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

FORM 10-Q

(Mark One)
☑ QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended March 31, 2018

OR

o 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: 001-35285

Vaxart, Inc.
(Exact Name of Registrant as Specified in its Charter)

Delaware	**59-1212264**
(State or other jurisdiction of incorporation or organization)	(IRS Employer Identification No.)

290 Utah Ave., Suite 200, South San Francisco, CA	**94080**
(Address of principal executive offices)	(Zip Code)

(650) 550-3500
(Registrant's telephone number, including area code)

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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted 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 and post such files). Yes ☑ No ☐

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

Large accelerated filer ☐	Accelerated filer ☐
Non-accelerated filer ☐ (Do not check if a smaller reporting company)	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. o

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes o No ☑

The Registrant had 7,141,189 shares of common stock, $0.10 par value, outstanding as of May 11, 2018.

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FOR THE QUARTER ENDED MARCH 31, 2018
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PART I FINANCIAL INFORMATION

Item 1. Financial Statements (Unaudited)

VAXART, INC. AND SUBSIDIARIES

Condensed Consolidated Balance Sheets
(In thousands, except share and per share amounts)

	March 31, 2018 (Unaudited)	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	$ 17,495	$ 1,571
Short-term investments	—	1,415
Accounts receivable, net of allowance	13,349	630
Prepaid expenses and other current assets	1,052	137
Total current assets	31,896	3,753
Property and equipment, net	1,014	730
Intangible assets, net	23,627	40
Total assets	$ 56,537	$ 4,523
Liabilities and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 1,744	$ 1,390
Current portion of secured promissory note payable to Oxford Finance	1,667	1,528
Short-term note payable	214	—
Liability related to sale of future royalties, current portion	2,037	—
Other accrued liabilities	2,139	1,605
Total current liabilities	7,801	4,523
Convertible promissory notes, long-term, related parties	—	35,282
Liability related to sale of future royalties, net of current portion	14,561	—
Secured promissory note payable to Oxford Finance, net of current portion	3,069	3,440
Total liabilities	25,431	43,245
Commitments and contingencies (Note 10)		
Stockholders' equity (deficit):		
Preferred Stock: $0.10 par value; 5,000,000 shares authorized; none issued and outstanding as of March 31, 2018; 1,221,064 issued and outstanding as of December 31, 2017, with aggregate liquidation value of $39,956	—	1
Common Stock: $0.10 par value; 200,000,000 shares authorized; 7,141,189 and 138,492 shares issued and outstanding as of March 31, 2018 and December 31, 2017, respectively	714	—
Additional paid-in capital	108,060	41,259
Accumulated deficit	(77,668)	(79,982)
Total stockholders' equity (deficit)	31,106	(38,722)
Total liabilities and stockholders' equity (deficit)	$ 56,537	$ 4,523

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

VAXART, INC. AND SUBSIDIARIES

Condensed Consolidated Statements of Operations and Comprehensive Income (Loss)
(In thousands, except share and per share amounts)
(Unaudited)

	Three Months Ended March 31,	
	2018	2017
Revenue:		
Revenue from government contract	$ 610	$ 2,310
Royalty revenue	893	—
Total revenue	1,503	2,310
Operating expenses:		
Research and development	3,408	3,879
General and administrative	2,010	678
Total operating expenses	5,418	4,557
Operating loss	(3,915)	(2,247)
Other income and (expenses):		
Bargain purchase gain	6,988	—
Interest income	5	13
Interest expense	(437)	(744)
Non-cash interest expense on liability related to sale of future royalties	(298)	—
(Loss) gain on revaluation of financial instruments	(3)	182
Foreign exchange gain, net	2	—
Total other income and (expenses)	6,257	(549)
Net income (loss) before income taxes	2,342	(2,796)
Provision for income taxes	28	—
Net income (loss)	2,314	(2,796)
Series B and C preferred dividend	(339)	(710)
Net comprehensive income (loss) attributable to common stockholders	$ 1,975	$ (3,506)
Net income (loss) per share – basic	$ 0.54	$ (25.84)
Net income (loss) per share - diluted	$ 0.49	$ (25.84)
Shares used to compute net income (loss) per share - basic	3,656,360	135,658
Shares used to compute net income (loss) per share - diluted	5,299,751	135,658

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

Condensed Consolidated Statement of Stockholders' Equity (Deficit)
(In thousands, except share amounts)
(Unaudited)

	Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' (Deficit) Equity
	Shares	Amount	Shares	Amount			
Balances as of January 1, 2018	1,221,064	$ 1	138,492	$ —	$ 41,259	$ (79,982)	$ (38,722)
Issuance of common stock upon conversion of convertible promissory notes, related parties	—	—	1,571,702	157	35,420	—	35,577
Issuance of common stock upon conversion of convertible preferred stock	(1,221,064)	(1)	1,918,543	192	(191)	—	—
Reclassification of warrant to equity	—	—	—	—	70	—	70
Issuance of common stock upon reverse merger	—	—	3,510,439	365	31,403	—	31,768
Issuance of common stock upon exercise of stock options	—	—	2,013	—	13	—	13
Stock-based compensation	—	—	—	—	86	—	86
Net income	—	—	—	—	—	2,314	2,314
Balances as of March 31, 2018	—	$ —	7,141,189	$ 714	$ 108,060	$ (77,668)	$ 31,106

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

VAXART, INC. AND SUBSIDIARIES

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

	Three Months Ended March 31,	
	2018	2017
Cash flows from operating activities:		
Net income (loss)	$ 2,314	$ (2,796)
Adjustments to reconcile net income (loss) to net cash used in operating activities:		
Bargain purchase gain	(6,988)	—
Depreciation and amortization	511	97
Stock-based compensation	86	124
Amortization of discount on short-term investments	—	5
Loss (gain) on revaluation of financial instruments	3	(181)
Non-cash interest expense	323	651
Amortization of note discount	18	36
Non-cash interest expense related to sale of future royalties	298	—
Change in operating assets and liabilities:		
Accounts receivable, net of allowance	1,947	(770)
Prepaid expenses and other assets	(469)	(187)
Accounts payable	(3,097)	(1,424)
Accrued liabilities	(5,536)	169
Net cash used in operating activities	(10,590)	(4,276)
Cash flows from investing activities:		
Purchase of property and equipment	(140)	(79)
Cash acquired in reverse merger	25,525	—
Cash paid for fractional shares in merger	(21)	—
Purchases of short-term investments	(573)	(4,430)
Proceeds from maturities of short-term investments	1,988	3,665
Net cash provided by (used in) investing activities	26,779	(844)
Cash flows from financing activities:		
Repayment of principal on secured promissory note payable to Oxford Finance	(278)	—
Proceeds from issuance of common stock upon exercise of stock options	13	—
Net cash used in financing activities	(265)	—
Net increase (decrease) in cash and cash equivalents	15,924	(5,120)
Cash and cash equivalents at beginning of the period	1,571	8,405
Cash and cash equivalents at end of the period	$ 17,495	$ 3,285

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

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

	Three Months Ended March 31,	
	2018	2017
Supplemental disclosure of cash flow information:		
Interest paid	$ 95	$ 57

Supplemental disclosure of non-cash financing activity:		
Issuance of common stock upon reverse merger, net of cash paid for partial shares	$ 31,768	$ —
Conversion of convertible promissory notes, related parties into common stock upon reverse merger	$ 35,577	$ —
Reclassification of convertible preferred stock warrant liability to equity	$ 70	$ —
Acquisition of property and equipment included in accounts payable	$ 72	$ —

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

VAXART, INC. AND SUBSIDIARIES

Notes to the Condensed Consolidated Financial Statements (Unaudited)

NOTE 1. Organization and Basis of Presentation

General

Vaxart Biosciences, Inc. was originally incorporated in California in March 2004, under the name West Coast Biologicals, Inc. The Company changed its name to Vaxart, Inc. ("Private Vaxart") in July 2007, and reincorporated in the state of Delaware.

On February 13, 2018, Private Vaxart completed a business combination with Aviragen Therapeutics, Inc. ("Aviragen"), pursuant to which Aviragen merged with Private Vaxart, with Private Vaxart surviving as a wholly-owned subsidiary of Aviragen (the "Merger"). Pursuant to the terms of the Merger, Aviragen changed its name to Vaxart, Inc. (together with its subsidiaries, the "Company" or "Vaxart") and Private Vaxart changed its name to Vaxart Biosciences, Inc. All of Private Vaxart's convertible promissory notes and convertible preferred stock was converted into common stock, following which each share of common stock was converted into approximately 0.22148 shares of the Company's common stock (the "Conversion"). Except as otherwise noted in these Financial Statements, all shares, equity securities and per share amounts of Private Vaxart are presented to give retroactive effect to the Conversion.

Immediately following the completion of the Merger, the Company effected a reverse stock split at a ratio of one new share for every eleven shares of the Company's common stock outstanding (the "Reverse Stock Split"). Except as otherwise noted in these Financial Statements, all share, equity security and per share amounts are presented to give retroactive effect to the Reverse Stock Split.

Immediately after the Reverse Stock Split there were approximately 7.1 million shares of the Company's common stock outstanding. Private Vaxart's stockholders, warrantholders and optionholders owned approximately 51% of the fully-diluted common stock of the Company, with Aviragen's stockholders and optionholders immediately prior to the Merger owning approximately 49% of the fully-diluted common stock of the Company. The Company also assumed all of Private Vaxart's outstanding stock options and warrants with proportionate adjustments to the number of underlying shares and exercise prices based on an exchange ratio, based on the combined impact of the Conversion and the Reverse Stock Split, of approximately 0.0201346 shares of the Company for each share of Private Vaxart.

The Company's principal operations are based in South San Francisco, California, and it operates in one reportable segment, which is the discovery and development of oral recombinant protein vaccines, based on its proprietary oral vaccine platform, and small-molecule antiviral drugs.

Liquidity and Going Concern

Since incorporation, the Company has been involved primarily in performing research and development activities, hiring personnel, and raising capital to support these activities. The Company has experienced losses and negative cash flows from operations since its inception. As of March 31, 2018, the Company had an accumulated deficit of $77.7 million and a loan with an outstanding balance of $4.7 million from Oxford Finance, LLC ("Oxford Finance"), repayable in monthly installments by the end of 2020 (see Note 9).

The Company expects to incur increasing costs as research and clinical trials are advanced and, therefore, expects to continue to incur losses and negative operating cash flows for the next several years. Absent additional funding or adjustments to currently planned operating activities, and in view of the uncertainties regarding future royalty revenue on sales of Relenza® and Inavir®, management believes that the Company's cash, cash equivalents and short-term investments, together with funds acquired from Aviragen through the Merger, are only sufficient to fund the Company into the first quarter of 2019.

The Company reviews its operations and clinical plans on a continuing basis and has not yet entered into any commitments for its upcoming clinical trials. The Company plans to finance its operations with royalty revenue on sales of Relenza® and Inavir®, additional equity or debt financing arrangements, revenue from its contract with the Department of Health and Human Services, Office of Biomedical Advanced Research and Development Authority ("HHS BARDA"), and potentially with additional funding from government contracts or strategic alliances with partner companies. The availability and amount of such funding is not certain.

The uncertainties inherent in the Company's future operations and in its ability to obtain additional funding raise substantial doubt about its ability to continue as a going concern beyond one year from the date these financial statements are issued. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

While management believes its plan to raise additional funds will alleviate the conditions that raise substantial doubt, these plans are not entirely within its control and cannot be assessed as being probable of occurring. If adequate funds are not available, the Company may be required to reduce operating expenses, delay or reduce the scope of its product development programs, obtain funds through arrangements with others that may require the Company to relinquish rights to certain of its technologies or products that the Company would otherwise seek to develop or commercialize itself, or cease operations.

NOTE 2. Summary of Significant Accounting Policies

Basis of Presentation – The Company has prepared the accompanying condensed consolidated financial statements pursuant to the rules and regulations of the Securities and Exchange Commission ("SEC"). Certain information and footnote disclosures normally included in consolidated financial statements prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP") have been condensed or omitted pursuant to these rules and regulations. These condensed consolidated financial statements should be read in conjunction with the audited financial statements of Vaxart Biosciences, Inc. and footnotes related thereto for the year ended December 31, 2017, included in our Form 8-K/A filed with the SEC on April 2, 2018. In the opinion of management, the unaudited condensed consolidated financial statements include all adjustments (consisting only of normal recurring adjustments) necessary to present fairly the Company's financial position and the results of its operations and cash flows. The results of operations for such interim periods are not necessarily indicative of the results to be expected for the full year.

Basis of Consolidation – The condensed consolidated financial statements include the financial statements of Vaxart, Inc. and its subsidiaries. All significant transactions and balances between Vaxart, Inc. and its subsidiaries have been eliminated in consolidation.

Use of Estimates – 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, liabilities, revenues and expenses and disclosure of contingent assets and liabilities in the financial statements and accompanying notes. Actual results and outcomes could differ from these estimates and assumptions.

Foreign Currencies – Foreign exchange gains and losses for assets and liabilities of the Company's non-U.S. subsidiaries for which the functional currency is the U.S. dollar are recorded in foreign exchange gain (loss), net in the Company's statement of operations and comprehensive income (loss). The Company has no subsidiaries for which the local currency is the functional currency.

Cash and Cash Equivalents – The Company considers all highly liquid debt investments with an original maturity of three months or less when purchased to be cash equivalents. Cash equivalents, which may consist of amounts invested in money market funds, corporate bonds and commercial paper, are stated at fair value.

Short-Term Investments – The Company's short term investments have only comprised commercial paper and corporate bonds. The short term investments are classified as held to maturity based on the Company's positive intent and ability to hold the securities to maturity. This classification is reevaluated at each balance sheet date. Short term investments are stated at amortized cost, adjusted for amortization of premiums and accretion of discounts to maturity. Such amortization is presented as interest income in the statement of operations and comprehensive income (loss). The specific identification method is used to determine the realized gain or loss on securities sold or otherwise disposed. When the fair value of a debt security classified as held to maturity is less than its amortized cost, the Company assesses whether or not: (i) it has the intent to sell the security or (ii) it is more likely than not that the Company will be required to sell the security before its anticipated recovery. If either of these conditions is met, the Company must recognize an other than temporary impairment through earnings for the difference between the debt security's amortized cost basis and its fair value. Gains and losses are recognized in earnings when the investments are sold or impaired.

Concentration of Credit Risk – Financial instruments that potentially subject the Company to significant concentrations of credit risk consist principally of cash, cash equivalents, short-term investments and accounts receivable. The Company places its cash, cash equivalents and shortterm investments at financial institutions that management believes are of high credit quality. The Company is exposed to credit risk in the event of default by the financial institutions holding the cash and cash equivalents to the extent such amounts are in excess of the federally insured limits. The Company has not experienced any losses on its deposits since inception.

The primary focus of the Company's investment strategy is to preserve capital and meet liquidity requirements. The Company's investment policy addresses the level of credit exposure by limiting the concentration in any one corporate issuer or sector and establishing a minimum allowable credit rating. The Company generally requires no collateral from its customers.

Accounts Receivable – Accounts receivable arise from the Company's royalty revenue receivable for sales, net of estimated returns, of Inavir® and Relenza®, and from its contract with HHS BARDA (see Note 6), and are reported at amounts expected to be collected in future periods. An allowance for uncollectible accounts will be recorded based on a combination of historical experience, aging analysis, and information on specific accounts, with related amounts not recorded as a reserve against revenue recognized. Account balances will be written off against the allowance after all means of collection have been exhausted and the potential for recovery is considered remote.

Property and Equipment – Property and equipment is carried at cost less accumulated depreciation. Depreciation is computed using the straight-line method over the estimated useful lives of the respective assets. Depreciation begins at the time the asset is placed in service. Maintenance and repairs are charged to operations as incurred. Upon sale or retirement of assets, the cost and related accumulated depreciation are removed from the balance sheet and the resulting gain or loss is reflected in other income and (expenses) in the period realized.

The useful lives of the property and equipment are as follows:

Laboratory equipment	5 years
Office and computer equipment	3 years
Leasehold improvements	Shorter of remaining lease term or estimated useful life

Intangible Assets – Intangible assets comprise developed technology, in-process research and development and intellectual property and are carried at cost less accumulated amortization. Amortization is computed using the straight-line method over useful lives ranging from 1.3 to 11.75 years for developed technology and 20 years for intellectual property. In-process research and development is considered to be indefinite-lived and is not amortized.

Impairment of Long-Lived Assets – The Company reviews its long lived assets, including property and equipment and intangible assets, for impairment whenever events or changes in circumstances indicate the carrying amount of these assets may not be recoverable. Recoverability of these assets is measured by comparison of the carrying amount of each asset to the future undiscounted cash flows the asset is expected to generate over its remaining life. When indications of impairment are present and the estimated undiscounted future cash flows from the use of these assets is less than the assets' carrying value, the related assets will be written down to fair value. There have been no impairments of the Company's long lived assets for the periods presented.

Accrued Clinical and Manufacturing Expenses – The Company accrues for estimated costs of research and development activities conducted by third party service providers, which include the conduct of preclinical studies and clinical trials, and contract manufacturing activities. The Company records the estimated costs of research and development activities based upon the estimated amount of services provided but not yet invoiced and includes these costs within other accrued liabilities in the balance sheets and within research and development expense in the condensed consolidated statements of operations and comprehensive income (loss). These costs are a significant component of the Company's research and development expenses.

The Company estimates the amount of services provided through discussions with internal personnel and external service providers as to the progress or stage of completion of the services and the agreed-upon fee to be paid for such services. The Company makes significant judgments and estimates in determining the accrued balance in each reporting period. As actual costs become known, it adjusts its accrued estimates. Although the Company does not expect its estimates to be materially different from amounts actually incurred, its understanding of the status and timing of services performed, the number of subjects enrolled, and the rate of enrollment may vary from its estimates and could result in the Company reporting amounts that are too high or too low in any particular period. The Company's accrued expenses are dependent, in part, upon the receipt of timely and accurate reporting from contract research organizations and other third-party service providers. To date, the Company has not experienced any material differences between accrued costs and actual costs incurred.

Convertible Preferred Stock Warrant Liability – The Company has issued certain convertible preferred stock warrants. These warrants were recorded within other accrued liabilities in the balance sheets at fair value due to down round protection features contained in the convertible preferred stock into which the warrants are exercisable. At the end of each reporting period, changes in fair value of the warrants since the prior period were recorded as a component of gain (loss) on revaluation of financial instruments in the condensed consolidated statements of operations and comprehensive income (loss). In the event that the terms of the warrant change such that liability accounting is no longer required, the fair value on the date of such change is released to equity.

Convertible Promissory Notes Embedded Derivative Liability – The Company recorded derivative instruments related to redemption features embedded within the outstanding convertible promissory notes. The embedded derivatives were accounted for as liabilities at their estimated fair value when the convertible promissory notes were issued and were re measured to fair value as of each balance sheet date, with the related re-measurement adjustment being recognized as a component of gain (loss) on revaluation of financial instruments in the condensed consolidated statements of operations and comprehensive income (loss).

Revenue Recognition – The Company recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the Company expects to receive in exchange for those goods or services. To determine revenue recognition, the Company performs the following five steps:

(i) identification of the promised goods or services in the contract;

(ii) determination of whether the promised goods or services are performance obligations including whether they are distinct in the context of the contract;

(iii) measurement of the transaction price, including the constraint on variable consideration;

(iv) allocation of the transaction price to the performance obligations based on estimated selling prices; and

(v) recognition of revenue when (or as) the Company satisfies each performance obligation. A performance obligation is a promise in a contract to transfer a distinct good or service to the customer and is the unit of account.

Revenue from royalties earned as a percentage of sales, including milestone payments based on achieving a specified level of sales, where a license is deemed to be the predominant item to which the royalties relate, is recognized as revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied).

The Company performs research and development work under its cost plus fixed fee contract with HHS BARDA. The Company recognizes revenue under research contracts only when a contract has been executed and the contract price is fixed or determinable. Revenue from the HHS BARDA contract is recognized in the period during which the related costs are incurred and the related services are rendered, provided that the applicable conditions under the contract have been met. Costs of contract revenue are recorded as a component of operating expenses in the condensed consolidated statements of operations and comprehensive income (loss).

Under the cost reimbursable contract with HHS BARDA, the Company is reimbursed for allowable costs, and recognizes revenue as allowable costs are incurred and the fixed fee is earned. Reimbursable costs under the contract primarily include direct labor, subcontract costs, materials, equipment, travel, and approved overhead and indirect costs. Fixed fees under cost reimbursable contracts are earned in proportion to the allowable costs incurred in performance of the work relative to total estimated contract costs, with such costs incurred representing a reasonable measurement of the proportional performance of the work completed. Under the HHS BARDA contract, certain activities must be pre approved in order for their costs to be deemed allowable direct costs. The HHS BARDA contract provides the U.S. government the ability to terminate the contract for convenience or to terminate for default if the Company fails to meet its obligations as set forth in the statement of work.

Management believes that if the government were to terminate the HHS BARDA contract for convenience, the costs incurred through the effective date of such termination and any settlement costs resulting from such termination would be allowable costs. Payments to the Company under cost reimbursable contracts, such as this contract, are provisional payments subject to adjustment upon annual audit by the government. Management believes that revenue for periods not yet audited has been recorded in amounts that are expected to be realized upon final audit and settlement. When the final determination of the allowable costs for any year has been made, revenue and billings may be adjusted accordingly in the period that the adjustment is known.

Research and Development Costs – Research and development costs are expensed as incurred. Research and development costs consist primarily of salaries and benefits, stock based compensation, consultant fees, third party costs for conducting clinical trials and the manufacture of clinical trial materials, certain facility costs and other costs associated with clinical trials. Payments made to other entities are under agreements that are generally cancelable by the Company. Advance payments for research and development activities are recorded as prepaid expenses. The prepaid amounts are expensed as the related services are performed.

Stock-Based Compensation – The Company measures the fair value of all stock-based awards to employees, including stock options, on the grant date and records the fair value of these awards, net of estimated forfeitures, to compensation expense over the service period. The fair value of awards to nonemployees is measured on the date of performance at the fair value of the consideration received or the fair value of the equity instruments issued, whichever is more reliably measured. The fair value of options is estimated using the Black-Scholes valuation model.

Net Income (Loss) Per Share Attributable to Common Stockholders – Basic net income (loss) per share is computed by dividing net income (loss) by the weighted average number of common shares outstanding during the period, without consideration of potential common shares. The net loss attributable to common stockholders is calculated by adjusting the net loss of the Company for the cumulative dividends on the Series B and Series C convertible preferred stock.

Diluted net income (loss) per common share is computed giving effect to all potential dilutive common shares, comprising common stock issuable upon exercise of stock options and warrants. The Company uses the treasury-stock method to compute diluted income (loss) per share with respect to its stock options and warrants. For purposes of this calculation, options and warrants to purchase common stock are considered to be potential common shares and are only included in the calculation of diluted net loss per share when their effect is dilutive. In the event of a net loss, the effects of all potentially dilutive shares are excluded from the diluted net loss per share calculation as their inclusion would be antidilutive.

Recently Adopted Accounting Pronouncements

In May 2017, the FASB issued ASU 2017-09, *Compensation - Stock Compensation (Topic 718): Scope of Modification Accounting.* This update provides guidance about which changes to the terms or conditions of a share-based payment award require an entity to apply modification accounting in Topic 718. This guidance is effective for annual periods beginning after December 15, 2017, including interim periods within that year, and must be applied prospectively to an award modified on or after the adoption date. The Company adopted this standard effective January 1, 2018, and its adoption had no effect on the Company's financial condition or results of operations.

In January 2017, the FASB issued ASU No. 2017 04 , *Intangibles Goodwill and Other (Topic 350) Simplifying the Test for Goodwill Impairment* ("ASU 2017 04"), which will simplify the goodwill impairment calculation by eliminating Step 2 from the current goodwill impairment test. The new standard does not change how a goodwill impairment is identified. The standard will be effective January 1, 2020, with early adoption permitted, and is to be applied prospectively from the date of adoption. The Company adopted this standard effective January 1, 2018, and its adoption had no effect on the Company's financial condition or results of operations.

In January 2017, the FASB issued ASU No. 2017 01, *Business Combinations (Topic 805) Clarifying the Definition of a Business* ("ASU 2017 01"), which will simplify the goodwill impairment calculation by eliminating Step 2 from the current goodwill impairment test. The new standard clarifies the definition of a business to help companies evaluate whether acquisition or disposal transactions should be accounted for as asset groups or as businesses. The Company adopted this standard when it became effective on January 1, 2018, and its adoption had no effect on the Company's financial condition or results of operations, although it was applied in the Company's determination that the Merger should be accounted for as a business combination.

In August 2016, the FASB issued Accounting Standards Update (ASU) 2016-15, *Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments*, which provides additional guidance on the presentation and classification of certain items in the statement of cash flows. The standard is effective for fiscal years beginning after December 15, 2017, with early adoption permitted. The Company adopted this standard effective January 1, 2018, and its adoption had no effect on the Company's financial condition or results of operations.

In May 2014, the FASB issued ASU 2014 09, *Revenue from Contracts with Customers (Topic 606)*, which supersedes nearly all existing revenue recognition guidance under Topic 605, *Revenue Recognition*. The new standard requires a company to recognize revenue when it transfers goods and services to customers in an amount that reflects the consideration that the company expects to receive for those goods or services. ASU 2014 09 defines a five step process that includes identifying the contract with the customer, identifying the performance obligations in the contract, determining the transaction price, allocating the transaction price to the performance obligations in the contract and recognizing revenue when (or as) the entity satisfies the performance obligations. In July 2015, the FASB approved a one year deferral of the effective date of the new standard to 2018 for public companies, with an option that would permit companies to adopt the new standard as early as the original effective date of 2017.

The Company has determined that its HHS BARDA government contract is not within the scope of ASU 2014-09 as the government entity is not a customer under the agreement. The Company adopted this standard with respect to its royalty revenue using the modified retrospective method on January 1, 2018. Under the modified retrospective transition method, the cumulative effect of applying the standard is recognized at the date of initial application for all contracts not completed as of the date of adoption. The adoption of ASU 2014 09 did not have any effect on the Company's financial condition or results of operations and therefore no cumulative effect adjustment was recorded, although the Company has modified its accounting policies to reflect the requirements of this standard and make additional disclosures.

Recent Accounting Pronouncements

In February 2016, the FASB issued ASU 2016 02 *Leases (Topic 842)*, which replaces most current lease guidance when it becomes effective. This standard update intends to increase the transparency and improve comparability by requiring entities to recognize assets and liabilities on the balance sheet for all leases, with certain exceptions. The new standard states that a lessee will recognize a lease liability for the obligation to make lease payments and a right-of-use asset for the right to use the underlying asset for the lease term. Leases will be classified as either finance or operating, with classification affecting the pattern of expense recognition in the statements of operations. The new guidance will be effective for the Company starting in the first quarter of fiscal 2019, with early adoption permitted. The Company plans to adopt the new guidance effective January 1, 2019, using the modified retrospective method. The adoption will have no impact on the Company's statements of operations or cash flows but will increase both its reported assets and reported liabilities in equal amounts that have not yet been quantified.

