations. These include the following fraud and abuse laws.

The federal Anti-Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce or in return for the referral of an individual for or purchasing, leasing, ordering or arranging for or recommending the purchase, lease or order of any item or service reimbursable under Medicare, Medicaid or other federal healthcare programs. The term "remuneration" has been broadly interpreted to include anything of value. The Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand and prescribers, purchasers and formulary managers on the other. Although there are a number of statutory exemptions and regulatory safe harbors protecting some common activities from prosecution, the exemptions and safe harbors are drawn narrowly. Practices that involve remuneration that may be alleged to be intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exemption or safe harbor. Moreover, there are no safe harbors for many common practices in the industry, including patient and product support programs, educational and research grants, and charitable donations. Several courts have interpreted the statute's intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered business, the statute has been violated. Liability under the Anti-Kickback Statute may be established without proving actual knowledge of this statute or specific intent to violate it. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act.

The federal civil False Claims Act imposes liability for, among other things, knowingly presenting, or causing to be presented, a false claim for payment of government funds or knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim, or for knowingly and improperly avoiding or decreasing an obligation to pay or transmit money

to the government. Actions under the False Claims Act can be brought by the federal government or as a qui tam action by a private individual in the name of the government, who may share in any judgments or settlements. Many pharmaceutical and other healthcare companies have been investigated and have reached substantial financial settlements with the federal government under the civil False Claims Act for a variety of alleged improper marketing activities, including allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product or causing false claims to be submitted because of the companies' marketing of products for unapproved, and thus non-reimbursable, uses. More recently, federal enforcement agencies are and have been investigating certain pharmaceutical companies' product and patient assistance programs, including manufacturer reimbursement support services, relationships with specialty pharmacies, and grants to independent charitable foundations. False Claims Act liability is potentially significant in the healthcare industry because the statute provides for treble damages and mandatory penalties in the tens of thousands of dollars. Conduct that results in a False Claims Act violation may also implicate various other federal criminal false claim and false statement statutes.

In addition, the federal Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, and its implementing regulations, or HIPAA, created federal criminal laws that prohibit knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private third-party payors, and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services.

Analogous state laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers; state laws that restrict the ability of manufacturers to offer co-pay support to patients for certain prescription drugs; state that require drug manufacturers to report information related to clinical trials, or information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; state laws and local ordinances that require identification or licensing of sales representatives. Foreign governments often have similar regulations, which we also will be subject to in those countries where we market and sell products.

The federal Physician Payments Sunshine Act, being implemented as the Open Payments program, which requires manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the Centers for Medicare and Medicaid Services information related to direct or indirect payments and other transfers of value to physicians and their immediate family members. Beginning in 2022, applicable manufacturers also will be required to report information regarding payments and transfers of value provided to physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, and certified nurse-midwives.

In addition, to the fraud and abuse laws described above, our business activities likely will be subject to data protection laws and regulations. In the U.S., numerous federal and state laws and regulations, including state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act), govern the collection, use, disclosure, and protection of health-related and other personal information. Failure to comply with data protection laws and regulations could result in government enforcement actions and create liability for us (which could include civil and/or criminal penalties), private litigation and/or adverse publicity. We may also obtain health information from third parties (e.g., healthcare providers who prescribe our products) that are subject to privacy and security requirements under HIPAA. Although we are not directly subject to HIPAA, other than potentially with respect to providing certain employee benefits, we could be subject to criminal penalties if we knowingly obtain or disclose individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA. HIPAA generally requires that healthcare providers and other covered entities obtain written authorizations from patients prior to disclosing protected health information of the patient (unless an exception to the authorization requirement applies). If authorization is required and the patient fails to execute an authorization, or the authorization fails to contain all required provisions, then we may not be allowed access to and use of the patient's information and our research efforts could be impaired or delayed. Furthermore, use of protected health information that is provided to us pursuant to a valid patient authorization is subject to the limits set forth in the authorization (e.g., for use in research and in submissions to regulatory authorities for product approvals). In addition, HIPAA does not replace federal, state, international or other laws that may grant individuals even greater privacy protections.

Because of the breadth of these laws and the narrowness of available statutory exemptions and regulatory safe harbors, our marketing, sales, and distribution of any products for which we obtain marketing approval could be subject to challenge, investigation or legal action under one or more of such laws or regulations. If our operations are found to be in violation of any of the federal and state laws described above or any other governmental regulations that apply to us, we may be subject to criminal liability and imprisonment, and significant civil and administrative penalties, including, without limitation, damages, fines, exclusion from

participation in government healthcare programs like Medicare and Medicaid, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. To the extent that any of our product candidates receive approval and are sold in a foreign country, we may be subject to similar foreign laws and regulations, which may include, for instance, applicable postmarketing requirements, including safety surveillance, anti-fraud and abuse laws, and implementation of corporate compliance programs and reporting of payments or transfers of value to healthcare professionals.

Healthcare Reform

In the United States and some foreign jurisdictions, there have been, and continue to be, a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any product candidates for which we obtain marketing approval. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. In March 2010, President Obama signed into law the Affordable Care Act, which has substantially changed the way healthcare is financed by both governmental and private insurers, and significantly impacted the pharmaceutical industry. Among the provisions of the Affordable Care Act (as amended by the Health Care and Education Reconciliation Act, collectively referred to herein as the Affordable Care Act) of importance to our business, including, without limitation, our ability to commercialize, and the prices we may obtain for, any of our product candidates that are approved for sale, are the following:

- an annual, nondeductible fee on any entity that manufactures or imports branded prescription drugs and biologic agents, apportioned among these entities according to their sales of branded prescription drugs under certain government healthcare programs such as Medicare and Medicaid;
- increases in the statutory minimum rebates a manufacturer must pay as a condition to having covered drugs available for payment under the Medicare Part B and Medicaid programs;
- expansion of healthcare fraud and abuse laws, including the federal False Claims Act and the federal Anti-Kickback Statute, and the addition of new government investigative powers and enhanced penalties for non-compliance;
- extension of a manufacturer's Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- a Medicare Part D coverage gap discount program, under which a participating manufacturer must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, commonly known as the "donut hole," as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D. The Bipartisan Budget Act of 2018, among other things, amended the Medicare statute, effective January 1, 2019, to reduce the coverage gap further by raising the required manufacturer discount to 70% off the negotiated price for Medicare Part D beneficiaries in the coverage gap beginning in 2019;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new eligibility categories for certain individuals with income at or below 133% of the federal poverty level beginning in 2014;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- the new requirements under the federal Open Payments program created as part of the Physician Payments Sunshine Act under Section 6002 of the Affordable Care Act and its implementing regulations, which requires manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the U.S. Department of Health and Human Services information related to "payments or other transfers of value" made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals. Applicable manufacturers and applicable group purchasing organizations must also report annually to the U.S. Department of Health and Human Services ownership and investment interests held by physicians (as defined above) and their immediate family members. Data collection for these reporting requirements began on August 1, 2013, and manufacturers were required to submit reports to the U.S. Department of Health and Human Services by March 31, 2014. Beginning in 2015, manufacturers are required to submit data reports by the 90th day of each calendar year. The U.S. Department of Health and Human Services discloses the information on a public website;
- a new requirement to annually report drug samples that manufacturers and distributors provide to physicians; and
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

Some of the provisions of the Affordable Care Act have yet to be fully implemented, and certain provisions have been subject to judicial and Congressional challenges. In addition, there have been efforts by the Trump administration to repeal or replace certain

aspects of the ACA and to alter the implementation of the ACA and related laws. For example, the Tax Cuts and Jobs Act enacted on December 22, 2017, or the Tax Act, eliminated the tax-based shared responsibility payment for individuals who fail to maintain minimum essential coverage under section 5000A of the Internal Revenue Code of 1986, commonly referred to as the "individual mandate," effective January 1, 2019. Additional legislative changes, regulatory changes, and judicial challenges related to the Affordable Care Act remain possible. It is unclear how the Affordable Care Act and its implementation, as well as efforts to repeal or replace, or invalidate, the Affordable Care Act, or portions thereof, will affect our business.

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. For example, beginning April 1, 2013, Medicare payments for all items and services, including prescription drugs and biologics, were reduced by 2% under the sequestration required by the Budget Control Act of 2011, as amended by the American Taxpayer Relief Act of 2012. Subsequent legislation has extended the reduction through 2027. The American Taxpayer Relief Act of 2012 also reduced Medicare payments to several types of health care providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. It is possible that the Affordable Care Act, as currently enacted or as may be amended in the future, as well as other health care reform measures that may be adopted in the future, may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, and new payment methodologies, as well as in additional downward pressure on coverage and payment and the price that we receive for any approved product, once commercialized. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payers.

Regulation Outside of the United States

We are also subject to numerous federal, state and local laws relating to such matters as safe working conditions, manufacturing practices, environmental protection, fire hazard control, and disposal of hazardous or potentially hazardous substances. We may incur significant costs to comply with such laws and regulations now or in the future.

Employees

As of December 31, 2018, we had 44 full-time employees and no part-time employees. Of the full-time employees, 35 were primarily engaged in research and development activities and 15 have an M.D. or a Ph.D. degree. None of our employees are represented by labor unions or covered by collective bargaining agreements. We believe our relationship with our employees is good.

Financing Arrangements with Canadian Investors

Vaccinex Products

Beginning in November 2009, we entered into financing arrangements with certain Canadian investors to advance the development of certain therapeutic monoclonal antibodies under development by us in certain indications. As a result of these investments, the investors, which included FCMI Financial Corp., or FCMI Financial, and its parent company, FCMI Parent, each of which are related parties and controlled by our chairman, Albert D. Friedberg, received noncontrolling interests in two Delaware partnerships, VX Therapeutics LP, or VX1, and VX2 (Delaware) LP, or VX2. In connection with the initial investments in VX1 and VX2, we licensed to Vaccinex Products, LLC, or Products LLC, our wholly owned subsidiary, and Products LLC then sublicensed to VX1 and VX2, certain intellectual property rights in the relevant antibodies. In consideration therefor, VX1 and VX2 issued return-oriented securities to Products LLC that were convertible into partnership interests in VX1 and VX2, respectively, which had principal balances of $97,184,800 and $70,000,000, respectively. VX1 and VX2 also entered into separate services agreements with us under which we would develop such antibodies in exchange for service fees to be paid by VX1 and VX2 under the services agreements.

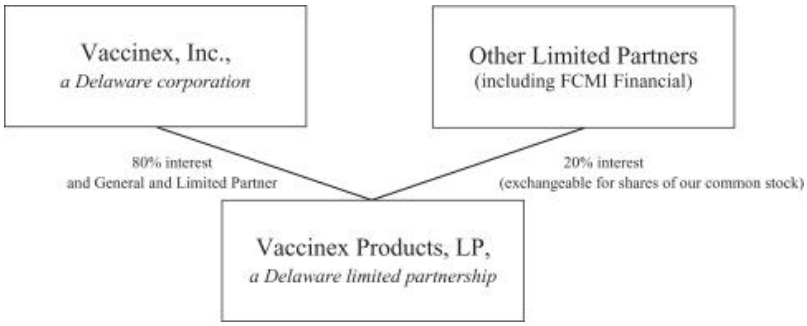
During 2012, VX1 transferred its rights to continue to develop antibodies to VX2 and the VX1 noncontrolling investors were given the option to exchange, at any time, their interests in VX1 for shares of our common stock. Also, during 2012, FCMI Parent invested $12.0 million of additional funds in VX2. In June 2012, FCMI Parent, as the assignee of FCMI Financial, exchanged an approximate 47.8% interest in VX1 for 247,342 shares of our common stock. In April 2013, FCMI Parent as the assignee of FCMI Financial exchanged an approximate 8.1% interest in VX1 for 41,720 shares of our common stock. As a result of these exchanges, we then owned 55.8% of the interests in VX1.

In October 2014, pursuant to a series of transactions we refer to as the Reorganization, we reorganized these entities to simplify the structure and the contractual relationships associated with the ownership of rights to our intellectual property. Under the Reorganization, Products LLC was merged with and into us and we became the successor to all existing licenses and service agreements between Products LLC and VX1 and VX2. As successor to Products LLC, we triggered a conversion of the return-oriented securities that had their original principal balances, plus certain accrued but unpaid annual payment obligations, that had previously been held by Products LLC into partnership interests in VX1 and VX2. We created a new partnership, Vaccinex Products, and VX1 and VX2 were consolidated with and into Vaccinex Products, pursuant to which VX1 and VX2 partnership interests were converted into a single class of limited partnership interests of Vaccinex Products. As a result of the Reorganization, Vaccinex Products retains the combined license rights previously held by VX1 and VX2 through an amended license agreement with us and we are currently an 80% owner and the sole general partner of Vaccinex Products. The former VX1 and VX2 noncontrolling investors, Vaccinex Products and we are parties to an amended exchange agreement pursuant to which each noncontrolling investor has the option, at any time, to exchange all, but not less than all, of its Vaccinex Products units on a 1-for-10 basis into shares of our common stock. To date, no such non-controlling investors have elected to convert their Vaccinex Products units into shares of our common stock. The exchange agreement also provides that in the event FCMI Financial exercises its option to exchange all, but not less than all, of its Vaccinex Products units for shares of our common stock, it would trigger the exchange of all Vaccinex Products units held by the other noncontrolling investors for shares of our common stock. Further, under the exchange agreement, we have a right to require the exchange of all units held by the noncontrolling investors for shares of our common stock in any of the following circumstances:

- we enter into a transaction such as a sale, merger or consolidation such that shares of our common stock are or will be sold or exchanged for cash and/or marketable securities;
- at any time on or after October 24, 2019;
- either we or Vaccinex Products enters into a licensing, partnering or similar transaction with respect to one or more products and indications licensed to Vaccinex Products by us, and all amounts then due and owing to Vaccinex Products in connection with such transaction have been paid to Vaccinex Products; or
- if in connection with such exchange, we purchase or repurchase the Vaccinex Products units or shares of our common stock that are held by or issuable to the noncontrolling investors for cash (or cash is otherwise distributed to the investors) in an amount equal to 15%, in the case of FCMI Financial, and 23%, in the case of all other investors, of the then fair market value of our common stock that would otherwise be delivered to such investor pursuant to such exchange.

In aggregate, the Vaccinex Products units held by the former VX1 and VX2 noncontrolling investors are exchangeable into 1,202,566 shares of our common stock, of which 967,983 shares would be beneficially owned by FCMI Parent.

Upon completion of the Reorganization in 2014 and our initial public offering, or IPO, the resulting ownership structure is as follows:



VX3

In November 2017, we entered into a license agreement, or the VX3 License Agreement, with VX3, which was formed in October 2017 by a group of Canadian investors including our majority stockholder FCMI Parent. Under the VX3 License Agreement, we granted VX3 the license to use, make, have made, sell, offer and import pepinemab for the treatment of Huntington's disease in the U.S. and Canada. Pursuant to the VX3 License Agreement, VX3 agreed to pay us up to an aggregate of $32.0 million in milestone payments in connection with the filing of a BLA or the receipt of regulatory approvals in the United States and/or Canada, as applicable. In addition, VX3 is entitled under the VX3 License Agreement to a share of any pepinemab profits and sublicensing revenue in an amount obtained by multiplying the profits and sublicensing revenue, respectively, by a fraction, the numerator of which is the sum of (A) the aggregate capital contributions made to VX3 by its limited partners and (B) the aggregate milestone payments paid to us under the VX3 License Agreement and the denominator of which is the sum of (1) $130 million and (2) the aggregate costs incurred by us for the pepinemab development costs incurred by us since the effective date of the VX3 License Agreement, and we are entitled to the remainder of the profits and sublicensing revenue. In connection with the VX3 License Agreement, we also entered into the Services Agreement with VX3 effective as of January 1, 2017, pursuant to which we will carry out development activities for pepinemab for the treatment of Huntington's disease in the U.S. and Canada in exchange for services payments from VX3, including a payment of $11.9 million for 2017 net of certain related expenses. On February 28, 2018, May 15, 2018 and June 12, 2018, the Services Agreement was amended to provide for additional payments of $8.0 million, $2.0 million and $2.0 million, respectively, from VX3 to us for services performed in 2018. The VX3 License Agreement expires upon the last to expire licensed patent and may be terminated by either party upon uncured material breach, the occurrence of certain transactions or financings including the consummation of an initial public offering by us, uncured failure of VX3 to make any payment due under the services agreement, or upon written notice after November 6, 2020. The Services Agreement may be terminated by either party upon uncured material breach and is automatically terminated upon termination of the VX3 License Agreement. The VX3 License Agreement provides that upon termination, we will issue to VX3 or its designees the number of shares of our common stock equal to the lesser of (1) the aggregate of all capital contributions made to VX3 by its partners (i.e. the Canadian investors) divided by $18.20 and (2) the then fair market value of VX3 divided by the then fair market value of one share of our common stock. We have determined VX3 to be a VIE in which we are the primary beneficiary.

On March 16, 2018, we entered into an agreement with VX3 and its partners, including FCMI Parent, pursuant to which the parties agreed, immediately prior to the consummation of our IPO, to execute an exchange agreement in the form attached thereto providing each VX3 partner with the right to exchange all, but not less than all, of its partnership interests in VX3 for shares of our common stock. The exchange agreement, which we entered into on August 13, 2018, provides that in the event FCMI Parent exercises its option to exchange its VX3 partnership interests for shares of our common stock, it would trigger the exchange of all VX3 partnership interests for shares of our common stock. Further, under the exchange agreement, we will have a right to require the exchange of all partnership interests in VX3 for shares of our common stock in any of the following circumstances:

- we enter into a transaction such as a sale, merger or consolidation such that shares of our common stock are or will be sold or exchanged for cash and/or marketable securities;
- at any time on or after the fifth anniversary of the exchange agreement; or
- either we or VX3 enters into a licensing, partnering or similar transaction with respect to one or more products and indications licensed to VX3 by us, and all amounts then due and owing to VX3 in connection with such transaction have been paid to VX3.

Corporate Information

We were incorporated under the laws of the State of Delaware in April 2001. Our website address is www.vaccinex.com. Our website and the information contained on, or that can be accessed through, the website will not be deemed to be incorporated by reference in, and are not considered part of, this Annual Report on Form 10-K.

Item 1A. Risk Factors.

We operate in rapidly changing business environments that present numerous risks, many of which are driven by factors we cannot control or predict. You should consider carefully the risks and uncertainties described below, together with the other information contained in this Annual Report on Form 10-K, including Management's Discussion and Analysis of Financial Condition and Results of Operations and the consolidated financial statements and related notes. We cannot assure you that any of the events discussed below will not occur. These events as well as additional risks and uncertainties we are unaware of, or currently believe are not material, could have a material and adverse impact on our business, results of operations, financial condition and cash flows.

Risks Related to Our Financial Position and Capital Needs

We have incurred net losses since our inception and anticipate that we will continue to incur net losses for the foreseeable future.

We are a clinical-stage biotechnology company with a limited operating history. Investment in biotechnology product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate efficacy or an acceptable safety profile, obtain regulatory approval or become commercially viable. We have not generated any revenue from product sales to date, and we continue to incur significant development and other expenses related to our ongoing operations. As a result, we are not and have never been profitable and have incurred losses in each period since our inception in 2001. For the years ended December 31, 2018, and 2017, we reported a net loss of $29.5 million, $18.8 million, respectively. As of December 31, 2018, we had an accumulated deficit of $216.8 million.

We expect to continue to incur significant losses for the foreseeable future, and we expect these losses to increase as we continue our research and development of, and seek regulatory approvals for, our product candidates. We may also encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenues, if any. Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders' equity and working capital.

We currently have no source of product revenue and may never achieve or maintain profitability.

To date, we have not generated any revenue from our product candidates. Our ability to generate product revenue and become profitable depends on a number of factors, including, but not limited to, our ability to:

- successfully complete research and clinical development of current and future product candidates;
- timely commence, enroll, conduct and complete clinical trials;
- secure and maintain collaborations, licensing or other arrangements for the future development and/or commercialization of our product candidates, as well as the terms of those arrangements;
- complete and submit applications to, and obtain regulatory approval from, the FDA and foreign regulatory authorities;
- identify and develop additional product candidates;
- achieve market acceptance for our product candidates if and when they are approved;
- develop a commercial organization capable of sales, marketing and distribution in our core strategic markets, or enter into relationships with third parties to do the same;
- obtain coverage and adequate product reimbursement from third-party, including government, payors;
- establish, maintain and protect our intellectual property rights; and
- attract, hire and retain additional qualified personnel.

In addition, due to the numerous risks and uncertainties associated with product development, including that our product candidates may not advance through development or achieve the endpoints of applicable clinical trials, we are unable to predict the timing or amount of expenses, or when or if we will generate revenue and ultimately be able to achieve or maintain profitability. Even if we are able to complete the process described above, we anticipate incurring significant costs associated with commercializing these products.

Even if we are able to generate revenues from the sale of our products, we may not become profitable and may need to obtain additional funding to continue operations. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and be forced to reduce our operations.

We will require additional capital to finance our operations prior to the commencement of the fourth quarter of 2019 to continue as a going concern, which may not be available to us on acceptable terms, if at all. As a result, we may not complete the development and commercialization of our product candidates or develop new product candidates and have identified conditions that raise substantial doubt about our ability to continue as a going concern.

Our recurring net losses and negative cash flows from operations raise substantial doubt about our ability to continue as a going concern within one year after the issuance of our consolidated financial statements as of and for the year ended December 31, 2018, as discussed in Note 1 to our consolidated financial statements as of and for the year ended December 31, 2018. Our independent registered public accounting firm has also noted this in the opinion they issued on our consolidated financial statements for the years ended December 31, 2018, and 2017. Our ability to continue as a going concern is dependent upon our ability to obtain additional equity or debt financing, attain further operating efficiencies, reduce expenditures, and, ultimately, to generate revenue. We will have to raise additional working capital and funds for operations. However, no assurance can be given that additional financing will be available, or, if available, will be on terms acceptable to us. Our financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Our operations have consumed substantial amounts of cash since inception. We expect to continue to spend substantial amounts to advance the clinical development of our product candidates. We may develop our own commercial organization to address specific markets, which may require additional capital. Given our projected operating requirements and our existing cash and cash equivalents and marketable securities, we plan to complete an additional financing transaction prior to the commencement of the fourth quarter of 2019 in order for us to continue operations. However, circumstances may cause us to consume capital even more rapidly than we currently anticipate. For example, as we move our lead product candidate through clinical trials and submit Investigational New Drug applications for new indications or other product candidates, we may have adverse results requiring us to find new product candidates or our development plans and anticipated clinical trial design may need to be altered.

Additional fundraising efforts may divert our management from our day-to-day activities, which may adversely affect our ability to develop and commercialize future product candidates. In addition, we cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us we may have to significantly delay, scale back or discontinue the development or commercialization of one or more of our product candidates or the range of indications for which they are developed. If we raise additional funds through the issuance of additional debt or equity securities, it could result in dilution to our existing stockholders, and/or increased fixed payment obligations. Furthermore, these securities may have rights senior to those of our common stock and could contain covenants that would restrict our operations and potentially impair our competitiveness, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. Any of these events could significantly harm our business, financial condition and prospects.

Our future capital requirements will depend on many factors, including, among others:

- the scope, rate of progress, results and costs of our clinical trials, preclinical studies and other research and development activities;
- the timing of, and the costs involved in, obtaining regulatory approvals for any of our current or future product candidates we may develop or in-license;
- the number and characteristics of product candidates that we develop or in-license, if any;
- the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- the effect of competing technological efforts and market developments;
- our ability to establish collaborative arrangements to the extent necessary;
- the economic and other terms, timing and success of any collaboration, licensing, distribution or other arrangements into which we may enter in the future;
- revenues received from any product candidates that are approved; and
- payments received under any current or future strategic partnerships.

If a lack of available capital prevents us from expanding our operations or otherwise capitalizing on our business opportunities, our business, financial condition and results of operations could be materially adversely affected. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us we may have to significantly delay, scale back or discontinue the development of one or more of our product candidates or cease operations.

We may have higher than anticipated tax liabilities, including related to our ability to use net operating loss carryforwards and as a result of the effects of changes in tax laws and regulations.

We plan to use our current year operating losses to offset taxable income from any revenue generated from operations. To the extent that our taxable income exceeds any current year operating losses, we plan to use our net operating loss, or NOL, carryforwards to offset income that would otherwise be taxable. However, under the Tax Reform Act of 1986, the amount of benefits from our NOL carryforwards may be impaired or limited if we incur a cumulative ownership change of more than 50%, as interpreted by the U.S. Internal Revenue Service, over a three-year period. As a result, our use of federal NOL carryforwards could be limited by the provisions of Section 382 of the U.S. Internal Revenue Code of 1986, as amended, depending upon the timing and amount of additional equity securities that we issue. In addition, we have not performed an analysis of limitations, and we may have experienced an ownership change under Section 382 as a result of past financings. State NOL carryforwards may be similarly limited. Any such disallowances may result in greater tax liabilities than we would incur in the absence of such a limitation and any increased liabilities could adversely affect our business, results of operations, financial condition and cash flow.

On December 22, 2017, the Tax Cuts and Jobs Act, or the Tax Act, was signed into law. The Tax Act, among other things, reduces the corporate tax rate to 21% effective January 1, 2018, generally limits utilization of losses generated after 2017 to 80% of future annual taxable income, eliminates the corporate alternative minimum tax, and modifies or repeals many business deductions and credits. Notwithstanding the reduction in the corporate tax rate, the overall impact of the Tax Act is uncertain and our business and financial condition could be adversely affected. In addition, it is uncertain how various states will respond to the Tax Act.

Risks Related to Our Business and Industry

Our product candidates are in preclinical development or early stages of clinical development. We cannot predict if we will receive regulatory approval to commercialize any of our product candidates.

All of our product candidates are in early stages of development, and they will require extensive preclinical and clinical testing. We cannot predict with any certainty if or when we might submit a biologics license application, or BLA, for regulatory approval for any of our product candidates or whether any such BLA will be accepted for review by the FDA, or whether any BLA will be approved.

Even if our clinical trials are completed as planned, we cannot be certain that their results will support our target indications. Success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful, and we cannot be sure that the results of later clinical trials will replicate the results of prior clinical trials. If our clinical trial results are not positive, we may terminate the clinical trials for a product candidate and abandon any further research or testing of that product candidate. Any delay in, or termination of, our clinical trials will delay and possibly preclude the submission of any BLAs to the FDA and, ultimately, our ability to obtain approval for and commercialize our product candidates and generate product revenues.

We depend heavily on the success of our lead product candidate pepinemab, and if we had to cease developing pepinemab, it would have adverse effects on our business and future prospects.

Pepinemab is our most advanced product candidate, and we are focused on developing it for NSCLC and Huntington’s disease. Additionally, one investigator-sponsored trial, or IST, is evaluating pepinemab in osteosarcoma and another is studying pepinemab in melanoma. We do not have control over trial design or conduct of ISTs, which may identify adverse reactions associated with our product candidates. Any problems that arise in development of pepinemab for one indication, or in one trial, may have an adverse effect on the development of pepinemab for other indications and could cause us to cease development of pepinemab altogether. Similarly, as part of our SEMA4D antibody platform strategy, we intend to also develop pepinemab in additional neurodegenerative disease and cancer indications. Any adverse result or event that causes us to cease developing or limits our development of pepinemab would have adverse effects on our existing business, as well as our future prospects.

