UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

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

For the quarterly period ended September 30, 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, New York	**14620**
(Address of principal executive offices)	**(Zip Code)**

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

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 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 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 November 13, 2018, the registrant had 11,475,749 shares of common stock, $0.0001 par value per share, outstanding.

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Item 1. Unaudited Condensed Consolidated Financial Statements

VACCINEX, INC.

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

	As of September 30, 2018	As of December 31, 2017
ASSETS		
Current assets:		
Cash and cash equivalents	$ 11,258	$ 4,180
Marketable securities	16,121	—
Accounts receivable, net	403	117
Prepaid expenses and other current assets	1,555	677
Total current assets	29,337	4,974
Property and equipment, net	544	601
TOTAL ASSETS	$ 29,881	$ 5,575
LIABILITIES, REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	$ 2,276	$ 1,910
Accrued expenses	3,818	1,957
Deferred revenue	42	298
Total current liabilities	6,136	4,165
Convertible promissory notes to related party, net	—	2,813
Derivative liabilities	—	369
TOTAL LIABILITIES	6,136	7,347
Commitments and contingencies (Note 9)		
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 September 30, 2018 and December 31, 2017; zero shares issued and outstanding as of September 30, 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 September, 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 September 30, 2018 and December 31, 2017 with aggregate liquidation preference of $0 and $7,684 as of September 30, 2018 and December 31, 2017	—	7,684
Common stock, par value of $0.0001 per share; 160,000,000 shares authorized as of September 30, 2018 and December 31, 2017; 11,476,601 and 1,103,396 shares issued as of September 30, 2018 and December 31, 2017; 11,475,749 and 1,102,560 shares outstanding as of September 30, 2018 and December 31, 2017	1	—
Additional paid-in capital	208,110	54,123
Treasury stock, at cost; zero and 163 shares of redeemable convertible preferred stock as of September 30, 2018 and December 31, 2017, and 852 and 836 shares of common stock as of September 30, 2018 and December 31, 2017	(11)	(11)
Accumulated deficit	(208,318)	(187,249)
Total Vaccinex, Inc. stockholders' deficit	(218)	(125,453)
Noncontrolling interests	23,963	11,963
TOTAL STOCKHOLDERS' EQUITY (DEFICIT)	23,745	(113,490)
TOTAL LIABILITIES, REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)	$ 29,881	$ 5,575

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

VACCINEX, INC.

Condensed Consolidated Statements of Operations and Comprehensive Loss (Unaudited)
(in thousands, except share and per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Revenue	$ 198	$ —	$ 530	$ —
Costs and expenses:				
Cost of revenue	246	—	732	—
Research and development	5,314	4,292	15,280	11,523
General and administrative	1,092	1,040	3,238	3,384
Total costs and expenses	6,652	5,332	19,250	14,907
Loss from operations	(6,454)	(5,332)	(18,720)	(14,907)
Change in fair value of derivative liabilities	31	157	369	(214)
Interest expense	(44)	(361)	(392)	(988)
Loss on extinguishment of related party convertible promissory note	(199)	—	(2,379)	—
Other income (expense), net	67	—	53	(23)
Loss before provision for income taxes	(6,599)	(5,536)	(21,069)	(16,132)
Provision for income taxes	—	—	—	—
Net loss	(6,599)	(5,536)	(21,069)	(16,132)
Net loss attributable to noncontrolling interests	—	—	—	—
Net loss attributable to Vaccinex, Inc.	(6,599)	(5,536)	(21,069)	(16,132)
Cumulative dividends on redeemable convertible preferred stock	—	(809)	—	(2,401)
Net loss attributable to Vaccinex, Inc. common stockholders, basic and diluted	$ (6,599)	$ (6,345)	$ (21,069)	$ (18,533)
Net loss per share attributable to Vaccinex, Inc. common stockholders, basic and diluted	$ (0.93)	$ (5.75)	$ (6.76)	$ (16.82)
Weighted-average shares used in computing net loss per share attributable to Vaccinex, Inc. common stockholders, basic and diluted	7,078,715	1,102,520	3,116,695	1,101,723

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

VACCINEX, INC.

Consolidated Statements of Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit) (Unaudited)
(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 December 31, 2016	48,694,355	$ 103,736	5,702,450	$ 7,684	1,101,359	$ —	$ 53,789	163	836	$ (11)	$ (168,527)	$ (107,065)	$ —	$ (107,065)
Stock-based compensation	—	—	—	—	—	—	249	—	—	—	—	249	—	249
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	—	—	—	—	—	—	—	—	—	—	(16,132)	(16,132)	—	(16,132)
Balance as of September 30, 2017	53,089,959	$ 111,718	5,702,450	$ 7,684	1,103,396	$ —	$ 54,053	163	836	$ (11)	$ (184,659)	$ (122,933)	$ —	$ (122,933)

	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 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
Stock-based compensation	—	—	—	—	—	—	131	—	—	—	—	131	—	131
Exercise of stock options	—	—	—	—	700	—	5	—	—	—	—	5	—	5
Net loss	—	—	—	—	—	—	—	—	—	—	(21,069)	(21,069)	—	(21,069)
Balance as of September 30, 2018	—	$ —	—	$ —	11,476,601	$ 1	$ 208,110	—	852	$ (11)	$ (208,318)	$ (218)	$ 23,963	$ 23,745

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

VACCINEX, INC.