The Company has reviewed all other significant newly-issued accounting pronouncements and concluded that they either are not applicable to the Company's operations or no material effect is expected on its condensed consolidated financial statements as a result of future adoption.

NOTE 3. Business Combination

On February 13, 2018, the Company acquired Aviragen in a reverse merger (see Note 1). Aviragen presently has in-process research and development as it is currently conducting a Phase 2 trial, it has previously developed drugs that were licensed to others who brought them to market and it has a workforce that is considered to have the necessary skills, knowledge, and experience to perform a process, that when applied to the in-process research and development is critical to the ability to convert it into outputs. Based on this evaluation, the Company determined that the Merger should be accounted for as a business combination.

Since the date of the Merger, the results of Aviragen's operations have been included in the condensed consolidated financial statements. As a result of the acquisition, the Company eliminated the majority of its debt and acquired a significant cash balance in exchange for equity securities.

The total purchase price for Aviragen is summarized as follows (in thousands):

Common stock	$	31,789
Total	$	31,789

In connection with the Aviragen acquisition, the Company allocated the total purchase consideration to the net assets and liabilities acquired, including identifiable intangible assets, based on their respective fair values at the acquisition date.

The following table summarizes the preliminary allocation of the purchase price to the fair value of the respective assets and liabilities acquired (in thousands):

Cash and cash equivalents	$ 25,525
Accounts receivable	14,666
Prepaid expenses	446
Property and equipment	170
Intangible assets:	
Developed technology (1)	22,400
In-process research and development (2)	1,600
Total assets	64,807
Accounts payable	(3,379)
Other current liabilities	(6,351)
Liability related to sale of future royalties	(16,300)
Net assets acquired	38,777
Purchase price	(31,789)
Bargain purchase gain (3)	$ 6,988

(1) Developed technology comprises Inavir® and Relenza®, both influenza vaccines on which the Company is presently receiving royalty revenue, which, based on preliminary valuations, are being amortized on a straight-line basis over the estimated periods of future royalties of 11.75 and 1.3 years, respectively.

(2) In-process research and development relates to teslexivir, or BTA074, a direct-acting antiviral that is being developed as a treatment for genital warts and is presently undergoing Phase 2 clinical trials. The preliminary valuation was prepared by an independent third party based on estimated discounted cash flows based on probability-weighted future development expenditures and revenue streams provided by the Company's management.

(3) The bargain purchase gain represents the excess of a preliminary valuation of the fair value of tangible and identified intangible assets, less liabilities, acquired over the purchase price.

In addition, the Company incurred and expensed costs directly related to the Merger totaling approximately $1.4 million, of which approximately $0.5 million was incurred in the three months ended March 31, 2018, and is included in general and administrative expenses in the condensed consolidated statement of operations and comprehensive income (loss). The Company is in the process of gathering the information necessary to evaluate the tax impact of the acquisition, including the treatment of the bargain purchase gain, and to finalize the discount rate and underlying assumptions utilized in the valuation of the intangible assets acquired. The Company expects to complete its evaluation of the impact, if any, during fiscal 2018.

Selected amounts related to Aviragen's business included in the Company's condensed consolidated statement of operations for the three months ended March 31, 2018, are as follows:

Revenue	$ 893,000
Net loss	$ (362,000)

The unaudited pro forma information in the table below summarizes the combined results of operations of Vaxart Biosciences, Inc. with those of Aviragen as though these entities were combined as of January 1, 2017. The results of Aviragen's business for the three months ended March 31, 2017, are based on the actual unaudited financial statements prepared for the three months ended March 31, 2017, and for the three months ended March 31, 2018, are based on the Company's results of operations, increased by Aviragen's activities in the forty-three days prior to the closing of the Merger. The pro forma financial information for all periods presented also includes the removal of direct acquisition-related costs, the reduction in interest expense on borrowing converted into equity in the reverse merger, and the actual depreciation and amortization that would have been charged assuming the fair value adjustments to property and equipment and intangible assets had been applied as of January 1, 2017. This unaudited pro forma information is summarized as follows:

	Three Months Ended March 31,	
	2018	2017
	(in thousands)	
Total revenue	$ 13,039	$ 7,176
Net income (loss)	$ 5,899	$ (7,915)

The pro forma financial information as presented above is for informational purposes only and is not indicative of the consolidated results of operations of future periods or the results of operations that would have been achieved had the acquisition had taken place on January 1, 2017.

NOTE 4. Fair Value of Financial Instruments

Fair value accounting is applied for all financial assets and liabilities and nonfinancial assets and liabilities that are recognized or disclosed at fair value in the financial statements on a recurring basis (at least annually). Financial instruments include cash and cash equivalents, short-term investments, accounts receivable, accounts payable and accrued liabilities that approximate fair value due to their relatively short maturities. As shortterm investments are classified as held-to-maturity, they are recorded at their amortized cost.

Assets and liabilities recorded at fair value on a recurring basis in the balance sheets are categorized based upon the level of judgment associated with inputs used to measure their fair values. The accounting guidance for fair value provides a framework for measuring fair value and requires certain disclosures about how fair value is determined. Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability (an exit price) in an orderly transaction between market participants at the reporting date. The accounting guidance also establishes a three-level valuation hierarchy that prioritizes the inputs to valuation techniques used to measure fair value based upon whether such inputs are observable or unobservable. Observable inputs reflect market data obtained from independent sources, while unobservable inputs reflect market assumptions made by the reporting entity.

The three-level hierarchy for the inputs to valuation techniques is briefly summarized as follows:

Level 1 – Inputs are unadjusted, quoted prices in active markets for identical assets or liabilities at the measurement date;

Level 2 – Inputs are observable, unadjusted quoted prices in active markets for similar assets or liabilities, unadjusted quoted prices for identical or similar assets or liabilities 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 related assets or liabilities; and

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

The Company’s money market funds are classified within Level 1 of the fair value hierarchy and are valued based on quoted prices in active markets for identical securities. The Company’s corporate bonds and commercial paper, classified as cash equivalents, are classified within Level 2 of the fair value hierarchy and are valued based on quoted prices for similar assets or prices derived from observable market data. Level 3 liabilities consist of convertible promissory notes embedded derivative liabilities and a convertible preferred stock warrant liability as they are valued by using inputs that are unobservable in the market. The determination of the fair values of the convertible promissory notes embedded derivative is discussed in Note 8.

The following tables present the Company’s financial assets and liabilities that are measured at fair value at March 31, 2018 and December 31, 2017:

March 31, 2018	Level 1	Level 2	Level 3	Total
		(in thousands)		
Recurring Financial Assets:				
Money Market Funds	$ 5,600	$ —	$ —	$ 5,600
Corporate Bonds	—	—	—	—
Total assets	$ 5,600	$ —	$ —	$ 5,600

March 31, 2018	Level 1	Level 2	Level 3	Total
		(in thousands)		
Recurring Financial Liabilities:				
Convertible promissory notes embedded derivative liability	$ —	$ —	$ —	$ —
Convertible preferred stock warrant liability	—	—	—	—
Total liabilities	$ —	$ —	$ —	$ —

December 31, 2017	Level 1	Level 2	Level 3	Total
		(in thousands)		
Recurring Financial Assets:				
Money Market Funds	$ 1,192	$ —	$ —	$ 1,192
Corporate Bonds	—	1,415	—	1,415
Total assets	$ 1,192	$ 1,415	$ —	$ 2,607

December 31, 2017	Level 1	Level 2	Level 3	Total
		(in thousands)		
Recurring Financial Liabilities:				
Convertible promissory notes embedded derivative liability	$ —	$ —	$ —	$ —
Convertible preferred stock warrant liability	—	—	67	67
Total liabilities	$ —	$ —	$ 67	$ 67

The following tables present a reconciliation of all liabilities measured at fair value on a recurring basis using significant unobservable inputs (Level 3) for the three months ended March 31, 2018 and 2017:

	Convertible Preferred Stock Warrant Liability	Convertible Promissory Notes Embedded Derivative Liability	Total
		(in thousands)	
Balance at January 1, 2018	$ 67	$ —	$ 67
Issuances	—	—	—
Revaluation loss included in (loss) gain on revaluation of financial instruments, net	3	—	3
Settlements	(70)	—	(70)
Balance at March 31, 2018	$ —	$ —	$ —
Total gains included in other income and (expenses) attributable to liabilities still held as of March 31, 2018	$ —	$ —	$ —

	Convertible Preferred Stock Warrant Liability	Convertible Promissory Notes Embedded Derivative Liability	Total
		(in thousands)	
Balance at January 1, 2017	$ 134	$ 3,280	$ 3,414
Issuances	—	—	—
Revaluation gains included in (loss) gain on revaluation of financial instruments, net	(32)	(150)	(182)
Settlements	—	—	—
Balance at March 31, 2017	$ 102	$ 3,130	$ 3,232
Total gains included in other income and (expenses) attributable to liabilities still held as of March 31, 2017	$ 32	$ 150	$ 182

NOTE 5. Balance Sheet Components

(a) ***Cash Equivalents and Short Term Investments***

Cash equivalents and short term investments, all of which are classified as held to maturity securities and mature within one year, consisted of the following:

	March 31, 2018				
	Amortized Cost	Gross Unrecognized Gains	Gross Unrecognized Losses	Estimated Fair Value	Carrying Value
			(in thousands)		
Money market funds	$ 5,600	$ —	$ —	$ 5,600	$ 5,600
Corporate bonds	—	—	—	—	—
Total	$ 5,600	$ —	$ —	$ 5,600	$ 5,600
Reported as:					
Cash equivalents	$ 5,600	$ —	$ —	$ 5,600	$ 5,600
Short-term investments	—	—	—	—	—
Total	$ 5,600	$ —	$ —	$ 5,600	$ 5,600

	December 31, 2017				
	Amortized Cost	Gross Unrecognized Gains	Gross Unrecognized Losses	Estimated Fair Value	Carrying Value
			(in thousands)		
Money market funds	$ 1,192	$ —	$ —	$ 1,192	$ 1,192
Corporate bonds	1,415	—	—	1,415	1,415
Total	$ 2,607	$ —	$ —	$ 2,607	$ 2,607
Reported as:					
Cash equivalents	$ 1,192	$ —	$ —	$ 1,192	$ 1,192
Short-term investments	1,415	—	—	1,415	1,415
Total	$ 2,607	$ —	$ —	$ 2,607	$ 2,607

(b) ***Accounts Receivable, Net of Allowance***

Accounts receivable, net of allowance, comprises the following:

	March 31, 2018	December 31, 2017
	(in thousands)	
Royalties receivable	$ 11,939	$ —
Government contract - billed	230	477
Government contract - unbilled	112	153
Tax credit receivable	1,068	—
Accounts receivable, net of allowance	$ 13,349	$ 630

(c) ***Property and Equipment, Net***

Property and equipment, net consists of the following:

	March 31, 2018	December 31, 2017
	(in thousands)	
Laboratory equipment	$ 1,771	$ 1,565
Office and computer equipment	296	175
Leasehold improvements	281	226
Total property and equipment	2,348	1,966
Less: accumulated depreciation	(1,334)	(1,236)
Property and equipment, net	$ 1,014	$ 730

Depreciation expense for the three months ended March 31, 2018 and 2017, was $98,000 and $96,000, respectively.

(d) ***Intangible Assets***

Intangible assets consist of the following:

	March 31, 2018	December 31, 2017
	(in thousands)	
Purchased technology	$ 22,400	$ —
In-process research and development	1,600	—
Intellectual property	80	80
Total cost	24,080	80
Less accumulated amortization	453	40
Intangible assets, net	$ 23,627	$ 40

Total amortization expense was $413,000 and $1,000 in the three-month periods ended March 31, 2018 and 2017, respectively. As of March 31, 2018, the estimated future amortization expense by year is as follows (in thousands):

	December 31, 2017
2018 (nine months remaining)	$ 2,428
2019	2,254
2020	1,757
2021	1,758
2022	1,757
Thereafter	12,073
Total	$ 22,027

(e) ***Accrued Liabilities***

Accrued liabilities consist of the following:

	March 31, 2018	December 31, 2017
	(in thousands)	
Accrued compensation	$ 1,076	$ 1,320
Accrued clinical and manufacturing expenses	359	69
Accrued professional and consulting services	254	113
Convertible preferred stock warrant liability	—	67
Other	450	36
Total	$ 2,139	$ 1,605

NOTE 6. Revenue

U.S. Government HHS BARDA Contract

In September 2015, HHS BARDA awarded the Company a contract to support the advanced development of a more effective and universal influenza vaccine to improve seasonal and pandemic influenza preparedness. On each of May 25 and July 18, 2017, the Company entered into a Modification of Contract with HHS BARDA, the combined effect being to increase the value of the existing $14 million contract by $1.7 million and to extend it through June 30, 2018. The modified contract is a cost plus fixed fee contract, which reimburses the Company for allowable direct contract costs plus allowable indirect costs and a fixed fee, totaling $15.7 million. During the three months ended March 31, 2018 and 2017, the Company recognized revenue of $0.6 million and $2.3 million, respectively. Billings under the contract are based on approved provisional indirect billing rates, which permit recovery of fringe benefits, overhead and general and administrative expenses. Indirect rates as well as allowable costs are subject to audit by HHS BARDA on an annual basis. Management believes that revenues recognized to date have been recorded in amounts that are expected to be realized upon final audit and settlement. When the final determination of the allowable costs for any year has been made, revenue and billings may be adjusted accordingly in the period that the adjustments are known and collection is probable. Costs relating to contract acquisition are expensed as incurred.

The Company does not consider any of the revenue recorded as of March 31, 2018 or 2017, to be at risk of reversal.

Royalty agreements

Aviragen entered into a royalty-bearing research and license agreement with GlaxoSmithKline, plc (“GSK”) in 1990 for the development and commercialization of zanamivir, a neuraminidase inhibitor (“NI”) marketed by GSK as Relenza® to treat influenza. Most of the Company’s Relenza® patents have expired and the only substantial remaining intellectual property related to the Relenza® patent portfolio, which is solely owned by the Company and exclusively licensed to GSK, is scheduled to expire in July 2019 in Japan. The post-Merger royalty revenue related to Relenza® recognized in the three months ended March 31, 2018, was $341,000.

The Company also generates royalty revenue from the sale of Inavir® in Japan, pursuant to a collaboration and license agreement that Aviragen entered into with Daiichi Sankyo in 2009. In September 2010, laninamivir octanoate was approved for sale by the Japanese Ministry of Health and Welfare for the treatment of influenza in adults and children, which Daiichi Sankyo markets as Inavir®. Under the agreement, the Company currently receives a 4% royalty on net sales of Inavir® in Japan and was eligible to earn sales milestone payments, including a one-off payment of $5.0 million if net sales exceeded 20 billion Yen in one year. This target was achieved in the three months ended March 31, 2018, prior to the Merger, and Aviragen recognized the related $5.0 million as royalty revenue prior to the Merger. The post-Merger royalty revenue related to Inavir® recognized in the three months ended March 31, 2018, was $552,000. Such royalty revenue is subject to a 5% withholding tax in Japan, for which $28,000 was included in income tax expense.

Under the Inavir® collaboration and license agreement, the Company and Daiichi Sankyo have cross-licensed the world-wide rights to develop and commercialize the related intellectual property, and have agreed to share equally in any royalties, license fees, or milestone or other payments received from any third-party licenses outside of Japan. Patents on the composition of matter for LANI in Japan generally expire in 2024.

In April 2016, Aviragen entered into a Royalty Interest Acquisition Agreement (the “HCRP Agreement”) with HealthCare Royalty Partners III, L.P. (“HCRP”) (See Note 7). Under the Agreement, HCRP made a $20.0 million cash payment to Aviragen in consideration for acquiring certain royalty rights (“Royalty Rights”) related to the approved product Inavir® in the Japanese market. The Royalty Rights were obtained pursuant to the collaboration and license agreements (the “License Agreement”) and a commercialization agreement that the Company entered into with Daiichi Sankyo Company, Limited.

NOTE 7. Liabilities Related to Sale of Future Royalties

In April 2016, Aviragen sold certain royalty rights related to the approved product Inavir®, sold by Daiichi Sankyo in the Japanese market, for $20.0 million to HCRP. Under the relevant accounting guidance, due to a limit on the amount of royalties that HCRP can earn under the arrangement, this transaction was accounted for as a liability that will be amortized using the interest method over the life of the arrangement. The Company has no obligation to pay any amounts to HCRP other than to pass through to HCRP its share of royalties as they are received from Daiichi Sankyo. In order to record the amortization of the liability, the Company is required to estimate the total amount of future royalty payments to be received under the License Agreement and the payments that will be passed through to HCRP over the life of this agreement. The sum of the pass-through amounts less the net proceeds received will be recorded as non-cash interest expense over the life of the liability. Consequently, the Company imputes interest on the unamortized portion of the liability and records non-cash interest expense using an estimated effective interest rate. The Company will periodically assess the expected royalty payments, and to the extent such payments are greater or less than the initial estimate, the Company will adjust the amortization of the liability and interest rate. As a result of this accounting, even though the Company does not retain HCRP's share of the royalties, it will continue to record non-cash revenue related to those royalties until the amount of the associated liability and related interest is fully amortized.

The following table shows the activity within the liability account since the Merger (in thousands):

Total Liability related to sale of future royalties, February 13, 2018	$	16,300
Non-cash interest expense recognized		298
Total Liability related to sale of future royalties, March 31, 2018	$	16,598

NOTE 8. Convertible Promissory Notes, Related Parties

On December 10, 2014, the Company entered into a note purchase agreement with certain existing preferred stockholders under which the Company issued convertible promissory notes during December 2014 for total proceeds of $18.4 million.

On November 20, 2015, the Company entered into a second note purchase agreement with certain existing preferred stockholders under which the Company issued convertible promissory notes during November and December 2015 for total proceeds of $11.0 million. These notes were issued with the same terms as the notes issued in 2014.

As the holders of the convertible promissory notes each have an equity ownership in the Company, the convertible promissory notes were considered to be a related party transaction.

The convertible promissory notes bore interest at a rate of 8.0% per annum. The principal and accrued interest on the notes were automatically convertible, upon a future issuance of convertible preferred stock having total proceeds of at least $25.0 million, into that same stock at a conversion price equal to 90% of the price paid by other investors in the financing event. Upon a liquidation event, such as an acquisition or initial public offering, at the election of the majority of the noteholders in each issuance, the principal and accrued interest on the notes could either (i) be paid in full at the initial closing of the liquidation event, or (ii) automatically convert into the Company's Series C convertible preferred stock at a conversion price based on a specified valuation.

After two years, if the notes had not been converted, the holders of a majority of the principal amount had the option to require the entire principal balance and accrued interest to become due and payable. However, in December 2016, in conjunction with the loan agreement with Oxford Finance (see note 9), all of the holders of convertible promissory notes signed subordination agreements, under which they agreed not to demand or receive any payment until all amounts owed to Oxford Finance under the loan agreement were fully paid in cash, thus extending the due dates of the promissory notes potentially to January 2021. This change reflected a debt modification that was not considered substantially significant. Accordingly, the Company did not apply extinguishment accounting, but accounted for the modification on a prospective basis.

The convertible promissory notes had redemption features that were determined to be a compound embedded derivative requiring bifurcation and separate accounting at estimated fair value. The estimated fair value of the embedded derivative upon issuance was a liability of $1.9 million for the notes issued in 2014 and $1.3 million for the notes issued in 2015. The estimated fair value of these derivative instruments was recognized as a debt discount and as an embedded derivative liability on the balance sheet upon issuance of the convertible promissory notes. The embedded derivative required periodic re measurements to fair value while the instruments were still outstanding (see Note 4). There was no beneficial conversion feature as the conversion feature value was accounted for in the embedded derivative.

The Company estimated the fair value of the compound embedded derivative utilizing a Monte Carlo Simulation model. The inputs used to determine the estimated fair value of the embedded derivative instrument included the probability of an underlying event triggering the redemption event and its timing prior to the maturity date of the convertible promissory notes. The fair value measurement was based upon significant inputs not observable in the market, including a valuation of the Company performed by an independent third-party at each balance sheet date. By December 31, 2017, the embedded derivative had zero value because the Merger (see Note 1), which was considered 90% probable of occurring, would not have triggered redemption and, had the Merger not occurred, it was unlikely that the Company would have found an alternative source of financing on favorable terms, so there would have been zero redemption value. The embedded derivative was extinguished when the Merger occurred on February 13, 2018.

The Company incurred total debt issuance costs of $20,000 in connection with the 2014 issuance and $7,000 in connection with the 2015 issuance. The debt issuance costs, which were recorded as an additional debt discount, were being amortized over the term of the notes.

The Company’s accrued interest associated with the convertible promissory notes amounted to $6.3 million and the unamortized debt discount to $0.4 million as of December 31, 2017.

On February 13, 2018, the balance of the convertible promissory notes was $35.6 million, comprising accrued interest associated with the convertible promissory notes amounted to $6.6 million plus principal of $29.4 million, offset by the unamortized debt discount to $0.4 million. On that date, in conjunction with the Merger, the convertible promissory notes were exchanged for 1,571,702 shares of the Company’s common stock which, based on the closing stock price of $9.05, had a value of $14.2 million. The difference of $21.4 million was recorded as a capital contribution.

NOTE 9. Secured Promissory Note Payable to Oxford Finance

On December 22, 2016, the Company entered into a loan and security agreement (the "Loan Agreement") with Oxford Finance, under which the Company borrowed $5.0 million. The $5.0 million loan, which bears interest at 30-day U.S. LIBOR plus 6.17%, is evidenced by a secured promissory note and is repayable over four years, with interest only payable over the first 12 months and the balance fully amortized over the subsequent 36 months. The loan is secured by substantially all the Company's assets, except for intellectual property.

In conjunction with the execution of the Loan Agreement, all the holders of convertible promissory notes signed subordination agreements, under which they agreed to subordinate in favor of Oxford Finance all amounts due under their promissory notes and any security interest in the Company's property. In addition, the holders of the notes agreed that they would not demand or receive any payment until all amounts owed to Oxford Finance under the Loan Agreement have been fully paid in cash. Upon repayment, an additional final payment equal to $325,000 is due, which is being accreted as interest expense over the term of the loan using the effective interest method.

In connection with the Loan Agreement, the Company issued a warrant to Oxford Finance to purchase 7,563 shares of its Series C convertible preferred stock at an exercise price of $33.11 per share (the "Warrant"). The fair value of the Warrant at the date of issuance was approximately $134,000, which was recorded as debt discount and is being amortized as interest expense over the term of the loan using the effective interest method. The annual effective interest rate of the note, including the accretion of the final payment and the amortization of the debt discount, is approximately 10.5%. The Company recorded interest expense related to the Loan Agreement of $130,000, of which $95,000 was paid, during the three months ended March 31, 2018, and $126,000, of which $57,000 was paid, during the three months ended March 31, 2017.

The Warrant provided that if the share price at the next equity financing was less than the Warrant exercise price, then the Warrant would be for the new class of shares, the exercise price would be the new class share price, and the number of shares would be calculated by dividing $250,000 by the new class share price. Due to this anti-dilution protection, the Company determined that the Warrant needed to be recorded as a liability, and therefore estimated the fair value of the Warrant upon issuance and at each balance sheet date, with any changes in the fair value being recorded within the gain (loss) on revaluation of financial instruments line in the statements of operations and comprehensive income (loss).

Due to the antidilution protection, following the Merger, the Warrant was amended to allow the holder to purchase 10,914 shares of common stock at an exercise price of $22.99 per share. Since the amended Warrant contains no non-standard antidilution protections or similar features, the fair value of approximately $70,000 on February 13, 2018, was transferred to equity.

NOTE 10. Commitments and Contingencies

(a) ***Leases***

The Company has leased four office and research and development facilities in South San Francisco, California, under noncancelable operating leases. The first lease, for office and research and development premises, expired on July 31, 2017, following the landlord's exercise of its six-month termination option on January 31, 2017. The second lease, for office and research and development premises, expires in April 2020, subject to the Company's option to extend the lease at the then market rate for an additional five year period. The third lease, for office premises, was entered in May 2017 and has been extended until December 31, 2018. The fourth lease, for office premises, began in April 2018 and expires on December 31, 2018. In addition, following the Merger, the Company also leases office space in Alpharetta, Georgia, under a lease expiring on February 28, 2021. Rent expense is recognized on a straight line basis over the noncancelable term of each operating lease and, accordingly, the Company records the difference between cash rent payments and the recognition of rent expense as a deferred rent liability, which is included within accrued expenses. Rent expense was $146,000 and $161,000 for the three months ended March 31, 2018 and 2017, respectively. Under the terms of the lease agreements, the Company is also responsible for certain insurance, property tax and maintenance expenses. Future minimum payments under the facility leases as of December 31, 2018 as follows (in thousands):

Year ending December 31,	
2018 (9 months remaining)	$ 548
2019	568
2020	411
2021	56
Thereafter	—
Total	$ 1,583

(b) ***Indemnifications***

In the ordinary course of business, the Company enters into agreements that may include indemnification provisions. Pursuant to such agreements, the Company may indemnify, hold harmless and defend indemnified parties for losses suffered or incurred by the indemnified party. Some of the provisions will limit losses to those arising from third party actions. In some cases, the indemnification will continue after the termination of the agreement. The maximum potential amount of future payments the Company could be required to make under these provisions is not determinable. The Company has never incurred material costs to defend lawsuits or settle claims related to these indemnification provisions. The Company has also entered into indemnification agreements with its directors and officers that may require the Company to indemnify its directors and officers against liabilities that may arise by reason of their status or service as directors or officers to the fullest extent permitted by Delaware corporate law. The Company currently has directors' and officers' insurance.

(c) ***Litigation***

From time to time the Company may be involved in claims arising in connection with its business. Based on information currently available, the Company believes that the amount, or range, of reasonably possible losses in connection with any pending actions against it in excess of established reserves, in the aggregate, not to be material to its consolidated financial condition or cash flows. However, losses may be material to the Company's operating results for any particular future period, depending on the level of income or loss for such period.

NOTE 11. Stockholders' Equity

(a) Convertible Preferred Stock

The Company is authorized to issue 5,000,000 shares of preferred stock, $0.10 par value per share. The Company's board of directors may, without further action by the stockholders, fix the rights, preferences, privileges and restrictions of up to an aggregate of 5,000,000 shares of preferred stock in one or more series and authorize their issuance. These rights, preferences and privileges could include dividend rights, conversion rights, voting rights, terms of redemption, liquidation preferences, sinking fund terms and the number of shares constituting any series or the designation of such series, any or all of which may be greater than the rights of our common stock. The issuance of preferred stock could adversely affect the voting power of holders of common stock and the likelihood that such holders will receive dividend payments and payments upon liquidation. In addition, the issuance of preferred stock could have the effect of delaying, deterring or preventing a change of control or other corporate action. No shares of preferred stock are currently outstanding, and we have no present plan to issue any shares of preferred stock.