If our product candidates fail to meet safety and efficacy endpoints in clinical trials to the satisfaction of regulatory authorities or do not otherwise produce positive results, they will not receive regulatory approval, and we will be unable to market them.

Before obtaining marketing approval from regulatory authorities for the sale of our future product candidates, we or our collaborators must conduct extensive clinical trials to demonstrate the safety and efficacy of the product candidates in humans. Clinical testing is expensive and difficult to design and implement, can take many years to complete and is uncertain as to outcome. A failure of one or more clinical trials can occur at any stage of testing. The outcome of preclinical studies and early clinical trials may not predict the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in advanced clinical trials due to lack

of efficacy or unacceptable safety profiles, notwithstanding promising results in earlier trials. Despite the results reported in our Phase 1 clinical trials for pepinemab and in preclinical studies for pepinemab and our other product candidates, we do not know whether the clinical trials we or our collaborators may conduct will demonstrate adequate efficacy and safety to result in regulatory approval to market any of our product candidates in any particular jurisdiction or jurisdictions. If later-stage clinical trials do not produce favorable results, our or our collaborators' ability to achieve regulatory approval for any of our product candidates may be adversely impacted.

If we experience delays in clinical testing, we will be delayed in obtaining approval of our product candidates, our costs may increase, and our business may be harmed.

We do not know whether any of our clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. Our product development costs will increase if we experience delays in clinical testing. Significant clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do, which would impair our ability to successfully commercialize our product candidates and may harm our business, results of operations and prospects. Numerous circumstances may result in a delay or failure in attaining successful completion of clinical development, including but not limited to:

- delays or failure in obtaining approval from institutional review boards, or IRBs, or ethics committees, or ECs, to begin clinical trials at study sites;
- imposition of a clinical hold by the FDA, or a decision by the FDA, other regulatory authorities, IRBs, ECs, or recommendation by a data safety monitoring board to suspend or terminate clinical trials at any time for safety issues or for any other reason;
- delays in reaching agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites;
- deviations from the trial protocol by clinical trial sites and investigators, or failure to conduct the trial in accordance with regulatory requirements;
- failure of third parties, such as CROs, to satisfy their contractual duties or meet expected deadlines;
- delays in the testing, validation, manufacturing and delivery of the product candidates to the clinical sites;
- for clinical trials in selected patient populations, delays in identification and auditing of central or other laboratories and the development, transfer and validation of assays or tests to be used to identify selected patients;
- delays in enrolling and having patients complete participation in a trial or return for post-treatment follow-up;
- delays caused by patients dropping out of a trial due to side effects, disease progression or other reasons;
- withdrawal of clinical trial sites from our clinical trials as a result of changing standards of care or the ineligibility of a site to participate in our clinical trials; or
- changes in government regulations or administrative actions or lack of adequate funding to continue the clinical trials.

Any inability by us or our collaborators to timely complete clinical development could result in additional costs to us or impair our ability to generate product revenues or development, regulatory, commercialization and sales milestone payments, or royalties on product sales.

If we or our collaborators encounter difficulties enrolling patients in clinical trials, the clinical trials could be delayed or otherwise adversely affected.

The timely completion of clinical trials largely depends on patient enrollment. Many factors affect patient enrollment, including:

- the nature and size of the patient population;
- the number and location of participating clinical sites;
- competition with other companies for clinical sites or patients;
- design of the trial protocol;
- ability to obtain informed consents from patients; and
- clinicians' and patients' perceptions as to the potential advantages of the drug being studied in relation to other available therapies, including any drugs that may already be approved for the indications we are investigating.

If we have difficulty enrolling a sufficient number of patients to conduct our clinical trials as planned, we may need to delay or terminate ongoing or planned clinical trials, either of which would have an adverse effect on our business.

We may not successfully identify, develop or commercialize potential product candidates.

The success of our business depends primarily upon our ability to identify and validate new biotherapeutics and/or applications, including through the use of our SEMA4D antibody platform, our ActivMAb antibody discovery platform and our NKT cell-based vaccine platform, and identify, develop and commercialize antibodies and product candidates, which we may develop ourselves or develop on behalf of or out-license to others. Our research efforts may initially show promise in discovering potential new targets or biotherapeutic product candidates, yet fail to result in product candidates for clinical development for a number of reasons, including:

- our research methodology may not successfully identify potential antibodies that can serve as biotherapeutic product candidates to the targets that we or our collaborators believe are medically important;
- we identify and select from our ActivMAb and NKT vaccine platforms novel, untested antibodies for the particular targets we are pursuing, which we may fail to validate after further research work;
- we may encounter product manufacturing difficulties that limit yield or produce undesirable characteristics that increase the cost of goods, cause delays or make the product candidates unmarketable;
- our product candidates may not demonstrate a meaningful benefit to patients; and
- our collaborators may change their development profiles or plans for potential product candidates or abandon a therapeutic area or the development of a partnered product.

If any of these events occur, we may be forced to abandon our development efforts for a program or programs, which would have a material adverse effect on our business, operating results and prospects and could potentially cause us to cease operations. Research programs to identify new product candidates require substantial technical, financial and human resources. We may focus our efforts and resources on potential programs or product candidates that ultimately prove to be unsuccessful.

Our product candidates may cause undesirable side effects or have other properties that could prevent their regulatory approval, limit the commercial scope of their approved uses, or result in significant negative consequences following any marketing approval.

Undesirable side effects caused by our product candidates could cause us or regulatory authorities to delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign regulatory authorities. Results of our trials could reveal unacceptable side effects or unexpected characteristics. In such an event, we could suspend or terminate our clinical trials, or the FDA or comparable foreign regulatory authorities could order us to cease clinical trials or deny approval of our product candidates for any or all targeted indications. Drug-related side effects could affect patient recruitment or the ability of enrolled subjects to complete the trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly.

Additionally, if one or more of our product candidates receives marketing approval, and we or others later identify undesirable side effects caused by any such products, a number of potentially significant negative consequences could result, including:

- we may suspend marketing of, or withdraw or recall, such product;
- regulatory authorities may withdraw approvals of such product;
- regulatory authorities may require additional warnings on the label or otherwise seek to limit the scope of the approved uses reflected in the label of such product;
- the FDA may require the use of or modification of a Risk Evaluation and Mitigation Strategy, or REMS, or a comparable foreign regulatory authority may require the establishment or modification of a similar strategy that may, for instance, restrict distribution of our products and impose other implementation requirements on us;
- regulatory authorities may require that we conduct post-marketing studies;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate or otherwise materially harm the commercial prospects for the product candidate, if approved, and could significantly harm our business, results of operations and prospects.

We may be required to suspend, repeat or terminate our clinical trials if they are not conducted in accordance with regulatory requirements, the results are negative or inconclusive or the trials are not well designed.

Clinical trials must be conducted in accordance with the FDA's current Good Clinical Practices requirements, or analogous requirements of applicable foreign regulatory authorities. Clinical trials are subject to oversight by the FDA, other foreign governmental agencies, and IRBs or ECs at the study sites where the clinical trials are conducted. In addition, clinical trials must be conducted with product candidates produced in accordance with applicable current Good Manufacturing Practices, or cGMPs. Clinical trials may be suspended by the FDA, other foreign regulatory authorities, or us, or by an IRB or EC with respect to a particular clinical trial site, for various reasons, including:

- deficiencies in the conduct of the clinical trials, including failure to conduct the clinical trial in accordance with regulatory requirements or study protocols;
- deficiencies in the clinical trial operations or trial sites;
- unforeseen adverse side effects or the emergence of undue risks to study subjects;
- deficiencies in the trial design necessary to demonstrate efficacy;
- the product candidate may not appear to offer benefits over current therapies; or
- the quality or stability of the product candidate may fall below acceptable standards.

We have limited experience designing and implementing clinical trials, and failure to adequately design a trial, or incorrect assumptions about the design of the trial, could adversely affect the ability to initiate the trial, enroll patients, complete the trial, or obtain regulatory approval on the basis of the trial results, as well as lead to increased or unexpected costs.

The design and implementation of clinical trials is a complex process. We have limited experience designing and implementing clinical trials, and we may not successfully or cost-effectively design and implement clinical trials that achieve our desired clinical endpoints efficiently, or at all. A clinical trial that is not well designed may delay or even prevent initiation of the trial, can lead to increased difficulty in enrolling patients, may make it more difficult to obtain regulatory approval for the product candidate on the basis of the study results, or, even if a product candidate is approved, could make it more difficult to commercialize the product successfully or obtain reimbursement from third party payors. Additionally, a trial that is not well-designed could be inefficient or more expensive than it otherwise would have been, or we may incorrectly estimate the costs to implement the clinical trial, which could lead to a shortfall in funding.

We are subject to multiple manufacturing risks, any of which could substantially increase our costs and limit supply of our product candidates.

The process of manufacturing biologics, including our product candidates, is complex and subject to several risks, including:

- product loss during the manufacturing process, including loss caused by contamination, equipment failure or improper installation or operation of equipment, or vendor or operator error. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects and other supply disruptions. If microbial, viral or other contaminations are discovered in our products or in the manufacturing facilities in which our products are made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination;
- the manufacturing facilities in which our products are made could be adversely affected by equipment failures, labor and raw material shortages, natural disasters, power failures and numerous other factors; and
- any adverse developments affecting manufacturing operations for our products may result in shipment delays, inventory shortages, lot failures, product withdrawals or recalls, or other interruptions in the supply of our products. We may also have to take inventory write-offs and incur other charges and expenses for products that fail to meet specifications, undertake costly remediation efforts or seek more costly manufacturing alternatives.

The regulatory review processes of the FDA and comparable foreign regulatory authorities are lengthy, time consuming and inherently unpredictable. Our inability to obtain regulatory approval for our product candidates would substantially harm our business.

The time required to obtain approval by the FDA and comparable foreign regulatory authorities is difficult to predict but typically takes many years following the commencement of preclinical studies and clinical trials and depends upon numerous factors. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval vary among jurisdictions. We have not obtained regulatory approval for any product candidate and it is possible that none of our existing product candidates or

any future product candidates will ever obtain regulatory approval even if our preclinical studies or clinical trials initially appear to be successful.

Our product candidates could fail to receive approval from the FDA or comparable foreign regulatory authorities for many reasons, including:

- disagreement with the design or implementation of our clinical trials, including the endpoints used to assess effectiveness and/or safety;
- failure to demonstrate that a product candidate is safe and effective for its proposed indication;
- failure of clinical trials' endpoints to meet the level of statistical significance required for approval;
- failure to demonstrate that a product candidate's benefits outweigh its risks;
- disagreement with our interpretation of data from preclinical studies or clinical trials;
- the insufficiency of data collected from clinical trials of our product candidates to support a BLA or other submission or to obtain regulatory approval; or
- changes in the approval policies or regulations that render our preclinical and clinical data insufficient for approval.

The FDA or a comparable foreign regulatory authority may require more information, including additional preclinical or clinical data to support approval, which may delay or prevent approval and our commercialization plans, or we may decide to abandon the development program. If we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Regulatory authorities' assessment of the data and results required to demonstrate safety and efficacy can change over time and can be affected by many factors, such as the emergence of new information, including on other products, changing policies and agency funding, staffing and leadership.

Even if our product candidates receive regulatory approval, they may still face future development and regulatory difficulties.

Even if we obtain regulatory approval for a product candidate, it will be subject to ongoing regulation by the FDA and comparable foreign, state and local regulatory authorities, including requirements governing the manufacture, quality control, further development, labeling, packaging, tracking, storage, distribution, safety surveillance, import, export, advertising, promotion, recordkeeping and reporting of safety and other post-market information. The FDA and other applicable foreign regulatory authorities continue to closely monitor the safety and effectiveness profile of any product even after approval. If we receive an approval, we will be required to submit periodic reports to the FDA and notify it of adverse events of which we become aware. If the FDA or other applicable foreign regulatory authorities become aware of new safety information after approval of any of our product candidates, they may, among other measures, require labeling changes or establishment of a REMS or similar strategy, impose significant restrictions on a product's indicated uses or marketing, or impose ongoing requirements for potentially costly post-approval studies or post-market surveillance.

In addition, manufacturers of drug products and their facilities are subject to periodic inspections by the FDA and other regulatory authorities for compliance with cGMP. If we or a regulatory agency discover previously unknown problems with a product, such as adverse events, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions on that product, the manufacturing facility or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing. Our advertising and promotion of any product candidate that obtains approval for marketing also will be subject to ongoing scrutiny by the FDA and other regulatory authorities in the United States and applicable international jurisdictions.

If we or the manufacturing facilities for our product candidates fail to comply with applicable regulatory requirements, a regulatory agency may:

- issue warning letters or untitled letters;
- conduct inspections, audits, inquiries, or investigations of us or our facilities or of our collaborators or their facilities;
- mandate modifications to promotional materials or require us to provide corrective information to healthcare practitioners;
- impose a consent decree, which can include various fines, reimbursements for inspection costs, required due dates for specific actions and penalties for noncompliance;
- seek an injunction or impose civil or criminal penalties or monetary fines;

- suspend or withdraw regulatory approval;
- suspend any ongoing clinical trials;
- refuse to approve pending applications or supplements to applications;
- suspend or impose restrictions on operations, including costly new manufacturing requirements; or
- seize or detain products, refuse to permit the import or export of products, or require us to initiate a product recall.

The occurrence of any event or penalty described above may inhibit our ability to commercialize our products and generate revenue.

Advertising and promotion of any product candidate prior to its approval or after it obtains approval in the United States will be subject to scrutiny by the FDA. Violations of applicable requirements, including promotion of our product candidates prior to their approval, or promotion of our approved products for unapproved, or off-label, uses, may be subject to enforcement letters, inquiries and investigations, as well as civil and criminal sanctions. Additionally, comparable foreign regulatory authorities may scrutinize advertising and promotion of any product candidate both before and after it obtains approval in their respective jurisdictions.

In the United States, engaging in the impermissible promotion of our products for off-label uses can also subject us to false claims litigation under federal and state statutes, which can lead to administrative, civil and criminal penalties, damages, monetary fines, disgorgement, individual imprisonment, exclusion from participation in Medicare, Medicaid and other federal healthcare programs, curtailment or restructuring of our operations and agreements that materially restrict the manner in which a company promotes or distributes drug products. These false claims statutes include, but are not limited to, the federal civil False Claims Act, which imposes civil penalties against individuals and entities for, among other things, knowingly presenting or causing to be presented, false or fraudulent claims for payment of government funds. Actions under the False Claims Act can be brought by the federal government or as a qui tam action by private individuals in the name of the government, who may receive a share of any judgments or settlement amounts. These False Claims Act lawsuits against pharmaceutical and biopharmaceutical companies have increased significantly in number and scope, leading to substantial civil settlements regarding certain sales practices, including promoting off-label uses. This growth in litigation has increased the risk that a pharmaceutical or biopharmaceutical company will have to defend a false claim action, pay settlement fines or restitution, agree to comply with burdensome reporting and compliance obligations in exchange for not being excluded from Medicare, Medicaid and other federal and state healthcare programs. If we do not lawfully promote our approved products, we may become subject to such litigation, which would have a material adverse effect on our business, financial condition and results of operations. Promotion prior to marketing approval or for off-label uses may also give rise to criminal prosecution in the European Union.

The FDA's and other applicable government agencies' policies may change, and additional laws or regulations may be enacted that could prevent, limit or delay regulatory approval, and thus the sale and promotion, of our product candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may face regulatory scrutiny, enforcement action or other consequences, including loss of any marketing approval that we may have obtained, any of which could adversely affect our business, prospects and ability to achieve or sustain profitability.

One of the indications we are pursuing for our lead product candidate pepinemab is for the treatment of Huntington's disease, and because there are no approved disease modifying treatments for Huntington's disease, the development pathway is uncertain, which may make development more unpredictable or difficult than we currently expect.

We are studying pepinemab as both a therapeutic and potentially preventative treatment for Huntington's disease, which is a neurodegenerative genetic disorder that typically manifests in mid-adult life. The development pathway for Huntington's disease is relatively uncertain, which we believe is in part because there are currently no approved disease modifying products for the treatment of Huntington's disease. Moreover, because we are also seeking to develop a treatment to prevent or delay progression of prodromal Huntington's disease, we are focusing on a target population of individuals who have not yet reached the point of clinical diagnosis or those who have been diagnosed relatively recently. This may make it more difficult to document that our drug is effective in preventing Huntington's disease because there are no clinical endpoints for preventative therapy that the FDA has accepted. We are employing biomarkers as endpoints in our Phase 2 clinical trial, and we believe that the FDA will accept these biomarkers for purposes of evaluating the results of our Phase 2 clinical trial. If we are to rely on these or other biomarkers for any future pivotal study or studies, however, we anticipate needing to establish that these biomarkers, or others, have a clinically meaningful cognitive or behavioral effect on patients, and there is no certainty that we will be able to do so.

Our failure to obtain regulatory approval in international jurisdictions would prevent us from marketing our product candidates in those jurisdictions.

In order to market and sell our products in other jurisdictions, we must obtain separate marketing approvals for those jurisdictions and comply with their numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain FDA approval. The regulatory approval process outside the United States generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside the United States, we must secure product reimbursement approvals before regulatory authorities will approve the product for sale in that country. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. Further, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not ensure approval in any other country, while a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory approval process in others. Also, if regulatory approval for any of our product candidates is granted, it may be later withdrawn. If we fail to comply with the regulatory requirements in international markets and do not receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed and our business will be adversely affected. We may not obtain foreign regulatory approvals on a timely basis, if at all. Our failure to obtain approval of any of our product candidates by regulatory authorities in countries outside of the United States may significantly diminish the commercial prospects of that product candidate and our business prospects could decline.

Our product candidates may not achieve adequate market acceptance among physicians, patients, healthcare payors and others in the medical community necessary for commercial success.

Even if our product candidates receive regulatory approval, they may not gain adequate market acceptance among physicians, patients, healthcare payors and others in the medical community. Our commercial success also depends on coverage and adequate reimbursement and pricing of our product candidates by third-party payors, including government payors, which may be difficult or time-consuming to obtain, may be limited in scope and may not be obtained in all jurisdictions in which we may seek to market our products. The degree of market acceptance of any of our approved product candidates will depend on a number of factors, including:

- the efficacy and safety profile as demonstrated in clinical trials;
- the timing of market introduction of the product candidate as well as competitive products;
- the clinical indications for which the product candidate is approved;
- acceptance of the product candidate as a safe and effective treatment by physicians, clinics and patients;
- the potential and perceived advantages of the product candidates, including relative to alternative treatments;
- the cost of treatment, including in relation to alternative treatments;
- the availability of coverage and adequate reimbursement and pricing by third-party payors, including government payors, and the willingness of patients to pay out-of-pocket in the absence of coverage by third-party payors;
- convenience and ease of administration, including relative to alternative treatments;
- the frequency and severity of adverse events;
- the strength and effectiveness of our sales and marketing efforts; and
- any unfavorable publicity relating to the product candidate.

Our competitors may develop and market products or services that are less expensive, more effective, safer, otherwise regarded as preferable to, or that reach the market sooner, than our product candidates, which may diminish or eliminate the commercial success of any products or services we commercialize.

The biotechnology industry is intensely competitive and subject to rapid and significant technological change. Our current product candidates may face competition from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide that have marketed drugs or are advancing product candidates to treat the same indications that we plan to treat or, in the case of competition or potential competition with our ActivMAb antibody discovery platform, that have marketed antibody discovery platforms or are advancing approaches that are an alternative to our ActivMAb platform. Many of our competitors have significantly greater financial, technical and human resources. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

Our competitors may obtain FDA or other regulatory approval of their product candidates more rapidly than we may or may obtain patent protection or other intellectual property rights that limit our ability to develop or commercialize our product candidates or platform technologies. Our competitors may also develop drugs or antibody discovery platforms that are more effective, more convenient, more widely used or less costly or, in the case of drugs, have a better safety profile than our platforms or product candidates. These competitors may also be more successful than us in manufacturing and marketing their products and have significantly greater financial resources and expertise in research and development.

Our competitors will also compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

We believe that our ability to successfully compete will depend on, among other things:

- the efficacy and safety profile of our product candidates, including relative to marketed products and product candidates in development by third parties;
- the success, or perceived success, of our platform technologies;
- the time it takes for our product candidates to complete clinical development and receive marketing approval;
- the ability to commercialize any of our product candidates that receive regulatory approval;
- the price of our drug products, including in comparison to branded or generic competitors;
- the price of our services, including with respect to the terms on which we are willing to collaborate, including in comparison to other antibody discovery approaches or platform technologies;
- whether coverage and adequate levels of reimbursement are available from private and governmental payors, including Medicare;
- the ability to establish, maintain and protect intellectual property rights related to our product candidates or platform technologies;
- the ability to manufacture commercial quantities of any of our product candidates that receive regulatory approval; and
- acceptance of any of our product candidates that receive regulatory approval by physicians and other healthcare providers or by patients.

If we do not compete successfully, we may not generate or derive sufficient revenue from any product candidate for which we obtain marketing approval and may not become or remain profitable.

We may not be able to achieve the benefits or synergistic effects of pepinemab in combination with other immunotherapies that we have observed in preclinical studies of pepinemab in combination with the anti-CTLA-4 antibody ipilimumab.

Based on our preclinical research, we believe that the combination of pepinemab with immunotherapeutic drugs, such as immune checkpoint inhibitors, could prove beneficial because pepinemab promotes infiltration of immune cells into a tumor. As such, we believe pepinemab could enhance the activity of other agents that increases peripheral immune responses. Most of the preclinical studies with respect to the combination of pepinemab with immunotherapies have involved the anti-CTLA-4 antibody ipilimumab. The results of these studies showed that pepinemab in combination with the CTLA-4 checkpoint inhibitor can greatly enhance the immune response to tumors by amplifying the benefits of this checkpoint inhibitor. However, while we have performed research with respect to pepinemab in combination with other immunotherapies, it is not clear that such combinations will have the same benefits or synergies demonstrated in animal models by the preclinical studies of pepinemab in combination with anti-CTLA-4 antibodies. Accordingly, we may not be able generate adequate data to demonstrate the efficacy and safety in clinical trials of pepinemab in combination with other immunotherapies, which could result in significant setbacks in clinical trials and changes to our development plans. If future clinical trials do not produce favorable results, our ability to achieve regulatory approval for pepinemab may be adversely impacted.

As a result of our development strategy, future arrangements with potential collaborators, or for other reasons, we may need to develop a second antibody to continue to develop our SEMA4D antibody platform for multiple indications.

Our SEMA4D antibody platform is the application of our extensive knowledge of SEMA4D biology to develop pepinemab for the treatment of various indications. We are currently focused on developing pepinemab for the treatment of NSCLC and Huntington’s disease. Additionally, one investigator is studying pepinemab in osteosarcoma and another is studying pepinemab in melanoma, and in the future, we intend to pursue other indications for pepinemab. However, as a result of our development strategy,

or for commercial reasons, including those that could arise from collaborative arrangements with third parties, we may determine that we need to develop a second anti-SEMA4D antibody to pursue one or more indications, including indications that we are currently pursuing or plan to pursue. While we have identified another potential antibody as part of our SEMA4D antibody platform, we have done limited preclinical research with it, and it may require a significant amount of time and cost to develop that antibody to the same stage of development where pepinemab is today. Even if we make the additional investment in this or another antibody, we may not be able to develop another antibody as part of our SEMA4D antibody platform.

We may need to develop or obtain additional capabilities, or enter into arrangements with third parties, to commercialize any product candidates that obtain regulatory approval, and we may encounter unexpected costs or difficulties in doing so.

We will need to obtain additional capabilities and effectively manage our operations and facilities to successfully pursue and complete future research, development and commercialization efforts. Currently, we have no experience in preparing applications for marketing approval, commercial-scale manufacturing, managing of large-scale information technology systems or managing a large-scale distribution system. We will need to enter into arrangements with third parties or add personnel and expand our capabilities, which may strain our existing managerial, operational, regulatory compliance, financial and other resources.

We plan to conduct process development activities to support late stage development and commercialization activities and seek approval of our product candidates. Should we not receive timely approval of our production process, our ability to produce the products following regulatory approval for sale could be delayed, which would further delay the period of time when we would be able to generate revenues from the sale of such products, if we are even able to generate revenues at all.

We do not currently have any sales, marketing or distribution experience or infrastructure and may rely on alliances with others possessing such capabilities to commercialize our products successfully.

We intend to market our product candidates, if and when such product candidates are approved by the FDA or comparable foreign regulatory authorities, either directly or through other alliances and distribution arrangements with third parties. There can be no assurance that we will be able to enter into third-party marketing or distribution arrangements on advantageous terms or at all. To the extent that we do enter into such arrangements, we will be dependent on our marketing and distribution partners. In entering into third-party marketing or distribution arrangements, we expect to incur significant additional expense. If we are unable to enter into such arrangements on acceptable terms or at all, we may not be able to successfully commercialize any of our product candidates that receive regulatory approval. Depending on the nature of the third-party relationship, we may have little control over such third parties, and any of these third parties may fail to devote the necessary resources and attention to sell, market and distribute our products effectively and/or in compliance with applicable legal and regulatory requirements. If we are not successful in commercializing our product candidates, either on our own or through collaborations with one or more third parties, our future product revenue will suffer, and we may incur significant additional losses.

Even if we commercialize a product candidate, it or any other product candidates that we develop may become subject to unfavorable pricing regulations, third-party coverage or reimbursement practices or healthcare reform initiatives, which could harm our business.

Our ability to commercialize any product candidates successfully will depend in part on the extent to which coverage and adequate reimbursement for our product candidates will be available from government health administration authorities, private health insurers and other organizations. The laws that govern marketing approvals, pricing and reimbursement for new drug products vary widely from country to country. We cannot be sure that coverage and reimbursement will be available for any product that we commercialize and, if reimbursement is available, what the level of reimbursement will be. Coverage and reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. If coverage and reimbursement are not available or reimbursement is available only to limited levels, we may not successfully commercialize any product candidate for which we obtain marketing approval.

If we successfully commercialize any of our product candidates, we may participate in the Medicaid Drug Rebate program. Participation is required for federal funds to be available for our covered outpatient drugs under Medicaid and, if applicable, Medicare Part B. Under the Medicaid Drug Rebate Program, we would be required to pay a rebate to each state Medicaid program for our covered outpatient drugs that are dispensed to Medicaid beneficiaries and paid for by a state Medicaid program as a condition of having federal funds being made available to the states for our drugs under Medicaid and, if applicable, Part B of the Medicare program.

Federal law requires that any company that participates in the Medicaid Drug Rebate Program also participate in the Public Health Service's 340B drug pricing program in order for federal funds to be available for the manufacturer's drugs under Medicaid and Medicare Part B. The 340B drug pricing program requires participating manufacturers to agree to charge statutorily-defined covered entities no more than the 340B "ceiling price" for the manufacturer's covered outpatient drugs. These 340B covered entities include a variety of community health clinics and other entities that receive health services grants from the Public Health Service, as well as hospitals that serve a disproportionate share of low-income patients.