Condensed Consolidated Statements of Cash Flows (Unaudited)
(in thousands)

	Nine Months Ended September 30,	
	2018	**2017**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (21,069)	$ (16,132)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	166	152
Amortization of debt discount	308	886
Net amortization of premiums and discounts on marketable securities	(29)	—
Stock-based compensation	131	249
Change in fair value of derivative liabilities	(369)	214
Loss on extinguishment of related party convertible promissory note	2,379	—
Changes in operating assets and liabilities:		
Accounts receivable	(286)	(13)
Prepaid expenses and other current assets	(878)	(456)
Accounts payable	323	60
Accrued expenses	1,861	(169)
Deferred revenue	(256)	69
Net cash used in operating activities	(17,719)	(15,140)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of marketable securities	(16,092)	—
Purchase of property and equipment	(66)	(65)
Net cash used in investing activities	(16,158)	(65)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of convertible promissory notes to related parties, net of issuance cost	—	5,976
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	—
Payments of initial public offering costs	(2,675)	—
Proceeds from exercise of stock options	5	15
Repayment of convertible promissory note, related party	(5,500)	—
Proceeds from capital contribution	12,000	—
Net cash provided by financing activities	40,955	13,973
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	7,078	(1,232)
CASH AND CASH EQUIVALENTS–Beginning of period	4,180	1,661
CASH AND CASH EQUIVALENTS–End of period	$ 11,258	$ 429
SUPPLEMENTAL DISCLOSURES OF NONCASH INVESTING AND FINANCING ACTIVITIES:		
Cash paid for interest	$ 275	$ —
Purchase of property and equipment in accounts payable	$ 52	$ —
Conversion of redeemable convertible preferred stock into common stock	$ 111,718	$ —
Conversion of convertible preferred stock into common stock	$ 7,684	$ —
Issuance of common stock	$ 1	$ —

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

1. COMPANY AND NATURE OF BUSINESS

Description 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.

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 effected; 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.

Liquidity

These condensed 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 $17.7 million and $15.1 million for the nine months ended September 30, 2018 and 2017, respectively, an accumulated deficit of $208.3 million and $187.2 million and stockholders' equity of $23.7 million as of September 30, 2018 and stockholders' deficit of $113.5 million as of December 31, 2017, respectively. 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 condensed 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. The Company believes that its existing cash and cash equivalents and marketable securities balances of $11.3 million and $16.1 million as of September 30, 2018, respectively, are

sufficient to provide liquidity to fund its operations through the 3rd quarter of 2019. Management is currently evaluating different strategies to obtain the required funding of future operations and growth. 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, or a secondary public offering of the Company's common stock. 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 favorable terms.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation and Consolidation

These condensed 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. All intercompany transactions and balances have been eliminated.

The accompanying condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP"), and following the requirements of the Securities and Exchange Commission ("SEC"), for interim reporting. As permitted under those rules, certain footnotes or other financial information that are normally required by U.S. GAAP can be condensed or omitted. These condensed consolidated financial statements have been prepared on the same basis as the Company's annual consolidated financial statements and, in the opinion of management, reflect all adjustments, consisting only of normal recurring adjustments that are necessary for a fair statement of the Company's financial information. The results of operations for the interim periods presented are not necessarily indicative of the results to be expected for any subsequent quarter or for the entire year ending December 31, 2018. The year-end balance sheet data was derived from audited consolidated financial statements, but does not include all disclosures required by U.S. GAAP. Certain information and note disclosures normally included in annual consolidated financial statements prepared in accordance with U.S. GAAP have been omitted under the rules and regulations of the SEC.

These condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and related notes contained in the final prospectus related to the Company's IPO (the "Prospectus"), which was filed with the SEC on August 10, 2018 pursuant to Rule 424(b) of the Securities Act of 1933, as amended, relating to the Company's Registration Statement on Form S-1 (File No. 333-226103). The accounting policies followed in the preparation of these consolidated condensed financial statements are consistent in all material respects with those presented in Note 2 to the financial statements included in the Company's Prospectus, except for the Company's accounting policy, as described below, for its recently purchased marketable securities.

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, which is a separate component of stockholders' equity (deficit). 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 condensed 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.

Use of Estimates

These condensed consolidated financial statements have been prepared in conformity with 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 condensed 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.

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 and marketable securities. Cash equivalents are deposited in interest-bearing money market accounts and short-term investments consist of highly liquid U.S. government treasury bills and notes. The Company deposits its cash with multiple financial institutions and 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.

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.

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 plans to adopt the new revenue standards using the modified retrospective method when they become effective for the Company, which is at the earlier of losing the emerging growth company status or 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 condensed 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 condensed 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 condensed 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 condensed 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 condensed consolidated financial statements and related disclosures.

In March 2016, the FASB issued ASU No. 2016-09, *Compensation–Stock Compensation: Improvements to Employee Share-Based Payment Accounting*, which simplifies several aspects of the accounting for share-based payment transactions, including the income tax consequences, application of award forfeitures to expense, classification of awards as either equity or liabilities, and classification on the statement of cash flows. The new standard is effective for the Company's fiscal year effective January 1, 2018. On January 1, 2017, the Company adopted the standard early and there was no material impact on its condensed consolidated financial statements and related disclosures.

3. BALANCE SHEET COMPONENTS

Property and Equipment

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

	As of September 30, 2018	As of December 31, 2017
Leasehold improvements	$ 3,145	$ 3,140
Research equipment	3,102	2,998
Furniture and fixtures	350	350
Computer equipment	214	214
Property and equipment, gross	6,811	6,702
Less: accumulated depreciation and amortization	(6,267)	(6,101)
Property and equipment, net	$ 544	$ 601

Depreciation and amortization expense related to property and equipment was $54,000 for the three months ended September 30, 2018 and 2017, and $166,000 and $152,000 for the nine months ended September 30, 2018 and 2017, respectively.

Accrued Expenses

Accrued expenses consist of the following (in thousands):

	As of September 30, 2018	As of December 31, 2017
Accrued clinical trial cost	$ 3,260	$ 891
Accrued consulting and legal	287	239
Accrued payroll and related benefits	227	311
Accrued interest	—	192
Accrued other	44	324
Accrued expenses	$ 3,818	$ 1,957

4. MARKETABLE SECURITIES

As of September 30, 2018, the fair value of available-for-sale marketable securities was as follows (in thousands):

	September 30, 2018			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Marketable securities:				
U.S. Treasury securities	$ 16,121	$ —	$ —	$ 16,121
	$ 16,121	$ —	$ —	$ 16,121

All of the Company's available-for-sale marketable securities at September 30, 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 condensed 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):

	September 30, 2018			
	Fair Value	Level 1	Level 2	Level 3
Financial Assets:				
Cash equivalents:				
Money market fund	$ 1,512	$ 1,512	$ —	$ —
U. S. Treasury securities	6,741	—	6,741	—
Marketable securities:				
U. S. Treasury securities	16,121	—	16,121	—
Total Financial Assets	$ 24,374	$ 1,512	$ 22,862	$ —

	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 nine months ended September 30, 2018.