All of Private Vaxart's convertible preferred stock was converted into common stock on February 13, 2018, in conjunction with the Merger. As of December 31, 2017, convertible preferred stock consisted of the following:

	Shares authorized	Shares outstanding	Net carrying value	Liquidation preference
			(in thousands)	(in thousands)
Series A	94,988	94,988	$ 2,949	$ 2,737
Series B	747,095	520,973	16,115	17,219
Series C	820,088	605,103	19,877	20,000
Total	1,662,171	1,221,064	$ 38,941	$ 39,956

Significant provisions of the convertible preferred stock were as follows:

Dividends – The holders of Series C convertible preferred stock were entitled to receive non-compounding cumulative dividends, in preference to any dividends payable to holders of Series B and Series A convertible preferred stock or common stock, at an annual dividend rate of $2.64416 per share, as adjusted for any stock splits, stock dividends, recapitalizations, or the like. Such cumulative dividends were payable within ten days of demand of the holders of at least a majority of the then outstanding Series C convertible preferred stock, or automatically upon a liquidation event. Dividends accumulated from the date of issuance and were payable, whether or not declared, before any dividend on Series B and Series A convertible preferred stock or common stock could be paid or declared. Series C convertible preferred stock shares issued as stock dividends were not entitled to cumulative dividends. The holders of Series C convertible preferred stock could elect whether the cumulative dividends would be paid in cash or in shares of Series C convertible preferred stock based on the original issue price of Series C convertible preferred stock of $33.05196 per share. In the event the board of directors declared a cash dividend in addition to the above cumulative dividends (a Special Dividend), the holders of Series C convertible preferred stock would have been entitled to receive, in preference to any dividends payable to the holders of Series B and Series A convertible preferred stock or common stock, a per share amount equal to the sum of: (a) the original issue price of Series C convertible preferred stock, and (b) all accrued and/or declared but unpaid dividends on such Series C convertible preferred stock, including the cumulative dividends. No dividends were declared during any of the periods presented. As of February 13, 2018, when the convertible preferred stock was converted into common stock, and December 31, 2017, accumulated and undeclared dividends for Series C convertible preferred stock were $7.3 million and $7.1 million, respectively ($12.06 per share and $11.74 per share, respectively, of the outstanding Series C convertible preferred stock). On February 13, 2018, in conjunction with the Merger, the Series C convertible preferred stock and the related accumulated dividends were converted into 696,028 and 253,851 shares of common stock, respectively.

The holders of Series B convertible preferred stock were entitled to receive non-compounding cumulative dividends, in preference to any dividends payable to holders of Series A convertible preferred stock or common stock, at the annual dividend rate of $2.64416 per share, as adjusted for any stock splits, stock dividends, recapitalizations, or the like. Such cumulative dividends were payable within ten days of demand of the holders of at least a majority of the then outstanding Series B convertible preferred stock or automatically upon a liquidation event. Dividends accumulated from the date of issuance and were payable, whether or not declared, before any dividend on Series A convertible preferred stock or common stock could be paid or declared. Series B convertible preferred shares issued as stock dividends were not entitled to cumulative dividends. The holders of Series B convertible preferred stock could elect whether the cumulative dividends would be paid in cash or in shares of Series B convertible preferred stock based on the original issue price of Series B convertible preferred stock of $33.05196 per share. In the event the board of directors declared a cash dividend in addition to the above cumulative dividends (a Special Dividend), the holders of Series B convertible preferred stock would have been entitled to receive, in preference to any dividends payable to the holders of Series A convertible preferred stock or common stock, a per share amount equal to the sum of: (a) the original issue price of Series B convertible preferred stock, and (b) all accrued and/or declared but unpaid dividends on such Series B convertible preferred stock, including the cumulative dividends. No dividends were declared during any of the periods presented. As of February 13, 2018, when the convertible preferred stock was converted into common stock, and December 31, 2017, accumulated and undeclared dividends for Series B convertible preferred stock were $7.6 million and $7.5 million, respectively ($15.78 per share and $15.56 per share, respectively, of the 483,387 shares of outstanding Series B convertible preferred stock on which dividends accrued). On February 13, 2018, in conjunction with the Merger, the Series B convertible preferred stock and the related accumulated dividends were converted into 599,259 and 265,340 shares of common stock, respectively.

The holders of Series A convertible preferred stock were entitled to receive noncumulative dividends, in preference to any dividends payable to holders of common stock, at the annual dividend rate of $2.30449 per share, as adjusted for any stock splits, stock dividends, recapitalizations, or the like, if declared by the board of directors. On February 13, 2018, in conjunction with the Merger, the Series A convertible preferred stock was converted into 104,065 shares of common stock.

Conversion – At the option of the holder, each share of convertible preferred stock was convertible, one for one, subject to adjustment for anti dilution protection, into shares of common stock. Each share automatically converted into the number of shares of common stock into which the shares were convertible at the then applicable conversion ratio upon: (1) the closing of the sale of the Company's common stock in a public offering provided the offering price per share was not less than three times the Series C convertible preferred stock original issue price of $33.05196 and the aggregate gross proceeds were not less than $30.0 million, or (2) upon receipt of a written consent of the holders of a majority of the then outstanding shares of convertible preferred stock voting as a single class on an as converted basis.

Liquidation – In the event of any liquidation, dissolution or winding up of the Company, including a merger or acquisition where the beneficial owners of the Company's common and convertible preferred stock owned less than 50% of the surviving entity, or a sale of all or substantially all assets, the holders of Series C convertible preferred stock would have been entitled to receive a per share amount equal to $33.05196 (subject to adjustment for stock splits, stock dividends, recapitalizations, or the like), plus all dividends accrued, payable and/or in arrears (whether or not declared) minus the amount of any Special Dividends previously paid. After payment of the full liquidation preference of Series C convertible preferred stock, the holders of Series B convertible preferred stock would have been entitled to receive a per share amount equal to $33.05196 (subject to adjustment for stock splits, stock dividends, recapitalizations, or the like), plus all dividends accrued, payable and/or in arrears (whether or not declared) minus the amount of any Special Dividends previously paid. After payment of the full liquidation preference of Series B convertible preferred stock, the holders of Series A convertible preferred stock would have been entitled to receive an amount equal to $28.80613 per share, as adjusted, plus all declared but unpaid dividends prior and in preference to any distribution to the holders of common stock. In each case, if the proceeds of such an event were insufficient to permit the liquidation payment to a particular class, any proceeds legally available for distribution to that class would have been distributed ratably among the holders of that class in proportion to the preferential amounts that each holder was entitled to receive. Following payment of all convertible preferred stock preferences, any remaining legally available assets of the Company would have been distributed to the holders of common stock and convertible preferred stock pro rata, based on the greatest number of shares of common stock held on an as converted basis.

Voting – The holders of convertible preferred stock were entitled to the number of votes equal to the number of shares of common stock into which each share of Series A, Series B, and Series C convertible preferred stock could have been converted on the record date for the vote or consent of the stockholders, except as otherwise required by law, and had voting rights and powers equal to the voting rights and powers of the common stockholders. The holders of Series A convertible preferred stock, voting as a separate class, were entitled to elect one member of the board of directors. As long as a specified investor held at least one share of Series C convertible preferred stock, the specified investor was able to designate one member of the board of directors, who would have been elected by the holders of Series C convertible preferred stock voting as a separate class. As long as a specified investor held least one share of Series B convertible preferred stock, the specified investor was able to designate one member of the board of directors, who would have been elected by the holders of Series B convertible preferred stock voting as a separate class. The holders of common stock, voting as a separate class, were entitled to elect two members of the board of directors, one of whom was the duly appointed chief executive officer of the Company.

Protective Provisions – So long as at least 20,134 shares of Series C convertible preferred stock remained outstanding and for so long as at least 20,134 shares of Series B convertible preferred stock remained outstanding, Series C holders and Series B holders, voting as a single class on an asconverted basis, needed to approve certain specified corporate actions such as amending the certificate of incorporation, authorizing additional shares of stock or additional directors, redeeming stock and entering into certain strategic relationships.

Redemption – The convertible preferred stock was not redeemable. There were no liquidation events under the control of preferred stockholders that could have resulted in liquidation in which only the preferred stockholders would have participated. Accordingly, the convertible preferred stock was classified within stockholders' equity (deficit) on the Company's condensed consolidated balance sheets.

(b) ***Common Stock***

Except as otherwise required by law or as otherwise provided in any certificate of designation for any series of preferred stock, the holders of common stock possess all voting power for the election of the Company's directors and all other matters requiring stockholder action. Holders of common stock are entitled to one vote per share on matters to be voted on by stockholders. Holders of common stock are entitled to receive such dividends, if any, as may be declared from time to time by the Company's board of directors in its discretion out of funds legally available therefore. In no event will any stock dividends or stock splits or combinations of stock be declared or made on common stock unless the shares of common stock at the time outstanding are treated equally and identically. As of March 31, 2018, no dividends had been declared by the board of directors.

In the event of the Company's voluntary or involuntary liquidation, dissolution, distribution of assets or winding-up, the holders of the common stock will be entitled to receive an equal amount per share of all of the Company's assets of whatever kind available for distribution to stockholders, after the rights of the holders of the preferred stock have been satisfied. There are no sinking fund provisions applicable to the common stock.

The Company had shares of common stock reserved for issuance as follows:

	March 31, 2018	December 31, 2017
Convertible preferred stock outstanding	—	1,221,064
Options issued and outstanding	832,942	304,850
Available for future grants of equity awards	380,426	—
Cumulative convertible preferred stock dividends	—	441,096
Convertible preferred stock warrants	10,914	10,914
Total	1,224,282	1,977,924

NOTE 12. Equity Incentive Plans

Prior to the Merger, the Company issued equity awards for compensation purposes to employees, directors and consultants under the Company's 2007 Equity Incentive Plan (the "2007 Plan"). The 2007 Plan expired in July 2017. As of March 31, 2018, the Company had no shares of common stock available for issuance under the 2007 Plan. Equity awards under the 2007 Plan do not become available for future issuance if such awards are forfeited or otherwise terminate. Each stock option to acquire shares of Private Vaxart stock, whether vested or unvested, that had not previously been exercised was assumed in the Merger.

In November 2016, Aviragen's stockholders approved the 2016 Equity Incentive Plan ("2016 Equity Plan"), under which all outstanding awards under their previous plans became available for issuance under the 2016 Equity Plan if such awards are forfeited or otherwise terminate. The purpose of the 2016 Equity Plan is to assist the Company in attracting and retaining valued employees, consultants and non-employee directors by offering them a greater stake in the Company's success and a closer identity with it, and to encourage ownership of the Company's shares by such persons.

Under the 2016 Equity Plan, the Company is authorized to issue incentive stock options ("ISOs"), non-qualified stock options ("NQSOs"), restricted stock ("RSAs") and restricted stock units ("RSUs"). Awards that expire or are canceled generally become available for issuance again under the 2016 Equity Plan. The number of shares of the Company's common stock available under the 2016 Equity Plan will be subject to adjustment in the event of a stock split, stock dividend or other extraordinary dividend, or other similar change in the Company's common stock or capital structure. Awards may vest over varying periods, as specified by the Company's Board of Directors for each grant, and have a maximum term of ten years from the grant date.

A summary of stock option transactions in the three months ended March 31, 2018, is as follows:

	Shares Available For Grant	Number of Options Outstanding	Weighted Average Exercise Price
Balance at January 1, 2018	—	304,850	$ 9.50
Assumed on consummation of Merger	291,102	627,106	$ 24.14
Exercised	—	(2,013)	$ 6.49
Forfeited	—	(17,208)	$ 8.83
Canceled	66,597	(79,793)	$ 23.53
Balance at March 31, 2018	357,699	832,942	$ 19.20

In addition, the 2016 Equity Plan has a reserve of 22,727 shares available for future issuance as RSAs and RSUs. As of March 31, 2018, no such awards have been granted under the 2016 Equity Plan.

Total stock based compensation recognized for options was as follows:

	Three Months Ended March 31.	
	2018	2017
	(in thousands)	
Research and development	$ 44	$ 69
General and administrative	42	55
Total stock-based compensation	$ 86	$ 124

As of March 31, 2018, the unrecognized stock based compensation cost related to outstanding unvested stock options that are expected to vest was $0.4 million, which the Company expects to recognize over an estimated weighted average period of 1.90 years.

NOTE 13. Net Loss Per Share Attributable to Common Stockholders

The following table presents the calculation of basic and diluted net loss per share (in thousands, except share and per share amounts):

	Three Months Ended March 31,	
	2018	2017
Net income (loss) attributable to common stockholders – basic calculation	$ 1,975	$ (3,506)
Interest charges applicable to convertible promissory notes	295	—
Series B and C preferred dividend	339	—
Series A preferred dividend	(28)	—
Net income (loss) used for net income (loss) per share – diluted calculation	2,581	(3,506)
Shares used to compute net income (loss) per share – basic	3,656,360	135,658
Potential common shares from exercise of options	25,550	—
Shares issuable upon conversion of convertible promissory notes, related party	750,924	—
Shares issuable upon conversion of Series B and C convertible preferred stock and accrued dividends	866,917	—
Shares used to compute net income (loss) per share – diluted	5,299,751	135,658
Net income (loss) per share – basic	$ 0.54	$ (25.84)
Net income (loss) per share – diluted	$ 0.49	$ (25.84)

No adjustment has been made to the net loss attributable to common stockholders in the three months ended March 31, 2017, as the effect would be anti-dilutive due to the net loss.

The following potentially dilutive securities were excluded from the computation of diluted weighted average shares outstanding because they would have been antidilutive:

	Three Months Ended March 31,	
	2018	2017
Options to purchase common stock	529,332	272,287
Warrant to purchase common stock	5,700	—
Warrant to purchase convertible preferred stock	3,613	7,563
Series B and C convertible preferred stock outstanding, including cumulative dividends	—	1,501,566
Series A convertible preferred stock outstanding	—	94,988
Convertible promissory notes, related party (as converted)	—	687,362
Total potentially dilutive securities excluded from denominator of the diluted earnings per share computation	538,645	2,563,766

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

You should carefully consider the following risk factors, as well as the other information in this Quarterly Report on Form 10-Q, and in our other public filings. The occurrence of any of the following risks could harm our business, financial condition, results of operations and/or growth prospects or cause our actual results to differ materially from those contained in forward-looking statements we have made in this Quarterly Report on Form 10-Q and those we may make from time to time. You should consider all of the risk factors described when evaluating our business.

Forward-Looking Statements

This discussion contains certain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. Forward-looking statements are identified by words such as "believe," "will," "may," "estimate," "continue," "anticipate," "intend," "should," "plan," "expect," "predict," "could," "potentially" or the negative of these terms or similar expressions. You should read these statements carefully because they discuss future expectations, contain projections of future results of operations or financial condition, or state other "forward-looking" information. These statements relate to our future plans, objectives, expectations, intentions and financial performance and the assumptions that underlie these statements. These forward-looking statements are subject to certain risks and uncertainties that could cause actual results to differ materially from those anticipated in the forward-looking statements. Factors that might cause such a difference include, but are not limited to, those discussed in this Quarterly Report on Form 10-Q in Part II, Item 1A — "Risk Factors," and elsewhere in this Quarterly Report on Form 10-Q. Forward-looking statements are based on our management's beliefs and assumptions and on information currently available to our management. These statements, like all statements in this Quarterly Report on Form 10-Q, speak only as of their date, and we undertake no obligation to update or revise these statements in light of future developments. We caution investors that our business and financial performance are subject to substantial risks and uncertainties.

Company Overview and Background

The Company is a clinical-stage company focused on the development of oral recombinant protein vaccines based on its proprietary oral vaccine platform and of small-molecule antiviral drugs. Recombinant vaccines rely on a genetically engineered antigen to generate an immune response. The tablet vaccine candidates are based on a proprietary vector-based technology platform and are designed to generate broad and durable immune responses to protect against infectious diseases. Management believes that tablet vaccines are easier to distribute and administer than injectable vaccines and have the potential to increase vaccination rates. The initial tablet vaccine candidates target a variety of infectious diseases, including: seasonal influenza, for which positive topline results were recently reported from a Phase 2 challenge study; norovirus, a widespread cause of the stomach flu, for which positive safety and immunogenicity results were recently reported from a Phase 1b study; respiratory syncytial virus, or RSV, a common cause of respiratory tract infections; and human papillomavirus, or HPV, a cause of cervical cancer.

The Company also has three Phase 2 clinical stage antiviral compounds: BTA074, or teslexivir, an antiviral treatment for condyloma caused by human papillomavirus types 6 & 11; vapendavir, a capsid inhibitor for the prevention or treatment of rhinovirus upper respiratory infections; and BTA585, or enzaplatovir, a fusion protein inhibitor in development for the treatment of RSV infections.

Vaxart's future funding requirements will depend on many factors, including the following:

- the timing and costs of its planned clinical trials for its product candidates, both tablet vaccines and small-molecule antiviral drugs;
- the timing and costs of its planned preclinical studies of its product candidates;
- its success in establishing and scaling commercial manufacturing capabilities;
- the amount and timing of royalties received on sales of Relenza® and Inavir®;
- the number and characteristics of product candidates that it pursues;
- the outcome, timing and costs of seeking regulatory approvals;

- revenue received from commercial sales of its product candidates, which will be subject to receipt of regulatory approval;
- the terms and timing of any future collaborations, licensing, consulting or other arrangements that it may enter into;
- the amount and timing of any payments that may be required in connection with the licensing, filing, prosecution, maintenance, defense and enforcement of any patents or patent applications or other intellectual property rights; and
- the extent to which Vaxart in-licenses or acquires other products and technologies.

Recent Events

On February 13, 2018, the Company completed the Merger with Aviragen and all of Private Vaxart's convertible promissory notes and convertible preferred stock were converted into common stock, following which each share of common stock was converted into approximately 0.22148 shares of the Company's common stock.

Immediately following the completion of the Merger, the Company effected a reverse stock split at a ratio of one new share for every eleven shares of its common stock outstanding, or the Reverse Stock Split. Except as otherwise noted in this Quarterly Report on Form 10-Q, all share, equity security and per share amounts are presented to give retroactive effect to the Reverse Stock Split.

Immediately after the Merger and the Reverse Stock Split there were approximately 7.1 million shares of the Company's common stock outstanding. In addition, immediately after the Merger, Private Vaxart's stockholders, warrantholders and optionholders owned approximately 51% of the common stock of the Company and the stockholders and optionholders of Aviragen immediately prior to the Merger owned approximately 49% of the common stock of the Company (on a fully diluted basis.

Results of Operations

The following table presents selected items in the condensed consolidated statements of operations and comprehensive loss for the three months ended March 31, 2018 and 2017, which include the operations of Aviragen for the period from February 13, 2018 to March 31, 2018:

	Three Months Ended March 31,	
	2018	2017
	(in thousands)	
Revenue:		
Revenue from government contract	$ 610	$ 2,310
Royalty revenue	893	—
Total revenue	1,503	2,310
Operating expenses:		
Research and development	3,408	3,879
General and administrative	2,010	678
Total operating expenses	5,418	4,557
Operating loss	(3,915)	(2,247)
Other income and (expenses):		
Bargain purchase gain	6,988	—
Interest income	5	13
Interest expense	(437)	(744)
Non-cash interest expense on liability related to sale of future royalties	(298)	—
(Loss) gain on revaluation of financial instruments	(3)	182
Foreign exchange gain, net	2	—
Total other income and (expenses)	6,257	(549)
Net income (loss) before income taxes	2,342	(2,796)
Provision for income taxes	28	—
Net income (loss)	$ 2,314	$ (2,796)

Revenue from Government Contract

The following table presents our revenue from a government contract for the three months ended March 31, 2018 and 2017, respectively:

Three Months Ended March 31,		
2018	2017	% Change
(dollars in thousands)		
$ 610	$ 2,310	(74)%

For the three months ended March 31, 2018, revenue from government contract decreased by $1.7 million, or 74%, compared to the three months ended March 31, 2017. The government contract with HHS BARDA, as modified, is a cost plus fixed fee contract, which reimburses the company for allowable direct contract costs plus allowable indirect costs and a fixed fee, totaling $15.7 million through June 30, 2018. During the three months ended March 31, 2018 and 2017, we recognized revenue of $0.6 million and $2.3 million, respectively. The active phase of the contract occurred in 2016 and 2017, whereas in 2018 activities are winding down, so future revenue from this contract is not expected to be material.

Royalty Revenue

The following table presents our royalty revenue for the three months ended March 31, 2018 and 2017, respectively:

Three Months Ended March 31,		
2018	2017	% Change
(dollars in thousands)		
$ 893	$ —	100%

For the three months ended March 31, 2018, royalty revenue increased by $893,000, or 100%, compared to the three months ended March 31, 2017. Royalty revenue is earned on sales of Relenza® and Inavir®, both treatments for influenza, which were acquired in the Merger and is based on fixed percentages of net sales of these drugs in the period from February 13 to March 31, 2018.

Research and Development

The following table presents our research and development expenses for the three months ended March 31, 2018 and 2017, respectively:

Three Months Ended March 31,		
2018	2017	% Change
(dollars in thousands)		
$ 3,408	$ 3,879	(12)%

For the three months ended March 31, 2018, research and development expenses decreased by $471,000, or 12%, compared to the three months ended March 31, 2017. Research and development expenses represent costs incurred to conduct research, including the development of Vaxart's tablet vaccine platform, its tablet vaccine candidates and, since the Merger, teslexivir, including preclinical, clinical and manufacturing costs for these activities. The reduction in the 2018 period is principally due to lower expenditures incurred under the HHS BARDA contract.

General and Administrative

The following table presents our general and administrative expenses for the three months ended March 31, 2018 and 2017, respectively:

Three Months Ended March 31,		
2018	2017	% Change
(dollars in thousands)		
$ 2,010	$ 678	196%

For the three months ended March 31, 2018, general and administrative expenses increased by $1,332,000, or 196%, compared to the three months ended March 31, 2017. General and administrative expenses consist of personnel costs, allocated expenses and expenses for outside professional services, including legal, audit, accounting, investor relations, market research and other consulting services. Personnel costs consist of salaries, benefits and stock-based compensation. Allocated expenses consist of rent, deprecation and other facilities related expenses. The increase in the 2018 period is due to the overlap of personnel due to transitioning following the Merger and additional expenses as a public company, including expenses related to compliance with the rules and regulations of the SEC and the Nasdaq Capital Market, as well as additional insurance, investor relations and other professional expenses. Approximately $0.5 million in legal, accounting and other third-party costs incurred in the three months ended March 31, 2018, related directly to the Merger and are not expected to recur.

Other Income and (Expenses)

The following table presents our non-operating income and expenses for the three months ended March 31, 2018 and 2017, respectively:

Three Months Ended March 31,		
2018	2017	% Change
(dollars in thousands)		
$ 6,257	$ (549)	N/A

For the three months ended March 31, 2018, we recorded net non-operating income of $6.3 million, compared to net non-operating expenses of $549,000 in the three months ended March 31, 2017. The principal source of non-operating income in the three months ended March 31, 2018, was a bargain purchase gain of $7.0 million, representing the excess of the fair value of net assets acquired over the fair value of the common stock issued to acquire them in the Merger. Interest expense was $437,000 in the 2018 period, decreasing from $744,000 in the 2017 period due to Private Vaxart's convertible promissory notes being outstanding for only 43 days prior to the Merger, whereas they earned interest for 90 days in the 2017 period. Non-cash interest expense on liability related to sale of future royalties of $298,000 in the post-Merger period in 2018 relates to accounting for sums that will become payable to HCRP for royalty revenue earned from Inavir® as debt. The gain on revaluation of financial instruments in the 2017 period is principally caused by an embedded derivative liability related to the conversion feature on Private Vaxart's convertible promissory notes, which had a fair value of $3.3 million as of December 31, 2016, and zero value as of December 31, 2017. Of this change in fair value, $150,000 occurred in the three months ended March 31, 2017. Since Private Vaxart's convertible promissory notes and warrants converted to equity on the Merger, there are no longer any comparable financial instruments outstanding on which a change in fair value will be recorded.

Provision for income taxes

The following table presents our provision for income taxes for the three months ended March 31, 2018 and 2017, respectively:

Three Months Ended March 31,		
2018	2017	% Change
(dollars in thousands)		
$ 28	$ —	100%

The provision for income taxes comprises $28,000 of withholding tax on royalty revenue earned on sales of Inavir® in Japan, which is potentially recoverable as a foreign tax credit but expensed because we record a 100% valuation allowance against our deferred tax assets.

Liquidity and Capital Resources

Since inception, Vaxart's operations have been financed primarily by net proceeds of $38.9 million and $29.4 million from the sale of its convertible preferred stock and the issuance of convertible promissory notes, respectively, all of which were converted into common stock in the Merger, and $4.9 million from the issuance of secured promissory notes to Oxford Finance, repayable by January 2021. Vaxart gained $25.5 million in cash from Aviragen in the Merger, of which $4.9 million was used to pay for severance, banker fee, D&O tail insurance, legal and other professional costs incurred by Aviragen prior to or upon the Merger. As of March 31, 2018, Vaxart had $17.5 million of cash and cash equivalents. Management believes these funds are sufficient to fund Vaxart into, but possibly not beyond, the first quarter of 2019.

Vaxart's primary uses of cash are to fund operating expenses, primarily research and development expenditures. Cash used to fund operating expenses is impacted by the timing of when these expenses are paid, as reflected in the change in its outstanding accounts payable and accrued expenses.

Vaxart plans to continue to fund its operations and capital funding needs through equity and/or debt financing. Vaxart may also enter into government funding programs and consider selectively partnering for clinical development and commercialization. The sale of additional equity would result in additional dilution to its stockholders. Incurring debt financing would result in debt service obligations, and the instruments governing such debt could provide for operating and financing covenants that would restrict the company's operations. If Vaxart is unable to raise additional capital in sufficient amounts or on acceptable terms, it may be required to delay, limit, reduce, or terminate its product development or future commercialization efforts or grant rights to develop and market vaccine candidates that it would otherwise prefer to develop and market itself. Any of these actions could harm its business, results of operations and prospects.