In addition, in order to be eligible to have its products paid for with federal funds under the Medicaid and Medicare Part B programs and purchased by certain federal agencies and grantees, a manufacturer also must participate in the U.S. Department of Veterans Affairs, or the VA, Federal Supply Schedule, or FSS, pricing program. Under this program, the manufacturer is obligated to make its innovator and single source products available for procurement on an FSS contract and charge a price to four federal agencies, U.S. Department of Defense, or DoD, Public Health Service and U.S. Coast Guard, that is no higher than the statutory Federal Ceiling Price. Moreover, pursuant to regulations issued by the DoD Defense Health Agency to implement Section 703 of the National Defense Authorization Act for Fiscal Year 2008, manufacturers are required to provide rebates on utilization of their innovator and single source products that are dispensed to TRICARE beneficiaries by TRICARE network retail pharmacies. The requirements under the 340B, FSS, and TRICARE programs could reduce the revenue we may generate from any products that are commercialized in the future and could adversely affect our business and operating results.

Current and future legislation may increase the difficulty and cost for commercialization of our product candidates and affect the prices we or our partners may obtain.

The United States and many foreign jurisdictions have enacted or proposed legislative and regulatory changes affecting the healthcare system that could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any product candidate for which we obtain marketing approval.

In the United States, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or the Medicare Modernization Act, changed the way Medicare covers and pays for pharmaceutical products. The legislation expanded Medicare coverage for drug purchases by the elderly by establishing Medicare Part D and introduced a new reimbursement methodology based on average sales prices for physician-administered drugs under Medicare Part B. In addition, this legislation provided authority for limiting the number of drugs that Medicare will cover in any therapeutic class under the new Medicare Part D program. Cost reduction initiatives and other provisions of this legislation could decrease the coverage and reimbursement rate that we receive for any of our approved products. While the Medicare Modernization Act applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates. Therefore, any reduction in reimbursement that results from the Medicare Modernization Act may result in a similar reduction in payments from private payors.

In March 2010, Congress enacted the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively, the Affordable Care Act, which includes measures that have significantly changed the way healthcare is financed by both governmental and private insurers. Some of the provisions of the Affordable Care Act have yet to be fully implemented, and certain provisions have been subject to judicial and congressional challenges to certain aspects of the Affordable Care Act. In addition, there have been efforts by the Trump administration to repeal or replace certain aspects of the Affordable Care Act and to alter the implementation of the Affordable Care Act and related laws. Since January 2017, President Trump has signed Executive Orders that may affect the implementation of certain provisions of the Affordable Care Act or otherwise affect some of the federal requirements governing health insurance. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the Affordable Care Act. While Congress has not passed comprehensive repeal legislation, two bills affecting the implementation of certain taxes under the Affordable Care Act have been signed into law. The Tax Act includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the Affordable Care Act on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." Additionally, on January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018, referred to as the Bipartisan Budget Act of 2018, that delayed the implementation of certain Affordable Care Act-mandated fees, including the so-called "Cadillac" tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices. The Bipartisan Budget Act of 2018 also increased the required manufacturer discount to 70% off the negotiated price for Medicare Part D beneficiaries in the coverage gap, commonly referred to as the "donut hole," beginning in 2019. Additional legislative changes to, regulatory changes, and judicial challenges related to the Affordable Care Act remain possible. We continue to evaluate the effect that the Affordable Care Act, as currently enacted or as it may be amended in the future, has on our business.

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. For example, in August 2011, then-President Obama signed into law the Budget Control Act of 2011, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals in spending reductions. The Joint Select Committee on Deficit Reduction did not achieve a targeted deficit reduction, which triggered the legislation's automatic reduction to several government programs. In concert with subsequent legislation, this includes aggregate reductions to Medicare payments to providers of, on average, 2% per fiscal year through 2027 unless Congress takes additional action. Recently, there has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. congressional inquiries and proposed bills designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for drugs. At the state level, legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure, and transparency measures.

We expect that the healthcare reform measures that have been adopted and may be adopted in the future may result in additional reductions in Medicare and other health care funding, more rigorous coverage criteria, new payment methodologies and additional downward pressure on coverage, payment and the price that we receive for any approved product and could seriously harm our future revenues. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our products.

If we are able to successfully commercialize any of our product candidates and if we participate in the Medicaid drug rebate program or other governmental pricing programs, failure to comply with reporting and payment obligations under these programs could result in additional reimbursement requirements, penalties, sanctions and fines which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

The Medicaid Drug Rebate Program and other governmental pricing programs require participating manufacturers to report pricing data to various government agencies. Pricing calculations vary among products and programs and include average manufacturer price and best price for the Medicaid Drug Rebate Program, average sales price for certain categories of drugs that are paid under Part B of the Medicare program, and non-federal average manufacturer price for the VA FSS pricing program. If we successfully commercialize any of our products and participate in such governmental pricing programs, we will be liable for errors associated with our submission of pricing data. That liability could be significant. For example, if we are found to have knowingly submitted false average manufacturer price, average sales price, best price, or non-federal average manufacturer price information to the government, or fail to timely submit such information, we may be liable for significant civil monetary penalties. The foregoing also could be grounds for other sanctions, such as termination from the Medicaid Drug Rebate Program.

Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of our product candidates.

We face an inherent risk of product liability exposure related to the testing of our product candidates in human trials and may face greater risk if we commercialize any products that we develop. Product liability claims may be brought against us by subjects enrolled in our trials, patients, healthcare providers or others using, administering or selling our products. If we cannot successfully defend ourselves against such claims, we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for our products;
- termination of clinical trial sites or entire trial programs;
- injury to our reputation and significant negative media attention;
- withdrawal of trial participants;
- significant costs to defend the related litigation;
- substantial monetary awards to trial subjects or patients;
- diversion of management and scientific resources from our business operations; and
- the inability to commercialize any products that we may develop.

While we currently hold trial liability insurance coverage consistent with industry standards, the amount of coverage may not adequately cover all liabilities that we may incur. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise. We intend to expand our insurance coverage for products to include the sale of commercial products if we obtain marketing approval for our product candidates, but we may be unable to obtain commercially reasonable product liability insurance. A successful product liability claim or series of claims brought against us, particularly if judgments exceed our insurance coverage, could decrease our cash and adversely affect our business and financial condition.

Our relationships with customers and third-party payors will be subject to applicable anti-kickback, fraud and abuse, transparency and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm, administrative burdens and diminished profits and future earnings.

Healthcare providers, physicians and third-party payors will play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our arrangements with third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute any products for which we obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations, include, but are not limited to, the following:

- the federal Anti-Kickback Statute prohibits persons from, among other things, knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, the referral of an individual for the furnishing or arranging for the furnishing, or the purchase, lease or order, or arranging for or recommending purchase, lease or order, or any good or service for which payment may be made under a federal healthcare program such as Medicare and Medicaid;
- the federal civil False Claims Act imposes liability, including through civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;
- HIPAA's fraud provisions impose criminal liability for knowingly and willfully executing a scheme to defraud any healthcare benefit program, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a health care offense, or knowingly and willfully making false statements relating to healthcare matters;
- HIPAA also imposes obligations on certain covered entity health care providers, health plans and health care clearinghouses as well as their business associates that perform certain services involving the use or disclosure of individually identifiable health information, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- the federal Physician Payment Sunshine Act, being implemented as the Open Payments Program, which requires manufacturers of drugs, devices, biologics, and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to CMS information related to direct or indirect payments and other transfers of value to physicians and teaching hospitals, as well as ownership and investment interests held in the company by physicians and their immediate family members. Beginning in 2022, applicable manufacturers also will be required to report information regarding payments and transfers of value provided to physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, and certified nurse-midwives; and
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to items or services reimbursed by non-governmental third-party payors, including private insurers; state and foreign laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers in those jurisdictions; state and foreign laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; some states also prohibit certain marketing-related activities including the provision of gifts, meals, or other items to certain health care providers, and others restrict the ability of manufacturers to offer co-pay support to patients for certain prescription drugs; other states and cities require identification or licensing of sales representatives; and state and foreign laws that govern the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Further information about these laws is provided above in the "Government Regulation" section under the heading "United States Government Regulation—Federal and State Fraud and Abuse and Data Privacy and Security Laws and Regulations." Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. Although compliance programs can help mitigate the risk of investigations and prosecution for violations of these laws, the risks cannot be eliminated entirely. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations.

Defending against actions or investigations for violations of these laws and regulations, even if ultimately successful, will incur significant legal expenses and divert management's attention from the operation of our business.

Our internal computer systems, or those used by our CROs or other contractors or consultants, may fail or suffer security breaches.

Despite the implementation of cybersecurity measures, our information technology and Internet based systems, including those of our current and future CROs and other contractors and consultants, are vulnerable to damage, interruption, or failure from computer viruses, unauthorized access, intrusion, and other cybersecurity incidents. This could result in the exposure of sensitive data including the loss of trade secrets, intellectual property, personal identifiable or sensitive information of employees, customers, partners, clinical trial patients, and others, leading to a material disruption of our development programs and our business operations. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, we partially rely on our third-party research institution collaborators for research and development of our drug candidates and other third parties for the manufacture of our drug candidates and to conduct clinical trials, and similar cybersecurity incidents relating to their computer systems could also have a material adverse effect on our business. Certain data security breaches must be reported to affected individuals and the government, and in some cases to the media, under provisions of HIPAA, other U.S. federal and state law, and requirements of non-U.S. jurisdictions, and financial penalties may also apply. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development and commercialization of our drug candidates could be delayed**.**

Our employees may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could have a material adverse effect on our business.

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include intentional failures to comply with FDA regulations or similar regulations of comparable foreign regulatory authorities, provide accurate information to the FDA or comparable foreign regulatory authorities, comply with manufacturing standards we have established, comply with federal and state healthcare fraud and abuse laws and regulations and similar laws and regulations established and enforced by comparable foreign regulatory authorities, report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. We have adopted a code of business conduct and ethics, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and results of operations, including the imposition of significant fines or other sanctions.

We depend on key personnel for our continued operations and future success and a loss of certain key personnel could significantly hinder our ability to move forward with our business plan.

To succeed, we must recruit, retain, manage and motivate qualified clinical, scientific, technical and management personnel and we face significant competition for experienced personnel. If we do not succeed in attracting and retaining qualified personnel, particularly at the management level, it could adversely affect our ability to execute our business plan and harm our operating results. In particular, we are highly dependent on Dr. Maurice Zauderer, our founder and Chief Executive Officer. The loss of Dr. Zauderer, or one or more of our other executive officers, could be detrimental to us if we cannot recruit suitable replacements in a timely manner. The competition for qualified personnel in the pharmaceutical field is intense and as a result, we may be unable to continue to attract and retain qualified personnel necessary for the development of our business or to recruit suitable replacement personnel.

Many of the other biopharmaceutical companies that we compete against for qualified personnel have greater financial and other resources and different risk profiles than we do. They also may provide more diverse opportunities and better chances for career advancement. If we are unable to continue to attract and retain high-quality personnel, the rate and success at which we can discover and develop product candidates and our business will be limited.

Risks Related to our Dependence on Third Parties

We rely on third parties to conduct our preclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties, comply with budgets and other financial obligations or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates in a timely or cost-effective manner.

We rely, and expect to continue to rely, on third-party CROs to conduct preclinical and clinical trials. Because we rely on third parties to conduct clinical trials, we must rely on the efforts of others and cannot always control or accurately predict the timing of such trials, the costs associated with such trials or the procedures that are followed for such trials. We do not anticipate significantly increasing our personnel in the foreseeable future and therefore, expect to continue to rely on third parties to conduct all of our future clinical trials. If these third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they do not carry out the trials in accordance with budgeted amounts, if the quality or accuracy of the clinical data they obtain is compromised due to their failure to adhere to our clinical protocols or for other reasons, or if they fail to maintain compliance with applicable government regulations and standards, our clinical trials may be extended, delayed or terminated or may become prohibitively expensive, we may be subject to potential enforcement by the FDA and analogous regulatory authorities in international jurisdictions for their failure to comply with applicable laws and regulations, and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates.

If our agreements with our current or future CROs are terminated or otherwise adversely affected, our drug development efforts could be delayed.

We rely on, and expect to develop additional relationships with, third-party vendors and CROs for preclinical studies and clinical trials related to our drug development efforts. Switching or adding additional CROs involves additional cost and requires management time and focus. Our CROs have the right to terminate their agreements with us in the event of an uncured material breach. Some of our CROs may have other rights to terminate their respective agreements with us, including for reasons such as: if it is determined that the safety of subjects participating in our clinical trials warrants such termination; if we make an assignment for the benefit of our creditors; or if we are liquidated. Identifying, qualifying and managing performance of third-party service providers can be difficult, time consuming and cause delays in our development programs. In addition, there is a natural transition period when a new CRO commences work and the new CRO may not provide the same type or level of services as the original provider. If any of our relationships with our third-party CROs terminates, we may not be able to enter into arrangements with alternative CROs or to do so on commercially reasonable terms and/or in a timely manner.

We depend on third-party manufacturers for the manufacture of drug substance and drug product for clinical trials as well as on third parties for our supply chain. Any problems we experience with any of these third parties could delay the manufacturing of our product candidates, which could harm our results of operations.

We do not currently operate manufacturing facilities for clinical or commercial production of our product candidates. We do not have, and we do not currently plan to acquire or develop, the facilities or capabilities to manufacture bulk drug substance or finish-fill drug product for use in human clinical trials or for potential commercialization.

Catalent Pharma Solutions, or Catalent, manufactures pepinemab for use in clinical trials according to the terms of a manufacturing agreement with us, and we use other third parties for other aspects of the manufacturing process. We have not contracted with alternate suppliers in the event the organizations we currently utilize, including Catalent, are unable to scale production, or if we otherwise experience any problems with them. If we encounter problems with any of them, including if they are unable to scale production or have problems at their facilities, and we are unable to arrange for alternative third-party manufacturing sources, or to do so on commercially reasonable terms or in a timely manner, we may be delayed in the development of our product candidates.

Reliance on third-party manufacturers entails risks to which we would not be subject if we manufactured product candidates or products ourselves, including reliance on the third party for regulatory compliance and quality assurance, the possibility of breach of the manufacturing agreement by the third party because of factors beyond our control (including a failure to manufacture our product candidates or any products we may eventually commercialize in accordance with our specifications) and the possibility of termination or nonrenewal of the agreement by the third party, based on its own business priorities, at a time that is costly or damaging to us.

We may not succeed in establishing and maintaining additional collaborations, which could adversely affect our ability to develop and commercialize product candidates.

In addition to our current research and development collaborations, a part of our strategy is to enter into additional research and development collaborations in the future, including collaborations with pharmaceutical companies. We face significant competition in seeking appropriate development partners and the negotiation process is time-consuming and complex. Moreover, we may not succeed in our efforts to establish collaborations or other alternative arrangements for any of our other existing or future product candidates and programs because our research and development pipeline may be insufficient, our product candidates and programs may be deemed to be at too early a stage of development for collaborative effort and third parties may not view our product candidates and programs as having the requisite potential to demonstrate safety and efficacy. Even if we are successful in our efforts to establish new collaborations, the terms that we agree upon may not be favorable to us and we may not be able to maintain such collaborations if, for example, development or approval of a product candidate is delayed or sales of an approved product candidate are disappointing.

Moreover, if we fail to establish and maintain additional collaborations related to our product candidates:

- the development of certain of our current or future product candidates may be terminated or delayed;
- our cash expenditures related to development of certain of our current or future product candidates would increase significantly and we may need to seek additional financing;
- we may be required to hire additional employees or otherwise develop expertise, such as sales and marketing expertise, for which we have not budgeted; and
- we will bear all of the risk related to the development of any such product candidates.

Collaborations may require us to relinquish important rights to and control over the development of our product candidates or otherwise be subject to unfavorable terms.

If we sign a collaboration agreement, license agreement or similar agreement with a collaborator to develop a product candidate, that collaborator may have certain rights to further the development of the product candidate, which could include the design and conduct of clinical trials, the preparation and filing of documents necessary to obtain regulatory approval, and the manufacturing, sale, marketing and other commercialization of the product if it obtains regulatory approval. For example, under the terms of our arrangement with Biocon Limited, or Biocon, Biocon has the right to control development of BVX20. Dependence on a corporate collaborator subjects us to a number of risks, including:

- we may not be able to control the amount and timing of resources that our collaborators devote to the development or commercialization of our product candidates, or to compliance with applicable legal and regulatory requirements;
- collaborators may delay clinical trials, provide insufficient funding, terminate a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new version of a product candidate for clinical testing;
- collaborators may not pursue further development and commercialization of products resulting from the strategic partnering arrangement or may elect to discontinue research and development programs;
- collaborators may not commit adequate resources to the marketing and distribution of our product candidates, limiting our potential revenues from these products;
- disputes may arise between us and our collaborators that result in the delay or termination of the research, development or commercialization of our product candidates or that result in costly litigation or arbitration that diverts management’s attention and consumes resources;
- collaborators may experience financial difficulties;
- collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in a manner that could jeopardize or invalidate our proprietary information or expose us to potential litigation;
- business combinations or significant changes in a collaborator’s business strategy may also adversely affect a collaborator’s willingness or ability to complete its obligations under any arrangement;
- collaborators could decide to move forward with a competing product candidate developed either independently or in collaboration with others, including our competitors; and
- collaborators could terminate the arrangement or allow it to expire, which would delay the development and may increase the cost of developing our product candidates.

Risks Related to Intellectual Property

If we are unable to obtain or protect intellectual property rights, we may not be able to compete effectively in our market.

Our success depends in significant part on our and our licensors', licensees' or collaborators' ability to establish, maintain and protect patents and other intellectual property rights and operate without infringing the intellectual property rights of others. We have filed numerous patent applications both in the United States and in foreign jurisdictions to obtain patent rights to our inventions. We have also licensed from third party's rights to patents. Some of these licenses give us the right to prepare, file and prosecute patent applications and maintain and enforce patents we licensed.

The patent prosecution process is expensive and time-consuming, and we and our current or future licensors, licensees or collaborators may not be able to prepare, file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we or our licensors, licensees or collaborators will fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. Moreover, in some circumstances, we may not have the right to control the preparation, filing, prosecution, and maintenance of patent applications and patents encompassing technology that we license from, or license to, third parties and in these circumstances are reliant on our licensors, licensees or collaborators. Therefore, these patents and patent applications may not at all times be prosecuted and enforced in a manner consistent with the best interests of our business. If our current or future licensors, licensees or collaborators fail to establish, maintain or protect such patents and other intellectual property rights, such rights may be reduced or eliminated. If our licensors, licensees or collaborators are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our and our current or future licensors', licensees' or collaborators' patent rights are highly uncertain. Our and our licensors', licensees' or collaborators' pending, and future patent applications may not result in patents being issued that protect our technology or products, in whole or in part, or that effectively prevent others from commercializing competitive technologies and products. The patent examination process may require us or our licensors, licensees or collaborators to narrow the scope of the claims of our or our licensors', licensees' or collaborators' pending and future patent applications, which may limit the scope of patent protection that may be obtained. Our and our licensors', licensees' or collaborators' patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications, and then such patent rights can only be enforced to the extent the issued claims cover the infringing technology.

Additionally, in some countries, applicants are not able to protect methods of treating human beings or medical treatment processes. Countries such as India and elsewhere have enacted various rules and laws precluding issuance of patent claims covering methods a doctor may practice on a human being or any other animal to treat a disease or condition. Further, many countries have enacted laws and regulatory regimes that do not provide patent protection for methods of use of known compounds. In such countries and jurisdictions, only product claims may be obtained, and only when those products are new or novel. The lack of such patent protection may have a materially adverse effect on our business and financial condition.

Furthermore, given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after those candidates receive regulatory approval and are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. We expect to seek patent term extensions where these are available upon regulatory approval in those countries where we are prosecuting patents. This includes in the United States under the Drug Price Competition and Patent Term Restoration Act of 1984, which permits a patent term extension of up to five years beyond the expiration of the patent, but no more than fourteen years beyond the date of product approval, for a product that represents the first permitted commercial use of the active ingredient. However, the applicable authorities, including the United States Patent and Trademark Office, or the USPTO, and the FDA in the United States, and equivalent regulatory authorities in other countries, may not agree with our assessment of whether such extensions are available, and may refuse to grant extensions to our patents, or may grant more limited extensions than we request. If this occurs, our competitors may be able to reference our clinical and preclinical data and launch their products earlier than might otherwise be possible.

Finally, our patent portfolio encompasses both issued patents and pending patent applications around the world in various jurisdictions, and the pending patent applications or issued patents encompassing each of the different technology areas may be assigned different relative and future values, either based on commercial relevance, patent position strength, patent coverage, claim scope, or any other variables associated with intellectual property. That is, some aspects of our patent portfolio, encompassing various aspects of our product candidates and platform technology, may be more valuable than other aspects of our patent portfolio. For example, the patents and patent applications encompassing the pepinemab technology may be of particular value to our company because they encompass specific product candidates and medical indications critical to the future of our business. Inability to obtain patents encompassing these critical technologies could more adversely impact our business than inability to obtain patents encompassing other aspects of our business. Thus, adverse events experienced within these specific patent portfolios could critically hamper our ability to commercialize and conduct business in these key technology areas.

We may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting, enforcing and defending patents on product candidates and laboratory methods or platform technology in all countries throughout the world would be prohibitively expensive, and our or our licensors' or collaborators' intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, as noted above, the laws of some foreign countries do not protect intellectual property rights to the same extent as laws in the United States. Consequently, we and our licensors or collaborators may not be able to prevent third parties from practicing our and our licensors' or collaborators' inventions in all countries outside the United States, or from selling or importing products made using our and our licensors' or collaborators' inventions in and into the United States or other jurisdictions. Competitors may use our and our licensors' or collaborators' technologies in jurisdictions where we have not obtained patent protection to develop their own products and further, may export otherwise infringing products to territories where we and our licensors or collaborators have patent protection, but where enforcement laws are not as protective as that in the United States. These products may compete with our product candidates and our and our licensors' or collaborators' patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biopharmaceuticals or laboratory platform technology, which could make it difficult for us and our licensors or collaborators to stop the infringement of our and our licensors' or collaborators' patents or stop the marketing of products competing with our and our licensors' or collaborators' commercial efforts generally. Proceedings to enforce our and our licensors' or collaborators' patent rights in foreign jurisdictions requires significant financial resources and can divert our and our licensors' or collaborators' efforts and attention away from other critical aspects of our business, could put our and our licensors' or collaborators' patents at risk of being invalidated or interpreted narrowly, and could place our and our licensors' or collaborators' patents at risk of not issuing. This could in turn provoke third parties to assert claims against us or our licensors or collaborators. We or our licensors or collaborators may not prevail in any lawsuits that we or our licensors or collaborators initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful.

The requirements for patentability may differ in certain countries, particularly developing countries. In India, unlike the United States, there is no link between regulatory approval of a drug and its patent status. Furthermore, generic or biosimilar drug manufacturers or other competitors may challenge the scope, validity or enforceability of our or our licensors' or collaborators' patents, requiring us or our licensors or collaborators to engage in complex, lengthy and costly litigation or other post-grant proceedings. Generic or biosimilar drug manufacturers may develop, seek approval for, and launch, biosimilar versions of our products in many countries without conducting extensive clinical trials. In addition to India, certain countries in Europe and developing countries, including China, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In those countries, we and our licensors or collaborators may have limited remedies if patents are infringed or if we or our licensors or collaborators are compelled to grant a license to a third party, which could materially diminish the value of those patents. This could limit our potential revenue opportunities. Accordingly, our and our licensors' or collaborators' efforts to enforce intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we own or license.

Changes in patent law and legal precedent concerning patents could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.

As is the case with other biotechnology and pharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involve technological and legal complexity, and obtaining and enforcing biopharmaceutical patents is costly, time-consuming, and inherently uncertain. The Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our and our licensors' or collaborators' ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our and our licensors' or collaborators' ability to obtain new patents or to enforce existing patents and patents we and our licensors or collaborators may obtain in the future.

Patent legislation could increase the uncertainties and costs surrounding the prosecution of our and our licensors' or collaborators' patent applications and the enforcement or defense of our or our licensors' or collaborators' issued patents. The Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law in 2011 and many of its implementing regulations became effective in 2013. The Leahy-Smith Act includes a number of significant changes to U.S. patent law, including changing U.S. patent law to award a patent to the first inventor to file, rather than to the first to invent. These changes include provisions that affect the way patent applications are prosecuted and may also affect patent litigation. The changes in patent law due to the Leahy-Smith Act and its implementing regulations could increase the uncertainties and costs surrounding the prosecution of our or our licensors' or collaborators' patent applications and the enforcement or defense of our or our licensors' or collaborators' issued patents, all of which could have a material adverse effect on our business and financial condition.

Additionally, the Leahy-Smith Act provides for various post-grant proceedings providing challengers various legal avenues and opportunities to challenge and invalidate any issued patents we may obtain in the United States. Thus, even when claims issue in patents in the United States, they are not invulnerable to attack, modification, and/or cancellation. New proposals continue to be announced in the U.S. Congress that aim to further change these laws, creating instability in both value and strength of U.S. patents, especially in the biotechnology field. Therefore, the Leahy-Smith Act, and any other follow-on laws that may be enacted in the United States represent a substantial risk in the valuation of our patent portfolio. For instance, legislation has been proposed that attempts to curb patent abuse by non-practicing entities that own patent rights. Such proposed legislation in the United States has included provisions making it substantially more expensive and risky to litigate patent rights in the United States. Should any of these provisions be enacted in the United States that compromise patentees' abilities to enforce their patent rights, substantial uncertainty will surround our ability to enforce our patents in the United States without incurring substantial financial risk.

Obtaining and maintaining our patent rights depends on compliance with various different procedural, document submission, fee payment and other requirements imposed by each individual governmental patent agency, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance and annuity fees are required to be paid to the USPTO and foreign patent agencies at several time periods over the lifetime of any patent. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process and following patent issuance. While an inadvertent lapse can in some instances be cured by payment of a late fee or by other means in accordance with the applicable rules of those countries, there are situations in which noncompliance can result in permanent abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Noncompliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. These rules governing procedural, documentary, fee payment and other provisions of patent prosecution and maintenance are not uniform and vary substantially from country to country, requiring country-specific patent expertise in each jurisdiction in which patent protection is sought. If we or our licensors or collaborators fail to maintain the patents and patent applications covering our product candidates or laboratory platform technology in one or more legal jurisdictions, our competitors might be able to enter the market in those jurisdictions, which would have a materially adverse effect on our business and financial condition.

We may become involved in lawsuits to protect or enforce our intellectual property rights, which could be expensive, time-consuming, distracting, unpredictable, and unsuccessful, and therefore could have a materially adverse impact on the success of our business and financial condition.

Third parties may infringe our or our licensors' or collaborators' patents or misappropriate or otherwise violate our or our licensors' or collaborators' intellectual property rights. Licensees or licensors may violate contractual agreements governing the practice of patented inventions. In the future, we or our licensors or collaborators may initiate legal proceedings to enforce or defend our or our licensors' or collaborators' intellectual property rights, to protect our or our licensors' or collaborators' trade secrets or to determine the validity or scope of intellectual property rights we own or control. Also, third parties may initiate legal proceedings against us or our licensors or collaborators to challenge the validity or scope of intellectual property rights we own or control. These legal proceedings can be expensive and time-consuming and many of our or our licensors' or collaborators' adversaries in these proceedings may have the ability to dedicate substantially greater resources to prosecuting these legal actions than we or our licensors or collaborators. Accordingly, despite our or our licensors' or collaborators' best efforts, we or our licensors or collaborators may not prevent third parties from infringing upon or misappropriating intellectual property rights we own or control, particularly in countries where the laws may not protect those rights as fully as in the United States, or in countries where enforcement is less robust due to local customs and underdeveloped enforcement protocols. Litigation could result in substantial costs and diversion of management resources, which could harm our business and financial results. In addition, in a patent infringement proceeding, a court may decide that a patent owned by or licensed to us is invalid or unenforceable, in part or in whole, or may refuse to stop the other party from using the technology at issue on the grounds that our or our licensors' or collaborators' patent claims do not encompass the putatively infringing technology in question. An adverse result in any litigation proceeding could place one or more of our or our licensors' or collaborators' patents at risk of being invalidated, held unenforceable or interpreted narrowly.