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 – December 31, 2017	$ 369
Change in fair value	(369)
Balance – September 30, 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.

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 condensed 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 $31,000 and $157,000 from the remeasurement of the derivative liabilities associated with the convertible promissory notes for the three months ended September 30, 2018 and 2017, respectively, and a gain of $369,000 and a loss of $214,000 for the nine months ended September 30, 2018 and 2017, respectively, and presents such amounts in its condensed consolidated statements of operations and comprehensive loss as changes in fair value of derivative liabilities. As of September 30, 2018 the convertible promissory notes had been paid in full.

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 VX15, 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 VX15 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 VX15 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 VX15 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 September 30, 2018 and December 31, 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 condensed 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 ending 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 September 30, 2018.

For the nine months ended September 30, 2018, the Company recorded the gross proceeds of $12.0 million, received from VX3 as capital contributions from noncontrolling interests on the condensed 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 was recognized as service revenue for the nine months ended September 30, 2018. Deferred revenue as of December 31, 2017 totaled $69,000. The research agreement expired in June 2018.

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 $63,000 and $188,000 was recognized as revenue from the amortization of this upfront fee for the three months and nine months ended September 30, 2018, respectively. The remaining $42,000 is reported as deferred revenue as of September 30, 2018. The Company also received $66,000 and $199,000 service fee payments for work conducted under the agreement, for the three months and nine months ended September 30, 2018, respectively. 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 three-month research service agreement with Heptares Therapeutics, Ltd. ("Heptares") to provide research services to Heptares. Under the agreement, Heptares will provide the Company compounds, materials or samples, and the Company will perform feasibility services to allow Heptares to evaluate the feasibility of the Company's technology. The Company received a payment of $69,000 from Heptares under the research agreement which was recognized as service revenue for the three months ended September 30, 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 September 30, 2018, the Company did not have any convertible promissory notes outstanding. See "Conversion and Repayment of Convertible Promissory Notes" below.

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, together with accrued interest, was convertible (i) automatically upon a future qualifying financing event, which includes the sale of shares in a future preferred stock financing with gross proceeds of at least $5.0 million or the issuance of shares of common stock in an IPO, (ii) upon a change of control (unless the lenders elect to treat such event as a default), or (iii) upon a future non-qualifying financing event at the election of the lenders. Upon a future qualifying financing event, the outstanding principal, together with accrued interest, would convert into shares of the newly issued securities at 85% of the price paid in the financing. However, a closing of the sale of the Company's convertible preferred stock with minimum gross proceeds of $5.0 million within 90 days of the effective date of the related convertible promissory notes was not considered a qualifying financing event, and the outstanding principal, together with accrued interest, would convert into shares of the newly issued securities at 100% of the price paid in financing. Upon the election to convert the convertible promissory notes in the event of a change of control, the outstanding principal, together with accrued interest, would convert based on the conversion price of the Series C redeemable convertible preferred stock, which was $18.20 per share as of December 31, 2017. Upon the election to convert the convertible promissory notes in the event of a non-qualifying financing event, the outstanding principal, together with accrued interest, would convert based on the lowest price per share paid for in the financing. The June 2016 Note was paid in full on August 17, 2018. See "Conversion and 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 "Conversion and Repayment of Convertible Promissory Notes" below.

Conversion Feature and Option

The conversion terms of the January 2017 Notes were similar to the June 2016 Note, except that the conversion price of the January 2017 Notes upon a qualifying financing was the lower of (1) $18.20 per share, or (2) 85% of the price per share of the newly issued securities. In connection with the issuance of the January 2017 Notes, the Company and the related party also entered into a side letter agreement 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 (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.

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 $17,000 and $324,000 for the amortization of the debt discounts during the three months ended September 30, 2018 and 2017, respectively, and $308,000 and $886,000 during the nine months ended September 30, 2018 and 2017, respectively.

Conversion and Repayment of Convertible Promissory Notes

In August 2016, the Company raised $10.7 million in Series D redeemable convertible preferred stock financing, which qualified as a Qualified Financing (preferred stock financing with gross proceeds of at least $5.0 million) for several convertible promissory notes issued in prior years. The outstanding principal and accrued interest of these convertible promissory notes totaling $27.1 million was converted into 17,485,445 shares of Series D redeemable convertible preferred stock at $1.547 per share, or 85% of the Series D redeemable convertible preferred stock issuance price of $1.82 per share, as specified in each convertible promissory note agreement. The $8.6 million unamortized debt discount was reclassified into Series D redeemable convertible preferred stock. The related embedded derivative liabilities totaling $4.8 million were marked to fair value on the conversion date and were included in the accounting for the conversion of the convertible promissory notes to Series D redeemable convertible preferred stock.

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 condensed consolidated statements of operations in the nine months ended September 30, 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 were written off and the $199,000 unamortized debt discount was recognized as a loss on extinguishment of related party convertible promissory note in the condensed consolidated statements of operations in the three months ended September 30, 2018.

As of December 31, 2017, the Company was in compliance with all financial covenants in the convertible promissory notes.

9. 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 September 30, 2018, the future minimum payments for the operating lease is $350,000.

Rent expense incurred under the operating lease was $42,000 for the three months ended September 30, 2017 and 2018, and $126,000 for the nine months ended September 30, 2017 and 2018.

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 September 30, 2018 and December 31, 2017, the Company was not involved in any material legal proceedings.