Cash Flows

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

	Three Months Ended March 31,	
	2018	2017
	(in thousands)	
Cash used in operating activities	$ (10,590)	$ (4,276)
Cash provided by (used in) investing activities	26,779	(844)
Cash used in financing activities	(265)	—
Net increase (decrease) in cash and cash equivalents	$ 17,495	$ (5,120)

Net Cash Used in Operating Activities

Vaxart experienced negative cash flow from operating activities for the three months ended March 31, 2018 and 2017, in the amounts of $10,590,000 and $4,276,000, respectively. The cash used in operating activities in the three months ended March 31, 2018, was due to net income of $2,314,000 being offset by $5,749,000 of adjustments for net non-cash income related to the bargain purchase gain, depreciation and amortization, stock-based compensation, loss on revaluation of financial instruments, non-cash interest, amortization of note discount and non-cash interest expense related to sale of future royalties and $7,155,000 used by a change in working capital. The cash used in operating activities in the three months ended March 31, 2017, was due to cash used to fund a net loss of $2,796,000, adjusted for net non-cash expenses related to depreciation and amortization, stock-based compensation, amortization of discount on short-term investments, gain on revaluation of financial instruments, non-cash interest and amortization of note discount totaling $732,000, and by a change in working capital of $2,212,000.

Net Cash Provided by (Used in) Investing Activities

In the three months ended March 31, 2018, Vaxart received cash of $25,525,000 in the Merger and $1,415,000 from maturities of short-term investments, net of purchases. This was offset by $140,000 to purchase property and equipment and $21,000 to pay for fractional shares of common stock in the Merger. In the three months ended March 31, 2017, Vaxart used $765,000 to purchase short-term investments, net of maturities, and $79,000 to purchase property and equipment.

Net Cash Used in Financing Activities

Vaxart used $278,000 in the three months ended March 31, 2018, in repayment of principal on the secured promissory note payable to Oxford Finance, offset by $13,000 received for the exercise of stock options. There were no financing activities in the three months ended March 31, 2017.

Availability of Additional Funds

Vaxart believes funds available at March 31, 2018, along with its revenue, are sufficient to fund its operations into the first quarter of 2019. To continue operations thereafter, it is likely that Vaxart will need to raise further capital, through the sale of additional securities or otherwise. Vaxart's operating needs include the planned costs to operate its business, including amounts required to fund working capital and capital expenditures. Vaxart currently has no material commitments for capital expenditures. Vaxart's future capital requirements and the adequacy of its available funds will depend on many factors, most notably its ability to successfully commercialize its products and services.

While we believe we have sufficient cash to fund our operating, investing and financing activities in the near term, we consider it likely that additional capital will be needed to sustain our operations before we achieve profitability. We have no commitments to obtain any additional funds and there can be no assurance that we will be able to raise sufficient additional capital as we need it on favorable terms, or at all. The sale of equity or convertible debt securities in the future may be dilutive to our stockholders, and debt financing arrangements may require us to pledge certain assets and enter into covenants that could restrict certain business activities or our ability to incur further indebtedness and may contain other terms that are not favorable to us or our stockholders. If we are unable to obtain additional capital as needed, we may not be able to continue our efforts to develop and commercialize our products and services and may be forced to significantly curtail or suspend our operations.

Principles of Consolidation

Vaxart's condensed consolidated financial statements include the accounts of Vaxart, Inc. and its subsidiaries Vaxart Biosciences, Inc., Biota Holdings Pty, Ltd., Biota Scientific Management Pty, Ltd., Biota Europe Limited and Anaconda Pharma S.A.S. All significant inter-company transactions and balances are eliminated in consolidation.

Critical Accounting Policies and Estimates

Our management's discussion and analysis of financial condition and results of operations is based on our condensed consolidated financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses. On an ongoing basis, we evaluate these estimates and judgments. We base our estimates on historical experience and on various assumptions that we believe to be reasonable under the circumstances. These estimates and assumptions form the basis for making judgments about the carrying values of assets and liabilities and the recording of expenses that are not readily apparent from other sources. Actual results may differ materially from these estimates. We believe that the accounting policies discussed below are critical to understanding our historical and future performance, as these policies relate to the more significant areas involving management's judgments and estimates.

Accrued Research and Development Expenses

We record accrued expenses for estimated costs of research and development activities conducted by external service providers, which include the conduct of clinical and contract formulation and manufacturing activities. We record the estimated costs of development activities based upon the estimated amount of services provided but not yet invoiced. We include these costs in accrued liabilities in the condensed consolidated balance sheet and within development expenses in the condensed consolidated statement of operations and comprehensive income (loss). These costs are a significant component our research and development expenses. We record accrued expenses for these costs based on the estimated amount of work completed and in accordance with agreements established with these external service providers.

We estimate the amount of work completed through discussions with internal personnel and external service providers as to the progress or stage of completion of the services and the agreed-upon fee to be paid for such services. We make significant judgments and estimates in determining the accrued balance in each reporting period. As actual costs become known, we adjust our accrued estimates.

Intangible Assets

Intangible assets acquired in the Merger on February 13, 2018, were recorded at their estimated fair values of $20.6 million and $1.8 million for developed technologies Inavir® and Relenza®, respectively, which are being amortized on a straight-line basis over the estimated periods of future royalties of 11.75 and 1.3 years, respectively, and $1.6 million for in-process research and development related to teslexivir which is indefinite-lived. These valuations were prepared by an independent third party based on estimated discounted cash flows based on probability-weighted future development expenditures and revenue streams, which are highly subjective.

Off-Balance Sheet Arrangements

We have no off-balance sheet arrangements that have or are reasonably likely to have a current or future effect on our financial condition, changes in financial condition, revenues or expenses, result of operations, liquidity, capital expenditures or capital resources that is material to stockholders.

Recent Accounting Pronouncements

See the “Recent Accounting Pronouncements” in Note 2 to the Condensed Consolidated Financial Statements in Part I, Item 1 for information related to the issuance of new accounting standards in the first quarter of 2018, none of which had a material impact on our condensed consolidated financial statements.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Not applicable.

Item 4. Controls and Procedures

Management's Report on Internal Control over Financial Reporting

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness 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), as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on such evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that as of March 31, 2018, our disclosure controls and procedures were not effective at the reasonable assurance level as a result of the material weakness described below.

Material Weakness

We identified the following material weakness in our internal controls over financial reporting as of March 31, 2018:

> We lacked sufficient qualified resources and adequate processes to appropriately segregate duties and perform effective and timely review of account reconciliations and nonroutine transactions. Therefore, there was a risk that a potential material misstatement of the financial statements would occur without being prevented or detected on a timely basis.

We are already taking steps to remediate this material weakness, including increasing the depth and experience within our accounting and finance organization, as well as designing and implementing improved processes and internal controls. However, our efforts to remediate this material weakness may not be effective or prevent any future material weakness or significant deficiency in our internal control over financial reporting. If our efforts are not successful, or other material weaknesses or control deficiencies occur in the future, we may be unable to report our financial results accurately on a timely basis, which could cause our reported financial results to be materially misstated and result in the loss of investor confidence and cause the market price of our common stock to decline.

Changes in Internal Control over Financial Reporting

There was no material change in our internal control over financial reporting that occurred during the quarter ended March 31, 2018, that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Limitations on Effectiveness of Controls and Procedures

In designing and evaluating the disclosure controls and procedures and internal control over financial reporting, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures and internal control over financial reporting must reflect the fact that there are resource constraints and that management is required to apply judgment in evaluating the benefits of possible controls and procedures relative to their costs.

PART II OTHER INFORMATION

Item 1. Legal Proceedings

We are not presently party to any material legal proceedings. From time to time we may be involved in claims arising in connection with our business. Based on information currently available, we believe that the amount, or range, of reasonably possible losses in connection with any pending actions against us in excess of established reserves, in the aggregate, not to be material to our consolidated financial condition or cash flows. However, losses may be material to our operating results for any particular future period, depending on the level of income for such period.

Item 1A. Risk Factors

We operate in a rapidly changing environment that involves a number of risks, some of which are beyond our control. This discussion highlights some of the risks that may affect future operating results. These are the risks and uncertainties we believe are most important to consider. We cannot be certain that we will successfully address these risks. If we are unable to address these risks, our business may not grow, our stock price may suffer and we may be unable to stay in business. Additional risks and uncertainties not presently known to us, which we currently deem immaterial or which are similar to those faced by other companies in our industry or business in general, may also impair our business operations. We have marked with an asterisk (*) those risks described below that reflect substantive changes from, or additions to, the risks described in Aviragen's Annual Report on Form 10-K for the year ended June 30, 2017.

Risks Related to Our Business, Financial Position and Capital Requirements

We have a limited operating history and have generated only limited product revenue.

Even though we generate royalty revenue from our two commercialized influenza products, we have not yet successfully completed a large-scale, pivotal clinical trial, obtained marketing approval, manufactured our tablet vaccine or small-molecule antiviral drug candidates at commercial scale, or conducted sales and marketing activities that will be necessary to successfully commercialize our product candidates. Consequently, predictions about our future success or viability may not be as accurate as they could be if it had a longer operating history or a history of successfully developing and commercializing product candidates.

Our ability to generate significant revenue and achieve and maintain profitability will depend upon our ability to successfully complete the development of our small molecule antivirals and tablet vaccine candidates for the treatment of norovirus, seasonal influenza, respiratory syncytial virus, or RSV, cervical cancer and dysplasia caused by human papillomavirus, or HPV and other infectious diseases and to obtain the necessary regulatory approvals.

Even if we receive regulatory approval for the sale of any of our product candidates, we do not know when we will begin to generate significant revenue, if at all. Our ability to generate significant revenue depends on a number of factors, including our ability to:

- set an acceptable price for our product candidates and obtain coverage and adequate reimbursement from third-party payors;
- receive royalties on our products and product candidates including in connection with sales of Relenza®• and Inavir®;
- establish sales, marketing, manufacturing and distribution systems;
- add operational, financial and management information systems and personnel, including personnel to support our clinical, manufacturing and planned future clinical development and commercialization efforts and operations as a public company;
- develop manufacturing capabilities for bulk materials and manufacture commercial quantities of our product candidates at acceptable cost levels;
- achieve broad market acceptance of our product candidates in the medical community and with third-party payors and consumers;
- attract and retain an experienced management and advisory team;
- launch commercial sales of our product candidates, whether alone or in collaboration with others; and

- maintain, expand and protect our intellectual property portfolio.

Because of the numerous risks and uncertainties associated with vaccine development and manufacturing, we are unable to predict the timing or amount of increased development expenses, or when we will be able to achieve or maintain profitability, if at all. Our expenses could increase beyond expectations if we are required by the U.S. Food and Drug Administration, or the FDA, or comparable non-U.S. regulatory authorities, to perform studies or clinical trials in addition to those we currently anticipate. Even if our product candidates are approved for commercial sale, we anticipate incurring significant costs associated with the commercial launch of and the related commercial-scale manufacturing requirements for our product candidates. If we cannot successfully execute on any of the factors listed above, our business may not succeed.

We have incurred significant losses since our inception and expect to continue to incur significant losses for the foreseeable future and may never achieve or maintain profitability.

We have generated only limited product revenues and we expect to continue to incur substantial and increasing losses as we continue to develop our product candidates. Our product candidates have not been approved for marketing in the United States and may never receive such approval. As a result, we are uncertain when or if we will achieve profitability and, if so, whether we will be able to sustain it. Our ability to generate significant revenue and achieve profitability is dependent on our ability to complete development, obtain necessary regulatory approvals, and have our product candidates manufactured and successfully marketed. We cannot be sure that we will be profitable even if we successfully commercialize one of our product candidates. If we do successfully obtain regulatory approval to market our tablet vaccine candidates, our revenues will be dependent, in part, upon the size of the markets in the territories for which regulatory approval is received, the number of competitors in such markets, the price at which we can offer our product candidates and whether we own the commercial rights for that territory. If the indication approved by regulatory authorities is narrower than we expect, or the treatment population is narrowed by competition, physician choice or treatment guidelines, we may not generate significant revenue from sales of our product candidates, even if approved. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. If we fail to become and remain profitable, the market price of our common stock and our ability to raise capital and continue operations will be adversely affected.

We expect research and development expenses to increase significantly for any of our small molecule antivirals and tablet vaccines, including those for the prevention of norovirus, influenza and RSV infection, as well as those for the treatment of HPV related dysplasia and cancer, and any other chronic viral infections and cancer. In addition, even if we obtain regulatory approval, significant sales and marketing expenses will be required to commercialize the tablet vaccine candidates. As a result, we expect to continue to incur significant and increasing operating losses and negative cash flows for the foreseeable future. These losses have had and will continue to have an adverse effect on its financial position and working capital. As of March 31, 2018, we had an accumulated deficit of $77.7 million.

We recently completed the Merger with Aviragen and the failure to successfully integrate could adversely affect our future results.

Our success will depend, in significant part, on our ability to integrate successfully and to manage successfully the challenges presented by the integration process in the Merger with Aviragen that was completed in February 2018. Potential difficulties that may be encountered in the integration process include the following:

- using our cash and assets efficiently to develop our business;
- appropriately managing our liabilities;
- potential unknown or currently unquantifiable liabilities associated with the Merger and our operations;
- difficulties in operating with a new management team as a public company; and
- performance shortfalls as a result of the diversion of the management’s attention caused by integrating the companies’ operations, in particular operating as a public company immediately post-merger with Aviragen.

We are largely dependent on the success of our tablet vaccine for the prevention of norovirus infection which is still in early-stage clinical development, and if this tablet vaccine does not receive regulatory approval or is not successfully commercialized, our business may be harmed.

None of our product candidates are in late-stage clinical development or approved for commercial sale and we may never be able to develop marketable tablet vaccine candidates. We expect that a substantial portion of our efforts and expenditures over the next few years will be devoted to our tablet vaccine candidate for norovirus. Accordingly, our business currently depends heavily on the successful development, regulatory approval and commercialization of our norovirus tablet vaccine. Our norovirus tablet vaccine may not receive regulatory approval or be successfully commercialized even if regulatory approval is received. The research, testing, manufacturing, labeling, approval, sale, marketing and distribution of tablet vaccine candidates are and will remain subject to extensive regulation by the FDA and other regulatory authorities in the United States and other countries that each have differing regulations. we are not permitted to market our norovirus tablet vaccine in the United States until we receive approval of a biologics license application, or BLA, from the FDA, or in any foreign countries until we receive the requisite approval from such countries. To date, we have only completed Phase 1 clinical trials for one of the two strains necessary for our bivalent tablet vaccine candidate. For our small molecule antivirals, we have only completed Phase 2 clinical trials. As a result, we have not submitted an NDA or BLA to the FDA or comparable applications to other regulatory authorities and do not expect to be in a position to do so for the foreseeable future. Obtaining approval of an NDA or BLA is an extensive, lengthy, expensive and inherently uncertain process, and the FDA may delay, limit or deny approval of its seasonal influenza tablet vaccine for many reasons, including:

- We may not be able to demonstrate that our norovirus tablet vaccine is safe and effective to the satisfaction of the FDA;
- the FDA may not agree that the completed Phase 1 clinical trials of the norovirus vaccine satisfy the FDA's requirements and may require us to conduct additional testing;
- the results of our clinical trials may not meet the level of statistical or clinical significance required by the FDA for marketing approval;
- the FDA may disagree with the number, design, size, conduct or implementation of one or more of our clinical trials;
- the contract research organizations, or CROs, that we retain to conduct clinical trials may take actions outside of our control that materially and adversely impact our clinical trials;
- the FDA may not find the data from our preclinical studies and clinical trials sufficient to demonstrate that the clinical and other benefits of our tablet vaccines outweigh the safety risks;
- the FDA may disagree with our interpretation of data from our preclinical studies and clinical trials;
- the FDA may not accept data generated at our clinical trial sites;
- if our NDA or BLA is reviewed by an advisory committee, the FDA may have difficulties scheduling an advisory committee meeting in a timely manner or the advisory committee may recommend against approval of our application or may recommend that the FDA require, as a condition of approval, additional preclinical studies or clinical trials, limitations on approved labeling or distribution and use restrictions;
- the FDA may require development of a risk evaluation and mitigation strategy, or REMS, as a condition of approval;
- the FDA may identify deficiencies in our manufacturing processes or facilities; or
- the FDA may change its approval policies or adopt new regulations.

Our independent auditors have expressed doubt about our ability to continue as a going concern.

Based on our losses and negative cash flows from operations, our accumulated deficit and debt obligations, our independent auditors have included an explanatory paragraph in their report on our financial statements as of and for the year ended December 31, 2017, expressing substantial doubt about our ability to continue as a going concern. We will require additional funding no later than the first quarter of 2019 to continue our operations at the level planned. If we are unable to continue as a going concern, we may be forced to liquidate our assets and the values we receive for our assets in liquidation or dissolution could be significantly lower than the values reflected in our financial statements.

We will require additional capital to fund our operations, and if we fail to obtain necessary financing, we may not be able to complete the development and commercialization of our tablet vaccine candidates.

We expect to spend substantial amounts to complete the development of, seek regulatory approvals for and commercialize our tablet vaccine candidates. Even with the cash reserves acquired in the Merger, we will require substantial additional capital to complete the development and potential commercialization of our tablet vaccine candidates for norovirus, seasonal influenza, RSV, HPV, and the development of other product candidates. If we are unable to raise capital or find appropriate partnering or licensing collaborations, when needed or on acceptable terms, we could be forced to delay, reduce or eliminate one or more of our development programs or any future commercialization efforts. In addition, attempting to secure additional financing may divert the time and attention of our management from day-to-day activities and harm our development efforts.

Based upon our current operating plan, we believe that our liquid funds will enable us to fund our operating expenses and capital expenditure requirements through at least the full year of 2018. Our estimate as to what we will be able to accomplish is based on assumptions that may prove to be inaccurate, and we could exhaust our available capital resources sooner than is currently expected. Because the length of time and activities associated with successful development of our product candidates is highly uncertain, we are unable to estimate the actual funds we will require for development and any approved marketing and commercialization activities. Our future funding requirements, both near and long-term, will depend on many factors, including, but not limited to:

- the initiation, progress, timing, costs and results of our planned clinical trials;
- the outcome, timing and cost of meeting regulatory requirements established by the FDA, the European Medicines Agency, or EMA, and other comparable foreign regulatory authorities;
- the cost of filing, prosecuting, defending and enforcing our patent claims and other intellectual property rights;
- the cost of defending potential intellectual property disputes, including any patent infringement actions brought by third parties against us now or in the future;
- the effect of competing technological and market developments;
- the cost of establishing sales, marketing and distribution capabilities in regions where we choose to commercialize our product candidates on our own; and
- the initiation, progress, timing and results of the commercialization of our product candidates, if approved, for commercial sale.

Additional funding may not be available on acceptable terms, or 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 our product candidates or potentially discontinue operations.

Raising additional funds by issuing securities may cause dilution to existing stockholders, and raising funds through lending and licensing arrangements may restrict our operations or require us to relinquish proprietary rights.

We expect that significant additional capital will be needed in the future to continue our planned operations. Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, strategic alliances and license and development agreements in connection with any collaborations. We do not currently have any committed external source of funds. To the extent that we raise additional capital by issuing equity securities, our existing stockholders' ownership may experience substantial dilution, and the terms of these securities may include liquidation or other preferences that adversely affect our common stockholders' rights. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, declaring dividends, creating liens, redeeming our stock or making investments.

If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, or through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties on acceptable terms, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise develop and market ourselves.

The terms of our credit facility place restrictions on our operating and financial flexibility.

In December 2016, we entered into a loan and security agreement, or the Loan Agreement, with Oxford Finance, LLC, or Oxford, under which we borrowed $5 million. Our outstanding debt facility with Oxford is collateralized by substantially all of our assets, except for intellectual property, and contains customary financial and operating covenants limiting our ability to transfer or dispose of assets, merge with or acquire other companies, make investments, pay dividends, incur additional indebtedness and liens and conduct transactions with affiliates. We therefore may not be able to engage in any of the foregoing transactions until our current debt obligations are paid in full or we obtain the consent of Oxford. Compliance with these covenants may limit our flexibility in operating our business and our ability to take actions that might be advantageous to us and our stockholders.

Under the Loan Agreement, an event of default will occur if, among other things:

- we fail to make payments under the Loan Agreement;
- we breach any of our covenants under the Loan Agreement, subject to specified cure periods with respect to certain breaches;
- there occurs an event that has a material adverse effect on:
  - our business, operations, properties, assets or financial condition;
  - our ability to perform or satisfy our obligations under the Loan Agreement as they become due or Oxford's ability to enforce its rights or remedies with respect to our obligations under the Loan Agreement; or
  - the collateral or liens securing our obligations under the Loan Agreement;
- we or our assets become subject to certain legal proceedings, such as bankruptcy proceedings;
- we are unable to pay our debts as they become due; or
- we default on contracts with third parties which would permit Oxford to accelerate the maturity of such indebtedness or that could have a material adverse effect on us.

We may not have enough available cash or be able to raise additional funds through equity or debt financings to repay such indebtedness at the time any such event of default occurs. In that case, we may be required to delay, limit, reduce or terminate our clinical development efforts or grant rights to develop and market product candidates to others that we would otherwise prefer to develop and market ourselves. Oxford could also exercise its rights as collateral agent to take possession and dispose of the collateral securing the Loan Agreement for its benefit. Our business would be harmed as a result of any of these events.

Our stock price is expected to be volatile, and the market price of our common stock has fallen since the Merger.

The market price of our common stock has been subject to significant fluctuations following the Merger. Market prices for securities of early-stage pharmaceutical, biotechnology and other life sciences companies have historically been particularly volatile. Some of the factors that cause the market price of our common stock to fluctuate include:

- our ability to develop product candidates and conduct clinical trials that demonstrate our product candidates are safe and effective;
- our ability to negotiate and receive royalty payments on the sales of our product candidates including Relenza® and Inavir®
- our ability to obtain regulatory approvals for our product candidates, and delays or failures to obtain such approvals;
- failure of any of our product candidates to demonstrate safety and efficacy, receive regulatory approval and achieve commercial success;
- failure to maintain its existing third-party license, manufacturing and supply agreements;
- our failure, or that of our licensors, to prosecute, maintain, or enforce our intellectual property rights;
- changes in laws or regulations applicable to our product candidates;
- any inability to obtain adequate supply of product candidates or the inability to do so at acceptable prices;
- adverse regulatory authority decisions;
- introduction of new or competing products by our competitors;
- failure to meet or exceed financial and development projections that we may provide to the public;
- the perception of the pharmaceutical industry by the public, legislatures, regulators and the investment community;
- announcements of significant acquisitions, strategic partnerships, joint ventures, or capital commitments by us or our competitors;
- disputes or other developments relating to proprietary rights, including patents, litigation matters, and our ability to obtain intellectual property protection for our technologies;
- additions or departures of key personnel;

- significant lawsuits, including intellectual property or stockholder litigation;
- if securities or industry analysts do not publish research or reports about us, or if they issue adverse or misleading opinions regarding our business and stock;
- changes in the market valuations of similar companies;
- general market or macroeconomic conditions;
- sales of our common stock by our existing stockholders in the future;
- trading volume of our common stock;
- adverse publicity relating to our markets generally, including with respect to other products and potential products in such markets;
- changes in the structure of health care payment systems; and
- period-to-period fluctuations in our financial results.

Moreover, the stock markets in general have experienced substantial volatility that has often been unrelated to the operating performance of individual companies. These broad market fluctuations may also adversely affect the trading price of our common stock.

In the past, following periods of volatility in the market price of a company's securities, stockholders have often instituted class action securities litigation against those companies. Such litigation, if instituted, could result in substantial costs and diversion of management attention and resources, which could significantly harm our operations, financial performance and reputation.

If we are required to make certain milestone payments pursuant to a stock purchase agreement with Anaconda Pharma, we may not have the cash necessary to make such payment or the cash set aside for planned expenditures may need to be diverted in order to make such payments, and if such payments are made in shares of our common stock, our existing stockholders' ownership interest would be diluted.

Pursuant to the stock purchase agreement, dated February 25, 2015, by and among the Company, certain shareholders of Anaconda Pharma, a French société par actions simplifiée, or Anaconda, and the other holder representative party thereto, an amount of up to $30.0 million as contingent financial consideration would be payable upon the successful achievement of two future clinical and regulatory milestones. Of such contingent consideration, $10.0 million would be payable, either in cash, shares of our common stock, or a combination of cash and shares of our common stock, at our election, upon the achievement of successful results in the Phase 2 clinical trial for teslexivir. Depending on the results of the Phase 2 clinical trial, the $10 million milestone may be due in the third quarter of 2018. The other contingent milestone would be payable in cash. If such contingent consideration becomes due and payable, our cash balances may not be sufficient to make such payments. If funds that are meant for corporate or research and development expenses are used to pay the contingent consideration, it could have an adverse impact on our growth. To the extent that such contingent consideration is paid in shares of our common stock, it would lead to a dilution of our existing stockholders' ownership.

We do not anticipate that we will pay any cash dividends in the foreseeable future.

The current expectation is that we will retain our future earnings, if any, to fund the development and growth of our business. As a result, capital appreciation, if any, of our common stock will be the sole source of gain, if any, for our stockholders.

****Future sales of shares by existing stockholders could cause our stock price to decline.***

If our existing stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market after legal restrictions on resale lapse, the trading price of our common stock could decline. Of the approximately 7.1 million shares outstanding as of March 31, 2018, approximately 3.6 million are freely tradable, without restriction, in the public market. The remaining approximately 3.5 million shares will become freely tradable on August 12, 2018, when the lock-up agreements that restrict the Company's executive officers and directors and principal stockholders' ability to transfer their shares, subject to specified exceptions, expire. After the lock-up agreements expire, approximately 3.1 million shares of our common stock presently held by directors, executive officers and major shareholders will be subject to volume limitations under Rule 144 under the Securities Act of 1933, as amended, and various vesting agreements.

One stockholder owns a significant percentage of our stock and, together with our management, will be able to exert significant control over matters subject to stockholder approval.

As of March 31, 2018, entities affiliated with Care Capital, a venture capital fund associated with two of our directors, owned approximately 39.2% of our common stock, and Care Capital together with our executive officers and directors owned approximately 43.6% of our common stock. Therefore, these stockholders may be able to determine all matters requiring stockholder approval, and the entities affiliated with Care Capital alone will have significant ability to influence decisions through their ownership position. For example, this concentration of ownership may enable a small number of stockholders to influence or control elections of directors, amendments to our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This concentration of ownership may not be in the best interests of all our stockholders.

Because the Merger resulted in an ownership change under Section 382 of the Code for Aviragen, pre-merger U.S. net operating loss carryforwards and certain other tax attributes are subject to limitations.