Third-party pre-issuance submission of prior art to the USPTO, or opposition, derivation, reexamination, post-grant review, inter partes review or interference proceedings, or other pre-issuance or post-grant proceedings in the United States or other jurisdictions instigated by third parties or brought by us or our licensors or collaborators may be necessary. For applications and granted patents not subject to the first to file provisions of the Leahy-Smith Act, interference proceedings may be initiated by the USPTO to determine the priority of inventions with respect to our or our licensors' or collaborators' patents or patent applications. An unfavorable outcome could require us or our licensors or collaborators to cease using the related technology and commercializing our product candidates, or to attempt to obtain a license to the disputed technology from the prevailing party. Our business could be harmed if the prevailing party does not offer us or our licensors or collaborators a license on commercially reasonable terms or if the prevailing party offers no

license at all. Even if we or our licensors or collaborators obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us or our licensors or collaborators. In addition, if the breadth or strength of protection provided by our or our licensors' or collaborators' patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates or platform technology. Even if we successfully defend such litigation or proceedings, they typically require substantial financial assets and it may distract our management and other employees during such proceedings. We could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a materially adverse effect on the price of shares of our common stock.

Third parties may initiate legal proceedings against us alleging that we infringe their intellectual property rights, or we may initiate legal proceedings against third parties to challenge the validity or scope of intellectual property rights controlled by third parties, the outcome of which would be uncertain and could have a materially adverse effect on the success of our business and financial condition.

Third parties may initiate legal proceedings against us or our licensors or collaborators alleging that we or our licensors or collaborators infringe their intellectual property rights or we or our licensors or collaborators may initiate legal proceedings against third parties to challenge the validity or scope of intellectual property rights controlled by third parties, including in oppositions, interferences, reexaminations, post-grant reviews, inter partes reviews, or derivation proceedings before the United States or other jurisdictions. These proceedings can be expensive and time-consuming and many of our or our licensors' or collaborators' adversaries in these proceedings may have the ability to dedicate substantially greater resources to prosecuting these legal actions than we or our licensors or collaborators can.

An unfavorable outcome could require us or our licensors or collaborators to cease using the related technology or developing or commercializing our product candidates, or to attempt to license rights to it from the prevailing party.

Our business could be harmed if the prevailing party does not offer us or our licensors or collaborators a license to the disputed technology on commercially reasonable terms or at all. Even if we or our licensors or collaborators obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us or our licensors or collaborators. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could materially harm our business and financial condition.

We may be subject to claims by third parties asserting that our employees or we have misappropriated their intellectual property or claiming ownership of what we regard as our own intellectual property.

Many of our employees, including our senior management, were previously employed at universities or in industry at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Some of these employees executed assignment, proprietary right, non-disclosure, or non-competition agreements in connection with such previous employment. Although we try to ensure that our employees do not use the proprietary information or know-how of any third parties in their work for us, we may be subject to claims that we or these employees have used or disclosed confidential information or intellectual property, including trade secrets or other proprietary information, of any such employee's former employer. Litigation may be necessary to defend against these claims, which could be costly and cause significant delays and could materially harm our business and financial condition.

If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, lose the services of key personnel, or sustain significant monetary damages. Such intellectual property rights could be awarded to a third party, and we could be required to obtain a license from such third party to commercialize our technology or products. Such a license may not be available on commercially reasonable terms or at all. Even if we successfully prosecute or defend against such claims, litigation could result in substantial costs and distract management.

Our inability to protect our confidential information and trade secrets would harm our business and competitive position.

In addition to seeking patents for some of our technology and products, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. We seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. Despite these efforts, any of these parties may breach these agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts

both within and outside the United States may be less willing or unwilling to protect trade secrets. If a competitor lawfully obtained or independently developed any of our trade secrets, we would have no right to prevent such competitor from using that technology or information to compete with us, which could harm our competitive position and our business.

Risks Related to Our Securities

The trading price of our common stock may be volatile.

The trading price of our common stock may be highly volatile and subject to wide fluctuations in response to various factors, some of which we cannot control. In addition to the factors discussed in this "Risk Factors" section, these factors include:

- the success of competitive products or technologies;
- regulatory actions with respect to our products or our competitors' products;
- announcements by us or our competitors of significant acquisitions, strategic collaborations, joint ventures, collaborations or capital commitments;
- results of clinical trials of our product candidates or those of our competitors;
- regulatory or legal developments in the United States and other countries;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- the level of expenses related to any of our product candidates or clinical development programs;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- variations in our financial results or those of companies that are perceived to be similar to us;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- share price and volume fluctuations attributable to inconsistent trading volume levels of our shares;
- announcement or expectation of additional financing efforts;
- sales of our common stock by us, our directors, officers or their affiliated funds or our other stockholders;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors; and
- general economic, industry and market conditions.

There can be no assurance that an adequate trading market for our common stock will be sustained, which may reduce the market value of our common stock and impair our ability to enter into strategic collaborations or acquire companies or products by using our shares of common stock as consideration.

In addition, the stock market in general, and The Nasdaq Global Market ("Nasdaq"), and biotechnology companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. The realization of any of the above risks or any of a broad range of other risks, including those described in this "Risk Factors" section, could have a dramatic and material adverse impact on the market price of our common stock.

We may sell additional equity or debt securities or enter into other arrangements to fund our operations, which may result in dilution to our stockholders and impose restrictions or limitations on our business.

Until we can generate a sufficient amount of revenue from our products, if ever, we expect to finance future cash needs through public or private equity or debt offerings. We may also seek additional funding through government or other third-party funding and other collaborations, strategic alliances and licensing arrangements.

These financing activities may have an adverse impact on our stockholders' rights as well as on our operations, and such additional funding may not be available on reasonable terms, if at all. If we raise additional funds through the issuance of additional debt or equity securities, it may result in dilution to our existing stockholders and/or increased fixed payment obligations. Furthermore, these securities may have rights senior to those of our common stock and could contain covenants that would restrict our operations and potentially impair our competitiveness, such as limitations on our ability to incur additional debt, limitations on our

ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. Additionally, if we seek funds through arrangements with collaborative partners, these arrangements may require us to relinquish rights to some of our technologies or product candidates or otherwise agree to terms unfavorable to us. Any of these events could significantly harm our business, financial condition and prospects.

If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline.

The trading market for our common stock depends in part on the research and reports that securities or industry analysts publish about us or our business. We do not currently have and may never obtain research coverage by securities and industry analysts. If no securities or industry analysts commence coverage of our company, the trading price for our stock would be negatively impacted. If we obtain securities or industry analyst coverage and if one or more of the analysts who covers us downgrades our stock, publishes inaccurate or unfavorable research about our business, our stock price would likely decline. If one or more of these analysts ceases coverage of us or fails to publish reports on us regularly, demand for our stock could decrease, which could cause our stock price and trading volume to decline.

Our management and their affiliates own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval.

As of December 31, 2018, our executive officers and directors and their respective affiliates beneficially owned approximately 69.8% of our outstanding voting stock, including Albert D. Friedberg, our Chairman, who beneficially owned 58.7% of our outstanding voting stock, including 55.5% of our outstanding voting stock beneficially owned by FCMI Parent.

As a result, these stockholders have the ability to control us through this ownership position. These stockholders may be able to determine all matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock. The interests of this group of stockholders may not always coincide with the interests of other stockholders and they may act in a manner that advances their best interests and not necessarily those of other stockholders, including seeking a premium value for their common stock, and might affect the prevailing market price for our common stock. These large affiliate holdings may also contribute to a lack of liquidity in our stock.

We are an "emerging growth company" as defined in the JOBS Act and will be able to avail ourselves of reduced disclosure requirements applicable to emerging growth companies, which could make our common stock less attractive to investors and adversely affect the market price of our common stock.

For so long as we remain an "emerging growth company" as defined in the JOBS Act, we may take advantage of certain exemptions from various requirements applicable to public companies that are not "emerging growth companies" including:

- the provisions of Section 404(b) of the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, requiring that our independent registered public accounting firm provide an attestation report on the effectiveness of our internal control over financial reporting;
- the "say on pay" provisions (requiring a non-binding shareholder vote to approve compensation of certain executive officers) and the "say on golden parachute" provisions (requiring a non-binding shareholder vote to approve golden parachute arrangements for certain executive officers in connection with mergers and certain other business combinations) of the Dodd-Frank Wall Street Reform and Protection Act, or the Dodd-Frank Act, and some of the disclosure requirements of the Dodd-Frank Act relating to compensation of our Chief Executive Officer;
- the requirement to provide detailed compensation discussion and analysis in proxy statements and reports filed under the Exchange Act and instead provide a reduced level of disclosure concerning executive compensation; and
- any rules that the Public Company Accounting Oversight Board may adopt requiring mandatory audit firm rotation or a supplement to the auditor's report on the financial statements.

We may take advantage of these exemptions until we are no longer an "emerging growth company." We would cease to be an "emerging growth company" upon the earliest of: (i) the first fiscal year following the fifth anniversary of our IPO; (ii) the first fiscal year after our annual gross revenues are $1.07 billion or more; (iii) the date on which we have, during the previous three-year period, issued more than $1.0 billion in non-convertible debt securities; or (iv) as of the end of any fiscal year in which the market value of our common stock held by non-affiliates exceeded $700 million as of the end of the second quarter of that fiscal year.

We currently intend to take advantage of some of the reduced regulatory and reporting requirements that will be available to us so long as we qualify as an "emerging growth company." For example, pursuant to Section 107(b) of the JOBS Act, we have elected to use the extended transition period for complying with new or revised accounting standards under Section 102(b) of the JOBS Act. This election allows us to delay the adoption of new or revised accounting standards that have different effective dates for public and private companies until those standards apply to private companies. As a result, our financial statements may not be comparable to companies that comply with public company effective dates.

Our independent registered public accounting firm will not be required to provide an attestation report on the effectiveness of our internal control over financial reporting so long as we qualify as an "emerging growth company," which may increase the risk that material weaknesses or significant deficiencies in our internal control over financial reporting go undetected. Likewise, so long as we qualify as an "emerging growth company," we may elect not to provide stockholders with certain information, including certain financial information and certain information regarding compensation of our executive officers, that we would otherwise have been required to provide in filings we make with the SEC, which may make it more difficult for investors and securities analysts to evaluate our company. We cannot predict if investors will find our common stock less attractive because we rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock, and our stock price may be more volatile and may decline.

Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

We are subject to the periodic reporting requirements of the Exchange Act. We designed our disclosure controls and procedures to reasonably assure that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well-conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple errors or mistakes. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected.

Sales of a substantial number of shares of our common stock in the public market could cause our stock price to fall.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock.

We may be subject to securities litigation, which is expensive and could divert management attention.

The market price of our common stock may be volatile, and in the past, companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation. We may be the target of this type of litigation in the future. Securities litigation against us could result in substantial costs and divert our management's attention from other business concerns, which could seriously harm our business.

Some provisions of our charter documents and Delaware law may have anti-takeover effects that could discourage an acquisition of us by others, even if an acquisition would benefit our stockholders and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our amended and restated certificate of incorporation and amended and restated bylaws, as well as provisions of Delaware law, could make it more difficult for a third party to acquire us or increase the cost of acquiring us, even if doing so would benefit our stockholders, or remove our current management. These provisions include:

- creating a classified board of directors whose members serve staggered three-year terms;
- authorizing the issuance of "blank check" preferred stock, the terms of which we may establish and shares of which we may issue without stockholder approval;
- prohibiting cumulative voting in the election of directors, which would otherwise allow for less than a majority of stockholders to elect director candidates;

- prohibiting stockholder action by written consent, thereby requiring all stockholder actions to be taken at a meeting of our stockholders;
- eliminating the ability of stockholders to call a special meeting of stockholders; and
- establishing advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted upon at stockholder meetings.

These provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, who are responsible for appointing the members of our management. Because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, or the DGCL, which may discourage, delay or prevent someone from acquiring us or merging with us whether or not it is desired by or beneficial to our stockholders. Under the DGCL, a corporation may not, in general, engage in a business combination with any holder of 15% or more of its capital stock unless the holder has held the stock for three years or, among other things, the board of directors has approved the transaction. However, because funds affiliated with FCMI Parent acquired their shares prior to our IPO, Section 203 is currently inapplicable to any business combination or transaction with it or its affiliates.

Any provision of our amended and restated certificate of incorporation or amended and restated bylaws or Delaware law that has the effect of delaying or deterring a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our common stock and could also affect the price that some investors are willing to pay for our common stock.

Item 1B. Unresolved Staff Comments.

None.

Item 2. Properties.

Our principal executive office is located in Rochester, New York, and consists of approximately 31,180 square feet of leased office and laboratory space. We believe that our facilities are adequate for our current needs and that suitable additional space will be available in the future if needed.

Item 3. Legal Proceedings.

From time to time we may become involved in legal proceedings or be subject to claims arising in the ordinary course of our business. We are not presently a party to any legal proceedings that, if determined adversely to us, would individually or taken together have a material adverse effect on our business, results of operations, financial condition or cash flows. Regardless of the outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Market Information

Our common stock has been listed on the Nasdaq Global Market under the symbol "VCNX" since August 9, 2018. Prior to that date, there was no public trading market for our common stock.

As of March 1, 2019, there were 141 holders of record of our common stock. The actual number of stockholders is greater than this number of record holders and includes stockholders who are beneficial owners but whose shares are held in street by brokers and other nominees.

Recent sales of Unregistered Securities

None.

Repurchases of Vaccinex Securities

We did not repurchase any shares during the fourth quarter of the year ended December 31, 2018.

Use of Proceeds from Registered Securities

On August 9, 2018, the SEC declared our Registration Statement on Form S-1 (File No. 333-226103) effective. Pursuant to that Registration Statement, our underwriters, Oppenheimer & Co. Inc., BTIG, LLC and Ladenburg Thalmann & Co. Inc. offered 3,333,334 shares of our common stock to the public for an aggregate offering price of approximately $40.0 million. Net proceeds of the offering were $34.5 million after deducting underwriting discounts and commissions of $2.8 million and offering expenses of $2.7 million. During the period from the closing of our IPO on August 13, 2018 through December 31, 2018, net proceeds from the IPO have been used as follows:

- approximately $2.0 million to fund development of pepinemab as a combination therapy with avelumab in patients with NSCLC who have not previously been treated with immunotherapy;
- approximately $7.4 million to fund development of pepinemab as a therapy in Huntington's disease;
- approximately $1.1 million to fund preclinical research using our platform technologies;
- approximately $1.8 million to repay a convertible promissory note (including accrued interest), or the June 2016 Note, held by Vaccinex (Rochester), L.L.C., which is majority owned and controlled by Dr. Maurice Zauderer, our President, Chief Executive Officer and a member of our Board of Directors;
- approximately $3.5 million for working capital and general corporate purposes; and
- approximately $18.7 million as investments in short-term, interest-bearing, investment-grade securities pending other uses.

Other than repayment of the June 2016 Note, no net proceeds were paid, directly or indirectly, to our directors or officers, to persons owning 10% or more of any class of our equity securities or to any of our affiliates. There has been no material change in the expected use of the net proceeds from our IPO as described in our registration statement on Form S-1.

Item 6. Selected Financial Data.

Not required.

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

You should read the following discussion and analysis of financial condition and results of operations together with our consolidated financial statements and related notes included elsewhere in this Annual Report on Form 10-K. As discussed in the section titled "Special Note Regarding Forward Looking Statements," the following discussion and analysis contains forward-looking statements that involve risks and uncertainties, as well as assumptions that, if they never materialize or prove incorrect, could cause our results to differ materially from those expressed or implied by such forward-looking statements. Factors that could cause or contribute to these differences include, but are not limited to, those discussed in the section titled "Risk Factors" under Part I, Item 1A in this Annual Report on Form 10-K.

Company Overview

We are a clinical-stage biotechnology 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. We believe we are the leader in the field of SEMA4D biology, and that we are the only company targeting SEMA4D as a potential treatment for cancer, neurodegenerative diseases, or autoimmune disorders. SEMA4D is an extracellular signaling molecule that regulates the migration of immune and inflammatory cells to sites of injury, cancer or infection. We are leveraging our SEMA4D antibody platform and our extensive knowledge of SEMA4D biology to develop our lead product candidate pepinemab, which we believe utilizes novel mechanisms of action. We are focused on developing pepinemab for the treatment of non-small cell lung cancer, or NSCLC, and Huntington's disease. Additionally, one investigator is studying pepinemab in osteosarcoma and another is studying pepinemab in melanoma. We have developed multiple proprietary platform technologies and are developing product candidates to address serious diseases or conditions that have a substantial impact on day-to-day functioning and for which treatment is not addressed adequately by available therapies. We employ our proprietary platform technologies, including through our work with our academic collaborators, to identify potential product candidates for sustained expansion of our internal product pipeline and to facilitate strategic development and commercial partnerships.

Our lead platform technologies include our SEMA4D antibody platform and our ActivMAb antibody discovery platform. In addition, we and our academic collaborators are using our Natural Killer T, or NKT, vaccine platform to discover product candidates that target and extend the activity of NKT cells. Our lead product candidate, pepinemab, is currently in clinical development for the treatment of NSCLC, osteosarcoma and Huntington's disease, through our efforts or through investigator sponsored trials, or ISTs. Our additional product candidates VX5 and VX25 are in earlier stages of development and were selected using our ActivMAb and NKT vaccine platforms, respectively. We believe our multiple platform technologies position us well for continued pipeline expansion and partnership opportunities going forward.

We have generated a limited amount of service revenue from collaboration agreements but have not generated any revenue from product sales to date. We continue to incur significant development and other expenses related to our ongoing operations. As a result, we are not and have never been profitable and have incurred losses in each period since our inception. For the years ended December 31, 2018 and 2017, we reported a net loss of $29.5 million and $18.8 million, respectively. As of December 31, 2018 and 2017, we had cash and cash equivalents and marketable securities of $19.7 million and $4.2 million, respectively. We expect to continue to incur significant losses for the foreseeable future, and we expect these losses to increase as we continue our research and development of, and seek regulatory approvals for, our product candidates. Our recurring net losses and negative cash flows from operations have raised substantial doubt regarding our ability to continue as a going concern within one year after the issuance of our financial statements for the year ended December 31, 2018, and as a result, our independent registered public accounting firm has noted this in the opinion they issued on our consolidated financial statements. We may also encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenues, if any. Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders' equity and working capital.

Financial Overview

Revenue

To date, we have not generated any revenue from product sales. During the years ended December 31, 2018 and 2017, we generated a limited amount of service revenue from our collaboration agreements, including with Surface Oncology, Inc., Merck Sharp & Dohme Corp., and Heptares Therapeutics, Ltd.

Our ability to generate revenue and become profitable depends on our ability to successfully obtain marketing approval of and commercialize our product candidates. We do not expect to generate product revenue in the foreseeable future as we continue our development of, and seek regulatory approvals for, our product candidates, and potentially commercialize approved products, if any.

Operating Expenses

Research and Development. Research and development expenses consist primarily of costs for our clinical trials and activities related to regulatory filings, employee compensation-related costs, supply expenses, equipment depreciation and amortization, consulting and other miscellaneous costs. The following table sets forth the components of our research and development expenses and the amount as a percentage of total research and development expenses for the periods indicated.

	Year Ended December 31,			
	2018		2017	
	(in thousands)	%	(in thousands)	%
Clinical trial costs	$ 16,698	75%	$ 10,801	65%
Wages, benefits, and related costs	3,029	13%	3,564	22%
Preclinical supplies and equipment depreciation	1,863	8%	1,527	9%
Consulting, non-clinical trial services, and other	567	3%	659	4%
Other	196	1%	-	0%
Total research and development expenses	$ 22,353		$ 16,551	

Our current research and development activities primarily relate to the clinical development of the following programs:

- **Non-Small Cell Lung Cancer (NSCLC).** In the CLASSICAL–Lung clinical trial, in which we are evaluating pepinemab in combination with avelumab in NSCLC, the dose escalation phase of the trial consisting of 12 subjects is complete, and we have identified the intended Phase 2 dose for the dose expansion phase. We plan to enroll a total of 50 subjects in each of two cohorts: 28 subjects in one cohort in which patients are immunotherapy naïve and 22 subjects in a second cohort whose tumors have progressed during or following an initial treatment with anti-PD1/PD-L1. Primary completion for this trial is expected in the second half of 2019.
- **Huntington's Disease.** Enrollment in Cohort B of our SIGNAL trial evaluating pepinemab for the treatment of Huntington's disease, consisting of 265 subjects, was completed in December 2018. We expect data from this study in the second half of 2020.
- In addition, pepinemab is also being evaluated in multiple investigator-sponsored trials, or ISTs, for additional cancer indications:
  - **Melanoma** - The UCLA School of Medicine, in collaboration with Bristol-Myers Squibb, is evaluating pepinemab in combination with the checkpoint inhibitors nivolumab and ipilumumab in two cohorts of patients with advanced melanoma.
  - **Osteosarcoma** - The National Cancer Institute's Children's Oncology Group is evaluating pepinemab for the treatment of osteosarcoma.
  - **Other** - Multiple "window of opportunity" trials are being conducted by the Winship Cancer Institute of Emory University to evaluate pepinemab in combination with immunotherapies in colorectal, pancreatic, head and neck cancer and melanoma.

As a result of our current research and development activities, the following milestones are anticipated:

- Second quarter of 2019 – Expected release of initial report of open label study of pepinemab in combination with avelumab in NSCLC
- Second half of 2019 – Estimated primary completion date of combination study in NSCLC
- First half of 2019 – Anticipated publication of SIGNAL Cohort A data in Huntington's disease
- Second half of 2020 – Expected topline data from Cohort B of ongoing SIGNAL trial of pepinemab in Huntington's disease

We expense research and development costs as incurred. We record costs for certain development activities, such as clinical trials, based on an evaluation of the progress to completion of specific tasks using data such as patient enrollment. We do not allocate employee related costs, depreciation, rental and other indirect costs to specific research and development programs because these costs are deployed across multiple of our product programs under research and development.

Results of Operations

The following table set forth our results of operations for the periods presented (in thousands):

	Year Ended December 31,	
	2018	2017
Revenue	$ 724	$ 90
Costs and expenses:		
Cost of revenue	1,033	160
Research and development	22,353	16,551
General and administrative	4,619	4,483
Total costs and expenses	28,005	21,194
Loss from operations	(27,281)	(21,104)
Change in fair value of derivative liabilities	369	3,743
Interest expense	(392)	(1,358)
Loss on extinguishment of related party convertible promissory note	(2,379)	-
Other income (expense), net	165	(40)
Loss before provision for income taxes	(29,518)	(18,759)
Provision for income taxes	-	-
Net loss	(29,518)	(18,759)
Net loss attributable to noncontrolling interests	-	37
Net loss attributable to Vaccinex, Inc.	$ (29,518)	$ (18,722)

Comparison of the Years Ended December 31, 2018 and 2017

Revenue and Cost of Revenue

The $724,000 service revenue and $1.0 million cost of revenue during the year ended December 31, 2018 was primarily due to recognition of deferred revenue and cost incurred for our collaboration agreements entered in December 2017. The $90,000 service revenue and $160,000 cost of revenue during the year ended December 31, 2017 was primarily due to recognition of deferred revenue and cost incurred for our collaboration agreements entered in December 2016.

Operating Expenses

	Year Ended December 31,			
	2018	2017	$ Change	% Change
	(in thousands)			
Research and development	$ 22,353	$ 16,551	$ 5,802	35%
General and administrative	4,619	4,483	136	3%
Total operating expenses	$ 26,972	$ 21,034	$ 5,938	38%

Research and Development. Research and development expenses in the year ended December 31, 2018 increased by $5.8 million, or 35%, compared to the year ended December 31, 2017. This increase was attributable to the increase in patients enrolled in active clinical trials.

General and Administrative. General and administrative expenses in the year ended December 31, 2018 increased by $136,000, or 3%, compared to the year ended December 31, 2017. This increase was primarily attributable to costs associated with our directors and officers liability insurance.

Change in Fair Value of Derivative Liabilities

	Year Ended December 31,			
	2018	2017	$ Change	% Change
	(in thousands)			
Change in fair value of derivative liabilities	$ 369	$ 3,743	$ (3,374)	(90)%

Change in fair value of derivative liabilities in the year ended December 31, 2018 changed by $3.4 million, or 90%, compared to the year ended December 31, 2017. The change was primarily due to a decrease of $369,000 in the fair value of derivative liabilities during the year ended December 31, 2018 associated with the repayment of the January 2017 Notes (defined below) and the waiving of the option arrangement in March 2018, repayment of the June 2016 Note (defined below) in August 2018, and an increase of $3.7 million in the fair value of derivative liabilities during the year ended December 31, 2017 as a result of increased conversion probability of the convertible promissory notes. For detailed descriptions of the convertible promissory notes and the option arrangement, please see "Convertible Promissory Notes" below.

Interest Expense

	Year Ended December 31,			
	2018	2017	$ Change	% Change
	(in thousands)			
Interest expense	$ 392	$ 1,358	$ (966)	(71)%

Interest expense in the year ended December 31, 2018 decreased $966,000, or 71%, compared to the year ended December 31, 2017 as a result of the repayment of the January 2017 Notes in March 2018 and the June 2016 Note in August 2018.

Loss on extinguishment of related party convertible promissory notes

The $2.4 million loss on extinguishment of related party convertible promissory notes in the year ended December 31, 2018 is associated with the write-off of the unamortized debt discount of the January 2017 Notes and June 2016 Note upon the repayment of such notes during the year ended December 31, 2018.

Liquidity and Capital Resources

To date, we have not generated any revenue from product sales. Since our inception in 2001, we have financed our operations principally through private placements of our preferred stock, issuances of convertible promissory notes and other promissory notes, the initial public offering, or IPO, of our common stock and funding from collaboration agreements with our variable interest entities. Through December 31, 2018, we have received net proceeds of $37.2 million from the IPO, $87.1 million from the issuance of shares of our preferred stock, $39.0 million from the issuance of convertible promissory notes and $72.1 million from our variable interest entities.

Operating Capital Requirements

Our primary uses of capital are, and we expect will continue to be, compensation and related expenses, third-party research services and amounts due to vendors for research supplies. As of December 31, 2018 and 2017, our principal source of liquidity was cash and cash equivalents and marketable securities in the amount of $19.7 million and $4.2 million, respectively. Given our projected operating requirements, our existing cash and cash equivalents and marketable securities, we plan to complete an additional financing transaction prior to the commencement of the fourth quarter of the year ended December 31, 2019 in order for us to continue operations.

Since our inception in 2001, we have incurred significant net losses and negative cash flows from operations. For the years ended December 31, 2018 and 2017, we reported a net loss of $29.5 million and $18.8 million, respectively. As of December 31, 2018 and 2017, we had an accumulated deficit of $216.8 million and $187.2 million, respectively. We anticipate that we will continue to generate losses for the foreseeable future, and we expect the losses to increase as we continue the development of, and seek regulatory approvals for, our product candidates. We are subject to all of the risks associated with the development of new biopharmaceutical products, and we may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. Our recurring net losses and negative cash flows from operations have raised substantial doubt regarding our ability to continue as a going concern within one year after the issuance of our financial statements for the year ended December 31, 2018.