10. COMMON STOCK RESERVED FOR ISSUANCE

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

	As of September 30, 2018	As of December 31, 2017
Conversion of outstanding preferred stock	—	7,039,155
Shares underlying outstanding stock options	403,686	420,956
Shares available for future stock option grants	425,000	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	3,350,049	9,341,111

11. STOCK-BASED COMPENSATION

Employee Equity Plans

In 2011, the Company adopted the 2011 Employee Equity Plan (the "2011 Plan") for the purpose of granting stock, stock option, and stock appreciation rights awards to employees, advisors and consultants. Stock options granted under the 2011 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 2011 Plan expire in five or ten years from the date of grant. Additionally, in August 2018, the Company adopted its 2018 Omnibus Incentive Plan (the "2018 Plan"). Under the 2018 Plan, 425,000 shares of common stock were reserved for future issuance to employees, directors, and consultants. The Company will not make any further grants under the 2011 Plan.

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

	Options Outstanding			
	Stock Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life (Years)	Aggregate Intrinsic Value
Balance as of December 31, 2017	420,956	$ 9.20	7.4	$ 5,021
Granted	28,000	13.60		
Exercised	(700)	7.10		
Canceled	(44,570)	7.10		
Balance as of September 30, 2018	403,686	$ 9.71	6.7	$ 4,598
Exercisable as of September 30, 2018	357,014	$ 9.49	6.5	$ 4,146

The weighted-average grant date fair value of stock options granted to employees for the nine months ended September 30, 2018 and 2017 was $15.63 and $9.00 per share, respectively. The aggregate grant date fair value of stock options that vested during the nine months ended September 30, 2018 and 2017 was $188,000 and $176,000, 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 September 30, 2018 and December 31, 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 $13,000 during the nine months ended September 30, 2018 and 2017, respectively.

As of September 30, 2018 and December 31, 2017, total unrecognized compensation cost related to stock options granted to employees was $471,000 and $216,000, respectively, which is expected to be recognized over a weighted-average period of 3.1 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:

	Nine Months Ended September 30,	
	2018	2017
Expected term (in years)	6.0	6.0
Expected volatility	75%	75%
Risk-free interest rate	2.6%	2.0%
Expected dividend yield	—%	—%

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Research and development	$ 16	$ 14	$ 50	$ 40
General and administrative	27	175	81	209
Total stock-based compensation expense	$ 43	$ 189	$ 131	$ 249

12. INCOME TAXES

No provision for income taxes was recorded in the three and nine months ended September 30, 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 September 30, 2018 and December 31, 2017.

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, Accounting Standards Codification 740 ("ASC 740") requires 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 ultimate impact of the income tax effects of the Tax Act may differ due to, among other things, additional analysis, changes in interpretations, and additional regulatory guidance that may be issued as a result of the Tax Act. The accounting is expected to be complete when the Company's 2017 U.S. corporate income tax return is filed in 2018. 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 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 September 30, 2018 and December 31, 2017, the Company had no unrecognized income tax benefits that would affect the Company's effective tax rate if recognized.

13. 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):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Net loss	$ (6,599)	$ (5,536)	$ (21,069)	$ (16,132)
Net loss attributable to noncontrolling interests	—	—	—	—
Net loss attributable to Vaccinex, Inc.	(6,599)	(5,536)	(21,069)	(16,132)
Cumulative dividends on preferred stock	—	(809)	—	(2,401)
Net loss attributable to Vaccinex, Inc. common stockholders, basic and diluted	$ (6,599)	$ (6,345)	$ (21,069)	$ (18,533)
Net loss per share attributable to Vaccinex, Inc. common stockholders, basic and diluted	$ (0.93)	$ (5.75)	$ (6.76)	$ (16.82)
Weighted-average shares used in computing net loss per share attributable to Vaccinex, Inc. common stockholders, basic and diluted	7,078,715	1,102,520	3,116,695	1,101,723

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Preferred stock (if converted)	—	7,020,044	—	6,771,176
Options to purchase common stock	403,686	408,782	412,934	406,596
Contingently issuable common stock upon exchange of Vaccinex Products, LP units	1,202,566	1,202,566	1,202,566	1,202,566
Contingently issuable common stock upon exchange of VX3 units	1,318,797	—	1,103,825	—

14. 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 September 30, 2018 and December 31, 2017, all long-lived assets are located in the United States.

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 September 30, 2018 and December 31, 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 9, 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 $126,000 for each of the nine months ended September 30, 2018 and 2017.

The Company issued $1.5 million convertible promissory note to Vaccinex LLC during the year ended December 31, 2016. Vaccinex LLC is majority owned and controlled by the Company's Chief Executive Officer. The loan balance was repaid in full on August 17, 2018.

Item 2. 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 condensed consolidated financial statements and related notes included elsewhere in this report. References in this report to the "Company," "we," "our," or "us" mean Vaccinex, Inc. and its subsidiaries except where the context otherwise requires. This discussion and other parts of this Quarterly Report on Form 10-Q (the "Report") contain forward-looking statements that involve risk and uncertainties, such as statements of our plans, objectives, expectations and intentions. Our actual results could differ materially from those discussed in these forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in the risk factors identified in Item 1A and in the cautionary statement below.

Cautionary Note Regarding Forward-Looking Statements

Some of the statements made in this Report constitute forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as "may," "will," "should," "expects," "plans," "anticipates," "believes," "estimates," "predicts," "potential," "intends" or "continue," or the negative of these terms or other comparable terminology.

Forward-looking statements include, but are not limited to, statements about:

- 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 Item 1A and elsewhere in this Report. 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 Report, 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.

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 VX15, which we believe utilizes novel mechanisms of action. We are focused on developing VX15 for the treatment of non-small cell lung cancer ("NSCLC") and Huntington's disease. Additionally, in coordination with us, one investigator is studying VX15 in osteosarcoma and another is studying VX15 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 ("NKT") vaccine platform to discover product candidates that target and extend the activity of NKT cells. Our lead product candidate, VX15, is currently in clinical development for the treatment of NSCLC, osteosarcoma and Huntington's disease, through our efforts or through exploratory studies ("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 three months ended September 30, 2018 and 2017, we reported a net loss of $6.6 million and $5.5 million, respectively, and $21.1 million and $16.1 million for the nine months ended September 30, 2018 and 2017, respectively. As of September 30, 2018 and December 31, 2017, we had cash and cash equivalents and marketable securities of $27.4 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, and as a result, our independent registered public accounting firm has noted this in the opinion they issued on our consolidated financial statements for the year ended December 31, 2017. 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 three and nine months ended September 30, 2018 and 2017, we generated a limited amount of service revenue from our collaboration agreements, including with Surface Oncology, Inc. ("Surface"), Merck Sharp & Dohme Corp. ("Merck") and Heptares Therapeutics, Ltd. ("Heptares").

