Table of Contents

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 June 30, 2019

OR

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

For the transition period from _____ to _____

Commission file number: 001-35285

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	**(650) 550-3500**
(Address of principal executive offices, including zip code)	(Registrant's telephone number, including area code)

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

Title of each class	Trading symbol	Name of each exchange on which registered
Common stock, $0.10 par value	**VXRT**	**The Nasdaq Capital Market**

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

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☑ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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 ☐
Non-accelerated filer ☑
Emerging growth company ☐

Accelerated filer ☐
Smaller reporting company ☑

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

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

The Registrant had 15,785,735 shares of common stock, $0.10 par value, outstanding as of August 6, 2019.

FORM 10-Q
FOR THE QUARTER ENDED JUNE 30, 2019
TABLE OF CONTENTS

PART I FINANCIAL INFORMATION

Item 1. Financial Statements

VAXART, INC. AND SUBSIDIARIES

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

	June 30, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 16,258	$ 11,506
Accounts receivable	35	1,796
Prepaid expenses and other current assets	814	1,343
Total current assets	17,107	14,645
Property and equipment, net	1,517	1,066
Right-of-use assets, net	565	—
Intangible assets, net	17,959	19,413
Other long-term assets	102	103
Total assets	$ 37,250	$ 35,227
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 610	$ 962
Current portion of secured promissory note payable to Oxford Finance	1,667	1,667
Current portion of operating lease liability	565	—
Liability related to sale of future royalties, current portion	3,150	3,328
Other accrued liabilities	1,485	1,518
Total current liabilities	7,477	7,475
Operating lease liability, net of current portion	216	—
Liability related to sale of future royalties, net of current portion	12,519	14,413
Secured promissory note payable to Oxford Finance, net of current portion	1,175	1,944
Other long-term liabilities	18	157
Total liabilities	21,405	23,989
Commitments and contingencies (Note 9)		
Stockholders' equity:		
Preferred Stock: $0.10 par value; 5,000,000 shares authorized; none issued and outstanding as of June 30, 2019 or December 31, 2018	—	—
Common Stock: $0.10 par value; 100,000,000 shares authorized; 15,785,735 and 7,141,189 shares issued and outstanding as of June 30, 2019 and December 31, 2018, respectively	1,579	714
Additional paid-in capital	119,258	108,513
Accumulated deficit	(104,992)	(97,989)
Total stockholders' equity	15,845	11,238
Total liabilities and stockholders' equity	$ 37,250	$ 35,227

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 Loss
(In thousands, except share and per share amounts)
(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Revenue:				
Revenue from government contract	$ —	$ 520	$ —	$ 1,130
Royalty revenue	69	70	3,728	963
Non-cash royalty revenue related to sale of future royalties	16	18	1,764	18
Total revenue	85	608	5,492	2,111
Operating expenses:				
Research and development	3,707	5,012	7,536	8,420
General and administrative	1,375	1,771	3,401	3,781
Impairment of intangible assets	—	1,600	—	1,600
Total operating expenses	5,082	8,383	10,937	13,801
Operating loss	(4,997)	(7,775)	(5,445)	(11,690)
Other income and (expenses):				
Bargain purchase gain	—	(328)	—	6,660
Interest income	34	36	39	41
Interest expense	(97)	(136)	(204)	(573)
Non-cash interest expense related to sale of future royalties	(516)	(468)	(1,060)	(766)
Loss on revaluation of financial instruments	—	—	—	(3)
Foreign exchange gain, net	(48)	(199)	(43)	(197)
Total other income and (expenses)	(627)	(1,095)	(1,268)	5,162
Net loss before income taxes	(5,624)	(8,870)	(6,713)	(6,528)
Provision for income taxes	13	1	263	29
Net loss	(5,637)	(8,871)	(6,976)	(6,557)
Series B and C preferred dividend	—	—	—	(339)
Net comprehensive loss attributable to common stockholders	$ (5,637)	$ (8,871)	$ (6,976)	$ (6,896)
Net loss per share - basic and diluted	$ (0.39)	$ (1.24)	$ (0.64)	$ (1.26)
Shares used to compute net loss per share - basic and diluted	14,597,446	7,141,189	10,969,473	5,477,265