Until we can generate a sufficient amount of revenue from our products, we expect to finance future cash needs through public or private equity, debt offerings, or capital contributions from our noncontrolling interests. In 2018, VX3 (DE) LLP, or VX3, received a commitment of $8.0 million of additional funding from FCMI Parent Co., or FCMI Parent, which was received in the first quarter of 2018, and commitments of $4.0 million of additional funding in the aggregate from FCMI Parent and another investor, which were received in the second quarter of 2018. In August 2018, we completed our IPO and received net proceeds of $37.2 million. Additional capital may not be available on reasonable terms, if at all. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us we may have to significantly delay, scale back or discontinue the development of one or more of our product candidates or cease operations. If we raise additional funds through the issuance of additional debt or equity securities it could result in dilution to our existing stockholders, increased fixed payment obligations and these securities may have rights senior to those of our common stock and could contain covenants that would restrict our operations and potentially impair our competitiveness, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license our intellectual property rights

and other operating restrictions that could adversely impact our ability to conduct our business. Any of these events could significantly harm our business, financial condition and prospects.

Cash Flows

The following table summarizes our cash flows for the periods presented:

	Year Ended December 31,	
	2018	2017
	(in thousands)	
Cash used in operating activities	$ (25,276)	$ (21,387)
Cash used in investing activities	(14,241)	(68)
Cash provided by financing activities	40,955	23,974

Operating Activities. We have historically experienced negative cash flows as we develop our product candidates and continue to expand our business. Our net cash used in operating activities primarily results from our net loss adjusted for non-cash expenses and changes in working capital components as we have continued our research and development and is influenced by the timing of cash payments for research related expenses. Our primary uses of cash from operating activities are compensation and related-expenses, employee-related expenditures, third-party research services and amounts due to vendors for research supplies. We expect our cash flows from operating activities will continue to be affected principally by the extent to which we increase spending on personnel, research and development and other operating activities as our business grows.

During the year ended December 31, 2018, operating activities used $25.3 million in cash, primarily as a result of our net loss of $29.5 million, aggregate non-cash items of $2.6 million, and $1.6 million net inflow change in our operating assets and liabilities. Non-cash items included a $2.4 million loss from unamortized debt issuance cost upon the repayment of the $4.0 million January 2017 Note in March 2018 and $1.5 million June 2016 Note in August 2018, a $369,000 gain in fair value change of derivative liabilities, a $308,000 amortization of debt discount related to the convertible promissory notes, $223,000 depreciation expense and $177,000 of stock-based compensation expense. The net inflow change in our operating assets and liabilities was primarily the result of a $2.4 million increase in accrued liabilities mainly attributable to increased clinical trial related accruals, a $421,000 increase in accounts payable due to increased clinical trial activities, partially offset by a $522,000 increase in accounts receivable, $384,000 increase in prepaid and other current assets as we made payments for clinical trial related expense, and a $298,000 decrease in deferred revenue as a result of the amortization of upfront payments from our collaboration agreements entered in 2017.

During the year ended December 31, 2017, operating activities used $21.4 million in cash, primarily as a result of our net loss of $18.8 million, aggregate non-cash items of $2.0 million, and $627,000 net change in our operating assets and liabilities. Non-cash items included $3.7 million gain in fair value of derivative liabilities, $1.2 million amortization of debt discount related to the convertible promissory notes, $319,000 of stock-based compensation expense and $206,000 depreciation expense. The net change in our operating assets and liabilities was primarily the result of $555,000 decrease in accounts payable and $330,000 decrease in prepaid and other current assets as we made payments for clinical trial related expense, partially offset by a $298,000 increase in deferred revenue as a result of cash receipts from our collaboration partners for services to be provided in future periods.

Investing Activities. Cash used in investing activities during the years ended December 31, 2018 and 2017 of $14.2 million and $68,000, respectively, resulted from purchases of marketable securities and capital expenditures to purchase property and equipment.

Financing Activities. During the year ended December 31, 2018, financing activities provided $41.0 million consisting of proceeds from our IPO, net of commissions and underwriting discounts of $37.1 million and the capital contribution from noncontrolling interests of $12.0 million partially offset by $5.5 million in repayments of convertible promissory notes and payments of initial public offering costs of $2.7 million.

During the year ended December 31, 2017, financing activities provided $24.0 million primarily attributable to the capital contribution from noncontrolling interests of $12.0 million, net proceeds of $10.0 million from the issuance of convertible promissory notes to related parties and $8.0 million from the issuance of Series D redeemable convertible preferred stock, which was partially offset by a $6.0 million repayment of convertible promissory notes and accrued interest to related parties.

Convertible Promissory Notes

During the year ended December 31, 2016, we raised approximately $6.5 million through the issuance of convertible promissory notes (including a $1.5 million convertible promissory note issued in June 2016 (the “June 2016 Note”)) of which $5.0 million converted into Series D redeemable convertible preferred stock in December 2016. During 2017, we raised funds through the issuance of $10.0 million of convertible promissory notes (the “January 2017 Notes”), of which $6.0 million were repaid in the same year. On March 8, 2018, we repaid the $4.0 million January 2017 Note and on August 17, 2018, the $1.5 million June 2016 Note was repaid. In connection with the issuance of the January 2017 Notes, we also entered into a side letter agreement with a related party that granted the related party an exclusive option to acquire shares with a fair value of up to $4.0 million in the next qualifying financing, or the

option arrangement, at a price per share equal to the conversion price of the January 2017 Notes, which option arrangement was waived on March 8, 2018.

Capital Contributions from Noncontrolling Interests

In November 2017, we entered into a license agreement, or the VX3 License Agreement, with VX3, which was formed in October 2017 by a group of Canadian investors including our majority stockholder, FCMI Parent. Under the VX3 License Agreement, we granted VX3 the license to use, make, have made, sell, offer and import pepinemab for the treatment of Huntington's disease in the U.S. and Canada. Pursuant to the VX3 License Agreement, VX3 agreed to pay us up to an aggregate of $32.0 million in milestone payments and to share any pepinemab profits and sublicensing revenue under the agreement in an amount based on a calculation set forth in the agreement. In connection with the VX3 License Agreement, we also entered into a services agreement with VX3 (the "Services Agreement"), effective as of January 1, 2017, pursuant to which we will carry out development activities for pepinemab for the treatment of Huntington's disease in the U.S. and Canada in exchange for services payments from VX3, including a payment of $11.9 million for 2017 net of certain related expenses. On February 28, 2018, May 15, 2018 and June 12, 2018, the Services Agreement was amended to provide for additional payments of $8.0 million, $2.0 million and $2.0 million, respectively, from VX3 for services performed in 2018. The VX3 License Agreement expires upon the last to expire licensed patent and may be terminated by either party upon uncured material breach, the occurrence of certain transactions or financings including the consummation of an initial public offering by us, uncured failure of VX3 to make any payment due under the services agreement, or upon written notice after November 6, 2020. The Services Agreement may be terminated by either party upon uncured material breach and is automatically terminated upon termination of the VX3 License Agreement. The VX3 License Agreement provides that upon termination, we will issue to VX3 or its designees the number of shares of our common stock equal to the lesser of (1) the aggregate of all capital contributions made to VX3 by its partners divided by $18.20 and (2) the then fair market value of VX3 divided by the then fair market value of one share of our common stock.

We have determined VX3 to be a variable interest entity in which we are the primary beneficiary. As such, we recorded the gross proceeds of $12.0 million received from VX3 as a capital contribution from noncontrolling interests on our consolidated financial statements for the year ended December 31, 2018.

Off-Balance Sheet Arrangements

We are not a party to any material off-balance sheet arrangements as defined in the rules and regulations of the SEC.

JOBS Act Accounting Election

We are an "emerging growth company" within the meaning of the Jumpstart Our Business Startups Act (the "JOBS Act"). Section 107(b) of the JOBS Act provides that an emerging growth company can leverage the extended transition period, provided in Section 102(b) of the JOBS Act, for complying with new or revised accounting standards. Thus, an emerging growth company can delay the adoption of new or revised accounting standards that have different effective dates for public and private companies until those standards apply to private companies. We have elected to use this extended transition period and, as a result, our consolidated financial statements may not be comparable to companies that comply with public company effective dates of such accounting standards.

Critical Accounting Policies and Estimates

Our consolidated financial statements are prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of these consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, expenses and related disclosures. We evaluate our estimates and assumptions on an ongoing basis. Our estimates are based on historical experience and various other assumptions that we believe to be reasonable under the circumstances. Our actual results could differ from these estimates.

We believe that the assumptions and estimates have the greatest potential impact on our consolidated financial statements. Therefore, we consider these to be our critical accounting policies and estimates. For further information on all of our significant accounting policies, see Note 2 to our consolidated financial statements.

Recent Accounting Pronouncements Not Yet Adopted

For a discussion of recent accounting pronouncements that we have not yet adopted, see Note 2 to our consolidated financial statements.

Recently Adopted Accounting Pronouncements

For a discussion of accounting pronouncements that we have recently adopted, see Note 2 to our consolidated financial statements.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

We are exposed to market risk in the ordinary course of our business. Market risk represents the risk of loss that may impact our financial position due to adverse changes in financial market prices and rates. Our market risk exposure is primarily a result of fluctuations in interest rates. We do not hold or issue financial instruments for trading purposes.

Interest Rate Risk

We had cash and cash equivalents of $5.6 million and marketable securities of $14.1 million as of December 31, 2018, which consist of U.S. government treasury bills and notes. Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of the interest rates in the United States. However, because of the short-term nature of the instruments in our portfolio, a sudden change in market interest rates would not be expected to have a material impact on our consolidated financial statements.

Foreign Currency Risk

The majority of our purchase contracts are denominated in U.S. dollars. However, we pay certain of our suppliers and third-party research and development service providers in a foreign currency under the terms of their supply agreements, and we may pay other suppliers and third-party research and development service providers in the future in foreign currency. To date, any resulting gains and losses from such transactions have not been significant. We do not currently engage in any hedging transactions.

Item 8. Financial Statements and Supplementary Data.

The financial information required by Item 8 is contained in Item 15 of Part IV of this Annual Report on Form 10-K.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

None.

Item 9A. Controls and Procedures.

Evaluation of disclosure controls and procedures

Our management, with the participation of our Chief Executive Officer (our principal executive officer) and Chief Financial Officer (our principal financial officer), evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the “Exchange Act”)) as of December 31, 2018, the end of the period covered by this Form 10-K. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of December 31, 2018, our disclosure controls and procedures were effective.

Internal control over financial reporting

This Annual Report on Form 10-K does not include a report of management’s assessment regarding internal control over financial reporting or an attestation report of the Company’s registered public accounting firm due to a transition period established by the rules of the SEC for newly public companies.

Changes in internal control over financial reporting

During the quarter ended December 31, 2018, there were no changes in our internal control over financial reporting that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

The information required by this item is incorporated herein by reference from the captions entitled “Proposal One: Election of Directors,” “Corporate Governance,” “Executive Officers and Senior Management” and “Section 16(a) Beneficial Ownership Reporting Compliance” contained in our definitive proxy statement for the 2019 Annual Meeting of Stockholders to be filed within 120 days after the December 31, 2018 fiscal year end (the “2019 Proxy Statement”).

Item 11. Executive Compensation.

The information required by this item is incorporated herein by reference from the captions entitled “Compensation of Named Executive Officers” and “Director Compensation” contained in the 2019 Proxy Statement.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The information required by this item is incorporated herein by reference from the captions entitled “Security Ownership of Certain Beneficial Owners,” “Security Ownership of Management” and “Equity Compensation Plan Information” contained in the 2019 Proxy Statement.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

The information required by this item is incorporated herein by reference from the captions “Certain Relationships and Related Person Transactions,” “Proposal One: Election of Directors,” and “Corporate Governance” contained in the 2019 Proxy Statement.

Item 14. Principal Accounting Fees and Services.

The information required by this item is incorporated herein by reference from the caption “Proposal Two: Ratification of the Selection of the Company’s Independent Registered Public Accounting Firm for Fiscal 2019” contained in the 2019 Proxy Statement.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

(a) Financial Statements

The consolidated financial statements listed in the accompanying index (page F-1) to the consolidated financial statements are filed as part of this Annual Report on Form 10-K.

(b) Exhibits

The following exhibits are filed with this Annual Report on Form 10-K or incorporated by reference herein:

Exhibit Number	Description
3.1	Amended and Restated Certificate of Incorporation of Vaccinex, Inc. (incorporated herein by reference from Exhibit 3.1 to the Company's Current Report on Form 8-K filed on August 13, 2018).
3.2	Amended and Restated Bylaws of Vaccinex, Inc. (incorporated herein by reference from Exhibit 3.2 to the Company's Current Report on Form 8-K filed on August 13, 2018).
10.1	First Amended and Restated Investor Rights Agreement, dated August 22, 2003, by and among the Company and the parties thereto (incorporated herein by reference from Exhibit 10.1 to the Company's Registration Statement on Form S-1 filed on July 9, 2018).
10.2+	Vaccinex, Inc. 2001 Employee Equity Plan, as amended (incorporated herein by reference from Exhibit 10.2 to the Company's Registration Statement on Form S-1 filed on August 8, 2018).
10.3+	Form of Stock Option Agreement under the Vaccinex, Inc. 2001 Employee Equity Plan (incorporated herein by reference from Exhibit 10.3 to the Company's Registration Statement on Form S-1 filed on July 9, 2018).
10.4+	Vaccinex, Inc. 2011 Employee Equity Plan (incorporated herein by reference from Exhibit 10.4 to the Company's Registration Statement on Form S-1 filed on July 9, 2018).
10.5+	May 15, 2014 Amendment to the Vaccinex, Inc. 2011 Employee Equity Plan (incorporated herein by reference from Exhibit 10.4(a) to the Company's Registration Statement on Form S-1 filed on August 8, 2018).
10.6+	Form of Stock Option Agreement under Vaccinex, Inc. 2011 Employee Equity Plan (incorporated herein by reference from Exhibit 10.5 to the Company's Registration Statement on Form S-1 filed on July 9, 2018).
10.7+	Vaccinex, Inc. 2018 Omnibus Incentive Plan (incorporated herein by reference from Exhibit 10.6 to the Company's Registration Statement on Form S-1 filed on July 23, 2018).
10.8+	Form of Incentive Stock Option Agreement under the Vaccinex, Inc. 2018 Omnibus Incentive Plan (incorporated herein by reference from Exhibit 10.7 to the Company's Registration Statement on Form S-1 filed on July 23, 2018).
10.9+	Form of Non-Qualified Stock Option Agreement under the Vaccinex, Inc. 2018 Omnibus Incentive Plan (incorporated herein by reference from Exhibit 10.8 to the Company's Registration Statement on Form S-1 filed on July 23, 2018).
10.10+	Severance Pay Plan (incorporated herein by reference from Exhibit 10.9 to the Company's Registration Statement on Form S-1 filed on July 9, 2018).
10.11+	Director Compensation Program (incorporated herein by reference from Exhibit 10.10 to the Company's Registration Statement on Form S-1 filed on July 23, 2018).
10.12+	Form of Indemnification Agreement by and between the Company and each of its directors and officers (incorporated herein by reference from Exhibit 10.11 to the Company's Registration Statement on Form S-1 filed on July 9, 2018).

10.13†	Exclusive License Agreement, dated December 29, 1998, by and between the Company and the University of Rochester (incorporated herein by reference from Exhibit 10.12 to the Company's Registration Statement on Form S-1 filed on July 9, 2018).
10.14†	GPEx® Development and Manufacturing Agreement, dated January 13, 2010, by and between the Company and Catalent Pharma Solutions, LLC (incorporated herein by reference from Exhibit 10.13 to the Company's Registration Statement on Form S-1 filed on July 9, 2018).
10.15†	GPEx® – Derived Cell Line Sale Agreement, dated January 13, 2010, by and between the Company and Catalent Pharma Solutions, LLC (incorporated herein by reference from Exhibit 10.14 to the Company's Registration Statement on Form S-1 filed on July 9, 2018).
10.16	Amended and Restated Exchange Agreement, dated October 24, 2014, by and among the Company and the parties listed therein (incorporated herein by reference from Exhibit 10.15 to the Company's Registration Statement on Form S-1 filed July 9, 2018).
10.17†	Clinical Trial Collaboration and Supply Agreement, dated October 4, 2016, by and between the Company and Ares Trading S.A. (incorporated herein by reference from Exhibit 10.16 to the Company's Registration Statement on Form S-1 filed on July 9, 2018).
10.18	License Agreement, dated November 6, 2017, by and between the Company and VX3 (DE) LP (incorporated herein by reference from Exhibit 10.17 to the Company's Registration Statement on Form S-1 filed on July 9, 2018).
10.19	Services Agreement, dated November 6, 2017, by and between the Company and VX3 (DE) LP (incorporated herein by reference from Exhibit 10.18 to the Company's Registration Statement on Form S-1 filed on July 9, 2018).
10.20	Consent and Amendment, dated February 28, 2018, by and among VX3 Inc., FCMI Parent Co., the Company and VX3 (DE) LP (incorporated herein by reference from Exhibit 10.19 to the Company's Registration Statement on Form S-1 filed on July 9, 2018).
10.21	Consent and Amendment, dated May 15, 2018, by and among VX3 Inc., FCMI Parent Co., the Company and VX3 (DE) LP (incorporated herein by reference from Exhibit 10.20 to the Company's Registration Statement on Form S-1 filed on July 9, 2018).
10.22	Consent and Amendment, dated June 12, 2018, by and among VX3, Inc., FCMI Parent Co., the Company and VX3 (DE) LP (incorporated herein by reference from Exhibit 10.21 to the Company's Registration Statement on Form S-1 filed on July 9, 2018).
10.23	Agreement, dated March 16, 2018, by and among the Company, VX3 (DE) LP, VX3 Inc., and each of the other parties on the signature pages thereto (incorporated herein by reference from Exhibit 10.22 to the Company's Registration Statement on Form S-1 filed on July 9, 2018).
10.24*	VX3 Exchange Agreement, dated August 13, 2018, by and among the Company, VX3 Inc., VX3 (DE) LP, FCMI Parent Co., and certain investors listed on Schedule A thereto.
21.1	Subsidiaries of the Company (incorporated herein by reference from Exhibit 21.1 to the Company's Registration Statement on Form S-1 filed on July 9, 2018).
23.1*	Consent of Deloitte & Touche LLP
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document

101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

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* Filed herewith.

\+ Management contract.

† The Company was granted confidential treatment for certain information contained in this exhibit. Such information was filed separately with the Securities and Exchange Commission.

Item 16. Form 10-K Summary.

None.

Signatures

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized**.**

Company Name

Date: March 13, 2019

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

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this Report has been signed below by the following persons on behalf of the Registrant in the capacities and on the dates indicated.

Name	Title	Date
/s/ Maurice Zauderer, Ph.D. Maurice Zauderer, Ph.D.	President, Chief Executive Officer and Director (Principal Executive Officer)	March 13, 2019
/s/ Scott E. Royer, CFA, MBA Scott E. Royer, CFA, MBA	Chief Financial Officer (Principal Financial and Accounting Officer)	March 13, 2019
/s/ Albert D. Friedberg Albert D. Friedberg	Chairman of the Board	March 13, 2019
/s/ Alejandro M. Berlin, M.D., MSc Alejandro M. Berlin, M.D., MSc	Director	March 13, 2019
/s/ Alan L. Crane Alan L. Crane	Director	March 13, 2019
/s/ Jacob B. Frieberg Jacob B. Frieberg	Director	March 13, 2019
/s/ J. Jeffrey Goater J. Jeffrey Goater	Director	March 13, 2019
/s/ Bala S. Manian, Ph.D. Bala S. Manian, Ph.D.	Director	March 13, 2019
/s/ Gerald E. Van Strydonck Gerald E. Van Strydonck	Director	March 13, 2019
/s/ Barbara Yanni Barbara Yanni	Director	March 13, 2019

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the stockholders and the Board of Directors of Vaccinex, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Vaccinex, Inc. and subsidiaries (the "Company") as of December 31, 2018 and 2017, the related consolidated statements of operations, redeemable convertible preferred stock and stockholders' equity (deficit), and cash flows for each of the two years in the period ended December 31, 2018, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2018 and 2017, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2018, in conformity with accounting principles generally accepted in the United States of America.

Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has suffered recurring losses and negative cash flows from operations that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Deloitte & Touche LLP

Rochester, New York
March 13, 2019

We have served as the Company's auditor since 2014.

VACCINEX, INC.

Consolidated Balance Sheets
(in thousands, except share and per share data)

	As of December 31, 2018	As of December 31, 2017
ASSETS		
Current assets:		
Cash and cash equivalents	$ 5,618	$ 4,180
Marketable securities	14,106	-
Accounts receivable, net	639	117
Prepaid expenses and other current assets	1,061	677
Total current assets	21,424	4,974
Property and equipment, net	604	601
TOTAL ASSETS	$ 22,028	$ 5,575
LIABILITIES, REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	$ 2,322	$ 1,910
Accrued expenses	4,364	1,957
Deferred revenue	-	298
Total current liabilities	6,686	4,165
Convertible promissory notes to related party, net	-	2,813
Derivative liabilities	-	369
TOTAL LIABILITIES	6,686	7,347
Commitments and contingencies (Note 10)		
Redeemable convertible preferred stock (Series B, B-1, B-2, C, D), par value of $0.001 per share; zero and 66,317,000 shares authorized as of December 31, 2018 and December 31, 2017; zero shares issued and outstanding as of December 31, 2018; 53,089,959 shares issued and 53,089,796 shares outstanding as of December 31, 2017 with aggregate liquidation preference of $0 and $140,261 as of December 31, 2018 and December 31, 2017	-	111,718
Stockholders' equity (deficit):		
Convertible preferred stock (Series A), par value of $0.001 per share; zero and 5,702,450 shares authorized, issued and outstanding as of December 31, 2018 and December 31, 2017 with aggregate liquidation preference of $0 and $7,684 as of December 31, 2018 and December 31, 2017	-	7,684
Common stock, par value of $0.0001 per share; 100,000,000 shares authorized as of December 31, 2018; 160,000,000 shares authorized as of December 31, 2017; 11,476,601 and 1,103,396 shares issued as of December 31, 2018 and December 31, 2017; 11,475,749 and 1,102,560 shares outstanding as of December 31, 2018 and December 31, 2017	1	-
Additional paid-in capital	208,156	54,123
Treasury stock, at cost; zero and 163 shares of redeemable convertible preferred stock as of December 31, 2018 and December 31, 2017, and 852 and 836 shares of common stock as of December 31, 2018 and December 31, 2017	(11)	(11)
Accumulated deficit	(216,767)	(187,249)
Total Vaccinex, Inc. stockholders' deficit	(8,621)	(125,453)
Noncontrolling interests	23,963	11,963
TOTAL STOCKHOLDERS' EQUITY (DEFICIT)	15,342	(113,490)
TOTAL LIABILITIES, REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY	$ 22,028	$ 5,575

The accompanying notes are an integral part of these consolidated financial statements.

VACCINEX, INC.

Consolidated Statements of Operations
(in thousands, except share and per share data)

	Year Ended December 31,	
	2018	2017
Revenue	$ 724	$ 90
Costs and expenses:		
Cost of revenue	1,033	160
Research and development	22,353	16,551
General and administrative	4,619	4,483
Total costs and expenses	28,005	21,194
Loss from operations	(27,281)	(21,104)
Change in fair value of derivative liabilities	369	3,743
Interest expense	(392)	(1,358)
Loss on extinguishment of related party convertible promissory note	(2,379)	-
Other income (expense), net	165	(40)
Loss before provision for income taxes	(29,518)	(18,759)
Provision for income taxes	-	-
Net loss	(29,518)	(18,759)
Net loss attributable to noncontrolling interests	-	37
Net loss attributable to Vaccinex, Inc.	(29,518)	(18,722)
Cumulative dividends on redeemable convertible preferred stock	-	(3,211)
Net loss attributable to Vaccinex, Inc. common stockholders, basic and diluted	$ (29,518)	$ (21,933)
Net loss per share attributable to Vaccinex, Inc. common stockholders, basic and diluted	$ (5.65)	$ (19.90)
Weighted-average shares used in computing net loss per share attributable to Vaccinex, Inc. common stockholders, basic and diluted	5,223,635	1,101,937

The accompanying notes are an integral part of these consolidated financial statements.

VACCINEX, INC.

Consolidated Statements of Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)
(in thousands, except share data)

	Redeemable Convertible Preferred Stock		Convertible Preferred Stock		Common Stock			Treasury Stock						
	Shares	Amount	Shares	Amount	Shares	Amount	Additional Paid-in Capital	Redeemable Convertible Preferred Stock Shares	Common Stock Shares	Amount	Accumulated Deficit	Total Vaccinex, Inc. Stockholders' Deficit	Noncontrolling Interests	Total Stockholders' Equity (Deficit)
Balance as of January 1, 2017	48,694,355	$ 103,736	5,702,450	$ 7,684	1,101,359	$ -	$ 53,789	163	836	$ (11)	$ (168,527)	$ (107,065)	$ -	$ (107,065)
Capital contribution	-	-	-	-	-	-	-	-	-	-	-	-	12,000	12,000
Stock-based compensation	-	-	-	-	-	-	319	-	-	-	-	319	-	319
Issuance of Series D redeemable convertible preferred stock, net of issuance cost of $18	4,395,604	7,982	-	-	-	-	-	-	-	-	-	-	-	-
Exercise of stock options	-	-	-	-	2,037	-	15	-	-	-	-	15	-	15
Net loss	-	-	-	-	-	-	-	-	-	-	(18,722)	(18,722)	(37)	(18,759)
Balance as of December 31, 2017	53,089,959	111,718	5,702,450	7,684	1,103,396	-	54,123	163	836	(11)	(187,249)	(125,453)	11,963	(113,490)
Initial public offering, net of issuance costs of $5,551	-	-	-	-	3,333,334	-	34,450	-	-	-	-	34,450	-	34,450
Conversion of redeemable convertible preferred stock (Series B, B-1, B-2, C, D) to common stock	(53,089,959)	(111,718)	-	-	6,468,933	1	111,717	(163)	16	-	-	111,718	-	111,718
Conversion of convertible preferred stock (Series A) to common stock	-	-	(5,702,450)	(7,684)	570,238	-	7,684	-	-	-	-	-	-	-
Capital contribution	-	-	-	-	-	-	-	-	-	-	-	-	12,000	12,000
Exercise of stock options	-	-	-	-	700	-	5			-	-	5	-	5
Stock-based compensation	-	-	-	-	-	-	177	-	-	-	-	177	-	177
Net loss	-	-	-	-	-	-	-	-	-	-	(29,518)	(29,518)	-	(29,518)
Balance as of December 31, 2018	-	$ -	-	$ -	11,476,601	$ 1	$ 208,156	-	852	$ (11)	$ (216,767)	$ (8,621)	$ 23,963	$ 15,342

The accompanying notes are an integral part of these consolidated financial statements.

VACCINEX, INC.