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.

	Three Months Ended September 30,				Nine Months Ended September 30,			
	2018		2017		2018		2017	
	(in thousands)	%	(in thousands)	%	(in thousands)	%	(in thousands)	%
Clinical trial costs	$ 3,953	74%	$ 2,843	66%	$ 11,057	71%	$ 7,128	62%
Wages, benefits, and related costs	754	14%	903	21%	2,294	15%	2,783	24%
Preclinical supplies and equipment depreciation	447	8%	370	9%	1,403	10%	1,123	10%
Consulting, non-clinical trial services, and other	126	3%	146	3%	388	3%	400	3%
Other	34	1%	30	1%	138	1%	89	1%
Total research and development expenses	$ 5,314		$ 4,292		$ 15,280		$ 11,523	

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

- **Non-Small Cell Lung Cancer (NSCLC).** In the our CLASSICAL study, which is evaluating pepinemab in combination with avelumab in NSCLC, the dose escalation phase of the trial is complete, and we have identified the intended Phase 2 dose for the dose expansion phase. We plan to enroll 28 patients in each of two cohorts: one in which patients are immunotherapy naïve and one with patients whose tumors have progressed during or following an initial treatment with anti-PD1/PD-L1. Data from this trial is expected in the second half of 2019.
- **Huntington's Disease.** Our SIGNAL trial evaluating pepinemab for the treatment of Huntington's Disease remains on-track to complete enrollment of 258 patients in Cohort B by the end of 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 (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 combination study of VX15 (pepinemab) with avelumab in NSCLC
- Fourth quarter 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):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Revenue	$ 198	$ —	$ 530	$ —
Costs and expenses:				
Cost of revenue	246	—	732	—
Research and development	5,314	4,292	15,280	11,523
General and administrative	1,092	1,040	3,238	3,384
Total costs and expenses	6,652	5,332	19,250	14,907
Loss from operations	(6,454)	(5,332)	(18,720)	(14,907)
Change in fair value of derivative liabilities	31	157	369	(214)
Interest expense	(44)	(361)	(392)	(988)
Loss on extinguishment of related party convertible promissory note	(199)	—	(2,379)	—
Other income (expense), net	67	—	53	(23)
Loss before provision for income taxes	(6,599)	(5,536)	(21,069)	(16,132)
Provision for income taxes	—	—	—	—
Net loss	(6,599)	(5,536)	(21,069)	(16,132)
Net loss attributable to noncontrolling interests	—	—	—	—
Net loss attributable to Vaccinex, Inc.	$ (6,599)	$ (5,536)	$ (21,069)	$ (16,132)

Comparison of the Three Months Ended September 30, 2018 and 2017

Revenue and Cost of Revenue

The $0.2 million service revenue and $0.2 million cost of revenue during the three months ended September 30, 2018 was primarily due to recognition of deferred revenue and cost incurred for our collaboration agreements entered in 2017. There was no service revenue or cost of revenue during the three months ended September 30, 2017.

Operating Expenses

	Three Months Ended September 30,			
	2018	2017	$ Change	% Change
	(in thousands)			
Research and development	$ 5,314	$ 4,292	$ 1,022	24%
General and administrative	1,092	1,040	52	5%
Total operating expenses	$ 6,406	$ 5,332	$ 1,074	20%

Research and Development. Research and development expenses in the three months ended September 30, 2018 increased by $1.0 million, or 24%, compared to the three months ended September 30, 2017. This increase was attributable to the increase in patients enrolled in active clinical trials.

General and Administrative. General and administrative expenses in the three months ended September 30, 2018 was consistent with the three months ended September 30, 2017.

Change in fair value of derivative liabilities

	Three Months Ended September 30,			
	2018	2017	$ Change	% Change
	(in thousands)			
Change in fair value of derivative liabilities	$ 31	$ 157	$ (126)	(80)%

Change in fair value of derivative liabilities in the three months ended September 30, 2018 decreased $0.1 million, or 80%, compared to the three months ended September 30, 2017, as a result of the repayment of the $10.0 million of convertible promissory notes to a related party (the “January 2017 Notes”) and the $1.5 million convertible promissory note issued in June 2016 (the “June 2016 Note”) to a related party, Vaccinex (Rochester), L.L.C., during the nine months ended September 30, 2018.

Interest Expense

	Three Months Ended September 30,			
	2018	2017	$ Change	% Change
	(in thousands)			
Interest expense	$ (44)	$ (361)	$ (317)	(88)%

In January 2017, the Company entered into a convertible promissory note and agreement whereby it agreed to issue the January 2017 Notes. Interest expense in the three months ended September 30, 2018 decreased $0.3 million, or 88%, compared to the three months ended September 30, 2017, as a result of the repayment of the January 2017 Notes in March 2018 and the June 2016 Note in August 2018.

Comparison of the Nine Months ended September 30, 2018 and 2017

Revenue and Cost of Revenue

The $0.5 million service revenue and $0.7 million cost of revenue during the nine months ended September 30, 2018 was primarily due to recognition of deferred revenue and cost incurred for our collaboration agreements entered in December 31, 2017. There was no service revenue or cost of revenue during the nine months ended September 30, 2017.

Operating Expenses

	Nine Months Ended September 30,			
	2018	2017	$ Change	% Change
	(in thousands)			
Research and development	$ 15,280	$ 11,523	3,757	33%
General and administrative	3,238	3,384	(146)	(4)%
Total operating expenses	$ 18,518	$ 14,907	$ 3,611	24%

Research and Development. Research and development expenses in the nine months ended September 30, 2018 increased by $3.8 million, or 33%, compared to the nine months ended September 30, 2017. This increase was attributable to the increase in patients enrolled in active clinical trials.