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

VAXART, INC. AND SUBSIDIARIES

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

	Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	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
Stock-based compensation	—	—	—	—	118	—	118
Net income	—	—	—	—	—	(8,871)	(8,871)
Balances as of June 30, 2018	—	—	7,141,189	$ 714	$ 108,178	$ (86,539)	$ 22,353

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balances as of December 31, 2018	7,141,189	$ 714	$ 108,513	$ (97,989)	$ 11,238
Cumulative effect of adoption of new leases standard	—	—	—	(27)	(27)
Balances as of January 1, 2019, as adjusted	7,141,189	$ 714	$ 108,513	$ (98,016)	$ 11,211
Issuance of common stock, net of offering costs of $560	1,200,000	120	2,320	—	2,440
Issuance of common stock warrants to placement agents' designees	—	—	100	—	100
Stock-based compensation	—	—	164	—	164
Net loss	—	—	—	(1,339)	(1,339)
Balances as of March 31, 2019	8,341,189	$ 834	$ 111,097	$ (99,355)	$ 12,576
Issuance of common stock, pre-funded warrants and common stock warrants, net of offering costs of $1,579	925,455	93	7,648	—	7,741
Issuance of common stock warrants to underwriters' designees	—	—	333	—	333
Issuance of common stock upon exercise of pre-funded warrants	6,519,091	652	—	—	652
Stock-based compensation	—	—	180	—	180
Net loss	—	—	—	(5,637)	(5,637)

Balances as of June 30, 2019	15,785,735	$ 1,579	$ 119,258	$ (104,992)	$ 15,845

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)

	Six Months Ended June 30,	
	2019	**2018**
Cash flows from operating activities:		
Net loss	$ (6,976)	$ (6,557)
Adjustments to reconcile net loss to net cash used in operating activities:		
Bargain purchase gain	—	(6,660)
Depreciation and amortization	2,097	1,437
Impairment of intangible assets	—	1,600
Stock-based compensation	344	204
Loss on revaluation of financial instruments	—	3
Non-cash interest expense	64	366
Amortization of note discount	—	18
Non-cash interest expense related to sale of future royalties	1,060	766
Non-cash revenue related to sale of future royalties	(3,132)	—
Change in operating assets and liabilities:		
Accounts receivable	1,761	14,735
Prepaid expenses and other assets	530	(448)
Accounts payable	(347)	(3,259)
Accrued liabilities	(371)	(5,693)
Net cash used in operating activities	(4,970)	(3,488)
Cash flows from investing activities:		
Purchase of property and equipment	(711)	(339)
Cash acquired in reverse merger	—	25,525
Cash paid for fractional shares in merger	—	(21)
Purchases of short-term investments	—	(573)
Proceeds from maturities of short-term investments	—	1,988
Net cash (used in) provided by investing activities	(711)	26,580
Cash flows from financing activities:		
Net proceeds from issuance of common stock in registered direct offering	2,540	—
Net proceeds from issuance of common stock, pre-funded warrants and common warrants in underwritten offering	8,074	—
Repayment of principal on secured promissory note payable to Oxford Finance	(833)	(694)
Repayment of short-term note	—	(61)
Proceeds from issuance of common stock upon exercise of pre-funded warrants	652	—
Proceeds from issuance of common stock upon exercise of stock options	—	13
Net cash provided by (used in) financing activities	10,433	(742)
Net increase in cash and cash equivalents	4,752	22,350
Cash, cash equivalents and restricted cash at beginning of the period	11,506	1,571
Cash, cash equivalents and restricted cash at end of the period	$ 16,258	$ 23,921

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)

	Six Months Ended June 30,	
	2019	**2018**
Supplemental disclosure of cash flow information:		
Interest paid	$ 136	$ 189
Supplemental disclosure of non-cash investing and financing activity:		
Issuance of warrants to placement agents' designees	$ 100	$ —
Issuance of warrants to underwriters' designees	$ 333	$ —
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	$ 47	$ 14

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.