Consolidated Statements of Cash Flows
(in thousands)

	Year Ended December 31,	
	2018	**2017**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (29,518)	$ (18,759)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	223	206
Amortization of debt discount	308	1,217
Net amortization of premiums and discounts on marketable securities	(100)	-
Stock-based compensation	177	319
Change in fair value of derivative liabilities	(369)	(3,743)
Loss on extinguishment of related party convertible promissory note	2,379	-
Changes in operating assets and liabilities:		
Accounts receivable	(522)	(13)
Prepaid expenses and other current assets	(384)	(330)
Accounts payable	421	(555)
Accrued expenses	2,407	(27)
Deferred revenue	(298)	298
Net cash used in operating activities	(25,276)	(21,387)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of marketable securities	(20,756)	-
Sales of marketable securities	6,750	-
Purchase of property and equipment	(235)	(68)
Net cash used in investing activities	(14,241)	(68)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of convertible promissory notes to related parties, net of issuance cost	-	9,977
Proceeds from issuance of Series D redeemable convertible preferred stock, net of issuance costs	-	7,982
Proceeds from initial public offering of common stock, net of commissions and underwriting discounts	37,125	-
Payment of initial public offering costs	(2,675)	-
Proceeds from exercise of stock options	5	15
Repayment of convertible promissory note, related party	(5,500)	(6,000)
Proceeds from capital contribution	12,000	12,000
Net cash provided by financing activities	40,955	23,974
NET INCREASE IN CASH AND CASH EQUIVALENTS	1,438	2,519
CASH AND CASH EQUIVALENTS–Beginning of period	4,180	1,661
CASH AND CASH EQUIVALENTS–End of period	$ 5,618	$ 4,180
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION:		
Cash paid for interest	$ 275	$ 13
SUPPLEMENTAL DISCLOSURES OF NONCASH INVESTING AND FINANCING ACTIVITIES:		
Purchase of property and equipment included in accounts payable	$ -	$ 9
Conversion of redeemable convertible preferred stock into common stock	$ 111,718	$ -
Conversion of convertible preferred stock into common stock	$ 7,684	$ -

The accompanying notes are an integral part of these consolidated financial statements.

1. COMPANY AND NATURE OF BUSINESS

Vaccinex, Inc. (together with its subsidiaries, the Company) was incorporated in Delaware in April 2001 and is headquartered in Rochester, New York. The Company is a clinical-stage biotechnology 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. Since its inception, the Company has devoted substantially all of its efforts toward product research and development, marketing development and raising capital.

The Company is subject to a number of risks common to other early-stage biotechnology companies including, but not limited to, the successful development and commercialization of its product candidates, rapid technological change and competition, dependence on key personnel and collaborative partners, uncertainty of protection of proprietary technology and patents, clinical trial uncertainty, fluctuation in operating results and financial performance, the need to obtain additional funding, potential product liability, compliance with governmental regulations, technological and medical risks, customer demand, management of growth and effectiveness of marketing by the Company. If the Company does not successfully commercialize or partner any of its product candidates, it will be unable to generate product revenue or achieve profitability.

Going Concern

These consolidated financial statements have been prepared on a going concern basis, which implies the Company will continue to realize its assets and discharge its liabilities in the normal course of business. The Company has incurred significant losses and negative cash flows from operations since inception and expects to incur additional losses until such time that it can generate significant revenue from the commercialization of its product candidates. The Company had negative cash flow from operations of $25.3 million and $21.4 million for the years ended December 31, 2018 and 2017, respectively, and an accumulated deficit of $216.8 million and $187.2 million as of December 31, 2018 and 2017. The Company's ability to continue as a going concern is at issue due to its historical net losses and negative cash flows from operations, and its need for additional financing to fund future operations. These conditions raise substantial doubt about the Company's ability to continue as a going concern. The consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of this uncertainty.

To date, the Company has relied on equity and debt financing to fund its operations. In addition, the Company also received $12.0 million in capital contributions from noncontrolling interests during each of the years ended December 31, 2018 and 2017. As the Company's product candidates are still in their early stages of development, substantial additional financing will be needed by the Company to fund its operations and ongoing research and development efforts prior to the commercialization, if any, of its product candidates. Given our projected operating requirements and our existing cash and cash equivalents and marketable securities, we plan to complete an additional financing transaction prior to the commencement of the 2019 fourth quarter in order for us to continue operations. Management is currently evaluating different strategies to obtain the required funding of future operations. These strategies may include, but are not limited to, additional funding from current or new investors, refinancing of existing debt obligations or obtaining additional debt financing. There can be no assurances that the Company will be able to secure such additional financing, or if available, that it will be sufficient to meet its needs or on ideal terms.

Initial Public Offering

In August 2018, the Company completed its initial public offering (the "IPO") in which it issued and sold 3,333,334 shares of its common stock, $0.0001 par value, at a public offering price of $12.00 per share. The Company received net proceeds of $37.2 million after deducting underwriting discounts and commissions of $2.8 million, but before deducting offering expenses of $2.7 million. In addition, in connection with the IPO:

- all shares of the Company's then-outstanding convertible preferred stock were automatically converted and reclassified into 7,039,155 shares of its common stock, $0.0001 par value;
- a 1-for-10 reverse stock split of the Company's common stock was affected; and
- the Company repaid a $1.5 million convertible promissory note issued in June 2016 (the "June 2016 Note"), held by a related party, Vaccinex (Rochester), L.L.C. ("Vaccinex LLC"), which is majority owned and controlled by Dr. Maurice Zauderer, the Company's President, Chief Executive Officer and a member of its board of directors.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

The accompanying consolidated financial statements reflect the consolidated application of certain significant accounting policies, as described below and elsewhere in the accompanying notes to the consolidated financial statements.

Basis of Presentation and Consolidation

These consolidated financial statements reflect the accounts and operations of the Company and those of its subsidiaries in which the Company has a controlling financial interest. As of December 31, 2018 and 2017, the Company's accounts include Vaccinex Products and VX3 (DE) LP, a Delaware limited partnership (VX3). VX3 was established in October 2017 by a group of Canadian investors and was determined to be a variable interest entity ("VIE") in which the Company is the primary beneficiary. The Company consolidates any VIE of which it is the primary beneficiary. The Company presents its noncontrolling interests as a separate component of stockholders' equity (deficit) and net loss from noncontrolling interests as a separate component within its consolidated statements of operations. The financial position of Vaccinex Products was not material as of December 31, 2018 and 2017, and there were no gains or losses for Vaccinex Products for the years ended December 31, 2018 and 2017. During the year ended December 31, 2017, VX3 had a net loss attributable to noncontrolling interests of $37,000. There were no gains or losses for VX3 for the year ended December 31, 2018. Intercompany transactions and balances have been eliminated.

Use of Estimates

These consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("U.S. GAAP"). The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities as of the date of the consolidated financial statements and the reported amount of expenses during the reporting period. Such management estimates include those relating to assumptions used in the valuation of stock option awards, the valuation of derivative instruments, and valuation allowances against deferred income tax assets. Actual results could differ from those estimates.

Cash and Cash Equivalents

The Company considers all highly liquid investments with an original maturity of three months or less at the date of purchase to be cash equivalents. The Company deposits its cash primarily in checking and money market accounts.

Concentration of Credit Risk, Other Risks and Uncertainties

Financial instruments that potentially subject the Company to concentrations of credit risk consist primarily of cash and cash equivalents. Cash equivalents are deposited in interest-bearing money market accounts. Although the Company deposits the cash with multiple financial institutions, cash balances may occasionally be in excess of the amounts insured by the Federal Deposit Insurance Corporation. Management believes the financial risk associated with these balances is minimal and has not experienced any losses to date.

The Company depends on third-party manufacturers for the manufacture of drug substance and drug product for clinical trials. The Company also relies on certain third parties for its supply chain. Disputes with these third- party manufacturers or shortages in goods or services from third-party suppliers could delay the manufacturing of the Company's product candidates and adversely impact its results of operations.

Marketable Securities

Marketable securities consist of investments with original maturities greater than 90 days at their acquisition date.

The Company classifies all of its marketable securities as available-for-sale securities. The Company's marketable securities are measured and reported at fair value using quoted prices in active markets for similar securities. Unrealized gains and losses on available-for-sale securities are reported as accumulated other comprehensive loss. The cost of securities sold is determined on a specific identification basis, and realized gains and losses are included in other income (expense), net in the consolidated statements of operations and comprehensive loss.

The Company evaluates its marketable securities with unrealized losses for other-than-temporary impairment. When assessing marketable securities for other-than-temporary declines in value, the Company considers such factors as, among other things, how significant the decline in value is as a percentage of the original cost, how long the market value of the investment has been less than its original cost, the Company's ability and intent to retain the investment for a period of time sufficient to allow for any anticipated recovery in fair value and market conditions in general. If any adjustment to fair value reflects a decline in the value of the investment that the Company considers to be "other-than-temporary," the Company reduces the investment to fair value through a charge to the statement of operations and comprehensive loss. No such adjustments were necessary during the periods presented.

Fair Value of Financial Instruments

Financial instruments consist of cash and cash equivalents, marketable securities, prepaid expenses and other current assets, accounts payable, accrued expenses, convertible promissory notes, and derivative liabilities. Cash equivalents and marketable securities are stated at fair value. Prepaid expenses and other current assets, accounts payable and accrued expenses are stated at their carrying value, which approximates fair value due to the short time to the expected receipt or payment date. The principal amount of the Company's convertible promissory notes approximates fair value as the stated interest rate approximates market rates currently available to the Company. The derivative liabilities are stated at fair value.

Property and Equipment, Net

Property and equipment are recorded at cost. Depreciation is computed over estimated useful lives of the related assets using the straight-line method. Leasehold improvements are amortized on a straight-line basis over the shorter of the useful life or term of the lease. Upon retirement or disposal, the cost and related accumulated depreciation are removed from the consolidated balance sheets and the resulting gain or loss is recorded to general and administrative expense in the consolidated statements of operations. Routine expenditures for maintenance and repairs are expensed as incurred.

Estimated useful lives for property and equipment are as follows:

Property and Equipment	Estimated Useful Life
Research equipment	5 years
Furniture and fixtures	5 years
Computer equipment	3 years
Leasehold improvements	Lesser of estimated useful life or remaining lease term

Impairment of Long-Lived Assets

The Company reviews the recoverability of its long-lived assets when events or changes in circumstances occur that indicate that the carrying value of the asset may not be recoverable. The assessment of possible impairment is based on the ability to recover the carrying value of the assets from the expected future cash flows (undiscounted and without interest expense) of the related operations. If these cash flows are less than the carrying value of such assets, an impairment loss for the difference between the estimated fair value and carrying value is recorded. There was no impairment loss recognized during the years ended December 31, 2018 and 2017.

Derivative Liabilities

The Company has outstanding derivative instruments related to certain features embedded within the Company's outstanding convertible promissory notes, and an outstanding derivative instrument related to an arrangement providing a holder of one of the Company's convertible promissory notes an option to purchase shares of equity in a future qualifying financing event. These derivatives are accounted for as derivative liabilities and remeasured to fair value as of each balance sheet date and the related remeasurement adjustments are recognized in the consolidated statements of operations. The Company records adjustments to the fair value of the derivative liabilities until the conversion or repayment of the related convertible promissory notes as discussed further in Note 8.

Treasury Stock

The Company records treasury stock activities under the cost method whereby the cost of the acquired stock is recorded as treasury stock. The Company's accounting policy upon the formal retirement of treasury stock is to deduct the par value from

common stock and to reflect any excess of cost over par value as a reduction to additional paid-in capital (to the extent created by previous issuances of the shares) and then retained earnings. There was no treasury stock repurchased for the years ended December 31, 2018 and 2017.

Comprehensive Loss

The Company did not have any other comprehensive income or loss for any of the periods presented and therefore comprehensive loss did not differ from net loss.

Revenue Recognition

The Company derives revenue primarily from service fees generated from collaboration agreements. Under the collaboration agreements, the Company recognizes service revenue when there is persuasive evidence of the arrangement, the fee is fixed or determinable, collection of the fee is reasonably assured, and delivery has occurred. Nonrefundable upfront payments, if any, are recorded as deferred revenue upon receipt and recognized as revenue over the service period.

The Company accounts for revenue arrangements with multiple deliverables by dividing items into separate units of accounting if certain criteria are met, including: (1) whether the delivered item has stand-alone value to the customer; (2) whether the arrangement includes a general right of return relative to the delivered item; and (3) there is objective and reliable evidence of the fair value for the undelivered items. The Company allocates the consideration it receives among the separate units of accounting based on their respective fair value and applies the applicable revenue recognition criteria to each of the separate units. A deliverable that does not qualify as a separate unit of accounting within the arrangement is combined with the other applicable undelivered item within the arrangement.

The Company determines the estimated selling price for deliverables under the collaboration agreements using the following hierarchy: (1) vender-specific objective evidence (“VSOE”); (2) third-party evidence (“TPE”); or (3) best estimate of selling price if neither VSOE nor TPE is available. Determining the best estimate of selling price for a deliverable requires significant judgment of various factors including market conditions, items contemplated during agreement negotiation as well as internally developed net present value models.

Research and Development Costs

Expenditures, including payroll, contractor expenses and supplies, for research and development of products are expensed as incurred. Clinical trial and other development costs incurred by third parties are expensed as the contracted work is performed. Where contingent milestone payments are due to third parties under research and development arrangements, the milestone payment obligations are expensed when the milestone results are probable of being achieved.

Stock-Based Compensation

The Company utilizes the Black-Scholes stock option-pricing model as the method for estimating the grant date fair value of its stock option awards. The Black-Scholes stock option-pricing model requires the use of highly subjective and complex assumptions, including the stock options’ expected term and the price volatility of the underlying stock. The grant date fair value of the portion of the stock option award that is ultimately expected to vest is recognized as compensation expense over the stock option awards’ requisite service periods. The Company recognizes stock-based compensation to expense using the straight-line method over the requisite service period. If there are any modifications or cancelations of stock option awards, the Company may be required to accelerate, increase or decrease any remaining unrecognized stock-based compensation expense.

Income Taxes

The Company uses the asset and liability method of accounting for income taxes. Deferred tax assets and liabilities are recognized for the estimated future tax consequences attributable to temporary differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. Deferred tax assets and liabilities, which relate primarily to the carrying amount of the Company's property and equipment and its net operating loss carryforward, are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. Deferred tax expense or benefit is the result of changes in the deferred tax assets and liabilities. Valuation allowances are established when necessary to reduce deferred tax assets where, based upon the available evidence, management concludes that it is more likely than not that the deferred tax assets will not be realized. In evaluating its ability to recover deferred tax assets, the Company considers all available positive and negative evidence, including its operating results, ongoing tax planning and forecasts of future taxable income on a jurisdiction-by-jurisdiction basis. Because of the uncertainty of the realization of the deferred tax assets, the Company has recorded a full valuation allowance against its deferred tax assets.

Reserves are provided for tax benefits for which realization is uncertain. Such benefits are only recognized when the underlying tax position is considered more likely than not to be sustained on examination by a taxing authority, assuming they possess full knowledge of the position and facts. Interest and penalties related to uncertain tax positions are recognized in the provision for income taxes; however, the Company currently has no interest or penalties related to income taxes.

Segment and Geographic Information

The Company's chief operating decision maker, its Chief Executive Officer, reviews its operating results on an aggregate basis for purposes of allocating resources and evaluating financial performance. The Company has one business activity, the discovery and development of targeted biotherapeutics to treat serious diseases and conditions with unmet medical needs, and there are no segment managers who are held accountable for operations or operating results. Accordingly, the Company operates in one segment. As of December 31, 2018 and 2017, all long-lived assets are located in the United States.

Net Loss Per Share Attributable to Vaccinex, Inc. Common Stockholders

The Company calculates its basic and diluted net loss per share attributable to Vaccinex, Inc. common stockholders in conformity with the two-class method required for companies with participating securities. The Company considers all series of its preferred stock to be participating securities. In the event a dividend is declared or paid on the Company's common stock, holders of preferred stock are entitled to a proportionate share of such dividend in proportion to the holders of common stock on an as-if converted basis. Under the two-class method, basic net loss per share attributable to Vaccinex, Inc. common stockholders is calculated by dividing the net loss attributable to Vaccinex, Inc. common stockholders by the weighted-average number of shares of common stock outstanding for the period. Net loss attributable to Vaccinex, Inc. common stockholders is determined by allocating undistributed earnings between common and preferred stockholders. The diluted net loss per share attributable to Vaccinex, Inc. common stockholders is computed by giving effect to all potential dilutive common stock equivalents outstanding for the period determined using the treasury stock method. The net loss attributable to Vaccinex, Inc. common stockholders was not allocated to the preferred stock under the two-class method as the preferred stock do not have a contractual obligation to share in the Company's losses.

For purposes of this calculation, redeemable convertible preferred stock, convertible preferred stock, and stock options to purchase common stock are considered common stock equivalents but have been excluded from the calculation of diluted net loss per share attributable to Vaccinex, Inc. common stockholders as their effect is anti-dilutive.

Recent Accounting Pronouncements Not Yet Adopted

In May 2014, the Financial Accounting Standards Board (FASB) issued Accounting Standard Update (ASU) No. 2014-09, *Revenue from Contracts with Customers*, which supersedes the revenue recognition requirements in Accounting Standards Codification (ASC) No. 605, *Revenue Recognition*. ASU No. 2014-09 is based on the principle that revenue is recognized to depict the transfer of goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. ASU No. 2014-09 also requires additional disclosure about the nature, amount, timing and uncertainty of revenues and cash flows arising from customer contracts, including significant judgments and changes in judgments and assets recognized from costs incurred to obtain or fulfill a contract. In August 2015, the FASB issued ASU No. 2015-14 to defer the effective date by one year with early adoption permitted as of the original effective date. In addition, the FASB issued ASU

Nos. 2016-08, 2016-10 and 2016-12 in March 2016, April 2016 and May 2016, respectively, to help provide interpretive clarification on the new guidance in ASC No. 606. ASU Nos. 2016-08, 2016-10 and 2016-12 are all effective beginning the same period as ASU No. 2014-09. The Company will adopt the new revenue standards using the modified retrospective method for the Company's fiscal year beginning January 1, 2019. The Company is in the process of evaluating the effect that the new revenue standards will have on its consolidated financial statements and related disclosures.

In February 2016, the FASB issued ASU No. 2016-02, Leases, which supersedes the ASC No. 840, *Leases*. ASU No. 2016-02 requires lessees to recognize all leases, with exception of short-term leases, as lease liabilities on the balance sheet. Under ASU No. 2016-02, a lease is defined as a lessee's obligation to make lease payments arising from a lease, measured on a discounted basis, and a right-of-use asset, which is an asset that represents the lessee's right to use, or control the use of, a specified asset during the lease term. ASU No. 2016-02 also requires additional disclosure about the amount, timing and uncertainty of cash flow from leases. The new standard is effective for the Company at the earlier of losing the emerging growth company status or the Company's fiscal year beginning January 1, 2020, and interim periods therein. Early adoption is permitted. This new standard will require the present value of these leases to be recorded in the consolidated balance sheets as a right-of-use asset and lease liability. The Company will adopt the new standard with modified retrospective method for fiscal year effective January 1, 2020 and is continuing to evaluate the impact of this guidance on its consolidated financial statements and related disclosures.

Recently Adopted Accounting Pronouncements

In August 2016, the FASB issued ASU No. 2016-15, *Statement of Cash Flows: Classification of Certain Cash Receipts and Cash Payments*, which eliminates the diversity in practice related to the classification of certain cash receipts and payments for debt prepayment or extinguishment costs, the maturing of a zero coupon bond, the settlement of contingent liabilities arising from a business combination, proceeds from insurance settlements, distributions from certain equity method investees and beneficial interests obtained in a financial asset securitization. ASU No. 2016-15 designates the appropriate cash flow classification, including requirements to allocate certain components of these cash receipts and payments among operating, investing and financing activities. ASU No. 2016-15 should be applied using the retrospective transition method, requiring adjustment to all comparative periods presented, unless it is impracticable for some of the amendments, in which case those amendments would be made prospectively as of the earliest date practicable. ASU No. 2016-15 is effective for the Company at the earlier of losing the emerging growth company status or the Company's fiscal year beginning January 1, 2019, and interim periods therein. The Company early adopted the new standard on January 1, 2018 using the retrospective transition method. The adoption of ASU No. 2016-15 did not have a material impact on its consolidated financial statements and related disclosures.

In May 2017, the FASB issued ASU No. 2017-09, *Compensation-Stock Compensation: Scope of Modification Accounting*, which provides clarified guidance on applying modification accounting to changes in the terms or conditions of a share-based payment award. Changes that do not impact the award's fair value, vesting conditions, or classification as an equity or liability instrument will not be subject to modification accounting. ASU No. 2017-09 is effective prospectively for the Company at the earlier of losing the emerging growth company status or the Company's fiscal year beginning January 1, 2019, and interim periods therein. The Company early adopted the new standard on January 1, 2018 using the prospective method, and the adoption of ASU No. 2017-09 did not have a material impact on its consolidated financial statements and related disclosures.

3. BALANCE SHEET COMPONENTS

Property and Equipment

Property and equipment consist of the following (in thousands):

	As of December 31,	
	2018	2017
Leasehold improvements	$ 3,145	$ 3,140
Research equipment	3,219	2,998
Furniture and fixtures	350	350
Computer equipment	214	214
Property and equipment, gross	6,928	6,702
Less: accumulated depreciation and amortization	(6,324)	(6,101)
Property and equipment, net	$ 604	$ 601

Depreciation and amortization expense related to property and equipment was $223,000 and $206,000 for the years ended December 31, 2018 and 2017.

Accrued Expenses

Accrued expenses consist of the following (in thousands):

	As of December 31,	
	2018	2017
Accrued clinical trial cost	$ 3,796	$ 891
Accrued payroll and related benefits	296	311
Accrued consulting and legal	236	239
Accrued other	36	324
Accrued interest	-	192
Accrued expenses	$ 4,364	$ 1,957

4. MARKETABLE SECURITIES

As of December 31, 2018, the fair value of available-for-sale marketable securities was as follows (in thousands):

	As of December 31, 2018			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Marketable securities:				
U.S. Treasury securities	$ 14,106	$ -	$ -	$ 14,106
	$ 14,106	$ -	$ -	$ 14,106

All of the Company's available-for-sale marketable securities at December 31, 2018 are maturing in one year or less.

5. FAIR VALUE OF FINANCIAL MEASUREMENTS

Assets and liabilities recorded at fair value on a recurring basis in the consolidated balance sheets are categorized based upon the level of judgment associated with the inputs used to measure their fair values. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. ASC 820 describes a fair value hierarchy based on the following three levels of inputs, of which the first two are considered observable and the last unobservable, that may be used to measure fair value:

Level 1 – Quoted prices in active markets for identical assets or liabilities.

Level 2 – Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Level 3 – Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

The assets' or liabilities' fair value measurement level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement.

The following table sets forth the fair value of the Company's financial assets by level within the fair value hierarchy (in thousands):

	As of December 31, 2018			
	Fair Value	Level 1	Level 2	Level 3
Financial Assets:				
Cash equivalents:				
Money market fund	$ 4,881	$ 4,881	$ -	$ -
Marketable securities:				
U. S. Treasury securities	14,106	-	14,106	-
Total Financial Assets	$ 18,987	$ 4,881	$ 14,106	$ -

	As of December 31, 2017			
	Fair Value	Level 1	Level 2	Level 3
Financial Assets:				
Cash equivalents:				
Money market fund	$ 1,011	$ 1,011	$ -	$ -
Total Financial Assets	$ 1,011	$ 1,011	$ -	$ -
Financial Liabilities:				
Derivative liability	$ 369	$ -	$ -	$ 369
Total Financial Liabilities	$ 369	$ -	$ -	$ 369

The Company did not transfer any assets measured at fair value on a recurring basis to or from Level 1 and Level 2 during the years ended December 31, 2018 and 2017.

The following table sets forth a summary of the changes in the fair value of the Company's Level 3 financial instruments as follows (in thousands):

	Derivative Liability
Balance – January 1, 2017	$ 694
Issuance of the January 2017 Notes	3,418
Change in fair value	(3,743)
Balance – December 31, 2017	369
Change in fair value	(369)
Balance – December 31, 2018	$ -

Level 3 instruments consist of the Company's embedded derivative liabilities related to conversion features within the outstanding convertible promissory notes as of December 31, 2017, and a free-standing derivative related to an option to purchase shares in a future equity financing as of December 31, 2017.

The fair value of the derivative liabilities was measured using a with-and-without valuation methodology. Inputs used to determine the estimated fair value of the derivative instruments include the probability estimates of potential settlement scenarios for the convertible promissory notes, a present value discount rate and an estimate of the expected timing of settlement. Certain unobservable inputs used in the fair value measurement of the derivative instruments associated with the convertible promissory notes are the scenario probabilities and the discount rate estimated at the valuation date. Generally, an increase or decrease in the discount rate would result in a directionally opposite impact to the fair value measurement of the derivative instruments. Also, changes in the probability scenarios would have varying impacts depending on the weighting of each specific scenario. As discussed further in Note 8, heavier weighting towards a qualified financing, including an IPO, would result in an increase in the fair value of the derivative instruments associated with the conversion option.

From the proceeds of the convertible promissory notes, a portion equal to the fair value of the derivative instruments was recognized as an additional debt discount and as derivative liabilities on the consolidated balance sheet upon issuance of the respective convertible promissory notes. The derivative liabilities require periodic remeasurements to fair value while the derivative is outstanding and, accordingly, the Company recognized a gain of $369,000 and $3.7 million from the remeasurement of the derivative liabilities associated with the convertible promissory notes for the years ended December 31, 2018 and 2017, respectively, and presents such amounts in its consolidated statements of operations as changes in fair value of derivative liabilities.

6. LICENSE AND SERVICES AGREEMENT

In November 2017, the Company entered into a license agreement (the "VX3 License Agreement") with VX3 (DE) LLP ("VX3"), which was formed by a group of Canadian investors including the Company's majority stockholder, FCMI Parent Co. ("FCMI Parent"). VX3 was created for the purpose of funding the Company's research and development activities for pepinemab, our most advanced product candidate. Under the VX3 License Agreement, the Company granted VX3 the license to use, make, have made, sell, offer and import pepinemab for the treatment of Huntington's disease in the U.S. and Canada and, in return, VX3 agreed to fund research and development activities with up to an aggregate of $32.0 million in milestone payments to the Company and to share any pepinemab profits and sublicensing revenue under the agreement in an amount based on a calculation set forth in the agreement. The Company also entered into a services agreement with VX3 (the "Services Agreement"), pursuant to which the Company will carry out development activities for pepinemab for the treatment of Huntington's disease in the U.S. and Canada in exchange for services payments from VX3, including a payment of $11.9 million in 2017. The VX3 License Agreement expires upon the last to expire licensed patent and may be terminated by either party upon uncured material breach, the occurrence of certain transactions or financings including the consummation of an initial public offering by the Company, uncured failure of VX3 to make any payment due under the Services Agreement, or upon written notice after November 6, 2020. The Services Agreement may be terminated by either party upon an uncured material breach and is automatically terminated upon termination of the VX3 License Agreement. The VX3 License Agreement provides that upon termination, the Company will issue to VX3 or its designees the number of shares of the Company's common stock equal to the lesser of (1) the aggregate of all payments made to VX3 by the Canadian investors divided by $18.20 and (2) the then fair market value of VX3 divided by the then fair market value of one share of the Company's common stock.