If a corporation undergoes an "ownership change" within the meaning of Section 382 of the Code, the corporation's U.S. net operating loss carryforwards and certain other tax attributes arising from before the ownership change are subject to limitations on use after the ownership change. In general, an ownership change occurs if there is a cumulative change in the corporation's equity ownership by certain stockholders that exceeds 50% over a three-year period. Similar rules may apply under state and foreign tax laws. The Merger resulted in an ownership change for Aviragen and, accordingly, Aviragen's U.S. net operating loss carryforwards and certain other tax attributes are subject to limitations on their use. Annual usage is restricted to 1.97% of Aviragen's value on February 13, 2018. Additional ownership changes in the future could result in additional limitations on the combined organization's net operating loss carryforwards. Consequently, even if we achieve profitability, we may not be able to utilize a material portion of our net operating loss carryforwards and other tax attributes, which could have a material adverse effect on cash flow and results of operations.

Changes in tax laws and regulations or in our operations may impact our effective tax rate and may adversely affect our business, financial condition and operating results.

Changes in tax laws in any jurisdiction in which we operate, or adverse outcomes from any tax audits that we may be subject to in any such jurisdictions, could result in an unfavorable change in our effective tax rate, which could adversely affect our business, financial condition, and operating results.

Anti-takeover provisions under Delaware law could make an acquisition more difficult and may prevent attempts by our stockholders to replace or remove our management.

Because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the DGCL, which prohibits stockholders owning in excess of 15% of the outstanding company voting stock from merging or combining with the company. Although we believe these provisions collectively provide for an opportunity to receive higher bids by requiring potential acquirers to negotiate with our board of directors, they would apply even if the offer was considered beneficial by some stockholders. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove management by making it more difficult for stockholders to replace members of our board of directors, which is responsible for appointing the members of management.

If we fail to obtain or maintain adequate coverage and reimbursement for our product candidates, our ability to generate significant revenue could be limited.

The availability and extent of reimbursement by governmental and private payors is essential for most patients to be able to afford expensive treatments. Sales of any of our product candidates that receive marketing approval will depend substantially, both in the United States and internationally, on the extent to which the costs of our product candidates will be paid by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or reimbursed by government health administration authorities, private health coverage insurers and other third-party payors. If reimbursement is not available, or is available only on a limited basis, we may not be able to successfully commercialize our product candidates. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain adequate pricing that will allow us to realize a sufficient return on our investment.

Outside the United States, international operations are generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost-containment initiatives in Europe, Canada and other countries may cause us to price our product candidates on less favorable terms that we currently anticipate. In many countries, particularly the countries of the European Union, the prices of medical products are subject to varying price control mechanisms as part of national health systems. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidates to other available therapies. In general, the prices of products under such systems are substantially lower than in the United States. Other countries allow companies to fix their own prices for products, but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our product candidates. Accordingly, in markets outside the United States, the level of reimbursement for our products is likely to be reduced compared with the United States and may be insufficient to generate commercially reasonable revenues and profits.

Moreover, increasing efforts by governmental and third-party payors, in the United States and internationally, to cap or reduce healthcare costs may cause such organizations to limit both coverage and level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for our product candidates. We expect to experience pricing pressures in connection with the sale of any of our product candidates due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs and surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products into the healthcare market.

Our future success depends on our ability to retain executive officers and attract, retain and motivate qualified personnel.

We are highly dependent on our executive officers and the other principal members of the executive and scientific teams, particularly our President and Chief Executive Officer, Wouter W. Latour and our Chief Scientific Officer, Sean N. Tucker. The employment of our executive officers is at-will and our executive officers may terminate their employment at any time. The loss of the services of any of our senior executive officers could impede the achievement of our research, development and commercialization objectives. We do not maintain “key person” insurance for any executive officer or employee.

Recruiting and retaining qualified scientific, clinical, manufacturing and sales and marketing personnel is also critical to our success. We may not be able to attract and retain these personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. Our industry has experienced an increasing rate of turnover of management and scientific personnel in recent years. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in devising our research and development and commercialization strategy. Our consultants and advisors may be employed by third parties and have commitments under consulting or advisory contracts with other entities that may limit their availability to advance our strategic objectives. If any of these advisors or consultants can no longer dedicate a sufficient amount of time to us, our business may be harmed.

We will need to expand our organization, and may experience difficulties in managing this growth, which could disrupt operations.

Our future financial performance and our ability to commercialize our product candidates, continue to earn royalties and compete effectively will depend, in part, on our ability to effectively manage any future growth. As of March 31, 2018, we had 29 full-time employees. We expect to hire additional employees for our managerial, clinical, scientific and engineering, operational, manufacturing, sales and marketing teams. We may have operational difficulties in connection with identifying, hiring and integrating new personnel. Future growth would impose significant additional responsibilities on our management, including the need to identify, recruit, maintain, motivate and integrate additional employees, consultants and contractors. Also, our management may need to divert a disproportionate amount of its attention away from our day-to-day activities and devote a substantial amount of time to managing these growth activities. We may not be able to effectively manage the expansion of our operations, which may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Our expected growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of our product candidates. If we are unable to effectively manage our growth, our expenses may increase more than expected, our ability to generate and/or grow revenues could be reduced, and we may not be able to implement our business strategy.

Many of the other pharmaceutical companies that we compete against for qualified personnel and consultants have greater financial and other resources, different risk profiles and a longer history in the industry than us. They may also provide more diverse opportunities and better chances for career advancement. Some of these characteristics may be more appealing to high-quality candidates and consultants than what we are able to offer. If we are unable to continue to attract and retain high-quality personnel and consultants, the rate and success at which we can select and develop our product candidates and our business will be limited.

Our employees, independent contractors, principal investigators, consultants, commercial collaborators, service providers and other vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could have an adverse effect on our results of operations.

We are exposed to the risk that our employees and contractors, including principal investigators, consultants, commercial collaborators, service providers and other vendors may engage in fraudulent or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or other unauthorized activities that violate the laws and regulations of the FDA and other similar regulatory bodies, including those laws that require the reporting of true, complete and accurate information to such regulatory bodies, manufacturing standards, federal and state healthcare fraud and abuse and health regulatory laws and other similar foreign fraudulent misconduct laws, or laws that require the true, complete and accurate reporting of financial information or data. Misconduct by these parties may also involve the improper use or misrepresentation of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter third-party 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 financial results, including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

Our business and operations would suffer in the event of system failures.

Our computer systems and those of our service providers, including our CROs, are vulnerable to damage from computer viruses, unauthorized access, natural disasters (including earthquakes), terrorism, war and telecommunication and electrical failures. If such an event were to occur and cause interruptions in our or their operations, it could result in a material disruption of our development programs. For example, the loss of preclinical or clinical trial data from completed, ongoing or planned trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of or damage to data or applications, or inappropriate disclosure of personal, confidential or proprietary information, we could incur liability and the further development of our product candidates could be delayed.

We have identified a material weakness in our internal control over financial reporting, and if we are unable to maintain proper and effective internal controls over financial reporting, the accuracy and timeliness of our financial reporting may be adversely affected.

In connection with the audits of our financial statements for each of the years ended December 31, 2015 through 2017, our management and our independent auditors identified a material weakness in our internal control over financial reporting. A “material weakness” is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. The material weakness relates to us lacking sufficient qualified resources and adequate processes thereby impacting our ability to appropriately segregate duties and perform effective and timely review of account reconciliations and nonroutine transactions.

We are already taking steps to remediate this material weakness, including increasing the depth and experience within our accounting and finance organization, as well as designing and implementing improved processes and internal controls. However, our efforts to remediate this material weakness may not be effective or prevent any future material weakness or significant deficiency in our internal control over financial reporting. If our efforts are not successful, or other material weaknesses or control deficiencies occur in the future, we may be unable to report our financial results accurately on a timely basis, which could cause our reported financial results to be materially misstated and result in the loss of investor confidence and cause the market price of our common stock to decline.

We are required, pursuant to Section 404 of the Sarbanes-Oxley Act, to annually furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting. This assessment will need to include disclosure of any material weaknesses identified by our management in our internal control over financial reporting. Our independent registered public accounting firm may be required to attest to the effectiveness of our internal control over financial reporting in the event that our public float exceeds $75 million. We will be required to disclose changes made in our internal control and procedures on a quarterly basis. To comply with the requirements of being a public company, we may need to undertake various actions, such as implementing new internal controls and procedures and hiring accounting or internal audit staff. We have begun the costly and challenging process of compiling the system and processing documentation necessary to perform the evaluation needed to comply with Section 404, when applicable; however, we may not be able to complete such evaluation, testing and any required remediation in a timely fashion.

We will incur significant additional costs and demands upon management as a result of complying with the laws and regulations affecting public companies.

We incur significant legal, accounting and other expenses associated with public company reporting requirements. We also incur costs associated with corporate governance requirements, including requirements under the Sarbanes-Oxley Act, as well as rules implemented by the SEC and The Nasdaq Stock Market LLC. These rules and regulations impose significant legal and financial compliance costs and make some activities more time-consuming and costly. For example, our management team consists of certain executive officers who have not previously managed and operated a public company. These executive officers and other personnel will need to devote substantial time to gaining expertise regarding operations as a public company and compliance with applicable laws and regulations. In addition, it may be more difficult for us to attract and retain qualified individuals to serve on our board of directors or as executive officers, which may adversely affect investor confidence and could cause our business or stock price to suffer.

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

The market price of our common stock has been and may continue to 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 management's attention from other business concerns, which could seriously harm our business.

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

The trading market for our common stock is influenced by independent research and reports that securities or industry analysts publish about us or our business from time to time. At present, there are no analysts covering our stock, which means we have low visibility in the financial markets, which could cause a low trading volume, which would tend to cause our stock price to decline. There can be no assurance that analysts will cover our stock in the future or, if they do, provide favorable ratings. If any analysts who cover us downgrade our stock, change their opinion of our stock or disseminate negative information regarding our business, our share price may decline.

Risks Related to Clinical Development, Regulatory Approval and Commercialization

If we fail to continue to develop and refine the formulations of our tablet vaccine candidates, we may not obtain regulatory approvals, and even if approved, the commercial acceptance of our tablet vaccine candidates would likely be limited.

In our H1N1 influenza Phase 2 trial we used vaccine tablets that contained approximately 1.5×10^{10} IU of vaccine. Accordingly, subjects in this trial were required to take 7 tablets in a single setting to reach the aggregate dose of 1×10^{11} IU, the target dose for this trial. We believe that in order for our seasonal influenza vaccine candidate to be commercially successful we will need to continue to refine our formulation and develop influenza vaccine tablets that contain the desired dose for each vaccine strain in a single tablet, resulting in a vaccination regime of no more than four tablets. In addition, we intend to develop a seasonal influenza vaccine tablet that contains the optimal effective dose for all four influenza vaccines necessary to create a quadrivalent vaccine, resulting in a vaccination regime of one tablet. Increasing the potency of the vaccine tablets may affect the stability profile of the vaccine and we may not be able to reduce the vaccination regime for an influenza strain to a single tablet or combine the four influenza strains into one vaccine tablet. In addition, increasing the potency of the vaccine tablets or combining the influenza strains necessary to create a quadrivalent vaccine may adversely affect manufacturing yields and render such tablets too costly to manufacture at commercial scale. Our efforts to develop tablet vaccine candidates for norovirus and RSV face similar formulation challenges. If we are unable to further develop and refine the formulations of our tablet vaccine candidates, we may be unable to obtain regulatory approval from the FDA or other regulatory authorities, and even if approved, the commercial acceptance of our tablet vaccine candidates would likely be limited.

Clinical trials are very expensive, time-consuming, difficult to design and implement and involve an uncertain outcome, and if they fail to demonstrate safety and efficacy to the satisfaction of the FDA, or similar regulatory authorities, we will be unable to commercialize our tablet vaccine candidates.

Our tablet vaccine candidates for norovirus and seasonal influenza are still in early-stage clinical development and teslexivir is in Phase 2 trials. Both will require extensive additional clinical testing before we are prepared to submit a BLA for regulatory approval for either indication or for any other treatment regime. We cannot predict with any certainty if or when we might submit a BLA for regulatory approval for any of our tablet vaccine candidates, which are currently in pre-clinical development, or whether any such BLAs will be approved by the FDA. Human clinical trials are very expensive and difficult to design and implement, in part because they are subject to rigorous regulatory requirements. For instance, the FDA may not agree with our proposed endpoints for any clinical trial we propose, which may delay the commencement of our clinical trials. The clinical trial process is also time-consuming. We estimate that the clinical trials we need to conduct to be in a position to submit BLAs for our tablet vaccine candidates for seasonal influenza, norovirus and RSV will take several years to complete. Furthermore, failure can occur at any stage of the trials, and we could encounter problems that cause us to abandon or repeat clinical trials. Tablet vaccine candidates in the later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials, and the results of early clinical trials of the tablet vaccine candidate for seasonal influenza as well as the pre-clinical results we have observed for our norovirus and RSV tablet vaccine candidates therefore may not be predictive of the results of our planned Phase 1 and 2 trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials.

Moreover, preclinical and clinical data are often susceptible to multiple interpretations and analyses. Many companies that have believed their vaccine candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their products. Success in preclinical testing and early clinical trials does not ensure that later clinical trials, which involve many more subjects and, for influenza, all four strains rather than the one strain we have studied in Phase 1 clinical trials to date and the results of later clinical trials may not replicate the results of prior clinical trials and preclinical testing.

We may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our ability to receive marketing approval or commercialize our tablet vaccine candidates, including that:

- regulators or institutional review boards may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- we may experience delays in reaching or fail to reach agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites;
- clinical trials of our tablet vaccine candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs;
- the number of subjects required for clinical trials of our tablet vaccine candidates may be larger than we anticipate; enrollment in these clinical trials may be slower than we anticipate, or participants may drop out of these clinical trials at a higher rate than we anticipate;
- Our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- regulators or institutional review boards may require that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;
- the cost of clinical trials of our tablet vaccine candidates may be greater than we anticipate; and
- the supply or quality of our tablet vaccine candidates or other materials necessary to conduct clinical trials may be insufficient or inadequate.

If we are required to conduct additional clinical trials or other testing of our tablet vaccine candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our tablet vaccine candidates or other testing, if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, we may:

- be delayed in obtaining marketing approval for our tablet vaccine candidates;
- not obtain marketing approval at all;

- obtain approval for indications or patient populations that are not as broad as intended or desired;
- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings, including boxed warnings;
- be subject to additional post-marketing testing requirements; or
- have the product removed from the market after obtaining marketing approval.

Product development costs will also increase if we experience delays in testing or in receiving marketing approvals. We do not know whether any clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. Significant clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our tablet vaccine candidates, could allow our competitors to bring products to market before we do, and could impair our ability to successfully commercialize our tablet vaccine candidates, any of which may harm our business and results of operations.

Our platform includes a novel vaccine adjuvant and all of our current tablet vaccine candidates include this novel adjuvant, which may make it difficult for us to predict the time and cost of tablet vaccine development as well as the requirements the FDA or other regulatory agencies may impose to demonstrate the safety of the tablet vaccine candidates.

Novel vaccine adjuvants, included in some of our tablet vaccine candidates, may pose an increased safety risk to patients. Adjuvants are compounds that are added to vaccine antigens to enhance the activation and improve immune response and efficacy of vaccines. Development of vaccines with novel adjuvants requires evaluation in larger numbers of patients prior to approval than would be typical for therapeutic drugs. Guidelines for evaluation of vaccines with novel adjuvants have been established by the FDA and other regulatory bodies and expert committees. Our tablet vaccine candidates, including for norovirus, may include one or more novel vaccine adjuvants. Any vaccine, because of the presence of an adjuvant, may have side effects considered to pose too great a risk to patients to warrant approval of the vaccine. Traditionally, regulatory authorities have required extensive study of novel adjuvants because vaccines typically get administered to healthy populations, in particular infants, children and the elderly, rather than to people with disease. Such extensive study has often included long-term monitoring of safety in large general populations that has at times exceeded 10,000 subjects. This contrasts with the few thousand subjects typically necessary for approval of novel therapeutics. To date, the FDA and other major regulatory agencies have only approved vaccines containing five adjuvants, which makes it difficult to determine how long it will take or how much it will cost to obtain regulatory approvals for our tablet vaccine candidates in the United States or elsewhere.

Enrollment and retention of subjects in clinical trials is an expensive and time-consuming process and could be made more difficult or rendered impossible by multiple factors outside our control.

We may encounter delays in enrolling, or be unable to enroll, a sufficient number of participants to complete any of our clinical trials. Once enrolled, we may be unable to retain a sufficient number of participants to complete any of our trials. Late-stage clinical trials of our tablet vaccine candidate for norovirus, in particular, will require the enrollment and retention of large numbers of subjects. Subject enrollment and retention in clinical trials depends on many factors, including the size of the subject population, the nature of the trial protocol, the existing body of safety and efficacy data with respect to the study drug, the number and nature of competing treatments and ongoing clinical trials of competing drugs for the same indication, the proximity of subjects to clinical sites and the eligibility criteria for the study. Further, since there are no reliable animal models to norovirus infection, human challenge studies have been used to understand viral activity and possible immune correlates that prevent infection making trials costlier than animal-based studies.

Furthermore, any negative results we may report in clinical trials of our tablet vaccine candidates may make it difficult or impossible to recruit and retain participants in other clinical trials of that same tablet vaccine candidate. Delays or failures in planned subject enrollment or retention may result in increased costs, program delays or both, which could have a harmful effect on our ability to develop our tablet vaccine candidates, or could render further development impossible. In addition, we expect to rely on CROs and clinical trial sites to ensure proper and timely conduct of our future clinical trials and, while we intend to enter into agreements governing their services, we will be limited in our ability to compel their actual performance in compliance with applicable regulations. Enforcement actions brought against these third parties may cause further delays and expenses related to our clinical development programs.

We face significant competition from other biotechnology and pharmaceutical companies, and our operating results will suffer if we fail to compete effectively.

Vaccine development is highly competitive and subject to rapid and significant technological advancements. In particular, for seasonal influenza vaccine, we face competition from various sources, including larger and better funded pharmaceutical, specialty pharmaceutical and biotechnology companies, as well as academic institutions, governmental agencies and public and private research institutions. These competitors are focused on delivering therapeutics for the treatment of influenza with products that are available and have gained market acceptance as the standard treatment protocol. Further, it is likely that additional drugs or other treatments will become available in the future for the treatment of influenza.

For tablet vaccines, we face competition from approved vaccines, against which new tablet vaccines must demonstrate compelling advantages in efficacy, convenience, tolerability and safety, and from competitors working to patent, discover, develop or commercialize medicines before we can do the same with tablet vaccines.

Many of our existing or potential competitors have substantially greater financial, technical and human resources than we do and significantly greater experience in the discovery and development of products for the treatment of influenza, as well as in obtaining regulatory approvals of those products in the United States and in foreign countries. Our current and potential future competitors also have significantly more experience commercializing drugs that have been approved for marketing. Mergers and acquisitions in the pharmaceutical and biotechnology industries could result in even more resources being concentrated among a small number of our competitors.

Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors may succeed in developing, acquiring or licensing, on an exclusive basis, drugs that are more effective or less costly than any tablet vaccine candidate that we may develop.

We will face competition from other drugs currently approved or that will be approved in the future for the treatment of the other infectious diseases we are currently targeting. Therefore, our ability to compete successfully will depend largely on our ability to:

- develop and commercialize tablet vaccine candidates that are superior to other vaccines in the market;
- demonstrate through our clinical trials that our tablet vaccine candidates are differentiated from existing and future therapies;
- attract qualified scientific, vaccine development and commercial personnel;
- obtain patent or other proprietary protection for our tablet vaccine candidates;
- obtain required regulatory approvals;
- obtain coverage and adequate reimbursement from, and negotiate competitive pricing with, third-party payors; and
- successfully develop and commercialize, independently or with collaborators, new tablet vaccine candidates.

The availability of our competitors' vaccines could limit the demand, and the price we are able to charge, for any tablet vaccine candidate we develop. The inability to compete with existing or subsequently introduced vaccines would have an adverse impact on our business, financial condition and prospects.

Established pharmaceutical companies may invest heavily to accelerate discovery and development of novel compounds or to in-license novel compounds that could make any of its tablet vaccine candidates less competitive. In addition, any new vaccine that competes with an approved vaccine must demonstrate compelling advantages in efficacy, convenience, tolerability and safety in order to overcome price competition and to be commercially successful. Accordingly, our competitors may succeed in obtaining patent protection, discovering, developing, receiving the FDA's approval for or commercializing medicines before we do, which would have an adverse impact on our business and results of operations.

The biotechnology and pharmaceutical industries are characterized by intense competition to develop new technologies and proprietary products. While we believe that our proprietary tablet vaccine candidates provide competitive advantages, we face competition from many different sources, including biotechnology and pharmaceutical companies, academic institutions, government agencies, as well as public and private research institutions. Any products that we may commercialize will have to compete with existing products and therapies as well as new products and therapies that may become available in the future.

There are other organizations working to improve existing therapies, vaccines or delivery methods, or to develop new vaccines, therapies or delivery methods for its selected indications. Depending on how successful these efforts are, it is possible they may increase the barriers to adoption and success of our vaccine candidates, if approved.

We anticipate that we will face intense and increasing competition as new vaccines enter the market and advanced technologies become available. We expect any tablet or other oral delivery vaccine candidates that we develop and commercialize to compete on the basis of, among other things, efficacy, safety, convenience of administration and delivery, price, availability of therapeutics, the level of generic competition and the availability of reimbursement from government and other third-party payors.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that we may develop. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for our vaccine candidates, which could result in our competitors establishing a strong market position before we are able to enter the market. In addition, our ability to compete may be affected in many cases by insurers or other third-party payors seeking to encourage the use of generic products.

We believe our seasonal influenza vaccine candidate will compete directly with approved vaccines in the market, which include non-recombinant and recombinant products that are administered via injection or intranasally. The major non-recombinant injectable vaccine competitors include Astellas Pharma Inc., Abbott Laboratories, AstraZeneca UK Limited, Baxter International Inc., Research Foundation for Microbial Diseases of Osaka University, Seqirus-bioCSL Inc., GlaxoSmithKline plc, or GlaxoSmithKline, Sanofi S.A., or Sanofi, Pfizer Inc., and Takeda Pharmaceutical Company Limited, or Takeda. Non-recombinant intranasal competition includes MedImmune, Inc., or MedImmune, and potentially others. Recombinant injectable competitors include Sanofi and Novavax, Inc., or Novavax. Many other groups are developing new or improved flu vaccine or delivery methods.

There is currently no approved norovirus vaccine for sale globally. While we are not aware of all of our competitors' efforts, we believe, based on public statements, that Takeda is also developing a virus-like particle-based norovirus vaccine that would be delivered by injection.

There is currently no approved RSV vaccine for sale globally; however, a number of vaccine manufacturers, academic institutions and other organizations currently have, or have had, programs to develop such a vaccine. In addition, many other companies are developing products to prevent disease caused by RSV using a variety of technology platforms, including monoclonal antibodies, small molecule therapeutics, as well as various viral vector and VLP based vaccine technologies. While we are not aware of all of our competitors' efforts, we believe, based on public statements, that several companies are in various stages of developing an RSV vaccine including GlaxoSmithKline, Johnson & Johnson, Bavarian Nordic, Astellas, MedImmune, Novavax, and Sanofi, as well as the National Institute of Allergy and Infectious Diseases, an institute under the U.S. National Institutes of Health, and possibly others.

There is currently no approved HPV therapeutic vaccine for sale globally; however, a number of vaccine manufacturers, academic institutions and other organizations currently have, or have had, programs to develop such a vaccine. We believe, based on public statements, that several companies are in various stages of developing an HPV therapeutic vaccine including Inovio, Advaxis, Genexine, and possibly others.

Our tablet vaccine candidates may cause adverse effects or have other properties that could delay or prevent their regulatory approval or limit the scope of any approved label or market acceptance.

Adverse events caused by our tablet vaccine candidates could cause reviewing entities, clinical trial sites or regulatory authorities to interrupt, delay or halt clinical trials and could result in the denial of regulatory approval. If an unacceptable frequency or severity of adverse events are reported in clinical trials for our tablet vaccine candidates, our ability to obtain regulatory approval for such tablet vaccine candidates may be negatively impacted.

Furthermore, if any of our tablet vaccines are approved and then cause serious or unexpected side effects, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw their approval of the tablet vaccine candidates or impose restrictions on its distribution or other risk management measures;
- regulatory authorities may require the addition of labeling statements, such as warnings or contraindications;
- we may be required to change the way our tablet vaccine candidates are administered or to conduct additional clinical trials;
- we could be sued and held liable for injuries sustained by patients;
- we could be subject to the Vaccine Injury Compensation Program;
- we could elect to discontinue the sale of its tablet vaccine candidates; and
- our reputation may suffer.

Any of these events could prevent Vaxart from achieving or maintaining market acceptance of the affected tablet vaccine candidate and could substantially increase the costs of commercialization.

If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals, we will not be able to commercialize, or will be delayed in commercializing, our tablet vaccine candidates, and our ability to generate significant revenue will be impaired.

Our tablet vaccine and small-molecule antiviral candidates and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale and distribution, are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and by comparable authorities in other countries. Failure to obtain marketing approval for a tablet vaccine candidate will prevent us from commercializing the tablet vaccine candidate. We have not received approval to market any of our tablet vaccine candidates from regulatory authorities in any jurisdiction. We have only limited experience in filing and supporting the applications necessary to gain marketing approvals and expect to rely on CROs to assist us in this process. Securing regulatory approval requires the submission of extensive preclinical and clinical data and supporting information to the various regulatory authorities for each therapeutic indication to establish the tablet vaccine candidate's safety and efficacy. Securing regulatory approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the relevant regulatory authority. Our tablet vaccine candidates may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude us obtaining marketing approval or prevent or limit commercial use.

The process of obtaining marketing approvals, both in the United States and elsewhere, is expensive, may take many years and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the tablet vaccine candidates involved. We cannot be sure that we will ever obtain any marketing approvals in any jurisdiction. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations or changes in regulatory review for each submitted product application may cause delays in the approval or rejection of an application. The FDA and comparable authorities in other countries have substantial discretion in the approval process and may refuse to accept any application or may decide that our data is insufficient for approval and require additional preclinical or other studies, and clinical trials. In addition, varying interpretations of the data obtained from preclinical testing and clinical trials could delay, limit or prevent marketing approval of a tablet vaccine candidate. Additionally, any marketing approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable.

Even if we obtain FDA approval in the United States, we may never obtain approval for or commercialize our tablet vaccine candidates in any other jurisdiction, which would limit our ability to realize each product's full market potential.

In order to market any of our tablet vaccine candidates in a particular jurisdiction, we must establish and comply with numerous and varying regulatory requirements on a country-by-country basis regarding safety and efficacy. Approval by the FDA in the United States does not ensure approval by regulatory authorities in other countries or jurisdictions. In addition, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not guarantee regulatory approval in any other country. Approval processes vary among countries and can involve additional tablet vaccine candidate testing and validation and additional administrative review periods. Seeking foreign regulatory approval could result in difficulties and costs for us and require additional preclinical studies or clinical trials which could be costly and time consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our tablet vaccine candidates in those countries. We do not have any tablet vaccine candidates approved for sale in any jurisdiction, including in international markets, and we do not have experience in obtaining regulatory approval in international markets. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, or if regulatory approvals in international markets are delayed, our target market will be reduced and our ability to realize the full market potential of any tablet vaccine candidate we develop will be unrealized.