General and Administrative. General and administrative expenses in the nine months ended September 30, 2018 decreased by $0.1 million, or 4%, compared to the nine months ended September 30, 2017. This decrease was primarily attributable to $0.2 million decrease in payroll related cost as a result of decrease in headcount and decreased legal fees as a result of decreased IP related applications and activities.

Change in Fair Value of Derivative Liabilities

	Nine Months Ended September 30,			
	2018	2017	$ Change	% Change
	(in thousands)			
Change in fair value of derivative liabilities	$ 369	$ (214)	$ 583	272%

Change in fair value of derivative liabilities in the nine months ended September 30, 2018 changed by $0.6 million, or 272%, compared to the nine months ended September 30, 2017. The change was primarily due to a decrease of $0.4 million in the fair value of derivative liabilities during the nine months ended September 30, 2018 associated with the repayment of the January 2017 Notes and the waiving of the option arrangement in March 2018, repayment of the June 2016 Note in August 2018, and an increase of $0.2 million in the fair value of derivative liabilities during the nine months ended September 30, 2017 as a result of increased conversion probability of the convertible promissory notes.

Interest Expense

	Nine Months Ended September 30,			
	2018	2017	$ Change	% Change
	(in thousands)			
Interest expense	$ (392)	$ (988)	$ (596)	(60)%

Interest expense in the nine months ended September 30, 2018 decreased $0.6 million, or 60%, compared to the nine months ended September 30, 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

	Nine Months Ended September 30,			
	2018	2017	$ Change	% Change
	(in thousands)			
Loss on extinguishment of related party convertible promissory note	$ (2,379)	$ —	$ (2,379)	(100)%

The $2.4 million loss on extinguishment of related party convertible promissory notes in the nine months ended September 30, 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 nine months ended September 30, 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 and funding from collaboration agreements with our variable interest entities. Through September 30, 2018, we have received net proceeds of $87.1 million from the issuance of shares of our preferred stock, $39.0 million from issuance of convertible promissory notes and $72.1 million from our variable interest entities.

In August 2018, we completed an initial public offering ("IPO") of our common stock. We received net proceeds of $37.2 million after deducting underwriting discounts and commissions of $2.8 million but before deducting offering costs of $2.7 million.

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 September 30, 2018 and December 31, 2017, our principal source of liquidity was cash and cash equivalents and marketable securities in the amount of $27.4 million and $4.2 million, respectively. We expect that our existing cash and cash equivalents and marketable securities will enable us to conduct our planned operations through the 3rd quarter of 2019.

Since our inception in 2001, we have incurred significant net losses and negative cash flows from operations. For the nine months ended September 30, 2018 and 2017, we reported a net loss of $21.0 million and $16.1 million, respectively. As of September 30, 2018 and December 31, 2017, we had an accumulated deficit of $208.2 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.

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 ("VX3"), received a commitment of $8.0 million of additional funding from FCMI Parent Co. ("FCMI Parent"), which was received in the first quarter, 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. 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. 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:

	Nine Months Ended September 30,	
	2018	2017
	(in thousands)	
Cash used in operating activities	$ (17,719)	$ (15,140)
Cash used in investing activities	(16,158)	(65)
Cash provided by financing activities	40,955	13,973

Operating Activities. We have historically experienced negative cash flows as we developed our product candidates and continued 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. 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 nine months ended September 30, 2018, operating activities used $17.7 million in cash, primarily as a result of our net loss of $21.1 million, aggregate non-cash items of $2.6 million, and $0.8 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 $0.4 million gain in fair value change of derivative liabilities, a $0.3 million amortization of debt discount related to the convertible promissory notes, $0.2 million depreciation expense and $0.1 of stock-based compensation expense. The net inflow change in our operating assets and liabilities was primarily the result of a $1.9 million increase in accrued liabilities mainly attributable to increased clinical trial related accruals, a $0.3 million increase in accounts payable due to increased clinical trial and initial public offering readiness activities, partially offset by a $0.3 million increase in accounts receivable, $0.9 million increase in prepaid and other current assets as we made payments for clinical trial related expense, and a $0.3 million decrease in deferred revenue as a result of the amortization of upfront payments from our collaboration agreements entered in 2017.

During the nine months ended September 30, 2017, operating activities used $15.1 million in cash, primarily as a result of our net loss of $16.1 million, aggregate non-cash items of $1.1 million, and $0.9 million net outflow change in our operating assets and liabilities. Non-cash items included a $0.9 million amortization of debt discount related to the convertible promissory notes, a $0.2 million loss in fair value of derivative liabilities, $152,000 depreciation expense and $249,000 of stock-based compensation expense. The net outflow change in our operating assets and liabilities was primarily the result of a $1.0 million increase in prepaid expense and other current assets.

Investing Activities. Cash used in investing activities during the nine months ended September 30, 2018 and 2017 of $16.2 million and $65,000, respectively, resulted from purchases of marketable securities and capital expenditures to purchase property and equipment.

Financing Activities. During the nine months ended September 30, 2018, financing activities provided $41.0 million consisting of proceeds from initial public offering of common stock, net of commissions and underwriting discounts of $37.1 million and the capital contribution from noncontrolling interests of $12.0 million partially offset by the $5.5 million in repayments of convertible promissory notes and payments of initial public offering costs of $2.7 million.

During the nine months ended September 30, 2017, financing activities provided $14.0 million primarily attributable to net proceeds of $6.0 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.

Convertible Promissory Notes

During the year ended December 31, 2017, we raised funds through the issuance of $10.0 million of convertible promissory 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.

The June 2016 Note, together with accrued interest, was convertible: (i) automatically upon a future qualifying financing event, which includes the sale of shares in a future preferred stock financing with gross proceeds of at least $5.0 million or the issuance of shares of common stock in an initial public offering; (ii) upon a change of control (unless the lenders elected to treat such event as a default); or (iii) upon a future non-qualifying financing event at the election of the lenders. Upon a future qualifying financing event, the outstanding principal, together with accrued interest, would convert into shares of the newly issued securities at 85% of the price paid in the financing. Upon the election to convert the June 2016 Note in the event of a change of control, the outstanding principal, together with accrued interest, would convert based on the conversion price of the Series C redeemable convertible preferred stock, which was $18.2 per share as of December 31, 2017, at the time of conversion. Upon the election to convert the June 2016 Note in the event of a non-qualifying financing event, the outstanding principal, together with accrued interest, would convert based on the lowest price per share paid for in the financing.