The Company has a variable interest in VX3 through FCMI Parent, which is majority owned and controlled by the Company's chairman, and it controls 90% and 96% of VX3's voting interest as of December 31, 2018 and 2017, respectively. VX3 does not have any business operations or generate any income or expenses and is primarily a funding mechanism specifically for the benefit of the Company, as its only activities consist of the receipt of funding and the contribution of such funding to the Company. Therefore, the Company determined that it is the primary beneficiary of VX3 and that the operating results of VX3 should be incorporated into the Company's consolidated financial statements accordingly.

In February, May and June 2018, the Services Agreement was amended to allow VX3 to provide additional funding for future research and development activities to take place in the year ended December 31, 2018 and to repay an outstanding convertible note in the amount of $4.0 million (Note 8). No other terms of the Services Agreement were amended; therefore, the above assessment resulting in the Company being the primary beneficiary of the VX3 entity remained unchanged as of December 31, 2018.

For each of the years ended December 31, 2018 and 2017, the Company recorded the gross proceeds of $12.0 million, received from VX3 as capital contributions from noncontrolling interests on the consolidated financial statements.

7. COLLABORATION AGREEMENTS

Merck Sharp & Dohme Corp.

In September 2017, the Company entered into a research agreement with Merck Sharp & Dohme Corp. ("Merck") to test vaccinia strain Modified Vaccinia Ankara. Under the research agreement, the Company designed genetic sequence for all constructs listed in the agreement and conducted research in accordance with the research protocol and a mutually agreed scope of work outlined in the agreement. Merck supplied the Company sufficient samples of the antibodies to carry out the research and has sole ownership of all right, title, interest and copy rights of the research results. The Company received quarterly service payments in the amount of $138,000 under the research agreement, of which $69,000 and $69,000 was recognized as service revenue for the years ended December 31, 2018 and 2017, respectively. The research agreement expired in June 2018. In the fourth quarter of 2018, the Company entered into a second agreement with Merck to test these antigen particles in an antibody discovery campaign.

Surface Oncology, Inc.

In November 2017, the Company entered into a research collaboration and license option agreement with Surface Oncology, Inc. ("Surface") to identify and select antibodies against two target antigens, using the Company's proprietary technology as described in the agreement. The term for each research program is nine to twelve months (not exceeding twelve months unless extended by written agreement) including time necessary for any functional assessment conducted by Surface following the commencement of the research program. Surface will provide the Company material to carry out the research activities. During the research program term, the Company also grants Surface non-exclusive, worldwide, limited-purpose license for each target to use the Company's research program materials for conducting the research work pursuant to the agreement.

Under the agreement, Surface has been granted exclusive options, exercisable by providing a written notice to the Company, to obtain (i) an exclusive product license to make, use, sell and import products incorporating the antibody targeting the first antigen and (ii) an exclusive research tool license to use the antibody targeting the second antigen to perform research.

Under the agreement, Surface will pay an upfront technology access fee of $250,000 and milestone payments upon completion of each of four designated milestones for the first target antigen specified in the agreement. For the second target antigen, Surface will make payments to the Company based on time incurred by the Company in the conduct of the work plan described in the agreement. Surface will reimburse the Company for expenses incurred (i) in the conduct of the work plan as detailed in the research funding budget and (ii) for patent filings and prosecution of the Company's program intellectual property as described in the agreement. The exercise of each option would also entail a license fee and annual maintenance fees, and in the case of the product license, royalties and additional milestone payments. During the year ended December 31, 2017, the Company received the upfront technology access fee of $250,000, of which $229,166 and $20,834 were recognized as revenue from the amortization of this upfront fee for the years ended December 31, 2018 and 2017, respectively. The Company also received $282,171 service fee payments for work conducted under the agreement for the year ended December 31, 2018. This agreement will expire upon the expiration of both research programs and all evaluation and testing periods.

Heptares Therapeutics, Ltd.

In June 2018, the Company entered into a research service agreement with Heptares Therapeutics, Ltd. ("Heptares") to provide research services to Heptares. Under the agreement, Heptares provides the Company compounds, materials or samples, and the Company performs feasibility services to allow Heptares to evaluate the feasibility of the Company's technology. The Company recognized service revenue of $138,556 from the Heptares research agreement for the year ended December 31, 2018.

8. CONVERTIBLE PROMISSORY NOTES

The following table sets forth a summary of the outstanding convertible promissory notes (in thousands):

	As of December 31, 2017
June 2016 Note	$ 1,500
Unamortized debt discount	(316)
Net June 2016 Note	1,184
January 2017 Notes	4,000
Unamortized debt discount	(2,371)
Net January 2017 Notes	1,629
Total convertible promissory notes, related parties	$ 2,813

As of December 31, 2018, the Company did not have any convertible promissory notes outstanding. See "Repayment of Convertible Promissory Notes" below.

June 2016 Note

In June 2016, the Company issued a $1.5 million convertible promissory note to a related party (the June 2016 Note). The June 2016 Note accrued interest at a compounded annual rate of 8% and had a maturity date three years from issuance, if not converted before then. Upon the occurrence of a default event, such as payment or performance defaults, bankruptcy, change in control (if elected to be treated as such by the lenders), or other violation, the interest rate would increase to a compounded annual rate of 12% until such time the default is cured. Upon maturity, the holder of these convertible promissory notes was to be repaid the outstanding principal plus all accrued interest. The Company also had the ability to prepay the convertible promissory notes, plus accrued interest, without penalty. The debt issuance costs for these convertible promissory notes were not material. The June 2016 Note was paid in full on August 17, 2018. See “Repayment of Convertible Promissory Notes” below.

January 2017 Notes

In January 2017, the Company entered into a convertible promissory note agreement whereby it agreed to issue, in the aggregate, $10.0 million of convertible promissory notes to a related party (the “January 2017 Notes”). The $4.0 million of the January 2017 Notes issued in January 2017 did not accrue interest, but the other $6.0 million of the January 2017 Notes issued in April, August and October 2017 accrued interest at an annual rate of 2%. The January 2017 Notes had a maturity date three years from issuance. Upon maturity, the holder of these convertible promissory notes was to be repaid the outstanding principal plus all accrued interest. The Company was also authorized to prepay the January 2017 Notes, plus accrued interest, without penalty. The debt issuance costs for these convertible promissory notes were not material. Of the January 2017 Notes, $6.0 million were paid in 2017 and the balance was paid in full on March 8, 2018. See “Repayment of Convertible Promissory Notes” below.

Derivative Liabilities

From the proceeds of the convertible promissory notes, the portion equal to the fair value of the embedded derivative liabilities and the option derivative at the time of each respective issuance was recognized as a debt discount to be amortized to interest expense over the term of the related convertible promissory notes. The Company recognized interest expense of $308,000 and $1.2 million for the amortization of the debt discounts during the years ended December 31, 2018 and 2017, respectively.

Repayment of Convertible Promissory Notes

Of the January 2017 Notes, $2.0 million issued in April 2017 was repaid along with accrued interest in May 2017, $4.0 million issued in August and October 2017 was repaid along with accrued interest in November 2017 and $4.0 million issued in January 2017 was repaid in March 2018. The option arrangement associated with the January 2017 Notes was also waived upon the repayment of the January 2017 Notes. As a result of this repayment, the related $0.3 million derivative liabilities associated with the conversion feature and the option arrangement were written off and the $2.2 million unamortized debt discount was recognized as a loss on extinguishment of related party convertible promissory note in the consolidated statements of operations in the year ended December 31, 2018.

The June 2016 Note was repaid along with accrued interest in August 2018. As a result of this repayment, the related $31,000 derivative liability associated with the conversion feature and the option arrangement was written off and the $199,000 unamortized debt discount was recognized as a loss on extinguishment of related party convertible promissory note in the consolidated statements of operations in the year ended December 31, 2018.

9. PREFERRED STOCK

The company had outstanding preferred stock as of December 31, 2017 which was converted to common stock in 2018 in connection with the Company’s IPO. The following paragraphs disclose the terms of the preferred stock outstanding as of December 31, 2017.

The Company's then outstanding preferred stock was issued in series, consisting of Series A convertible preferred stock and Series B, B-1, B-2, C and D redeemable convertible preferred stock (collectively referred to as preferred stock). In addition to the designations by series, the Company also designated the preferred stock as either convertible (i.e., not redeemable) or redeemable convertible (i.e., contingently redeemable). As discussed further below, the Series A preferred stock was designated as convertible preferred stock as these shares were only redeemable in a true liquidation scenario whereby the Company was liquidated, dissolved, or wound down. The Series B, B-1, B-2, C and D preferred stock was designated as redeemable convertible preferred stock as these shares were redeemable only upon a "Deemed Liquidation Event" as discussed further in the Redemption section below.

In May and June 2017, the Company raised $8.0 million from the issuance of 4,395,604 shares of Series D redeemable convertible preferred stock to one investor at $1.82 per share.

The issuance of Series D redeemable convertible preferred stock at the price of $1.82 per share triggered the downward revision to the conversion price of Series B-2 redeemable convertible preferred stock and resulted in the conversion price to decrease from $25.30 to $25.00 per share, effective May 31, 2017.

In August 2018, upon the closing of the Company's IPO, all outstanding shares of convertible preferred stock were automatically converted and reclassified into 7,039,155 shares of its common stock.

The Company's redeemable convertible preferred stock consisted of the following (dollars in thousands):

	As of December 31, 2017				
	Designated Shares Authorized	Shares Issued	Shares Outstanding	Aggregate Liquidation Preference	Net Carrying Value
Series B	6,500,000	6,335,543	6,335,380	$ 27,242	$ 9,717
Series B-1	6,417,000	6,416,144	6,416,144	18,725	9,945
Series B-2	7,500,000	5,344,748	5,344,748	19,220	16,568
Series C	12,400,000	7,205,882	7,205,882	24,500	33,579
Series D	33,500,000	27,787,642	27,787,642	50,574	41,909
Total	66,317,000	53,089,959	53,089,796	$ 140,261	$ 111,718

As of December 31, 2017, the Company had authorized, issued and outstanding 5,702,450 shares designated as Series A convertible preferred stock with an aggregate liquidation preference and net carrying value of $7.7 million.

The Company's preferred stock had the following rights, preferences, privileges and restrictions:

Dividends

The holders of Series D redeemable convertible preferred stock were entitled to receive dividends only when (1) the board of directors declared a dividend payable upon outstanding shares of the Series D redeemable convertible preferred stock or (2) the board of directors declared a dividend payable upon outstanding shares of Series A convertible preferred stock and Series B, B-1, B-2, and C redeemable convertible preferred stock and common stock, in which event, the board of directors would contemporaneously also declare a dividend to the holders of the Series D redeemable convertible preferred stock as though the shares had been fully converted into shares of common stock on the declaration date. The second scenario would not apply if the dividend payable declared by the board of directors were preferential dividends for Series B, B-1 and B-2 redeemable convertible preferred stock.

The holders of Series C redeemable convertible preferred stock were entitled to receive annual cumulative dividends at the per annum rate of 3% of the purchase price of $3.40 per share, if declared by the board of directors, prior and in preference to any declaration or payment of any dividends on the Series A convertible preferred stock and Series B, B-1 and B-2 redeemable convertible preferred stock and common stock. However, in July 2016 upon the issuance of Series D redeemable convertible preferred stock, the $2.3 million cumulative and unpaid dividend of Series C redeemable convertible preferred stock was forgiven, and the annual dividends rate of 3% per annum of the purchase price of $3.40 per share became non-cumulative.

The holders of Series B, B-1 and B-2 redeemable convertible preferred stock were entitled to annual cumulative dividends at the per annum rate of 8% of each respective purchase price of $2.15, $1.55 and $3.10 per share, if declared by the board of directors, prior and in preference to any declaration or payment of any dividends on the Series A convertible preferred stock and common stock.

The holders of Series A convertible preferred stock were entitled to receive non-cumulative dividends, if declared by the board of directors on either Series A convertible preferred stock or common stock, and in the event of the latter, the holders of Series A convertible preferred stock would participate in such dividend payment on an as-if-converted basis.

The Company has not recorded a liability for cumulative and unpaid dividends as of December 31, 2017, as no dividends have been declared by the Company.

Voting Rights

Each share of preferred stock is entitled to voting rights equal to the number of shares of common stock into which each share could be converted. The holders of shares of the preferred stock vote with holders of the common stock as a single class on all matters.

Conversion Rights

Each share of Series A convertible preferred stock and Series B, B-1, B-2, C and D redeemable convertible preferred stock was convertible by the holder at any time into common stock. The conversion rate was determined by dividing the original purchase price of $1.3475, $2.15, $1.55, $3.40 and $1.82 per share for Series A convertible preferred stock and Series B, B-1, C and D redeemable convertible preferred stock by the conversion price of $13.475, $13.1, $15.5, $18.2, $18.2 per share for Series A convertible preferred stock and Series B, B-1, C and D redeemable convertible preferred stock as of December 31, 2017. The conversion rate for Series B-2 redeemable convertible preferred stock was determined by dividing the original purchase price of $3.10 per share by the conversion price of $25.00 as of December 31, 2017.

The shares of Series C and Series D redeemable convertible preferred stock would automatically convert upon the occurrence of (i) the closing of an underwritten public offering at an offering price per share of not less than $5.00 per share and with gross proceeds to the Company of not less than $30.0 million or (ii) on the date specified by written consent or vote by the majority of the holders of the then outstanding shares of Series B, B-1, B-2, C and D redeemable convertible preferred stock voting as a single class on an as-converted basis.

The shares of Series B, B-1 or B-2 redeemable convertible preferred stock would automatically convert upon the occurrence of: (i) the closing of an underwritten public offering at an offering per share price of not less than two times the then applicable conversion prices for each series (in the event of Series B and B-1 redeemable convertible preferred stock) or not less than $5.00 per share (in the event of Series B-2 redeemable convertible preferred stock) and with gross proceeds to the Company of not less than $15.0 million; (ii) a qualified sale of the Company whereby the holders of common stock then issued and outstanding, including the conversion of outstanding shares of Series B, B-1 or B-2 redeemable convertible preferred stock, will be entitled to receive gross proceeds from such transaction on a per share basis of no less than two times of then applicable conversion prices for each Series; or (iii) on the date specified by written consent or vote by the majority of the holders of the then outstanding shares of Series B, B-1 or B-2 redeemable convertible preferred stock.

The shares of Series B-1 and B-2 redeemable convertible preferred stock also would automatically convert on the date specified by written consent or vote of two-thirds of the holders of the then outstanding shares of Series B-1 and B-2 redeemable convertible preferred stock, voting as a single class on an as-converted basis.

The shares of Series A convertible preferred stock would automatically convert into common stock upon the earlier of (i) the closing of an underwritten public offering or (ii) the affirmative vote of a majority of the holders of the then outstanding shares of Series A convertible preferred stock.

Liquidation Preference

Upon any liquidation, dissolution, or winding up of the Company, whether voluntary or involuntary, the holders of the Series C and D redeemable convertible preferred stock were entitled to receive, before any distribution or payment was made upon any shares of the Series A convertible preferred stock and Series B, B-1 and B-2 redeemable convertible preferred stock and common stock, an amount equal to $3.40 per share and $1.82 per share, respectively, plus any declared or accrued but unpaid dividends, for Series C and Series D redeemable convertible preferred stock. After payment to the holders of Series C and Series D redeemable convertible preferred stock, the holders of Series B, B-1 and B-2 redeemable convertible preferred stock, prior to any distribution to the holders of Series A convertible preferred stock and common stock, were entitled to receive an amount equal to $2.15, $1.55 and $3.10 per share, plus any declared or accrued but unpaid dividends. After payment to the holders of Series B, B-1, B-2, C and D redeemable convertible preferred stock, the holders of Series A convertible preferred stock were entitled to receive an amount equal to $1.3475 per share plus all declared or accrued but unpaid dividends.

Redemption

The shares of Series B, B-1, B-2, C and D redeemable convertible preferred stock were only redeemable upon a “Deemed Liquidation Event,” which included certain events that were outside the control of the Company such as the sale or merger of the Company in certain scenarios. Further, these shares did not contain any provisions that would ensure the holders were entitled to the same form of consideration upon the occurrence of a “Deemed Liquidation Event.” Accordingly, the shares of Series B, B-1, B-2, C and D redeemable convertible preferred stock were considered contingently redeemable and, therefore, classified outside of stockholders’ equity (deficit).

The shares of Series A were only redeemable upon a regular liquidation event within the Company’s control and were not redeemable at the option of the holder or under any other scenarios. Therefore, the shares of Series A convertible preferred stock were classified within stockholders’ equity (deficit).

10. COMMITMENTS AND CONTINGENCIES

Sublicense Termination Payments

In 2006, the Company licensed certain technology to EUSA Pharma SAS (“EUSA”) and in 2008, this technology was sublicensed by EUSA to Glaxo Group Limited (“GSK”) for development. GSK terminated its sub-license with EUSA in March 2010 and ownership of the technology reverted back to the Company. The Company may be required to pay EUSA up to $25.5 million plus ongoing royalty payments of 1% of net sales upon the occurrence of certain events involving the previously licensed technology, including Phase 3 clinical trial, FDA acceptance and approval and product sales. The Company is not planning any further commercialization efforts related to the previously licensed technology, and therefore does not anticipate any of the above described amounts will be paid.

Operating Lease

The Company leases its facilities from 1895 Management, Ltd., a New York corporation controlled by an entity affiliated with a director of the Company, under non-cancellable operating leases. Following entry into a lease extension agreement in July 2018, the lease agreement requires monthly rental payments of $14,000 through October 31, 2020. The Company is responsible for all maintenance, utilities, insurance and taxes related to the facility.

As of December 31, 2018, the future minimum payments for the operating leases is $168,000 in 2019 and $140,000 in 2020.

Rent expense incurred under the operating lease was $168,000 for each of the years ended December 31, 2018 and 2017.

Contingencies

The Company is subject to claims and assessments from time to time in the ordinary course of business. The Company records a provision for a liability when it believes that it is both probable that a liability has been incurred and the amount can be reasonably estimated. Significant judgment is required to determine both probability and the estimated amount.

In the normal course of business, the Company may become involved in legal proceedings. The Company will accrue a liability for such matters when it is probable that a liability has been incurred and the amount can be reasonably estimated. When only a range of possible loss can be established, the most probable amount in the range is accrued. If no amount within this range is a better estimate than any other amount within the range, the minimum amount in the range is accrued. The accrual for a litigation loss contingency might include, for example, estimates of potential damages, outside legal fees and other directly related costs expected to be incurred. As of December 31, 2018 and 2017, the Company was not involved in any material legal proceedings.

11. COMMON STOCK RESERVED FOR ISSUANCE

Common stock has been reserved for the following potential future issuances:

	As of December 31,	
	2018	2017
Conversion of outstanding preferred stock	-	7,039,155
Shares underlying outstanding stock options	405,683	420,956
Shares available for future stock option grants	423,000	19,034
Exchange of Vaccinex Products, LP units	1,202,566	1,202,566
Conversion of VX3 units	1,318,797	659,400
Total shares of common stock reserved	3,350,046	9,341,111

12. STOCK-BASED COMPENSATION

2011 Employee Equity Plan

The Company's 2011 Employee Equity Plan (the "2011 Plan") was terminated in connection with the adoption of the Company's 2018 Omnibus Incentive Plan (the "2018 Plan") in August 2018, and the Company will not grant any additional stock options under the 2011 Plan. However, the 2011 Plan will continue to govern the terms and conditions of the outstanding stock options previously granted thereunder. Stock options granted under the 2011 Plan expire in five or ten years from the date of grant.

2018 Omnibus Incentive Plan

In August 2018, the Company's Board of Directors adopted, and its stockholders approved, the 2018 Plan, which allows for the granting of stock, stock option, and stock appreciation rights awards to employees, advisors and consultants. Stock options granted under the 2018 Plan may be either incentive stock options or non-statutory stock options. Incentive stock options may be granted to employees, advisors and consultants at exercise prices of no less than the fair value of the common stock on the grant date. If at the time of grant, the optionee owns stock representing more than 10% of the voting power of all classes of stock of the Company, the exercise price must be at least 110% of the fair value of the common stock on the grant date as determined by the board of directors. Non-statutory stock options may be granted to employees, advisors and consultants at exercise prices of less than the fair market value of a share of common stock on the date the non-statutory stock option is granted but shall under no circumstances be less than adequate consideration as determined by the board of directors for such a share. Vesting period of stock option grants is determined by the board of directors, ranging from zero to eight years. Stock options granted under the 2018 Plan expire in five or ten years from the date of grant.

The Company reserved 425,000 shares of common stock for issuance, subject to certain adjustments, pursuant to awards under the 2018 Plan. Any shares of common stock related to awards outstanding under the 2011 Plan as of the effective date of the 2018 Plan, which thereafter terminate by expiration, forfeiture, cancellation or otherwise without the issuance of such shares, will be added to, and included in, the number of shares of common stock available for grant under the 2018 Plan. In addition, effective January 1, 2020 and continuing until the expiration of the 2018 Plan, the number of shares of common stock available for issuance under the 2018 Plan will automatically increase annually by 2% of the total number of issued and outstanding shares of our common stock as of December 31st of the immediately preceding year or such lesser number as our board of directors may decide, which may be zero.

A summary of the Company's stock option activity and related information is as follows:

	Options Outstanding			
	Shares Subject to Options Outstanding	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life (Years)	Aggregate Intrinsic Value
Balance as of January 1, 2017	405,658	$ 9.01	8.1	$ 1,978
Granted	33,976	13.60		
Exercised	(2,037)	7.10		
Canceled	(16,641)	14.60		
Balance as of December 31, 2017	420,956	9.20	7.4	5,021
Granted	30,000	13.10		
Exercised	(700)	7.10		
Canceled	(44,573)	7.10		
Balance as of December 31, 2018	405,683	$ 9.69	6.5	$ -
Exercisable as of December 31, 2018	366,463	$ 9.46	6.3	$ -

The weighted-average grant date fair value of stock options granted to employees for the years ended December 31, 2018 and 2017 was $14.87 and $9.00 per share, respectively. The aggregate grant date fair value of stock options that vested during the years ended December 31, 2018 and 2017 was $234,466 and $300,000, respectively.

The intrinsic value of stock options vested and expected to vest and exercisable is calculated based on the difference between the exercise price and the fair value of the Company's common stock as of December 31, 2018 and 2017. The intrinsic value of exercised stock options is the difference between the fair value of the underlying common stock and the exercise price as of the exercise date. The intrinsic value of stock options exercised was $11,000 and $29,000 during the years ended December 31, 2018 and 2017, respectively.

As of December 31, 2018, and 2017, total unrecognized compensation cost related to stock options granted to employees was $435,639 and $216,000, which is expected to be recognized over a weighted-average period of 2.8 and 1.9 years, respectively.

Determination of Fair Value

The determination of the fair value of stock options on the date of grant using the Black-Scholes option-pricing model is affected by the estimated fair value of the Company's common stock, as well as assumptions regarding a number of variables that are complex, subjective and generally require significant judgment to determine. The assumptions used to calculate the fair value of stock options were:

Fair Value of Common Stock

Prior to the IPO, the fair value of the common stock underlying the stock options was determined by the Company's board of directors, with input from management and third-party valuations. Subsequent to the IPO, the fair value of the Company's common stock was based on its publicly traded price per share.

Expected Term

The expected term represents the period that the Company's stock option awards are expected to be outstanding. Stock options granted have a maximum contractual life of ten years. The Company estimates the expected term of the stock option to be six years based on historical data on employee exercises and post-vesting employment termination behavior.

Expected Volatility

As the Company does not have a trading history for its common stock, the expected stock price volatility for the Company's common stock was estimated by taking the average historic price volatility for industry peers based on daily price observations over a period equivalent to the expected term of the stock option grants. Industry peers consist of several public companies in the Company's industry which are of similar size, complexity and stage of development. The Company intends to continue to consistently apply this process using the same or similar public companies until a sufficient amount of historical information regarding the volatility of its own share price becomes available, or unless circumstances change such that the identified companies are no longer similar to the Company, in which case, more suitable companies whose share prices are publicly available would be used in the calculation.

Risk-Free Interest Rate

The risk-free interest rate is based on the U.S. Treasury rate, with maturities similar to the expected term of the stock options.

Expected Dividend Yield

The Company does not anticipate paying any dividends in the foreseeable future and, therefore, uses an expected dividend yield of zero.

On January 1, 2017, the Company adopted ASU No. 2016-09 and started to account for forfeitures of stock options as they occur. The Company recorded the cumulative effect adjustment to accumulated deficit and the impact was not material.

The grant date fair value of employee stock options was estimated using a Black-Scholes option-pricing model with the following weighted-average assumptions:

	Year Ended December 31,	
	2018	2017
Expected term (in years)	6.0	6.0
Expected volatility	75.0%	75.0%
Risk-free interest rate	2.6%	2.0%
Expected dividend yield	-%	-%

Total stock-based compensation expense recognized in the consolidated statements of operations is as follows (in thousands):

	Year Ended December 31,	
	2018	2017
Research and development	$ 65	$ 54
General and administrative	112	265
Total stock-based compensation expense	$ 177	$ 319

13. INCOME TAXES

No provision for income taxes was recorded in the years ended December 31, 2018 and 2017. The Company remains in a cumulative loss position with a full valuation allowance recorded against its net deferred income tax assets as of December 31, 2018.

On December 22, 2017, the Tax Cuts and Jobs Act (the "Tax Act") was signed into law. The Tax Act makes broad and complex changes to the U.S. tax code including, but not limited to, reducing the U.S. federal corporate income tax rate. While the Tax Act reduces the U.S. federal corporate income tax rate from 35% to 21% for tax years beginning after December 31, 2017, ASC 740 required the Company to remeasure its deferred tax balances in 2017 in accordance with the 2018 rate reduction.

The SEC staff issued Staff Accounting Bulletin 118 ("SAB 118"), which provides guidance on accounting for the tax effects of the Tax Act. SAB 118 provides a measurement period that should not extend beyond one year from the U.S. tax reform enactment date for companies to complete the accounting under ASC 740. In accordance with SAB 118, a company must reflect the income tax effects of those aspects of the U.S. tax reform for which the accounting under ASC 740 is complete. Specifically, the Company revalued its U.S. deferred tax assets and liabilities due to the federal income tax rate reduction from 35% to 21%. Since the Company has provided a full valuation allowance against its deferred tax assets, the revaluation of the deferred tax assets did not have a material impact on any period presented.

The Company did not record provision for income taxes for the years ended December 31, 2018 and 2017. The Company's deferred income tax assets continue to be offset by a valuation allowance. The Company has recorded a reduction of deferred income tax assets of $20.7 million in the year ended December 31, 2017 related to the remeasurement of our net deferred tax assets to reflect the U.S. federal corporate income tax rate reduction to 21%, which was fully offset by a change to the Company's valuation allowance.