Even if we obtain regulatory approval, we will still face extensive ongoing regulatory requirements and our tablet vaccine candidates may face future development and regulatory difficulties.

Any tablet vaccine candidate for which we obtain marketing approval, along with the manufacturing processes, post- approval clinical data, labeling, packaging, distribution, adverse event reporting, storage, recordkeeping, export, import, advertising and promotional activities for such tablet vaccine candidate, among other things, will be subject to extensive and ongoing requirements of and review by the FDA and other regulatory authorities. These requirements include submissions of safety, efficacy and other post-marketing information and reports, establishment registration and drug listing requirements, continued compliance with current Good Manufacturing Practice, or cGMP, requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, requirements regarding the distribution of samples to physicians and recordkeeping and current GCP requirements for any clinical trials that we conduct post-approval. Even if marketing approval of a tablet vaccine candidate is granted, the approval may be subject to limitations on the indicated uses for which the tablet vaccine candidates may be marketed or to the conditions of approval. If its tablet vaccine candidate receives marketing approval, the accompanying label may limit the approved use of our tablet vaccine, which could limit sales.

The FDA may also impose requirements for costly post-marketing studies or clinical trials and surveillance to monitor the safety and/or efficacy of our tablet vaccine candidates. The FDA closely regulates the post-approval marketing and promotion of drugs to ensure drugs are marketed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA imposes stringent restrictions on manufacturers' communications regarding off-label use and if we do not market our tablet vaccine candidates for their approved indications, we may be subject to enforcement action for off-label marketing. Violations of the Federal Food, Drug, and Cosmetic Act relating to the promotion of prescription drugs may lead to FDA enforcement actions and investigations alleging violations of federal and state health care fraud and abuse laws, as well as state consumer protection laws.

In addition, later discovery of previously unknown adverse events or other problems with our tablet vaccine candidates, manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may yield various results, including:

- restrictions on manufacturing such tablet vaccine candidate;
- restrictions on the labeling or marketing of a tablet vaccine candidate;
- restrictions on tablet vaccine distribution or use;
- requirements to conduct post-marketing studies or clinical trials;
- warning letters;
- withdrawal of the tablet vaccine candidate from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of such tablet vaccine candidate;
- fines, restitution or disgorgement of profits or revenues;
- suspension or withdrawal of marketing approvals;
- refusal to permit the import or export of such tablet vaccine candidate;
- tablet vaccine candidate seizure; or
- injunctions or the imposition of civil or criminal penalties.

The FDA's policies may change, and additional government regulations may be enacted, that could prevent, limit or delay regulatory approval of any of our tablet vaccine 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.

Even if our tablet vaccine candidates receive marketing approval, they may fail to achieve market acceptance by physicians, patients, third-party payors or others in the medical community necessary for commercial success.

If our tablet vaccine candidates, including our vaccine for norovirus, receive marketing approval, they may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. If they do not achieve an adequate level of acceptance, we may not generate significant revenues and become profitable. The degree of market acceptance, if approved for commercial sale, will depend on a number of factors, including but not limited to:

- the efficacy and potential advantages compared to alternative treatments;
- effectiveness of sales and marketing efforts;

- the cost of treatment in relation to alternative treatments;
- our ability to offer our tablet vaccine candidates for sale at competitive prices;
- the convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the willingness of the medical community to offer customers our tablet vaccine candidate option in addition to, or in the place of, injectable vaccines;
- the strength of marketing and distribution support;
- the availability of third-party coverage and adequate reimbursement;
- the prevalence and severity of any side effects; and
- any restrictions on the use of our tablet vaccine together with other medications.

Because we expect sales of our tablet vaccine candidates for norovirus, if approved, to generate substantially all of our revenues for the foreseeable future, the failure of this tablet vaccine to achieve market acceptance would harm our business and could require us to seek additional financing sooner than it otherwise plans.

If we fail to comply with state and federal healthcare regulatory laws, we could face substantial penalties, damages, fines, disgorgement, exclusion from participation in governmental healthcare programs, and the curtailment of our operations, any of which could harm our business.

Although we do not provide healthcare services or submit claims for third-party reimbursement, we are subject to healthcare fraud and abuse regulation and enforcement by federal and state governments, which could significantly impact our business. The laws that may affect our ability to operate include, but are not limited to:

- the federal anti-kickback statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, receiving, offering, or paying remuneration, directly or indirectly, in cash or in kind, in exchange for or to induce either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service for which payment may be made, in whole or in part, under federal healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of this statute or specific intent to violate it;
- the civil False Claims Act, or FCA, which prohibits, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid or other third-party payors that are false or fraudulent; knowingly making, using, or causing to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the government; or knowingly making, using, or causing to be made or used, a false record or statement to avoid, decrease or conceal an obligation to pay money to the federal government;
- the criminal FCA, which imposes criminal fines or imprisonment against individuals or entities who make or present a claim to the government knowing such claim to be false, fictitious or fraudulent;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- the federal civil monetary penalties statute, which prohibits, among other things, the offering or giving of remuneration to a Medicare or Medicaid beneficiary that the person knows or should know is likely to influence the beneficiary's selection of a particular supplier of items or services reimbursable by a Federal or state governmental program;
- the federal physician sunshine requirements under the Affordable Care Act, which require certain manufacturers of drugs, devices, biologics, and medical supplies to report annually to the U.S. Department of Health and Human Services information related to payments and other transfers of value to physicians, other healthcare providers, and teaching hospitals, and ownership and investment interests held by physicians and other healthcare providers and their immediate family members; and
- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws that may apply to items or services reimbursed by any third-party payor, including commercial insurers; state laws that require pharmaceutical companies to comply with the device 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 and other potential referral sources; and state laws that require device manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures.

Further, the Affordable Care Act, among other things, amended the intent requirements of the federal anti-kickback statute and certain criminal statutes governing healthcare fraud. A person or entity can now be found guilty of violating the statute without actual knowledge of the statute or specific intent to violate it. In addition, Affordable Care Act provided that the government may assert that a claim including items or services resulting from a violation of the federal Anti- Kickback Statute constitutes a false or fraudulent claim for purposes of the FCA. Moreover, while we do not, and will not, submit claims and our customers will make the ultimate decision on how to submit claims, we may provide reimbursement guidance to our customers from time to time. If a government authority were to conclude that we provided improper advice to our customers or encouraged the submission of false claims for reimbursement, we could face action against us by government authorities. Any violations of these laws, or any action against us for violation of these laws, even if we successfully defend against it, could result in a material adverse effect on our reputation, business, results of operations and financial condition.

We have entered into consulting and scientific advisory board arrangements with physicians and other healthcare providers. Compensation for some of these arrangements includes the provision of stock options. While we have worked to structure our arrangements to comply with applicable laws, because of the complex and far-reaching nature of these laws, regulatory agencies may view these transactions as prohibited arrangements that must be restructured, or discontinued, or for which we could be subject to other significant penalties. We could be adversely affected if regulatory agencies interpret our financial relationships with providers who influence the ordering of and use our products to be in violation of applicable laws.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal and state enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry.

Responding to investigations can be time- and resource-consuming and can divert management’s attention from the business. Additionally, as a result of these investigations, healthcare providers and entities may have to agree to additional onerous compliance and reporting requirements as part of a consent decree or corporate integrity agreement. Any such investigation or settlement could increase our costs or otherwise have an adverse effect on our business.

Product liability lawsuits against us could cause us to incur substantial liabilities and could limit the commercialization of any tablet vaccine candidates we may develop.

We face an inherent risk of product liability exposure related to the testing of our tablet vaccine candidates in human clinical trials and will face an even greater risk if we commercially sell any products that we may develop after approval. For instance, since our norovirus tablet challenge study is being conducted in healthy human volunteers, any adverse reactions could result in claims from these injuries and we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any tablet vaccine candidates that it may develop;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- significant costs to defend any related litigation;
- substantial monetary awards to trial subjects or patients;
- loss of revenue; and
- the inability to commercialize any products we may develop.

Although we maintain product liability insurance coverage in the amount of up to $5 million per claim and in the aggregate, it may not be adequate to cover all liabilities that we may incur. Additionally, seasonal influenza is a covered vaccine of the National Vaccine Injury Compensation Program, and our participation in that program may require time and resources that impede product uptake, if approved. We anticipate that we will need to increase our insurance coverage as we continue clinical trials and if we successfully commercialize any products. Insurance coverage is increasingly expensive. 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.

If a product liability claim is successfully brought against us for uninsured liabilities, or such claim exceeds our insurance coverage, we could be forced to pay substantial damage awards that could materially harm our business.

The use of any of our existing or future product candidates in clinical trials and the sale of any approved pharmaceutical products may expose us to significant product liability claims. We currently have product liability insurance coverage for our ongoing clinical trials in the amount of $5 million. Further, we also require clinical research and manufacturing organizations that assist us in the conduct of our trials or manufacture materials used in these trials to carry product liability insurance against such claims. This insurance coverage may not protect us against any or all of the product liability claims that may be brought against us in the future. We may not be able to acquire or maintain adequate product liability insurance coverage at a commercially reasonable cost or in sufficient amounts or scope to protect ourselves against potential losses. In the event a product liability claim is brought against us, we may be required to pay legal and other expenses to defend the claim, as well as uncovered damage awards resulting from a claim brought successfully against us. In the event any of our product candidates are approved for sale by the FDA or similar regulatory authorities in other countries and commercialized, we may need to substantially increase the amount of our product liability coverage. Defending any product liability claim or claims could require us to expend significant financial and managerial resources, which could have an adverse effect on our business.

****If we are unable to establish sales, marketing and distribution capabilities either on our own or in collaboration with third parties, we may not be successful in commercializing our tablet vaccine candidates, if approved.***

We do not have any infrastructure for the sales, marketing or distribution of our tablet vaccine candidates, and the cost of establishing and maintaining such an organization may exceed the cost-effectiveness of doing so. In order to market any tablet vaccine candidates that may be approved, it must build our sales, distribution, marketing, managerial and other non-technical capabilities or make arrangements with third parties to perform these services. To achieve commercial success for any tablet vaccine candidates for which we have obtained marketing approval, we will need a sales and marketing organization. While we expect to partner our tablet vaccines for seasonal influenza and RSV, we expect to build a focused sales, distribution and marketing infrastructure to market our other tablet vaccine candidates in the United States, if approved. There are significant expenses and risks involved with establishing our own sales, marketing and distribution capabilities, including our ability to hire, retain and appropriately incentivize qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel, and effectively manage a geographically dispersed sales and marketing team. Any failure or delay in the development of our internal sales, marketing and distribution capabilities could delay any tablet vaccine candidate launch, which would adversely impact commercialization.

Factors that may inhibit our efforts to commercialize our tablet vaccine candidates on our own include:

- our inability to recruit, train and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to physicians or attain adequate numbers of physicians to administer our tablet vaccines; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

We intend to pursue collaborative arrangements regarding the sale and marketing of our tablet vaccine candidates, if approved, for certain international markets; however, we may not be able to establish or maintain such collaborative arrangements and, if able to do so, our collaborators may not have effective sales. To the extent that we depend on third parties for marketing and distribution, any revenues we receive will depend upon the efforts of such third parties, and there can be no assurance that such efforts will be successful.

If we are unable to build our own sales force in the United States or negotiate a collaborative relationship for the commercialization of our tablet vaccine candidates outside the United States we may be forced to delay the potential commercialization or reduce the scope of our sales and marketing activities. We could have to enter into arrangements with third parties at an earlier stage than we would otherwise choose and we may be required to relinquish rights to our intellectual property or otherwise agree to terms unfavorable to us, any of which may have an adverse effect on our business, operating results and prospects.

We may be competing with many companies that currently have extensive and well-funded marketing and sales operations. Without an internal team or the support of a third-party to perform marketing and sales functions, we may be unable to compete successfully against these more established companies.

If we obtain approval to commercialize any tablet vaccine candidates outside of the United States, a variety of risks associated with international operations could harm our business.

If our tablet vaccine candidates are approved for commercialization, we intend to enter into agreements with third parties to market them in certain jurisdictions outside the United States. We expect that we will be subject to additional risks related to international operations or entering into international business relationships, including:

- different regulatory requirements for drug approvals and rules governing drug commercialization in foreign countries;
- reduced protection for intellectual property rights;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign reimbursement, pricing and insurance regimes;
- foreign taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenues, and other obligations incident to doing business in another country;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- potential noncompliance with the U.S. Foreign Corrupt Practices Act, the U.K. Bribery Act 2010 and similar anti-bribery and anticorruption laws in other jurisdictions;
- tablet vaccination shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters including earthquakes, typhoons, floods and fires.

We have no prior experience in these areas. In addition, there are complex regulatory, tax, labor and other legal requirements imposed by both the European Union and many of the individual countries in Europe with which we will need to comply.

Recently enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval of, and to commercialize, our tablet vaccine candidates and affect the prices we may obtain.

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could, among other things, prevent or delay marketing approval of our tablet vaccine candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any tablet vaccine candidates for which it obtains marketing approval.

For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care Education Reconciliation Act, collectively the Affordable Care Act, was enacted to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for health care and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. Although the full effect of the Affordable Care Act may not yet be fully understood, the law has continued the downward pressure on pharmaceutical pricing, especially under the Medicare program, and increased the industry's regulatory burdens and operating costs.

Moreover, the Drug Supply Chain Security Act imposes obligations on manufacturers of prescription drugs in finished dosage forms. We have not yet adopted the significant measures that will be required to comply with this law. We are not sure whether additional legislative changes will be enacted, or whether the current regulations, guidance or interpretations will be changed, or what the impact of such changes on our business, if any, may be.

We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare vaccines, which could result in reduced demand for our tablet vaccine candidates or additional pricing pressures.

Government involvement may limit the commercial success of our tablet vaccine candidates for influenza.

If an influenza outbreak occurs and is classified as a pandemic or large epidemic by public health authorities, it is possible that one or more government entities may take actions that directly or indirectly have the effect of abrogating some of our rights or opportunities. We have not manufactured a pandemic vaccine to date, but if we were to do so, the economic value of such a vaccine to us could be limited.

Various government entities, including the U.S. government, are offering incentives, grants and contracts to encourage additional investment by commercial organizations into preventative and therapeutic agents against influenza, which may have the effect of increasing the number of competitors and/or providing advantages to known competitors. Accordingly, there can be no assurance that we will be able to successfully establish a competitive market share for our influenza vaccines.

In addition, current influenza vaccines are generally trivalent (contain three strains) or quadrivalent (contain four strains). If the FDA requires or recommends, changes in influenza vaccines, for example for a monovalent vaccine or for use of a strain that is not currently circulating in the human population, it is uncertain whether we will be able to produce or manufacture such a vaccine at commercially reasonable rates.

The seasonal nature of our target indications, in particular influenza, may cause unpredictable royalty revenues from Relenza® and Inavir® and significant fluctuations in our operating results.

Influenza is seasonal in nature with sales of current vaccines occurring primarily in the first and fourth quarters of the calendar year. In addition, outbreaks of norovirus and RSV typically occur in the winter season. This seasonal concentration of product sales could cause quarter-to-quarter operating results to vary widely and can exaggerate the consequences of revenues of any manufacturing or supply delays, any sudden loss of inventory, any inability to satisfy product demand, the inability to estimate the effect of returns and rebates, normal or unusual fluctuations in customer buying patterns, or of any unsuccessful sales or marketing strategies during the sales seasons.

We currently earn royalty revenue from the net sales of Relenza® and Inavir®, which are marketed by our licensees. Although the royalty rates paid to us by our licensees are fixed at a proportion of the licensees' net sales of these products, our periodic and annual revenues from these royalties have historically been variable and subject to fluctuation based on the seasonal incidence and severity of influenza. In addition, returns of products to our licensees that were sold in prior years are taken into account in the calculation of net sales for purposes of determining the royalty revenue we receive and the amount of such returns are generally unpredictable. Our licensees may encounter competition from new products entering the market, which could adversely affect our royalty income. In addition, most of our Relenza® patents have expired and the only substantial remaining intellectual property related to the Relenza® patent portfolio is scheduled to expire in July 2019 in Japan. Further, we sold a portion of our Inavir® royalties to HealthCare Royalty Partners III, L.P., or HCRP, in April 2016. We cannot predict with any certainty what our royalty revenues are likely to be in any given year.

If safety, tolerability, resistance, drug-drug interactions, or efficacy concerns should arise with Relenza® or Inavir®, our future royalty revenue may be reduced, which would adversely affect our financial condition and business.

We currently earn royalty revenue from Relenza® and Inavir®, which are marketed by our licensees. Data supporting the marketing approvals and forming the basis for the safety warnings in the product labels for these products were obtained in controlled clinical trials of limited duration in limited patient populations and, in some cases, from post-approval use. As these marketed products are used over longer periods of time and by more patients, some with underlying health problems or taking other medicines, new issues such as safety, tolerability, resistance or drug-drug interaction issues could arise, which may require our licensees to provide additional warnings or contraindications on their product labels, or otherwise narrow the approved indications. Further, additional information from ongoing research or clinical trials of these products that raise any doubts or concerns about their efficacy may arise. If serious safety, tolerability, resistance, drug-drug interaction, efficacy, or any other concerns or issues arise with respect to these marketed products, sales of these products could be impaired, limited or abandoned by our licensees or by regulatory authorities, in which case our royalty revenue would decrease.

Our success depends largely upon our ability to advance our product candidates through the various stages of drug development. If we are unable to successfully advance or develop our product candidates, our business will be materially harmed.

Even though we generate royalty revenue from our two commercialized influenza products, all of our remaining product candidates are in early stages of development and their commercial viability remains subject to the successful outcome of future preclinical studies, clinical trials, manufacturing processes, regulatory approvals and the risks generally inherent in the development of pharmaceutical product candidates. Failure to advance the development of one or more of our product candidates may have a material adverse effect on our business. The long-term success of our business ultimately depends upon our ability to advance the development of our product candidates through preclinical studies and clinical trials, appropriately formulate and consistently manufacture them in accordance with strict specifications and regulations, obtain approval of our product candidates for sale by the FDA or similar regulatory authorities in other countries, and ultimately have our product candidates successfully commercialized, either by us or by a strategic partner or licensee. We cannot be sure that the results of our ongoing or future research, preclinical studies or clinical trials will support or justify the continued development of our product candidates, or that we will ultimately receive approval from the FDA, or similar regulatory authorities in other countries, to advance the development of our product candidates.

Our product candidates must satisfy rigorous regulatory standards of safety, efficacy and manufacturing before we can advance or complete their development and before they can be approved for sale by the FDA or similar regulatory authorities in other countries. To satisfy these standards, we must engage in expensive and lengthy studies and clinical trials, develop acceptable and cost-effective manufacturing processes, and obtain regulatory approval of our product candidates. Despite these efforts, our product candidates may not:

- demonstrate clinically meaningful therapeutic or other medical benefits as compared to a patient receiving no treatment or over existing drugs or other product candidates in development to treat the same patient population;
- be shown to be safe and effective in future preclinical studies or clinical trials;
- have the desired therapeutic or medical effects;
- be tolerable or free from undesirable or unexpected side effects;
- meet applicable regulatory standards;
- be capable of being appropriately formulated and manufactured in commercially suitable quantities or scale and at an acceptable cost; or
- be successfully commercialized, either by us or by our licensees or collaborators.

Even if we demonstrate favorable results in preclinical studies and early-stage clinical trials, we cannot be sure that the results of late-stage clinical trials will be sufficient to support the continued development of our product candidates. Many, if not most, companies in the pharmaceutical and biopharmaceutical industries have experienced significant delays, setbacks and failures in all stages of development, including late-stage clinical trials, even after achieving promising results in preclinical testing or early-stage clinical trials. Accordingly, results from completed preclinical studies and early-stage clinical trials of our product candidates may not be predictive of the results we may obtain in future late-stage trials. Furthermore, even if the data collected from preclinical studies and clinical trials involving any of our product candidates demonstrate a satisfactory safety, tolerability and efficacy profile, such results may not be sufficient to obtain regulatory approval from the FDA in the United States, or other similar regulatory agencies in other jurisdictions, which is required to market and sell the product.

If the actual or perceived therapeutic benefits, or the safety or tolerability profile of any of our product candidates are not equal to or superior to other competing treatments approved for sale or in clinical development, we may terminate the development of any of our product candidates at any time, and our business prospects and potential profitability could be harmed.

We are aware of a number of companies marketing or developing various classes of anti-infective product candidates or products for the treatment of patients infected with Human Rhinovirus, or HRV, HPV and RSV that are either approved for sale or further advanced in clinical development than ours, such that their time to approval and commercialization may be shorter than that for our product candidates.

Currently, there no approved HPV-specific direct acting anti-viral drugs to treat genital warts. Treatments for genital warts can be divided broadly into two categories: provider-administered ablative/cytodestructive therapies (including cryotherapy, laser ablation, and trichloroacetic acid) and patient-administered topical therapies such as podophyllotoxin (Condylox®; Actavis), sinecatechins (Veregen®; Fougera Pharmaceuticals, Inc.), and imiquimod (Zyclara®, Aldara®; Valeant). We are aware that there are compounds under clinical development to treat genital warts, including Novan's SB206 and Cassiopea's CB-06-02. We anticipate that teslexivir, if successfully developed, would directly compete with the patient-applied topical treatments for genital warts. We believe that key differentiating features of teslexivir could be its mechanism of action, favorable local skin tolerability, efficacy, and lower reoccurrence rate. Three prophylactic vaccines, primarily designed to prevent cervical, vulvar, vaginal, and anal cancers, are currently marketed: a bivalent HPV16/18 vaccine (Cervarix®; GSK), quadrivalent HPV16/18/6/11 (Gardasil®; Merck) and the 9-valent HPV 6/11/16/18/33/52/58 (Gardasil®9; Merck). Gardasil® 9 is indicated for females aged 9 through 26 and males aged 9 through 15, to prevent various HPV related cancers and genital warts in both sexes. Gardasil®, Gardasil® 9, and Cervarix® are not known to exhibit a therapeutic effect on existing HPV lesions.

Currently, there are no approved direct-acting antiviral drugs to treat HRV infections. However, if ever approved, our vapendavir product candidate would indirectly compete with drugs approved to reduce the incidence of exacerbations or improve lung function in patients with asthma and COPD, such as fluticasone propionate (Advair®), tiotoprium bromide (Spiriva®), fluticasone furoate/vilanterol (Breo Ellipta®), and roflumilast (Daliresp®). In addition to these approved drugs, there are compounds at the clinical development stage that if successfully developed for the treatment of HRV infections could compete with vapendavir in the future.

Effective treatments of RSV infections in pediatrics, the elderly, and the immunocompromised are very limited. Currently, only Virazole® (ribavirin) is indicated for the treatment of hospitalized infants and young children with severe lower respiratory tract infections due to RSV. We are aware that the following compounds are under development to treat RSV infections: Gilead's presatovir, Johnson & Johnson's JJ-53718678 (ALS-8176), Ablynx's ALX-0171 and Ark Biosciences' AK0529. The only approved drug for the prevention of RSV infections in high risk infants is MedImmune's palivizumab (Synagis®), a monoclonal antibody. There are several vaccines and antibody products designed to prevent RSV infections in clinical development. Among the clinical stage product candidates in development are Novavax's RSV F vaccine, GSK's GSK3003898A vaccine, GSK's GSK3389245A vaccine, Bavarian Nordic's BN® RSV vaccine, MedImmune's MEDI ÄM2-2 vaccine and MedImmune's monoclonal antibody MEDI8897.

If at any time we believe that any of our product candidates may not provide meaningful or differentiated therapeutic benefits, perceived or real, equal to or better than our competitors' products or product candidates, or we believe that our product candidates may not have as favorable a safety or tolerability profile as potentially competitive compounds, we may delay or terminate the future development of any of our product candidates. We cannot provide any assurance that the future development of any of our product candidates will demonstrate any meaningful therapeutic benefits over potentially competitive compounds currently approved for sale or in development, or an acceptable safety or tolerability profile sufficient to justify their continued development.

Our product candidates may exhibit undesirable side effects when used alone or in combination with other approved pharmaceutical products, which may delay or preclude their development or regulatory approval or limit their use if ever approved.

Throughout the drug development process, we must continually demonstrate the activity, safety and tolerability of our product candidates in order to obtain regulatory approval to further advance their clinical development, or to eventually market them. Even if our product candidates demonstrate adequate biologic activity and clear clinical benefit, any unacceptable side effects or adverse events, when administered alone or in the presence of other pharmaceutical products, may outweigh these potential benefits. We may observe adverse or serious adverse events or drug-drug interactions in preclinical studies or clinical trials of our product candidates, which could result in the delay or termination of their development, prevent regulatory approval, or limit their market acceptance if they are ultimately approved.

If the results from preclinical studies or clinical trials of our product candidates, including those that are subject to existing or future license or collaboration agreements, are unfavorable, we could be delayed or precluded from the further development or commercialization of our product candidates, which could materially harm our business.

In order to further advance the development of, and ultimately receive marketing approval to sell our product candidates, we must conduct extensive preclinical studies and clinical trials to demonstrate their safety and efficacy to the satisfaction of the FDA or similar regulatory authorities in other countries, as the case may be. Preclinical studies and clinical trials are expensive, complex, can take many years to complete, and have highly uncertain outcomes. Delays, setbacks, or failures can and do occur at any time, and in any phase of preclinical or clinical testing, and can result from concerns about safety, tolerability, toxicity, a lack of demonstrated biologic activity or improved efficacy over similar products that have been approved for sale or are in more advanced stages of development, poor study or trial design, and issues related to the formulation or manufacturing process of the materials used to conduct the trials. The results of prior preclinical studies or early-stage clinical trials are not predictive of the results we may observe in late-stage clinical trials. In many cases, product candidates in clinical development may fail to show the desired tolerability, safety and efficacy characteristics, despite having favorably demonstrated such characteristics in preclinical studies or early-stage clinical trials.