All of the convertible promissory notes were allowed to be prepaid, plus accrued interest if applicable, without penalty.

Capital Contributions from Noncontrolling Interests

In November 2017, we entered into a license agreement (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 VX15 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 VX15 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 VX15 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 (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 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 condensed consolidated financial statements for the nine months ended September 30, 2018.

Contractual Obligations

There were no significant changes to our contractual obligations described in our Prospectus dated August 9, 2018 (the "Prospectus") related to the Company's IPO, which was filed with the Securities and Exchange Commission (the "SEC") on August 10, 2018 pursuant to Rule 424(b) of the Securities Act of 1933, as amended, relating to the Company's Registration Statement on Form S-1 (File No. 333-226103).

Off-Balance Sheet Arrangements

We did not have any 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 condensed consolidated financial statements may not be comparable to companies that comply with public company effective dates.

Critical Accounting Policies and Estimates

Our condensed consolidated financial statements are prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of these condensed 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.

There have been no material changes to our critical accounting policies and significant judgments as compared to the critical accounting policies and estimates disclosed in the Prospectus.

Recent Accounting Pronouncements Not Yet Adopted

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

Recently Adopted Accounting Pronouncements

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

Item 3. 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 $11.3 and marketable securities of $16.1 as of September 30, 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 condensed 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 4. 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 September 30, 2018, the end of the period covered by this Form 10-Q. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of September 30, 2018, our disclosure controls and procedures were effective.

Changes in internal control over financial reporting

This report 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.

Part II - OTHER INFORMATION

Item 1. Legal Proceedings

We are not currently subject to any material legal proceedings.

Item 1A. Risk Factors

The Company operates in rapidly changing business environments which 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 Quarterly Report on Form 10-Q, 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 the Company is unaware of, or currently believes are not material, could have a material and adverse impact on our business, results of operations, financial condition and cash flows. If that were to happen, the trading price of our common stock could decline, and you could lose all or part of your investment.

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 year ended December 31, 2017 and for the nine months ended September 30, 2017 and 2018, we reported a net loss of $18.8 million, $16.1 million and $21.1 million, respectively. As of September 30, 2018, we had an accumulated deficit of $208.3 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, 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.

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. We believe our existing cash and cash equivalents and marketable securities will fund our projected operating requirements through the 3rd quarter of 2019. However, circumstances may cause us to consume capital 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.

If we need to secure additional financing, such 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.

Our ability to continue as a going concern will require us to obtain additional financing to fund our current operations, which may be unavailable on acceptable terms, or at all.

Our recurring net losses and negative cash flows from operations raise substantial doubt about our ability to continue as a going concern, as discussed in Note 1 to our consolidated financial statements as of and for the years ended December 31, 2017. 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, 2016 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.

We may have higher than anticipated tax liabilities, including related to our ability to use net operating loss ("NOL") 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 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 (the "Tax Act"), was signed into law. We are in the process of analyzing the Tax Act and its possible effects on us, including on our subsidiaries. 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.

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 Accounting Standards Codification 740 ("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, we revalued our U.S. deferred tax assets and liabilities due to the federal income tax rate reduction from 35% to 21%. Since we have provided a full valuation allowance against our deferred tax assets, the revaluation of the deferred tax assets did not have a material impact on any period presented. The ultimate impact of the income tax effects of the Tax Act may differ due to, among other things, additional analysis, changes in interpretations, and additional regulatory guidance that may be issued as a result of the Tax Act. The accounting is expected to be complete when our 2017 U.S. corporate income tax return is filed in 2018.

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, ("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 VX15, and if we had to cease developing VX15, it would have adverse effects on our business and future prospects.

VX15 is our most advanced product candidate, and we are focused on developing it for NSCLC and Huntington's disease. Additionally, in coordination with us, one IST is evaluating VX15 in osteosarcoma and another is studying VX15 in melanoma. We do not have control over trial design or conduct of investigator sponsored trials, which may identify adverse reactions associated with our product candidates. Any problems that arise in development of VX15 for one indication, or in one trial, may have an adverse effect on the development of VX15 for other indications and could cause us to cease development of VX15 altogether. Similarly, as part of our SEMA4D antibody platform strategy, we intend to also develop VX15 in additional neurodegenerative disease and cancer indications. Any adverse result or event that causes us to cease developing or limits our development of VX15 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 VX15 and in preclinical studies for VX15 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. Events which may result in a delay or failure in attaining successful completion of clinical development include:

- delays or failure in obtaining approval from institutional review boards ("IRBs"), or ethics committees ("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 ("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 ("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 ("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 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 products 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;
- 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 that obtains approval in the United States will be subject to ongoing scrutiny by the FDA. Violations of applicable requirements, including promotion of our 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 that 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 Attorney General 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 government 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 lose any marketing approval that we may have obtained, which would adversely affect our business, prospects and ability to achieve or sustain profitability.

One of the indications we are pursuing for our lead product candidate VX15 is for the treatment of Huntington's disease, and because there are no approved preventative 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 VX15 as a 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 products for the preventative treatment of Huntington's disease. Moreover, because we are seeking to develop a treatment for the prevention 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 intend to employ biomarkers as endpoints in our Phase 2 clinical trial, and we believe that the FDA will accept these biomarkers for purposes of our Phase 2 clinical trial. If we are to rely on these or other biomarkers for any future pivotal study, 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 product candidates over alternative treatments;
- the cost of treatment 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;
- relative convenience and ease of administration;
- 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, or safer, 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 VX15 in combination with other immunotherapies that we have observed in preclinical studies of VX15 in combination with the anti-CTLA-4 antibody ipilimumab.