The reconciliation of federal statutory income tax rate to the Company's effective income tax rate is as follows:

	Year Ended December 31,	
	2018	2017
Expected income tax benefit at the federal statutory rate	21.0%	34.0%
Federal tax rate change effect	-	(110.3)
State taxes, net of federal benefit	5.2	5.4
Research and development credit, net	10.3	17.0
Non-deductible items and others	(0.4)	0.7
Change in valuation allowance	(36.1)	53.2
Total	0.0%	0.0%

Deferred income taxes reflect the net effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. The principal components of the Company's deferred tax assets consisted of the following as of December 31, 2018 and 2017 (in thousands):

	As of December 31,	
	2018	2017
Deferred tax assets:		
Federal and state net operating loss carryforwards	$ 52,362	$ 45,057
Research and development tax credits	14,592	11,542
Depreciation and amortization	468	504
Reserves and accruals	56	115
Derivative liabilities	-	96
Deferred revenue	-	78
Other	202	330
Total deferred tax assets	67,680	57,722
Less: valuation allowance	(67,680)	(57,026)
Net deferred tax assets	-	696
Deferred tax liability:		
Debt discount	-	(696)
Net deferred tax assets and liability	$ -	$ -

The Company's valuation allowance increased by $10.7 million and decreased by $10.0 million for the years ended December 31, 2018 and 2017, respectively, in order to maintain a full valuation allowance against its deferred tax assets. Based on the Company's history of losses, the Company recorded a full valuation allowance against its deferred tax assets as of December 31, 2018 and 2017. The Company intends to maintain a valuation allowance until sufficient positive evidence exists to support a reversal of the valuation allowance.

As of December 31, 2018, the Company had federal and state operating loss carryforwards of $198.2 million and $209.3 million, which begin to expire in the years ending December 31, 2024 and 2034, respectively. The Company had federal research and development tax credit carryforwards of $14.6 million as of December 31, 2018. This credit begins to expire from in the year ending December 31, 2021.

Under the provisions of Section 382 of the Internal Revenue Code (the IRC), net operating loss and credit carryforwards and other tax attributes may be subject to limitation if there has been a significant change in ownership of the Company, as defined by the IRC. Future owner or equity shifts, including an IPO, could result in limitations on net operating loss and credit carryforwards.

The Company files income tax returns in the U.S. federal jurisdiction as well as many U.S. state jurisdictions. The tax years from January 1, 2015 to December 31, 2018 remain open to examination by the major jurisdictions in which the Company is subject to tax. Fiscal years outside the normal statute of limitations remain open to audit by tax authorities due to tax attributes generated in those early years, which have been carried forward and may be audited in subsequent years when utilized.

The Company evaluates tax positions for recognition using a more-likely-than-not recognition threshold, and those tax positions eligible for recognition are measured as the largest amount of tax benefit that is greater than 50% likely of being realized upon the effective settlement with a taxing authority that has full knowledge of all relevant information. As of December 31, 2018, and 2017, the Company had no unrecognized income tax benefits that would affect the Company's effective tax rate if recognized.

14. NET LOSS PER SHARE ATTRIBUTABLE TO COMMON STOCKHOLDERS

The following table sets forth the computation of the Company's basic and diluted net loss per share for the periods presented (in thousands, except share and per share data):

	Year Ended December 31,	
	2018	2017
Net loss	$ (29,518)	$ (18,759)
Net loss attributable to noncontrolling interests	-	37
Net loss attributable to Vaccinex, Inc.	(29,518)	(18,722)
Cumulative dividends on preferred stock	-	(3,211)
Net loss attributable to Vaccinex, Inc. common stockholders, basic and diluted	$ (29,518)	$ (21,933)
Net loss per share attributable to Vaccinex, Inc. common stockholders, basic and diluted	$ (5.65)	$ (19.90)
Weighted-average shares used in computing net loss per share attributable to Vaccinex, Inc. common stockholders, basic and diluted	5,223,635	1,101,937

The following weighted-average common stock equivalents were excluded from the calculation of diluted net loss per share for the periods presented as they had an anti-dilutive effect:

	Year Ended December 31,	
	2018	2017
Preferred stock (if converted)	-	6,837,585
Options to purchase common stock	410,886	408,373
Contingently issuable common stock upon exchange of Vaccinex Products, LP units	1,202,566	1,202,566
Contingently issuable common stock upon exchange of VX3 units	1,158,009	99,361

15. EMPLOYEE BENEFIT PLAN

The Company sponsors a 401(k) plan that stipulates that eligible employees can elect to contribute to the 401(k) plan, subject to certain limitations, up to the lesser of the statutory maximum or 100% of eligible compensation on a pre-tax basis. Through December 31, 2018 and 2017, the Company has not elected to match employee contributions as permitted by the plan. The Company pays the administrative costs for the plan.

16. RELATED PARTY TRANSACTIONS

As discussed in Note 10, the Company also leases its facility from 1895 Management, Ltd., a New York corporation controlled by an entity affiliated with the Company's chairman and major stockholder of the Company. Rent expense incurred under this operating lease was $168,000 for each of the years ended December 31, 2018 and 2017.

In 2016, the Company issued in aggregate $3.0 million convertible promissory note to FCMI Parent Co. ("FCMI Parent") and $1.5 million convertible promissory note to Vaccinex (Rochester), L.L.C. ("Vaccinex LLC"). FCMI Parent is majority owned and controlled by the Company's chairman and Vaccinex LLC is majority owned and controlled by the Company's Chief Executive Officer. During the year ended December 31, 2017, the Company issued an additional $10.0 million in convertible promissory notes to FCMI Parent, which was fully repaid in March 2018. The $1.5 million convertible promissory note to Vaccinex LLC was fully repaid in August 2018. The aggregate accrued interest payable and interest expense derived from these convertible promissory notes to related parties were $0 and $392,000 as of and for the year ended December 31, 2018, and $192,000 and $138,000 as of and for the year ended December 31, 2017. The aggregate balance of $2.8 million in convertible promissory notes to related parties was outstanding as of December 31, 2017. See Note 8 for more information.

During the year ended December 31, 2017, the Company raised $8.0 million from the issuance of 4,395,604 shares of Series D redeemable convertible preferred stock to the Company's chairman at $1.82 per share. See Note 9 for more information.

VX3 EXCHANGE AGREEMENT

THIS VX3 EXCHANGE AGREEMENT (this "**Agreement**") is entered into as of August 13, 2018, by and among:

(1) **VX 3 INC.**, an Ontario corporation ("**VX GP**");

(2) **VX3 (DE) LP**, a Delaware limited partnership ("**LP**");

(3) **VACCINEX, INC.**, a Delaware corporation ("**Vaccinex**");

(4) **FCMI PARENT CO.**, a Nova Scotia Unlimited Liability Company ("**FCMI**"); and

(5) Certain investors listed on Schedule A attached hereto to whom LP issued units of limited partnership interest (the "**Units**") (the "**Investors**")

Each of the above are referred to herein individually, as a "**Party**," and collectively, as the "**Parties**."

WHEREAS, VX GP is the general partner of LP;

AND WHEREAS, LP issued Units to the Investors;

AND WHEREAS, as of the date hereof, the Investors set forth on Schedule A are all the limited partners of LP (the "**Limited Partners**");

AND WHEREAS, the number of Units held by the Limited Partners and the aggregate number of Units issued and outstanding, in each case, as of the date hereof, are set forth on Schedule A;

AND WHEREAS, VX GP is entering into this agreement on behalf of the Limited Partners.

NOW THEREFORE THIS AGREEMENT WITNESSETH that in consideration of the mutual covenants and agreements herein contained and other good and valuable consideration, the Parties hereby agree as follows:

1 As used herein, the following terms have the following meanings:

"**Exchange**" means the transfer by an Investor to Vaccinex of the number of Units in exchange for a number of Vaccinex Shares calculated pursuant to the Exchange Ratio. As of the date hereof, the Investors hold an aggregate of 24,000,000 Units which are exchangeable hereunder for an aggregate of up to 1,318,797 Vaccinex Shares.

"**Exchange Notice**" means a notice, in substantially the form of Schedule B attached hereto, provided by or on behalf of an Investor to exercise such Investor's Exchange Right.

"**Exchange Ratio**" means 0.05495 Vaccinex Shares for every 1 Unit transferred pursuant to an Exchange (subject to appropriate adjustment in the event of any splits, dividends, combinations, subdivisions, recapitalizations or the like, affecting the Units or Vaccinex Shares, in each case, following the date hereof, provided, however, that no such adjustment shall be made to effect any such event affecting the Vaccinex Shares to the extent that a corresponding adjustment is made to all issued and outstanding Units prior to such Exchange under the terms of the LPA).

"**Exchange Right**" means the right of the Investors, FCMI and Vaccinex hereunder to initiate an Exchange.

"**LPA**" means the Agreement of Limited Partnership of LP, dated October 27, 2017, by and among VX GP, the Investors, and any other persons who shall in the future execute and deliver the LPA as additional Limited Partners.

"**Vaccinex Shares**" means shares of authorized common stock, par value $0.0001 per share, of Vaccinex.

2 In the event of a request of an Investor made to Vaccinex to exercise such Investor's Exchange Right in respect of all but not less than all of that Investor's Units ("**Exchange Units**"):

(a) Such Investor will transfer to Vaccinex the Exchange Units, or such transfer may be effected by VX GP, pursuant to the power of attorney granted by such Investor to VX GP as general partner of LP under the LPA;

(b) Vaccinex will issue to such Investor the number of Vaccinex Shares as determined by the Exchange Ratio (and as listed in Schedule A) in exchange for such Exchange Units.

The right of Investors to exercise an Exchange Right is expressly limited to those Units held by the Investors as of the date hereof (subject to appropriate adjustment in the event of any splits, dividends, combinations, subdivisions, recapitalizations or the like, affecting the Units following the date hereof), which Units are set forth on Schedule A to the LPA as of the date hereof.

3 Without limiting Section 2, in the event of a request of FCMI made to Vaccinex to exercise FCMI's Exchange Right in respect of all but not less than all of FCMI's Units:

(a) Each Investor, including FCMI, will transfer to Vaccinex all but not less than all of that Investor's Units, or such transfer may be effected by VX GP, pursuant to the power of attorney granted by such Investor to VX GP as general partner of LP under the LPA;

(b) Vaccinex will issue to each Investor, including FCMI, the number of Vaccinex Shares as determined by the Exchange Ratio in exchange for such Investor's Units.

4 Vaccinex may exercise the Exchange Right at its option, at any time, so as to result in the transfer of all but not less than all of the then-outstanding Units to Vaccinex in any of the following circumstances:

(a) Vaccinex has entered into (including by entering into definitive documents related thereto) a transaction such as a sale, merger or consolidation such that Vaccinex Shares are or will be sold or, exchanged for cash and/or marketable securities;

(b) At any time on or after the fifth anniversary of the date hereof; and

(c) Vaccinex or LP has entered into (including by entering into definitive documents related thereto) a licensing, partnering or similar transaction, including a product sale or option to enter into the foregoing, with respect to one or more of the products and indications licensed to LP by Vaccinex, and all amounts then due and owing to LP in connection with such transaction have been paid to LP; provided, that Vaccinex will use its commercially reasonable efforts to structure the transaction, or enter into such related transactions, such that the Investors are either able to defer tax liabilities, to the extent permitted by law, or to monetize a portion of their Units or Vaccinex Shares so as to defray any taxes arising as a result of the transaction, in each case, in accordance with applicable law.

For the avoidance of doubt, (i) following the consummation of an Exchange in accordance with this Agreement with respect to all Units, other than as a holder of Vaccinex Shares, if applicable, neither LP nor the Investors shall have a right to receive proceeds of such transaction paid to Vaccinex or LP following the consummation of such Exchange, and (ii) the Parties agree and acknowledge that nothing contained in this Agreement shall require Vaccinex or LP to obtain the consent of any Party hereto in order to enter into or consummate any such transaction.

5 In the event either an Investor, FCMI or Vaccinex exercise their Exchange Right hereunder, each Investor, FCMI and Vaccinex shall take all steps necessary to effect the applicable Exchange on the terms and conditions contained herein, including by taking any action reasonably requested by Vaccinex with respect to the transfer of Units.

6 Vaccinex Shares issued in connection with an Exchange shall be issued in accordance with the registration instructions set forth in the Exchange Notice, in the absence of which they shall be issued in the name of the applicable Investor.

7 Notwithstanding anything herein to the contrary, if applicable, no fractional Vaccinex Shares shall be issuable upon exercise of the Exchange Right or in connection with an Exchange. If applicable, the number of Vaccinex Shares to be issued shall be rounded down to the nearest whole number of Vaccinex Shares.

8 Prior to the consummation of an applicable Exchange in accordance with this Agreement, no Investor shall have any rights of a holder of Vaccinex Shares, or otherwise as a stockholder of Vaccinex, including, without limitation, the right to vote on any matter presented to the stockholders of Vaccinex or receive any dividends or distributions on Vaccinex Shares or other shares of Vaccinex stock. Following the consummation of an applicable Exchange in accordance with this Agreement, the Investors shall not have any rights as a holder of Units, including, without limitation, with respect to the management of LP, any distribution made to the holders of Units or any other interest in LP.

9 Vaccinex shall reserve and keep available during the term of this Agreement, out of its authorized and unissued shares of common stock, that number of Vaccinex Shares that will from time to time be sufficient to permit the exercise in full of the Exchange Right. If in connection with the exercise of an Exchange Right, Vaccinex does not have sufficient authorized and unissued Vaccinex Shares to permit the exercise in full of the Exchange Right, Vaccinex will promptly take such actions as are reasonably necessary to authorize additional Vaccinex Shares to permit the exercise in full of the Exchange Right, subject to applicable laws and the rights of Vaccinex stockholders.

10 The Parties hereby represent and warrant to each other as follows:

(a) Such Party has the full corporate or limited partnership power and authority, as applicable, to execute and deliver this Agreement and to carry out the transactions contemplated hereby;

(b) The execution and delivery of, and performance by such Party under, this Agreement and the consummation of the transactions contemplated hereby have been duly authorized by all necessary corporate or limited partnership action, as applicable, on the part of such Party and LP;

(c) Neither the execution and delivery of this Agreement nor the consummation of the transactions contemplated hereby will (i) violate any provision of the organizational documents of such Party, (ii) violate any provision of applicable law binding on such Party, or (iii) conflict with, result in a breach of, or constitute a default (or an event which, with notice or lapse of time, or both, would constitute a default) under any material contract binding on such Party.

11 LP and VX GP hereby represent and warrant to Vaccinex as follows:

(a) Schedule A to the LPA sets forth the true, correct and complete capitalization of LP, including all issued and outstanding Units and the holders thereof, and there are no holders of equity interests in or other securities of LP except for the Investors (all of whom are set forth on such Schedule A) and the general partnership interest of VX GP; and

(b) Except for the Units set forth on Schedule A to the LPA, there are no outstanding units or other partnership interests in LP, or options, warrants, rights (including conversion or preemptive rights and rights of first refusal or similar rights) or agreements, orally or in writing, to purchase or acquire from LP any units or partnership interests, or any securities convertible into or exchangeable for units or partnership interests of LP.

12 Vaccinex hereby represents and warrants to LP and VX GP as follows: all Vaccinex Shares which may be issued upon an Exchange hereunder shall, upon issuance in accordance with this Agreement, be duly authorized, validly issued, fully paid and nonassessable, and free of any liens and encumbrances except as may be provided herein, restrictions under applicable federal and state securities laws, the certificate of incorporation of Vaccinex, as then in effect, or the Stockholders Agreements (as defined below) if then in effect, and for such liens and encumbrances as may be created by an Investor.

13 VX GP and LP hereby covenant and agree that following the date hereof, without the prior written consent of Vaccinex, LP will not (a) issue any Units or any other units or other partnership or equity interests, including any securities convertible for exchangeable for units or other partnership or equity interests of LP, (b) declare or consummate any split, dividend, combination, subdivision, recapitalization or the like, affecting the Units or any other unit or partnership or equity interest in LP, or (c) cause or permit the transfer of any Units to any person or entity not listed on Schedule A attached hereto; provided, however, that (1) Vaccinex may not unreasonably withhold its consent from any proposed transfer of Units to any person or entity which is not an Investor as of the date hereof (as reflected on Schedule A to the LPA as of the date hereof), and (2) any holder of Units may, without the prior written consent of Vaccinex, transfer Units for bona fide estate planning purposes, either during or after such holder's lifetime or upon death by will or intestacy, to his or her spouse, child (natural or adopted), or any other direct lineal descendant of such holder (or of his or her spouse) (all of the foregoing collectively referred to as "**Family Members**"), or any custodian or trustee of any trust, partnership or limited liability company for the benefit of, or the ownership interests of which are owned wholly by, such holder or any such family members; provided, that (i) such holder shall deliver prior written notice to Vaccinex of such transfer, (ii) such Units and such transferee(s) shall remain subject to the terms of this Agreement; and (iii) such transfer shall be permitted by applicable law.

14 The obligations of Vaccinex to issue Vaccinex Shares and the rights of any holder of Units to receive Vaccinex Shares hereunder in connection with an Exchange are expressly subject to the execution and delivery by any recipient of Vaccinex Shares (including Investors, as applicable) of joinders or counter-part signature pages to all stockholders agreements binding on holders of Vaccinex Shares and such other documents or instruments as may be reasonably requested by Vaccinex, which may include transfer instruments with respect to the Units, transfer restrictions applicable to other holders of Vaccinex Shares, representations and warranties of such recipient regarding their ownership of the Units and/or the Vaccinex Shares or as may be necessary or advisable under United States federal and state securities laws (the "**Stockholders Agreements**").

15 This Agreement shall be effective as of the date first written above upon the execution and delivery hereof by each Party hereto.

16 This Agreement may be amended by mutual written agreement of Vaccinex and FCMI.

17 This Agreement may be terminated by mutual written agreement of Vaccinex and FCMI, and shall automatically terminate upon (a) the consummation of the Exchange with respect to all Units or (b) upon FCMI's prior written consent (which consent shall not be unreasonably withheld, conditioned or delayed), a merger or consolidation of LP with or into Vaccinex or any of its direct or indirect subsidiaries or controlled affiliates.

18 Any notice, consent, waiver or other communication given under this Agreement must be in writing and may be given by delivering it or sending it by confirmed email addressed:

(a) to Vaccinex:

Attention: Maurice Zauderer
Email:

with a copy (which shall not constitute notice) to:

Attention: Asher M. Rubin
Email:

(b) to LP:

Attention: Richard Sutin
Email:

with a copy (which shall not constitute notice) to:

Attention: Asher M. Rubin
Email:

(c) to FCMI:

Attention: Dan Scheiner
Email:

Any such communication is deemed to have been delivered on the date of confirmed transmission, unless that day is not a business day in Canada or in the United States or if such confirmed transmission is not received during normal business hours of the recipient, in which event it will be deemed delivered on the next following business day. Any Party may change its email address for service by notice given in accordance with the foregoing and any subsequent notice must be sent to such Party at its changed email address.

19 None of the Parties shall sell, transfer or assign (including by operation of law) its interest in this Agreement without (a) providing reasonable prior written notice to the other Parties, and (b) subject to Section 13, obtaining the prior written consent of Vaccinex. Any transfer or assignment not permitted under this section shall be null and void and of no effect whatsoever.

20 The provisions hereof shall inure to the benefit of the Parties and their respective successors and permitted assigns.

21 Nothing in this Agreement, express or implied, is intended to confer upon any person other than the Parties hereto or their respective successors and permitted assigns and the Investors any rights, remedies, obligations, or liabilities under or by reason of this Agreement.

22 Without limiting anything else contained herein, the Parties shall do or cause to be done all such reasonable acts and things as may be necessary, proper, or advisable, consistent with all applicable laws, to consummate and make effective the transactions contemplated hereby on the terms and subject to the conditions contained herein. Without limiting the foregoing, each Party shall use its commercially reasonable efforts, and the other Parties shall cooperate with such efforts, to (a) execute and deliver, or cause to be executed and delivered, such further documents and instruments, including tax certifications and documents, in each case as may be necessary or proper in the reasonable judgment of Vaccinex, to carry out the provisions and purposes of this Agreement and to comply with applicable legal requirements and (b) obtain any consents, approvals or authorization, or effect the notification of or filing with, each person, whether private or governmental, whose consent or approval is required in order to permit the consummation of the transactions contemplated hereby on the terms and subject to the conditions contained herein.

23 The construction and performance of this Agreement shall be governed by the laws of the State of Delaware.

24 This Agreement may be executed in one or more counterparts, each of which will be deemed an original and all of which together will constitute one and the same instrument. This Agreement may be executed through delivery of duly executed signature pages by facsimile or electronic mail.

[*signature pages follow*]

IN WITNESS WHEREOF the Parties have executed this VX3 Exchange Agreement as of the date first above written.

VX 3 INC.

By: /s/ Richard Sutin

Name: Richard Sutin

Title: President

[*Signature Page to VX3 Exchange Agreement*]

IN WITNESS WHEREOF the Parties have executed this VX3 Exchange Agreement as of the date first above written.

VX3 (DE) LP

By: VX 3 Inc., its general partner

By: /s/ Richard Sutin

Name: Richard Sutin

Title: President

[*Signature Page to VX3 Exchange Agreement*]

IN WITNESS WHEREOF the Parties have executed this VX3 Exchange Agreement as of the date first above written.

VACCINEX, INC.

By: /s/ Scott E. Royer

Name: Scott E. Royer

Title: Chief Financial Officer

[*Signature Page to VX3 Exchange Agreement*]

IN WITNESS WHEREOF the Parties have executed this VX3 Exchange Agreement as of the date first above written.

FCMI PARENT CO.

By: /s/ Dan Scheiner

Name: Dan Scheiner

Title: Vice President

[*Signature Page to VX3 Exchange Agreement*]

IN WITNESS WHEREOF the Parties have executed this VX3 Exchange Agreement as of the date first above written.

By: /s/ Benjamin Zarnett

Name: Benjamin Zarnett

Title:

[*Signature Page to VX3 Exchange Agreement*]

IN WITNESS WHEREOF the Parties have executed this VX3 Exchange Agreement as of the date first above written.

Gee Eff Services Limited

By: /s/ Jack Frieberg

Name: Jack Frieberg

Title:

[*Signature Page to VX3 Exchange Agreement*]

IN WITNESS WHEREOF the Parties have executed this VX3 Exchange Agreement as of the date first above written.

By: /s/ Joseph Rutman

Name: Joseph Rutman

Title:

[*Signature Page to VX3 Exchange Agreement*]

IN WITNESS WHEREOF the Parties have executed this VX3 Exchange Agreement as of the date first above written.

Joseph Rutman, as bare trustee for:
Jonathan Rutman
Shawna Rutman Iankelevic
Gerald Rutman
Joseph Rutman
Laila Rutman Alter
Reena Rutman Lauterpacht

By: /s/ Joseph Rutman

Name: Joseph Rutman

Title: Trustee

[*Signature Page to VX3 Exchange Agreement*]

IN WITNESS WHEREOF the Parties have executed this VX3 Exchange Agreement as of the date first above written.

By: /s/ Lawrence Chernin

Name: Lawrence Chernin

Title:

[*Signature Page to VX3 Exchange Agreement*]

IN WITNESS WHEREOF the Parties have executed this VX3 Exchange Agreement as of the date first above written.

By: /s/ Stephen Halperin

Name: Stephen Halperin

Title:

[*Signature Page to VX3 Exchange Agreement*]

IN WITNESS WHEREOF the Parties have executed this VX3 Exchange Agreement as of the date first above written.

By: /s/ Richard Sutin

Name: Richard Sutin

Title:

[*Signature Page to VX3 Exchange Agreement*]

SCHEDULE A

INVESTORS

Partner Name and Address	VX GP Units	Units	Voting Interest	Initial Capital Contribution	Total Capital Contributions	Vaccinex Shares (Post-Exchange)
VX3 Inc. Attn: Richard S. Sutin Email:	1	0	0%	$1	$1	0
SUBTOTAL	1	0	0%	$1	$1	0
FCMI Parent Co. Attn: Dan Scheiner Email:	0	21,475,000	89.479%	$11,475,000	$21,475,000[1]	1,180,051
Richard Sutin Norton Rose Fulbright Canada LLP Email:	0	75,000	0.313%	$75,000	$75,000	4,121
Benjamin Zarnett Goodmans LLP Email:	0	25,000	0.104%	$25,000	$25,000	1,373
Joseph Rutman, as bare trustee for: Jonathan Rutman Shawna Rutman Iankelevic Gerald Rutman Joseph Rutman Laila Rutman Alter Reena Rutman Lauterpacht, in equal shares Email:	0	300,000	1.250%	$300,000	$300,000	16,485
Stephen Halperin Goodmans LLP Email:	0	25,000	0.104%	$25,000	$25,000	1,373
Lawrence Chernin Goodmans LLP Email:	0	25,000	0.104%	$25,000	$25,000	1,373
Gee Eff Services Limited Email:	0	75,000	0.313%	$75,000	$75,000	4,121

[1] FCMI Parent Co. made Capital Contributions to the LP in the amounts of US$8,000,000 and US$2,000,000 on or about February 28, 2018 and May 15, 2018, respectively.

[2] Joseph Rutman, Trustee, made a Capital Contribution to the LP in the amount of US$2,000,000 on or about June 12, 2018.

Partner Name and Address	VX GP Units	Units	Voting Interest	Initial Capital Contribution	Total Capital Contributions	Vaccinex Shares (Post-Exchange)
Joseph Rutman, Trustee[2] Email:	0	2,000,000	8.333%	$0	$2,000,000	109,900
SUBTOTAL	0	24,000,000	100%	$12,000,000	$24,000,000	1,318,797
TOTAL	1	24,000,000	100%	$12,000,001	$24,000,001	1,318,797

SCHEDULE B

EXCHANGE NOTICE

Vaccinex, Inc.
1895 Mt. Hope Avenue
Rochester, NY 14620

1. The undersigned hereby irrevocably elects to exercise its Exchange Right in respect of all but not less than all of its Units.

2. Please issue a certificate or certificates representing the Vaccinex Shares issuable upon the exchange of such Units in the name of the undersigned or in such other name as is specified below:

_____

_____

_____

(*please print name and address above*)

3. The undersigned represents it is acquiring the Vaccinex Shares solely for its own account and not as a nominee for any other party and not with a view toward the resale or distribution thereof except in compliance with applicable securities laws.

4. Capitalized terms used but not defined herein shall have the meanings ascribed to such terms in the VX3 Exchange Agreement, dated August 13, 2018, among VX 3 Inc., VX3 (DE) LP, Vaccinex, Inc., FCMI Parent Co. and certain investors listed on Schedule A attached thereto to whom VX3 (DE) LP issued units of limited partnership interest.

_____

[INVESTOR'S NAME]

Date: _____

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in Registration Statement No. 333-226964 on Form S-8 of our report dated March 13, 2019, relating to the consolidated financial statements of Vaccinex, Inc. and subsidiaries (which report expresses an unqualified opinion and includes an explanatory paragraph regarding a going concern uncertainty), appearing in this Annual Report on Form 10-K of Vaccinex, Inc. for the year ended December 31, 2018.

/s/ Deloitte & Touche LLP

Rochester, New York
March 13, 2019

Exhibit 31.1

Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Maurice Zauderer, certify that:

1. I have reviewed this annual report on Form 10-K for the year ended December 31, 2018 of Vaccinex, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: March 13, 2019

By: /s/ Maurice Zauderer

Maurice Zauderer, Ph.D.
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Scott E. Royer, certify that:

1. I have reviewed this annual report on Form 10-K for the year ended December 31, 2018 of Vaccinex, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: March 13, 2019

By: /s/ Scott E. Royer

Scott E. Royer
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

In connection with the annual report of Vaccinex, Inc., (the "Company") on Form 10-K for the year ended December 31, 2018 as filed with the Securities and Exchange Commission on the day hereof (the "Report"), I, Maurice Zauderer, Ph.D., President and Chief Executive Officer of the Company and Scott E. Royer, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: March 13, 2019

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

Dated: March 13, 2019

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