In addition, we may experience numerous unforeseen events during, or as a result of, preclinical studies and the clinical trial process, which could delay or impede our ability to advance the development of, receive marketing approval for, or commercialize our product candidates, including, but not limited to:

- communications with the FDA, or similar regulatory authorities in different countries, regarding the scope or design of a trial or trials, or placing the development of a product candidate on clinical hold or delaying the next phase of development until questions or issues are satisfactorily resolved, including performing additional studies to answer their queries;
- regulatory authorities or institutional review boards, or IRBs, not authorizing us to commence or conduct a clinical trial at a prospective trial site;
- enrollment in our clinical trials being delayed, or proceeding at a slower pace than we expected, because we have difficulty recruiting participants or participants drop out of our clinical trials at a higher rate than we anticipated;
- our third-party contractors, upon whom we rely to conduct preclinical studies, clinical trials and the manufacturing of our clinical trial materials, failing to comply with regulatory requirements or meet their contractual obligations to us in a timely manner;
- having to suspend or ultimately terminate a clinical trial if participants are being exposed to unacceptable health or safety risks;
- regulatory authorities or IRBs requiring that we hold, suspend or terminate its preclinical studies and clinical trials for various reasons, including non-compliance with regulatory requirements; and
- the supply or quality of material necessary to conduct our preclinical studies or clinical trials being insufficient, inadequate or unavailable.

Even if the data collected from preclinical studies or clinical trials involving our product candidates demonstrate a satisfactory tolerability, safety and efficacy profile, such results may not be sufficient to support the submission of a BLA or NDA to obtain regulatory approval from the FDA in the United States, or other similar regulatory authorities in other foreign jurisdictions, which is required for us to market and sell our product candidates.

We intend to manufacture the vaccine tablets for the upcoming clinical studies for the foreseeable future at our own facility. If we are unable to do so, or we are delayed, or if the cost of manufacturing is not economically feasible or if we cannot find a third-party supplier, we may be unable to produce tablet vaccine candidates in a sufficient quantity to meet future demand.

From 2012 through the end of December 2017, we relied on a third-party contract manufacturer, Lonza Houston, Inc., for the manufacture, labeling, packaging, storage, and distribution of vaccine tablets to supply the clinical phase 1 and phase 2 trials we have conducted to date. Going forward, we intend to manufacture Phase 1 and Phase 2 clinical trial materials for all our vaccine candidates at our own facility in South San Francisco, California. This transition may result in unanticipated delays and cost more than expected due to a number of factors, including regulatory requirements.

If we are not able to manufacture sufficient quantities of our tablet vaccine candidates, our development activities would be impaired. In addition, our manufacturing facility will be subject to ongoing, periodic inspection by the FDA or other comparable regulatory agencies to ensure compliance with cGMP. Any failure to follow and document our adherence to such cGMP regulations or other regulatory requirements may lead to significant delays in the availability of clinical bulk drug substance and finished vaccine tablets for clinical trials, which may result in the termination of, or a hold on, a clinical trial, and may delay or prevent filing or approval of marketing applications for our tablet vaccine candidates. We also may encounter problems with the following:

- achieving adequate or clinical-grade materials that meet FDA or other comparable regulatory agency standards or specifications with consistent and acceptable production yield and costs;
- shortages of qualified personnel, raw materials or key contractors; and
- ongoing compliance with cGMP regulations and other requirements of the FDA or other comparable regulatory agencies.

Developing advanced manufacturing techniques and process controls is required to fully utilize our facilities. Advances in manufacturing techniques may render our facilities and equipment inadequate or obsolete.

If we encounter any of these problems or are otherwise delayed, or if the cost of manufacturing at the South San Francisco facility is not economically feasible and we cannot find a third-party supplier, we may not be able to produce tablet vaccine candidates in a sufficient quantity to meet future demand.

If third-party vendors, upon whom we rely to conduct our preclinical studies or clinical trials, do not perform or fail to comply with strict regulations, these studies or trials may be delayed, terminated, or fail, or we could incur significant additional expenses, which could materially harm our business.

We have limited resources dedicated to designing, conducting and managing our preclinical studies and clinical trials. We have historically relied on, and intend to continue to rely on, third parties, including clinical research organizations, consultants and principal investigators, to assist us in designing, managing, conducting, monitoring and analyzing the data from our preclinical studies and clinical trials. We rely on these vendors and individuals to perform many facets of the clinical development process on our behalf, including conducting preclinical studies, the recruitment of sites and patients for participation in our clinical trials, maintenance of good relations with the clinical sites, and ensuring that these sites are conducting our trials in compliance with the trial protocol and applicable regulations. If these third parties fail to perform satisfactorily, or do not adequately fulfill their obligations under the terms of our agreements with them, we may not be able to enter into alternative arrangements without undue delay or additional expenditures, and therefore the preclinical studies and clinical trials of our product candidates may be delayed or prove unsuccessful.

Further, the FDA, or similar regulatory authorities in other countries, may inspect some of the clinical sites participating in our clinical trials or our third-party vendors' sites to determine if our clinical trials are being conducted according to GCP or similar regulations. If we, or a regulatory authority, determine that our third-party vendors are not in compliance with, or have not conducted our clinical trials according to, applicable regulations, we may be forced to exclude certain data from the results of the trial, or delay, repeat or terminate such clinical trials.

We have a limited capacity for managing clinical trials, which could delay or impair our ability to initiate or complete clinical trials of our product candidates on a timely basis and materially harm our business.

We have a limited capacity to recruit and manage all of the clinical trials necessary to obtain approval for our product candidates by the FDA or similar regulatory authorities in other countries. By contrast, larger pharmaceutical and biopharmaceutical companies often have substantial staff or departments with extensive experience in conducting clinical trials with multiple product candidates across multiple indications and obtaining regulatory approval in various countries. In addition, these companies may have greater financial resources to compete for the same clinical investigators, sites and patients that we are attempting to recruit for our clinical trials. As a result, we may be at a competitive disadvantage that could delay the initiation, recruitment, timing and completion of our clinical trials and obtaining of marketing approvals, if achieved at all, for our product candidates.

Our industry is highly competitive and subject to rapid technological changes. As a result, we may be unable to compete successfully or develop innovative or differentiated products, which could harm our business.

Our industry is highly competitive and characterized by rapid technological change. Key competitive factors in our industry include, among others, the ability to successfully advance the development of a product candidate through preclinical and clinical trials; the efficacy, toxicology, tolerability, safety, resistance or cross-resistance, interaction or dosing profile of a product or product candidate; the timing and scope of marketing approvals, if ever achieved; reimbursement rates for and the average selling price of competing products and pharmaceutical products in general; the availability of raw materials and qualified contract manufacturing and manufacturing capacity to produce our product candidates; relative manufacturing costs; establishing, maintaining and protecting our intellectual property and patent rights; and sales and marketing capabilities.

Developing pharmaceutical product candidates is a highly competitive, expensive and risky activity with a long business cycle. Many organizations, including the large pharmaceutical and biopharmaceutical companies that have existing products on the market or in clinical development that may compete with our product candidates, have substantially more resources than us, as well as much greater capabilities and experience than we have in research and discovery, designing and conducting preclinical studies and clinical trials, operating in a highly regulated environment, formulating and manufacturing drug substances, products and devices, and marketing and sales. Our competitors may be more successful than us in obtaining regulatory approvals for their product candidates and achieving broad market acceptance once they are approved. Our competitors' products or product candidates may be more effective, have fewer adverse effects, be more convenient to administer, have a more favorable resistance profile, or be more effectively marketed and sold than any product that we, or our potential future licensees or collaborators, may develop or commercialize. New drugs or classes of drugs from competitors may render our product candidates obsolete or non-competitive before we are able to successfully develop them or, if approved, before we can recover the expenses of developing and commercializing them. We anticipate that we, or our potential future licensees or collaborators, will face intense and increasing competition as new drugs and drug classes enter the market and advanced technologies or new drug targets become available. If our product candidates do not demonstrate any meaningful competitive advantages over existing products, or new products or product candidates, we may terminate the development or commercialization of our product candidates at any time.

Our competitors, either alone or with their collaborators, may succeed in developing product candidates or products that are more effective, safer, less expensive or easier to administer than ours. Accordingly, our competitors may succeed in obtaining regulatory approval for their product candidates more rapidly than we can. Companies that can complete clinical trials, obtain required marketing approvals and commercialize their products before their competitors do so may achieve a significant competitive advantage, including certain patent and marketing exclusivity rights that could delay the ability of competitors to market certain products.

We also face, and expect that we will continue to face, intense competition from other companies in a number of other areas, including (i) attracting larger pharmaceutical and biopharmaceutical companies to enter into collaborative arrangements with us to acquire, license or co-develop our product candidates, (ii) identifying and obtaining additional clinical-stage development programs to bolster our pipeline, (iii) attracting investigators and clinical sites capable of conducting our clinical trials, and (iv) recruiting patients to participate in our clinical trials. There can be no assurance that product candidates resulting from our research and development efforts, or from joint efforts with our potential future licensees or collaborators, will be able to compete successfully with our competitors' existing products or product candidates in development.

We may be unable to successfully develop a product candidate that is the subject of an existing or future license agreement or collaboration if our licensee or collaborator does not perform or fulfill its contractual obligations, delays the development of our product candidate, or terminates the agreement.

We expect to continue to enter into and rely on license and collaboration agreements in the future, or other similar business arrangements with third parties, to further develop and/or commercialize some or all of our existing and future product candidates. Such licensees or collaborators may not perform as agreed upon or anticipated, may fail to comply with strict regulations, or may elect to delay or terminate their efforts in developing or commercializing our product candidates even though we have met our obligations under the arrangement.

A majority of the potential revenue from existing and any future licenses and collaborations we may enter into will likely consist of contingent milestone payments, such as payments received for achieving development or regulatory milestones, and royalties payable on the sales of approved products. Milestone and royalty revenues that we may receive under these licenses and collaborations will depend primarily upon our licensees' or collaborators' ability to successfully develop and commercialize our product candidates. In addition, our licensees or collaborators may decide to enter into arrangements with third parties to commercialize products developed under our existing or future collaborations using our technologies, which could reduce the milestone and royalty revenue that we may receive, if any. In many cases, we will not be directly or closely involved in the development or commercialization of our product candidates that are subject to licenses or collaborations and, accordingly, we will depend largely on our licensees or collaborators to develop or commercialize our product candidates. Our licensees may encounter competition from new products entering the market, which could adversely affect our royalty income. Our licensees or collaborators may fail to develop or effectively commercialize our product candidates because they:

- do not allocate the necessary resources due to internal constraints, such as limited personnel with the requisite scientific expertise, limited capital resources, or the belief that other product candidates or internal programs may have a higher likelihood of obtaining regulatory approval, or may potentially generate a greater return on investment;
- do not have sufficient resources necessary to fully support the product candidate through clinical development, regulatory approval and commercialization;
- are unable to obtain the necessary regulatory approvals; or
- prioritize other programs or otherwise diminish their support for developing and/or marketing our product candidate or product due to a change in management, business operations or strategy.

Should any of these events occur, we may not realize the full potential or intended benefit of our license or collaboration arrangements, and our results of operations may be adversely affected. In addition, a licensee or collaborator may decide to pursue the development of a competitive product candidate developed outside of our agreement with them. Conflicts may also arise if there is a dispute about the progress of, or other activities related to, the clinical development or commercialization of a product candidate, the achievement and payment of a milestone amount, the ownership of intellectual property that is developed during the course of the arrangement, or other license agreement terms. If a licensee or collaborator fails to develop or effectively commercialize our product candidates for any of these reasons, we may not be able to replace them with another third party willing to develop and commercialize our product candidates under similar terms, if at all. Similarly, we may disagree with a licensee or collaborator as to which party owns newly or jointly-developed intellectual property. Should an agreement be revised or terminated as a result of a dispute and before we have realized the anticipated benefits of the arrangement, we may not be able to obtain certain development support or revenues that we anticipated receiving. We may also be unable to obtain, on terms acceptable to us, a license from such collaboration partner to any of its intellectual property that may be necessary or useful for us to continue to develop and commercialize the product candidate. There can be no assurance that any product candidates will emerge from any existing or future license or collaboration agreements we may enter into for any of our product candidates.

If government and third-party payers fail to provide adequate reimbursement or coverage for our products or those that are developed through licenses or collaborations, our revenues and potential for profitability may be harmed.

In the United States and most foreign markets, product revenues or related royalty revenue, and therefore the inherent value of our products, will depend largely upon the reimbursement rates established by third-party payers for such products. Third-party payers include government health administration authorities, managed-care organizations, private health insurers and other similar organizations. Third-party payers are increasingly examining the cost effectiveness of medical products, services and pharmaceutical drugs and challenging the price of these products and services. In addition, significant uncertainty exists as to the reimbursement status, if any, of newly approved pharmaceutical products. Further, the comparative effectiveness of new products over existing therapies and the assessment of other non-clinical outcomes are increasingly being considered in the decision by payers to establish reimbursement rates. We, or our licensees or collaborators if applicable, may also be required to conduct post-marketing clinical trials in order to demonstrate the cost-effectiveness of our products. Such studies may require us to commit a significant amount of management time and financial resources. There can be no assurance that any products that we or our licensees or collaborators may successfully develop will be reimbursed in part, or at all, by any third-party payers in any country.

Many governments continue to propose legislation designed to expand the coverage, yet reduce the cost, of healthcare, including pharmaceutical products. In many foreign markets, governmental agencies control the pricing of prescription drugs. In the United States, significant changes in federal health care policy were approved over the past several years and continue to evolve and will likely result in reduced reimbursement rates for many pharmaceutical products in the future. We expect that there will continue to be federal and state proposals to implement increased government control over reimbursement rates of pharmaceutical products. In addition, we expect that increasing emphasis on managed care and government intervention in the U.S. healthcare system will continue to put downward pressure on the pricing of pharmaceutical products there. Recent events have resulted in increased public and governmental scrutiny of the cost of drugs, especially in connection with price increases following companies' acquisitions of the rights to certain drug products. In particular, U.S. federal prosecutors recently issued subpoenas to a pharmaceutical company seeking information about its drug pricing practices, among other issues, and members of the U.S. Congress have sought information from certain pharmaceutical companies relating to post-acquisition drug-price increases. Our revenue and future profitability could be negatively affected if these inquiries were to result in legislative or regulatory proposals that limit our ability to increase the prices of our products that may be approved for sale in the future. Legislation and regulations affecting the pricing of pharmaceutical products may change before our product candidates are approved for sale, which could further limit or eliminate their reimbursement rates. Further, social and patient activist groups, whose goal it is to reduce the cost of healthcare, and in particular the price of pharmaceutical products, may also place downward pressure on the price of these products, which could result in decreases in the price of our products.

If any product candidates that we develop independently, or through licensees or collaborators if applicable, are approved but do not gain meaningful acceptance in their intended markets, we are not likely to generate significant revenues.

Even if our product candidates are successfully developed and we or a licensee or collaborator obtains the requisite regulatory approvals to market them in the future, they may not gain market acceptance or broad utilization among physicians, patients or third-party payers. The degree of market acceptance that any of our products may achieve will depend on a number of factors, including:

- the efficacy or perceived clinical benefit of the product, if any, relative to existing therapies;
- the timing of market approval and the existing market for competitive drugs, including the presence of generic drugs;
- the level of reimbursement provided by third-party payers to cover the cost of the product to patients;
- the net cost of the product to the user or third-party payer;
- the convenience and ease of administration of the product;
- the product's potential advantages over existing or alternative therapies;
- the actual or perceived safety of similar classes of products;
- the actual or perceived existence, incidence and severity of adverse effects;
- the effectiveness of sales, marketing and distribution capabilities; and
- the scope of the product label approved by the FDA or similar regulatory agencies in other jurisdictions.

There can be no assurance that physicians will choose to prescribe or administer our products, if approved, to the intended patient population. If our products do not achieve meaningful market acceptance, or if the market for our products proves to be smaller than anticipated, we may never generate significant revenues.

Our headquarters is located near known earthquake fault zones. The occurrence of an earthquake, fire or any other catastrophic event could disrupt our operations or the operations of third parties who provide vital support functions to us, which could have a material adverse effect on our business and financial condition.

We are vulnerable to damage from catastrophic events, such as power loss, natural disasters, terrorism and similar unforeseen events beyond our control. Our corporate headquarters and other facilities are located in the San Francisco Bay Area, which in the past has experienced severe earthquakes and fires.

We do not have a disaster recovery and business continuity plan in place. Earthquakes or other natural disasters could severely disrupt our operations and have a material adverse effect on our business, results of operations, financial condition and prospects.

If a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of our headquarters, damaged critical infrastructure, such as our financial systems or manufacturing facility, or that otherwise disrupted our operations, it may be difficult or, in certain cases, impossible for us to continue business operations for a substantial period of time.

Risks Related to Dependence on Third Parties

If third-party contract manufacturers, upon whom we may have to rely to formulate and manufacture our product candidates, do not perform, fail to manufacture according to our specifications, or fail to comply with strict government regulations, our preclinical studies or clinical trials could be adversely affected and the development of our product candidates could be delayed or terminated, or we could incur significant additional expenses.

Our reliance on these third-party contract manufacturers, which in some cases may be sole sourced, exposes us to a number of risks, any of which could delay or prevent the completion of our preclinical studies or clinical trials, or the regulatory approval or commercialization of our product candidates, result in higher costs, or deprive us of potential product revenues in the future. Some of these risks include, but are not limited to:

- our contract manufacturers failing to develop an acceptable formulation to support late-stage clinical trials for, or the commercialization of, our product candidates;
- our contract manufacturers failing to manufacture our product candidates according to their own standards, our specifications, current good manufacturing practices, or cGMP, or regulatory guidelines, or otherwise manufacturing material that we or regulatory authorities deem to be unsuitable for our clinical trials or commercial use;
- our contract manufacturers being unable to increase the scale of or the capacity for, or reformulate the form of, our product candidates, which may cause us to experience a shortage in supply or cause the cost to manufacture our product candidates to increase. There can be no assurance that our contract manufacturers will be able to manufacture our product candidates at a suitable commercial scale, or that we will be able to find alternative manufacturers acceptable to us that can do so;
- our contract manufacturers placing a priority on the manufacture of other customers’ or their own products, rather than our products;
- our contract manufacturers failing to perform as agreed or exiting from the contract manufacturing business; and
- our contract manufacturers’ plants being closed as a result of regulatory sanctions or a natural disaster.

Manufacturers of pharmaceutical drug products are subject to ongoing periodic inspections by the FDA, the U.S. Drug Enforcement Administration, or DEA, and corresponding state and other foreign agencies to ensure strict compliance with FDA-mandated cGMPs, other government regulations and corresponding foreign standards. We do not have control over our third-party contract manufacturers' compliance with these regulations and standards and accordingly, failure by our third-party manufacturers, or us, to comply with applicable regulations could result in sanctions being imposed on us or our manufacturers, which could significantly and adversely affect our business.

In the event that we need to change our third-party contract manufacturers, our preclinical studies or our clinical trials, the commercialization of our product candidates could be delayed, adversely affected or terminated, or such a change may result in the need for us to incur significantly higher costs, which could materially harm our business.

Due to various regulatory restrictions in the United States and many other countries, as well as potential capacity constraints on manufacturing that occur from time-to-time in our industry, various steps in the manufacture of our product candidates are sole-sourced to certain contract manufacturers. In accordance with cGMPs, changing manufacturers may require the re-validation of manufacturing processes and procedures, and may require further preclinical studies or clinical trials to show comparability between the materials produced by different manufacturers. Changing our current or future contract manufacturers may be difficult, if not impossible for us, and could be extremely costly if we do make such a change, which could result in our inability to manufacture its product candidates for an extended period of time and a delay in the development of its product candidates. Further, in order to maintain its development timelines in the event of a change in a third-party contract manufacturer, we may incur significantly higher costs to manufacture our product candidates.

****We may not be able to manufacture our product candidates in sufficient quantities to commercialize them.***

In order to receive FDA approval of our product candidates, we will need to manufacture such product candidates in larger quantities. We may not be able to increase successfully the manufacturing capacity for our product candidates in a timely or economic manner, or at all. In the event FDA approval is received, we will need to increase production of our product candidates. Significant scale-up of manufacturing may require additional validation studies, which the FDA must review and approve. If we are unable to successfully increase the manufacturing capacity for our product candidates, the clinical trials, the regulatory approval and the commercial launch of our product candidates may be delayed, or there may be a shortage in supply. Our product candidates require precise, high quality manufacturing. Failure to achieve and maintain high quality manufacturing, including the incidence of manufacturing errors, could result in patient injury or death, delays or failures in testing or delivery, cost overruns or other problems that could harm our business, financial condition and results of operations.

****The manufacture of pharmaceutical products in compliance with cGMP regulations requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls.***

Manufacturers of pharmaceutical products often encounter difficulties in production, including difficulties with production costs and yields, quality control, including stability of the product candidates and quality assurance testing, or shortages of qualified personnel. If we were to encounter any of these difficulties or otherwise fail to comply with our obligations under applicable regulations, our ability to provide study materials in our clinical trials would be jeopardized. Any delay or interruption in the supply of clinical trial materials could delay the completion of our clinical trials, increase the costs associated with maintaining our clinical trial programs and, depending upon the period of delay, require us to commence new trials at significant additional expense or to terminate the studies and trials completely.

We must comply with cGMP requirements enforced by the FDA through its facilities inspection program. These requirements include, among other things, quality control, quality assurance and the maintenance of records and documentation. Manufacturers of our component materials may be unable to comply with these cGMP requirements and with other FDA, state and foreign regulatory requirements. The FDA or similar foreign regulatory agencies at any time may also implement new standards, or change their interpretation and enforcement of existing standards for manufacture, packaging or testing of products. We have little control over our manufacturers' compliance with these regulations and standards. A failure to comply with these requirements may result in fines and civil penalties, suspension of production, suspension or delay in product approval, product seizure or recall, or withdrawal of product approval. If the safety of any product supplied is compromised due to our failure, or that our third-party manufacturers, to adhere to applicable laws or for other reasons, we may not be able to obtain regulatory approval for or successfully commercialize our products, and we may be held liable for any injuries sustained as a result. Any of these factors could cause a delay of clinical trials, regulatory submissions, approvals or commercialization of any product candidates we may develop or acquire in the future, or entail higher costs, or impair our reputation.

We currently rely on single source vendors for key tablet vaccine components and certain strains needed in our tablet vaccine candidates, which could impair our ability to manufacture and supply our tablet vaccine candidates.

We currently depend on single source vendors for certain raw materials used in the manufacture of our tablet vaccine candidates. Any production shortfall that impairs the supply of the relevant raw materials could have a material adverse effect on our business, financial condition and results of operations. An inability to continue to source product from these suppliers, which could be due to regulatory actions or requirements affecting the supplier, adverse financial or other strategic developments experienced by a supplier, labor disputes or shortages, unexpected demands or quality issues, could materially adversely affect our operating results or our ability to conduct clinical trials, either of which could significantly harm our business.

We intend to rely on third parties to conduct, supervise and monitor our clinical trials, and if those third parties perform in an unsatisfactory manner, it may harm our business.

We intend to rely on CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials, and we expect to have limited influence over their actual performance.

We intend to rely upon CROs to monitor and manage data for our clinical programs, as well as the execution of future nonclinical studies. We expect to control only certain aspects of our CROs' activities. Nevertheless, we will be responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards and our reliance on the CROs does not relieve us of these regulatory responsibilities.

We and our CROs will be required to comply with the Good Laboratory Practices and GCPs, which are regulations and guidelines enforced by the FDA and are also required by the Competent Authorities of the Member States of the European Economic Area and comparable foreign regulatory authorities in the form of International Conference on Harmonization guidelines for any of our product candidates that are in preclinical and clinical development. The Regulatory authorities enforce GCPs through periodic inspections of trial sponsors, principal investigators and clinical trial sites. If we or our CROs fail to comply with GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. Accordingly, if our CROs fail to comply with these regulations or fail to recruit a sufficient number of subjects, we may be required to repeat clinical trials, which would delay the regulatory approval process.

Our CROs will not be our employees, and we will not control whether or not they devote sufficient time and resources to our future clinical and nonclinical programs. These CROs may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials, or other drug development activities which could harm our competitive position. We face the risk of potential unauthorized disclosure or misappropriation of our intellectual property by CROs, which may reduce our trade secret protection and allow our potential competitors to access and exploit our proprietary technology. If our CROs do not successfully carry out their contractual duties or obligations, fail to meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for any other reasons, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for, or successfully commercialize, any product candidate that we develop. As a result, our financial results and the commercial prospects for any product candidate that we develop would be harmed, our costs could increase, and our ability to generate significant revenues could be delayed.

If our relationship with these CROs terminate, we may not be able to enter into arrangements with alternative CROs or do so on commercially reasonable terms. Switching or adding additional CROs involves substantial cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Though we intend to carefully manage our relationships with our CROs, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have an adverse impact on our business, financial condition and prospects.

We may seek to selectively establish collaborations, and, if we are unable to establish them on commercially reasonable terms, we may have to alter our development and commercialization plans.

Our product development programs and the potential commercialization of our product candidates will require substantial additional cash to fund expenses. For some of our product candidates, including our seasonable influenza and RSV tablets, we may decide to collaborate with governmental entities or additional pharmaceutical and biotechnology companies for the development and potential commercialization of those product candidates.

We face significant competition in seeking appropriate collaborators. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of clinical trials, the likelihood of approval by the FDA or similar regulatory authorities outside the United States, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge and industry and market conditions generally. The collaborator may also consider alternative product candidates for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our product candidate.

Our relationships with customers and third-party payors will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm 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 medicines for which we obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations include the following:

- the federal healthcare anti-kickback statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under federal and state healthcare programs such as Medicare and Medicaid;
- the federal FCA imposes criminal and civil penalties, including 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 HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program and also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- the federal false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services;
- the federal transparency requirements under the Affordable Care Act requires manufacturers of drugs, devices, biologics and medical supplies to report to the Department of Health and Human Services information related to physician payments and other transfers of value and physician ownership and investment interests; and
- analogous state laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non- governmental third-party payors, including private insurers, and some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring vaccine manufacturers to report information related to payments to physicians and other health care providers or marketing expenditures.

Risks Related to Intellectual Property

If we are unable to obtain and maintain patent protection for our platform technology and product candidates or if the scope of the patent protection obtained is not sufficiently broad, we may not be able to compete effectively in our markets.

We rely upon a combination of patents, trade secret protections and confidentiality agreements to protect the intellectual property related to our drug development programs and product candidates. Our success depends in large part on our ability to obtain and maintain patent protection in the United States and other countries. We seek to protect our proprietary position by filing patent applications in the United States and abroad related to our development programs and product candidates. The patent prosecution process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner.

It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. The patent applications that we own or in-license may fail to result in issued patents with claims that cover any of our product candidates in the United States or in other countries. There is no assurance that the entire potentially relevant prior art relating to our patents and patent applications has been found, which can invalidate a patent or prevent a patent from issuing from a pending patent application. Even if patents do successfully issue, third parties may challenge their validity, enforceability or scope, which may result in such patents being narrowed, invalidated, or held unenforceable. Any successful challenge to these patents or any other patents owned by or licensed to us could deprive us of rights necessary for the successful commercialization of any product candidates or companion diagnostic that we may develop. Further, if we encounter delays in regulatory approvals, the period of time during which we could market a product candidate and companion diagnostic under patent protection could be reduced.