Based on our preclinical research, we believe that the combination of VX15 with immunotherapeutic drugs, such as immune checkpoint inhibitors, could prove beneficial because VX15 promotes infiltration of immune cells into a tumor. As such, we believe VX15 could enhance the activity of other agents that increases peripheral immune responses. Most of the preclinical studies with respect to the combination of VX15 with immunotherapies have involved the anti-CTLA-4 antibody ipilimumab. The results of these studies showed that VX15 in combination with the CTLA-4checkpoint 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 VX15 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 VX15 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 VX15 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 VX15 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 VX15 for the treatment of various indications. We are currently focused on developing VX15 for the treatment of NSCLC and Huntington's disease. Additionally, in coordination with us, one investigator is studying VX15 in osteosarcoma and another is studying VX15 in melanoma, and in the future, we intend to pursue other indications for VX15. 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 VX15 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 immunotherapy 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. 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 (the "VA"), Federal Supply Schedule ("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 ("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 ("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 (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 there have been judicial and congressional challenges to certain aspects of the Affordable Care Act. 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 and regulatory changes under 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 2025 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 more rigorous coverage criteria and in additional downward pressure on 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 play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our future 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 our 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 False Claims Act imposes criminal and civil penalties, 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;

- 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 ("HIPAA"), imposes 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 Payments Sunshine Act, implemented as the Open Payments program, requires certain 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 within the U.S. Department of Health and Human Services information related to payments or other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by physicians (as defined above) and their immediate family members; 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.

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 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 terminate, we may not be able to enter into arrangements with alternative CROs or to do so on commercially reasonable terms.

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 ("Catalent"), manufactures VX15 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 ("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;
- 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 parties 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 (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 VX15 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 (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 market price of our stock may be volatile, and you could lose all or part of your investment.

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 develop or 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 principal stockholders and management own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval.

Prior to our IPO, our executive officers and directors and their respective affiliates beneficially owned approximately 64.6% of our outstanding voting stock, including Albert D. Friedberg, our Chairman, who beneficially owned 47.8% of our outstanding voting stock, including 42.6% of our outstanding voting stock beneficially owned by FCMI Parent. Upon completion of our IPO, with Mr. Friedberg's affiliates having purchased $29.5 million in shares of our common stock in the offering at the initial offering price, that same group and Mr. Friedberg beneficially own approximately 72.8% and 62.0% (of which 54.5% is beneficially owned by FCMI Parent), respectively, of our outstanding voting stock (assuming beneficial ownership is calculated in the same manner as set forth in the section entitled "Principal Stockholders" beginning on page 140 of the Prospectus).

As a result, these stockholders will 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 that you may feel are in your best interest as one of our stockholders. The interests of this group of stockholders may not always coincide with your interests or 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.

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 (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 ("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 you 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.

We incur significant costs as a result of operating as a public company, and our management is required to devote substantial time to meet compliance obligations.

As a public company, we will incur significant legal, accounting and other expenses that we did not incur as a private company. We are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act and the Dodd-Frank Act, as well as rules subsequently implemented thereunder by the SEC and Nasdaq, which will result in significant initial costs to us as well as ongoing increases in our legal, audit and financial compliance costs, particularly after we are no longer an "emerging growth company." Additionally, these laws, regulations and standards are subject to varying interpretations and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies.

Our management and other personnel will need to devote a substantial amount of time to compliance initiatives, which may divert their attention from revenue-generating activities. Moreover, we expect these rules and regulations to substantially increase our legal and financial compliance costs and to make some activities more time-consuming and costly. These costs may increase our consolidated net loss. For example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance, and we may be required to incur substantial costs to maintain sufficient coverage. We cannot predict or estimate the amount or timing of additional costs we may incur to respond to these requirements. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers. Any changes that we make to comply with these obligations may not be sufficient to allow us to satisfy our obligations as a public company on a timely basis, or at all.

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 (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 2. Unregistered Sales of Equity Securities and Use of Proceeds

Use of Proceeds

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. There have been no material changes in the planned use of proceeds as described in the Registration Statement.

Item 6. Exhibits

INDEX TO EXHIBITS

Exhibit No.	Description
3.1	Amended and Restated Certificate of Incorporation of Vaccinex, Inc., is incorporated herein by reference from Exhibit 3.1 to the Company's Current Report on Form 8-K (File No. 001-38624)
3.2	Amended and Restated Bylaws of Vaccinex, Inc., is incorporated herein by reference from Exhibit 3.2 to the Company's Current Report on Form 8-K (File No. 001-38624)
31.1*	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2*	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1*	Certification of Chief Executive Officer and Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, 18 U.S.C. Section 1350
101*	The following items from this Quarterly Report on Form 10-Q formatted in Extensible Business Reporting Language: (i) Condensed Consolidated Balance Sheets (unaudited), (ii) Condensed Consolidated Statements of Operations (unaudited), (iii) Consolidated Statements of Redeemable Convertible Preferred Stock and Stockholders' Deficit (unaudited), (iv) Condensed Consolidated Statements of Cash Flows (unaudited), and (v) Notes to Condensed Consolidated Financial Statements

* Filed herewith.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Vaccinex, Inc.
(Registrant)

November 13, 2018 By: /s/ Maurice Zauderer
Maurice Zauderer, Ph.D.
President & Chief Executive Officer
(Principal Executive Officer)

November 13, 2018 By: /s/ Scott E. Royer
Scott E. Royer, CFA, MBA
Chief Financial Officer
(Principal Financial Officer)

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 quarterly report on Form 10-Q for the three months ended September 30, 2018 for 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)) 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. 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

    c. 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: November 13, 2018

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 quarterly report on Form 10-Q for the three months ended September 30, 2018 for 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)) 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. 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

   c. 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: November 13, 2018

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 quarterly report of Vaccinex, Inc., (the "Company") on Form 10-Q for the quarter ended September 30, 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: November 13, 2018

By: /s/ Maurice Zauderer

Maurice Zauderer, Ph.D.
President and Chief Executive Officer

Dated: November 13, 2018

By: /s/ Scott E. Royer

Scott E. Royer
Chief Financial Officer