If the patent applications we hold with respect to our platform technology and product candidates fail to issue, if their breadth or strength of protection is threatened, or if they fail to provide meaningful exclusivity for our product candidates, it could dissuade companies from collaborating with us to develop product candidates and threaten our ability to commercialize future drugs. Any such outcome could harm our business.

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. In addition, the laws of foreign countries may not protect its rights to the same extent as the laws of the United States. For example, European patent law restricts the patentability of methods of treatment of the human body more than U.S. law does. Publications of discoveries in scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in our owned or licensed patents or pending patent applications, or that we were the first to file for patent protection of such inventions. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued which protect our technology or product candidates, in whole or in part, or which effectively prevent others from commercializing competitive technologies and vaccines. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection.

Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of its issued patents. On September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to United States patent law. These include provisions that affect the way patent applications are prosecuted and may also affect patent litigation. The U.S. Patent Office recently developed new regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first to file provisions, only became effective on March 16, 2013. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have an adverse effect on our business and financial condition.

Moreover, we may be subject to a third-party pre-issuance submission of prior art to the U.S. Patent and Trademark Office, or USPTO, or become involved in derivation, reexamination, inter partes review, post-grant review or interference proceedings challenging our patent rights or the patent rights of others. In other countries, we may be subject to or become involved in opposition proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission or proceeding could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or product candidates and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize product candidates without infringing third-party patent rights. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and tablet vaccines or small molecule antivirals, or limit the duration of the patent protection of our technology and product candidates. Moreover, patents have a limited lifespan. In the United States and other countries, the natural expiration of a patent is generally 20 years after it is filed. Various extensions may be available, however, the life of a patent, and the protection it affords, is limited. Without patent protection for our current or future tablet vaccine and small-molecule antiviral drug candidates, we may be open to competition from generic versions of such product candidates. 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 such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing product candidates similar or identical to ours.

If we are unable to adequately protect or expand our intellectual property related to products acquired in the Merger, our business prospects could be materially harmed.

Our business success depends in part on our ability to:

- obtain, maintain and protect our intellectual property rights;
- protect our trade secrets; and
- prevent others from infringing on our proprietary rights or patents.

We can protect our proprietary intellectual property rights from unauthorized use by third parties only to the extent that our proprietary rights are covered by valid and enforceable patents or are effectively maintained as trade secrets. The patent position of pharmaceutical and biopharmaceutical companies involves complex legal and factual questions, and, therefore, we cannot predict with certainty whether we will be able to ultimately enforce our patents or proprietary rights or avoid infringing on the patents or proprietary rights of others. Any issued patents that we own or otherwise have rights to may be challenged, invalidated or circumvented, and may not provide us with the protection against competitors that we anticipate.

The degree of future protection of our proprietary intellectual property rights is uncertain because issued patents and other legal means of establishing proprietary rights afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. Our future patent position will be influenced by the following factors:

- we, or our licensors, may not have been the first to discover the inventions covered by each of our, or our licensors', pending patent applications and issued patents, and we may have to engage in expensive and protracted interference proceedings to determine priority of invention;
- our, or our licensors', pending patent applications may be denied and may not result in issued patents;
- our, or its licensors', issued patents may not provide a basis for commercially viable products, may not provide us with any competitive advantages, or may be challenged by third parties; and
- third parties may develop intellectual property that circumvents our, or our licensors', patent claims, or design competitive intellectual property and ultimately product candidates that fall outside the scope of our, or our licensors', patents.

Due to the extensive time required for the development, testing and regulatory review and approval of a product candidate, it is possible that before our product candidates may be approved for sale and commercialized, our relevant patent rights may expire, or such patent rights may remain in force for only a short period following marketing approval. We currently rely on certain patents to provide us and our licensees with exclusive rights for certain of our products. When all patents underlying a license expire, our revenue from that license may cease, and there can be no assurance that we will be able to replace it with revenue from new or existing licenses.

Zanamivir, a neuraminidase inhibitor approved for the treatment and prevention of influenza A and B, is marketed worldwide as Relenza® by GSK. Most of our Relenza® patents have expired and the only substantial remaining intellectual property related to the Relenza® patent portfolio, which we own and have exclusively licensed to GSK, is scheduled to expire in July 2019 in Japan.

LANI, a long acting NI for the treatment and prevention of influenza A and B, is currently marketed as Inavir® in Japan by Daiichi-Sankyo. The patent relating to the structure of LANI expired in 2017 in the United States, the European Union, or EU, and Japan, although the product has received patent term extension in Japan until 2021 for treatment and 2022 for prevention. The patent relating to hydrates and the crystalline form of LANI actually used in the product expires in 2021 (not including extensions) in the United States and EU and in 2024 in Japan. In February 2015, a patent containing claims relevant to the manufacture of Inavir® was issued in Japan and expires in December 2029. The dry-powder inhaler device patent portfolio, which includes TwinCaps®, is owned by Hovione International Limited, or Hovione, and is exclusively licensed to Daiichi Sankyo and us worldwide for the prevention and treatment of influenza and other influenza-like viral infections. These patents will expire in 2029 in the United States, and in 2027 in the European Union and Japan. On Feb 23, 2018 Osaka-based drugmaker Shionogi & Co gained marketing approval for Xofluza, a new drug to treat influenza in Japan. The drug was approved for use against type A and B influenza viruses and requires only a single dose regardless of age. Xofluza may gain significant market share from Inavir® in Japan, substantially reducing the sales of Inavir®. This may significantly decrease the royalty payments we receive from Daiichi Sankyo.

Vapendavir is an oral antiviral picornavirus capsid binder that we are developing to treat HRV infections, although this project is presently inactive. We exclusively own the vapendavir patent portfolio. Issued claims under this portfolio will begin to expire in some countries in December 2021, not including extensions. Claims from patents related to a comparably bioavailable compound comprising an anhydrous crystalline free base form of vapendavir and the preferred commercialization form of vapendavir have been allowed in the United States and other countries and extend intellectual property to 2034 without extensions.

Teslexivir is a direct-acting antiviral that we are developing as a topical treatment for genital warts caused by HPV 6 and 11, which together comprise more than 95% of cases. The patent containing composition of matter claims expires in the United States in 2029 without extensions. A United States patent with claims to method of use have been issued and will expire in 2033 without extensions.

We also own a patent portfolio focused on developing oral antivirals for RSV. Issued patent claims covering the Enzaplatovir composition of matter will begin to expire in 2031 without extensions.

Patent rights may not provide us with adequate proprietary protection or competitive advantages against competitors with or developing similar technologies or approaches to ours. The laws of certain foreign countries do not protect intellectual property rights to the same extent as do the laws of the United States, and certain countries may lack adequate rules and procedures for defending our intellectual property rights. For example, we may not be able to prevent a third-party from infringing our patents in a country that does not recognize or enforce patent rights, or that imposes compulsory licenses on, or restricts the prices of, drugs. Changes in either patent laws or in interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property. We may need to in-license certain technologies to successfully develop and commercialize our product candidates. We may not develop or obtain rights to products or processes that are patentable. Even if we, or our licensors, do obtain patents, such patents may not adequately protect the products or technologies licensed, or may otherwise be limited in scope. In addition, we may not have total control over the patent prosecution of subject matter that we license from others. Accordingly, we may be unable to exercise the same degree of control over this intellectual property as we would over our own. Others may challenge, seek to invalidate, infringe or circumvent any pending or issued patents we own or license, and rights we receive under those issued patents may not provide us with competitive advantages. There can be no assurance of the degree of protection that will be afforded by any of our issued or pending patents, or those we license.

There can be no assurance that any patents will be issued from the patent applications we own or have licensed or, should any patents be issued, that we will be provided with adequate protection against potentially competitive products. Furthermore, we cannot be sure that patents issued or licensed to us will be of any commercial value, or that private parties or competitors will not successfully challenge these patents or circumvent our patent position in the United States or abroad. In the absence of adequate patent protection, our business may be adversely affected by competitors who develop comparable technology or products.

We may be involved in lawsuits to protect or enforce our patents, the patents of our licensors or our other intellectual property rights, which could be expensive, time consuming and unsuccessful.

Competitors may infringe or otherwise violate our patents, the patents of our licensors or our other intellectual property rights. To counter infringement or unauthorized use, we may be required to file legal claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours or our licensors is not valid, or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that such patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our patent applications at risk of not issuing. The initiation of a claim against a third-party may also cause the third-party to bring counter claims against us such as claims asserting that our patents are invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, non-enablement or lack of statutory subject matter. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant material information from the USPTO, or made a materially misleading statement, during prosecution. Third parties may also raise similar validity claims before the USPTO in post-grant proceedings such as inter partes review, or post-grant review, or oppositions or similar proceedings outside the United States, in parallel with litigation or even outside the context of litigation. The outcome following legal assertions of invalidity and unenforceability is unpredictable. We cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. For the patents and patent applications that we have licensed, we may have limited or no right to participate in the defense of any licensed patents against challenge by a third-party. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of any future patent protection on our current or future product candidates. Such a loss of patent protection could harm our business.

We may not be able to prevent, alone or with our licensors, misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States. Our business could be harmed if in litigation the prevailing party does not offer us a license on commercially reasonable terms. Any litigation or other proceedings to enforce our intellectual property rights may fail, and even if successful, may result in substantial costs and distract our management and other employees.

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 an adverse effect on the price of our common stock.

If a third party claims we are infringing on its intellectual property rights, we could incur significant expenses, or be prevented from further developing or commercializing our product candidates, which could materially harm our business.

Our success will largely depend on our ability to operate without infringing the patents and other proprietary intellectual property rights of third parties. This is generally referred to as having the “freedom to operate.” The biotechnology and pharmaceutical industries are characterized by extensive litigation regarding patents and other intellectual property rights. The defense and prosecution of intellectual property claims, interference proceedings and related legal and administrative proceedings, both in the United States and internationally, involve complex legal and factual questions. As a result, such proceedings are lengthy, costly and time-consuming, and their outcome is highly uncertain. We may become involved in protracted and expensive litigation in order to determine the enforceability, scope and validity of the proprietary rights of others, or to determine whether we have the freedom to operate with respect to the intellectual property rights of others.

Patent applications in the United States are, in most cases, maintained in secrecy until approximately 18 months after the patent application is filed. The publication of discoveries in scientific or patent literature frequently occurs substantially later than the date on which the underlying discoveries were made. Therefore, patent applications relating to product candidates similar to ours may have already been filed by others without our knowledge. In the event that a third party has also filed a patent application covering our product candidate or other claims, we may have to participate in an adversarial proceeding, known as an interference proceeding, in the USPTO, or similar proceedings in other countries, to determine the priority of invention. In the event an infringement claim is brought against us, we may be required to pay substantial legal fees and other expenses to defend such a claim and, should we be unsuccessful in defending the claim, we may be prevented from pursuing the development and commercialization of a product candidate and may be subject to injunctions and/or damage awards.

In the future, the USPTO or a foreign patent office may grant patent rights to our product candidates or other claims to third parties. Subject to the issuance of these future patents, the claims of which will be unknown until issued, we may need to obtain a license or sublicense to these rights in order to have the appropriate freedom to further develop or commercialize them. Any required licenses may not be available to us on acceptable terms, if at all. If we need to obtain such licenses or sublicenses, but are unable to do so, we could encounter delays in the development of our product candidates, or be prevented from developing, manufacturing and commercializing our product candidates at all. If it is determined that we have infringed an issued patent and do not have the freedom to operate, we could be subject to injunctions, and/or compelled to pay significant damages, including punitive damages. In cases where we have in-licensed intellectual property, our failure to comply with the terms and conditions of such agreements could harm our business.

It is becoming common for third parties to challenge patent claims on any successfully developed product candidate or approved drug. If we or our licensees or collaborators become involved in any patent litigation, interference or other legal proceedings, we could incur substantial expense, and the efforts and attention of our technical and management personnel could be significantly diverted. A negative outcome of such litigation or proceedings may expose us to the loss of our proprietary position or to significant liabilities or require us to seek licenses that may not be available from third parties on commercially acceptable terms, if at all. We may be restricted or prevented from developing, manufacturing and selling our product candidates in the event of an adverse determination in a judicial or administrative proceeding, or if we fail to obtain necessary licenses.

Obtaining and maintaining our patent protection depends on compliance with various procedures, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees on any issued patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies require compliance with a number of procedures, documentary fee payments and other provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we and our licensors fail to maintain the patents and patent applications covering our product candidates, our competitive position would be adversely affected.

****Changes in U.S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.***

The United States has recently enacted and implemented wide-ranging patent reform legislation. The United States 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 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 actions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce patents that we have licensed or that we might obtain in the future.

****We may not be able to protect our intellectual property rights throughout the world, which could impair our business.***

Filing, prosecuting and defending patents covering our product candidates throughout the world would be prohibitively expensive. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own vaccines and, further, may export otherwise infringing vaccines to territories where we may obtain patent protection, but where patent enforcement is not as strong as that in the United States. These vaccines may compete with our product candidates in jurisdictions where we do not have any issued or licensed patents and any future patent claims or other intellectual property rights may not be effective or sufficient to prevent them from so competing.

We may be subject to claims that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

Many of our employees, including our senior management, were previously employed at other biotechnology or pharmaceutical companies. These employees typically executed proprietary rights, non-disclosure and non-competition agreements in connection with their previous employment. Although we try to ensure that our employees do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that it or these employees have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee's former employer. We are not aware of any threatened or pending claims related to these matters, but in the future litigation may be necessary to defend against such claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.

We seek to protect our proprietary technology in part by entering into confidentiality agreements with third parties and, if applicable, material transfer agreements, consulting agreements or other similar agreements with our advisors, employees, third-party contractors and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, including our trade secrets. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor's discovery of our trade secrets or other unauthorized use or disclosure would impair our competitive position and may have an adverse effect on our business and results of operations.

In addition, these agreements typically restrict the ability of our advisors, employees, third-party contractors and consultants to publish data potentially relating to our trade secrets, although our agreements may contain certain limited publication rights. Despite our efforts to protect our trade secrets, our competitors may discover our trade secrets, either through breach of our agreements with third parties, independent development, or publication of information by any of our third-party collaborators. A competitor's discovery of our trade secrets would impair our competitive position and have an adverse impact on our business.

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

On March 12, 2018 Sean Tucker, Ph.D., our Chief Scientific Officer, exercised options to purchase 2,013 shares of our common stock at $6.49 per share. The exercise was exempt pursuant to Exchange Act Rule 16b-3 as it was a discretionary transaction made pursuant to a benefit plan. The exercise was done at the volition of Dr. Tucker, a recipient of grants made under our Amended and Restated 2007 Equity Incentive Plan. The exercise was not made in connection with Dr. Tucker's death, disability, retirement or termination of employment. The exercise was not required to be made available to Dr. Tucker pursuant to any provision of the Internal Revenue Code. The exercise resulted in a cash distribution funded by a volitional disposition of the equity security.

Item 3.Defaults Upon Senior Securities

Not applicable.

Item 4.Mine Safety Disclosures

Not applicable.

Item 5.Other Matters

Not applicable.

Item 6. Exhibits

Exhibit Number	Description of Document	Incorporated by Reference			
		Schedule/Form	File Number	Exhibit	Filing Date
2.1	Agreement and Plan of Merger and Reorganization dated October 27, 2017, by and among Aviragen Therapeutics, Inc., Vaxart, Inc. and Agora Merger Sub, Inc. (included as Annex A to the proxy statement/prospectus/information statement forming a part of this registration statement).	Form S-4	333-222009	2.1	December 29, 2017
2.2	Amendment No. 1 to Agreement and Plan of Merger and Reorganization dated February 7, 2018 by and among Aviragen Therapeutics, Inc., Vaxart, Inc. and Agora Merger Sub, Inc.	Form 8-K	001-35285	2.1	February 7, 2018
2.3	Stock Purchase Agreement dated February 25, 2015, among Biota Pharmaceuticals, Inc., each of the shareholders of Anaconda Pharma party thereto and the Holder Representative thereunder	Form 10-Q	001-35285	2.1	May 8, 2015
3.1	Restated Certificate of Incorporation of Aviragen Therapeutics, Inc.	Form 10-K	001-35285	3.1	September 13, 2016
3.2	Certificate of Amendment to Restated Certificate of Incorporation of Aviragen Therapeutics, Inc.	Form 8-K	001-35285	3.1	February 20, 2018
3.3	Certificate of Amendment to Restated Certificate of Incorporation of Vaxart, Inc.	Form 8-K	001-35285	3.2	February 20, 2018
3.4	Restated By-laws of Aviragen Therapeutics, Inc.	Form 10-K	001-35285	3.2	September 13, 2016
10.1+	Collaboration and License Agreement dated September 29, 2003, between Biota Holdings Limited and Sankyo Co., Ltd.	Form 10-Q	001-35285	10.5	May 10, 2013
10.2+	Amendment #1 to Collaboration and License Agreement dated June 30, 2005, between Biota Holdings Limited, Biota Scientific Management Pty. Ltd. and Sankyo Company, Ltd.	Form 10-Q	001-35285	10.6	May 10, 2013
10.3	Amendment #2 to Collaboration and License Agreement, dated March 27, 2009, between Biota Holdings Limited, Biota Scientific Management Pty. Ltd. and Daiichi Sankyo Company, Limited	Form 10-Q	001-35285	10.7	May 10, 2013
10.4+	Commercialization Agreement dated March 27, 2009, between Biota Holdings Limited, Biota Scientific Management Pty. Ltd and Daiichi Sankyo Company, Ltd.	Form 10-Q	001-35285	10.8	May 10, 2013
10.5+	Contract dated March 31, 2011, between Biota Scientific Management Pty. Ltd. and Office of Biomedical Advanced Research and Development Authority within the Office of the Assistant Secretary for preparedness and Response at the U.S. Department of Health and Human Services	Form 10-Q	001-35285	10.9	May 10, 2013
10.6+	Research and License Agreement dated February 21, 1990, by and among Biota Scientific Management Pty. Ltd., Biota Holdings Limited, Glaxo Australia Pty. Ltd. and Glaxo Group Limited	Form 10-K	001-35285	10.6	September 27, 2013
10.7	Form of Indemnification Agreement for Directors and Executive Officers	Form 8-K	001-35285	10.1	May 6, 2013
10.8#	Employment Agreement, dated as of October 1, 2014, between Biota Pharmaceuticals, Inc., and Russell H. Plumb	Form 10-Q	001-35285	10.18	February 6, 2015
10.9#	Amended Executive Employment Agreement, dated as of October 1, 2014, between Biota Pharmaceuticals, Inc., and Joseph M. Patti	Form 10-Q	001-35285	10.17	February 6, 2015
10.10#	Form Non-Plan Stock Units Agreement	Form 8-K	001-35285	10.3	November 14, 2012

Exhibit Number	Description of Document	Incorporated by Reference			
		Schedule/Form	File Number	Exhibit	Filing Date
10.11#	Form of Letter Agreement for Stock Option Grant	Form 8-K	001-35285	10.4	November 14, 2012
10.12#	2007 Omnibus Equity and Incentive Plan (included as Appendix A to the proxy statement)	DEF 14A	000-04829	-	April 12, 2007
10.13#	Executive Employment Agreement, dated as of November 26, 2013, between Biota Pharmaceuticals, Inc., and Peter Azzarello	Form 8-K	001-35285	10.1	November 27, 2013
10.14#	Form of Employee Stock Option Agreement under the 2007 Omnibus Equity and Incentive Plan	Form 8-K	001-35285	10.1	December 10, 2013
10.15#	Form of Market-Based Stock Unit Award Agreement under the 2007 Omnibus Equity and Incentive Plan	Form 8-K	001-35285	10.2	December 10, 2013
10.16#	Executive Employment Agreement, effective as of November 2, 2015, between Biota Pharmaceuticals, Inc. and Mark Colonnese	Form 8-K	001-35285	10.1	November 2, 2015
10.17+	Royalty Interest Acquisition Agreement by and between Aviragen Therapeutics, Inc., Biota Holdings Pty Ltd, Biota Scientific Management Pty. Ltd. and HealthCare Royalty Partners III, L.P. dated April 22, 2016	Form 8-K	001-35285	10.1	April 26, 2016
10.18	Protective Rights Agreement between Aviragen Therapeutics, Inc. and HealthCare Royalty Partners III, L.P. dated April 22, 2016	Form 8-K	001-35285	10.2	April 26, 2016
10.19#	Form of Employee Stock Option Agreement under the 2016 Equity Incentive Plan	Form 10-Q	001-35285	10.1	May 8, 2017
10.20#	2016 Equity Incentive Plan (included as Appendix A to the proxy statement)	DEF 14A	001-35285	-	September 27, 2016
10.21#	Director Stock Option Grant Form	Form S-4	333-222009	10.22	December 12, 2017
10.22	Form of Indemnity Agreement by and between Vaxart, Inc. and its directors and officers	Form S-4/A	333-222009	10.23	December 29, 2017
10.23#	Vaxart, Inc. Amended and Restated 2007 Equity Incentive Plan, Stock Option Agreement, form of Notice of Stock Option Grant, form of Additional Terms and Conditions to Option and Stock Option Exercise Agreement	Form S-4/A	333-222009	10.24	December 29, 2017
10.24#	Offer Letter, dated May 25, 2011, and Amendment to Offer Letter and Option Grant Agreement, dated October 1, 2011, by and between Vaxart, Inc. and Wouter W. Latour, M.D.	Form S-4/A	333-222009	10.25	December 29, 2017
10.25	Industrial Lease dated October 28, 2013, by and between Vaxart, Inc. and Oyster Point LLC	Form S-4/A	333-222009	10.26	December 29, 2017
10.26	Lease Agreement dated April 17, 2015, by and between Vaxart, Inc. and CRP Edgewater, LLC	Form S-4/A	333-222009	10.27	December 29, 2017
10.27	Loan and Security Agreement dated December 22, 2016, by and between Vaxart, Inc. and Oxford Finance LLC	Form S-4/A	333-222009	10.28	December 29, 2017
10.28	Warrant to Purchase Stock dated December 22, 2016, by and between Vaxart, Inc. and Oxford Finance LLC	Form S-4/A	333-222009	10.29	December 29, 2017

Exhibit Number	Description of Document	Incorporated by Reference			
		Schedule/Form	File Number	Exhibit	Filing Date
31.1*	Certification of Chief Executive Officer pursuant to Exchange Act Rule, 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002				
31.2*	Certification of Chief Financial Officer pursuant to Exchange Act Rule, 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002				
32.1*§	Certification of Principal Executive Officer and Principal Financial Officer pursuant to Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002				
32.2*§	Certification of Principal Financial Officer and Principal Financial Officer pursuant to Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002				
101 *	The following financial information from the Company's Quarterly Report on Form 10-Q for the period ended March 31, 2018, formatted in Extensible Business Reporting Language (XBRL): (i) the Condensed Consolidated Balance Sheets as of March 31, 2018 and December 31, 2017, (ii) the Condensed Consolidated Statements of Operations and Comprehensive Income (Loss) for the three months ended March 31, 2018 and 2017, (iii) the Condensed Consolidated Statements of Cash Flows for the three months ended March 31, 2018 and 2017, and (iv) Notes to the Condensed Consolidated Financial Statements				

* Filed herewith

\# Management contract or compensation plan or arrangement.

\+ Confidential portions of this exhibit have been omitted and filed separately with the Commission pursuant to confidential treatment granted under Rule 24b-2 promulgated under the Exchange Act.

§ In accordance with Item 601(b)(32)(ii) of Regulation S-K and SEC Release Nos. 33-8238 and 34-47986, Final Rule: Management's Reports on Internal Control Over Financial Reporting and Certification of Disclosure in Exchange Act Periodic Reports, the certifications furnished in Exhibits 32.1 and 32.2 hereto are deemed to accompany this Quarterly Report on Form 10-Q and will not be deemed "filed" for purposes of Section 18 of the Exchange Act. Such certifications will not be deemed to be incorporated by reference into any filing under the Securities Act or the Exchange Act, except to the extent that the registrant specifically incorporates it by reference.

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.

	VAXART, INC.
Dated: May 15, 2018	By: /s/ WOUTER W. LATOUR Wouter W. Latour President and Chief Executive Officer (Principal Executive Officer)
Dated: May 15, 2018	By: /s/ JOHN M. HARLAND John M. Harland Chief Financial Officer (Principal Financial Officer)

Exhibit 31.1

CERTIFICATION

I, Wouter W. Latour, M.D., certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Vaxart, 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) [reserved];

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

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

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

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

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

Date: May 15, 2018

By: /s/ WOUTER W. LATOUR, M.D.
Wouter W. Latour, M.D.
President, Chief Executive Officer and Director
(principal executive officer)

Exhibit 31.2

CERTIFICATION

I, John M. Harland, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Vaxart, 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) [reserved];

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

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

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

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

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

Date: May 15, 2018

By: /s/ JOHN M. HARLAND
John M. Harland
Chief Financial Officer
(principal financial officer)

Exhibit 32.1

CERTIFICATION

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. § 1350), Wouter W. Latour, M.D., the President and Chief Executive Officer of Vaxart, Inc. (the "Company"), hereby certifies that, to his knowledge:

(1) The Company's Quarterly Report on Form 10-Q for the period ended March 31, 2018, to which this Certification is attached as Exhibit 32.1 (the "Periodic Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and

(2) The information contained in the Periodic Report fairly presents, in all material respects, the financial condition of the Company at the end of the period covered by the Periodic Report and results of operations of the Company for the period covered by the Periodic Report.

Date: May 15, 2018

By: /s/ WOUTER W. LATOUR, M.D.
Wouter W. Latour, M.D.
President, Chief Executive Officer and Director
(principal executive officer)

A signed original of this written statement required by Section 906 of 18 U.S.C. § 1350 has been provided to Vaxart, Inc. and will be retained by Vaxart, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.

This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Exchange Act (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.

Exhibit 32.2

CERTIFICATION

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. § 1350), John M. Harland, the Chief Financial Officer of Vaxart, Inc. (the "Company"), hereby certifies that, to his knowledge:

(1) The Company's Quarterly Report on Form 10-Q for the period ended March 31, 2018, to which this Certification is attached as Exhibit 32.2 (the "Periodic Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and

(2) The information contained in the Periodic Report fairly presents, in all material respects, the financial condition of the Company at the end of the period covered by the Periodic Report and results of operations of the Company for the period covered by the Periodic Report.

Date: May 15, 2018

By: /s/ JOHN M. HARLAND
John M. Harland
Chief Financial Officer
(principal financial officer)

A signed original of this written statement required by Section 906 of 18 U.S.C. § 1350 has been provided to Vaxart, Inc. and will be retained by Vaxart, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.

This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Exchange Act (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.