On March 20, 2019, the Company completed a registered direct offering (the "March 2019 Offering") of 1,200,000 shares of the Company's common stock. The total gross proceeds from the offering to the Company were $3.0 million. After deducting placement agent fees and offering expenses payable by the Company, the aggregate net proceeds received by the Company totaled $2.5 million. Pursuant to the terms of the engagement letter with the placement agents, the Company paid the placement agents aggregate fees and reimbursable costs of $320,000. In addition, the Company issued the placement agents' designees 84,000 common stock warrants at the closing of the March 2019 Offering, each warrant entitling the holder to purchase one share of common stock for $3.125 at any time within five years of their issuance date. The aggregate fair value of these warrants at issuance was estimated to be $100,000 (see Note 10), which was recorded in offering costs.

On April 11, 2019, the Company completed a public underwritten offering (the "April 2019 Offering") of 925,455 shares of common stock, 8,165,455 pre-funded warrants, and warrants to purchase 10,454,546 shares of common stock (including 1,363,636 common stock warrants issued upon the exercise by the underwriters of their option to purchase such warrants). Each share of common stock with an accompanying common stock warrant was sold for $1.10, and each pre-funded warrant with an accompanying common stock warrant was sold for $1.00, with the amount paid for each accompanying common stock warrant being $0.10. Each pre-funded warrant entitles the holder to purchase one share of common stock for $0.10, is immediately exercisable, subject to certain ownership limitations, and may be exercised at any time until all of the pre-funded warrants are exercised in full. Each common stock warrant entitles the holder to purchase one share of common stock for $1.10, is exercisable immediately, subject to certain ownership limitations, and will expire five years from the date of issuance.

The total gross proceeds from the April 2019 Offering to the Company were $9.3 million. After deducting underwriting discounts, commissions and offering expenses payable by the Company, the aggregate net proceeds received by the Company were $8.1 million. In addition, as of June 30, 2019, a further $0.6 million had been received from the exercise of pre-funded warrants and 1,646,364 pre-funded warrants remained outstanding.

Pursuant to the terms of an underwriting agreement, the Company paid the underwriters aggregate commissions and reimbursable costs of $750,000. In addition, the Company issued the underwriters' designees 636,364 common stock warrants at the closing of the April 2019 Offering, each warrant entitling the holder to purchase one share of common stock for $1.375 at any time within five years of their issuance date. The aggregate fair value of these warrants at issuance was estimated to be $333,000 (see Note 10), which was recorded in offering costs.

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.

VAXART, INC. AND SUBSIDIARIES

Notes to the Condensed Consolidated Financial Statements (Unaudited)

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 June 30, 2019, the Company had an accumulated deficit of $105.0 million and a loan with an outstanding balance of $2.8 million from Oxford Finance, LLC ("Oxford Finance"), repayable in monthly installments by January 2021 (see Note 8).

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, management believes that the Company's cash and cash equivalents of $16.3 million held as of June 30, 2019, are sufficient to fund the Company into, but probably not beyond, the first quarter of 2020.

The Company reviews its operations and clinical plans on a continuing basis, including its commitments for upcoming clinical trials. The Company plans to finance its operations with royalty revenue on sales of Inavir, additional equity or debt financing arrangements, 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 Company's audited financial statements and footnotes related thereto for the year ended December 31, 2018, included in the Company's Annual Report on Form 10-K filed with the SEC on February 6, 2019 (the "Annual Report"). Except as noted below, there have been no material changes to the Company's significant accounting policies described in Note 2 to the consolidated financial statements included in the Annual Report. 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.

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 short-term 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.

Leases – Effective January 1, 2019, the Company records operating leases as right-of-use assets and operating lease liabilities in its condensed consolidated balance sheets for all operating leases with terms exceeding one year. Right-of-use assets represent the right to use an underlying asset for the lease term, including extension options considered reasonably certain to be exercised, and operating lease liabilities to make lease payments. Right-of-use assets and operating lease liabilities are recognized based on the present value of lease payments over the lease term. To the extent that lease agreements do not provide an implicit rate, the Company uses its incremental borrowing rate based on information available at the lease commencement date to determine the present value of lease payments. The expense for operating lease payments is recognized on a straight-line basis over the lease term and is included in operating expenses in the Company's statement of operations and comprehensive loss.

Recently Adopted Accounting Pronouncements

In February 2016, the FASB issued ASU 2016-02 *Leases (Topic 842)*, which replaced most current lease guidance when it became effective. This standard update was designed to increase 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 are classified as either finance or operating, with classification affecting the pattern of expense recognition in the statements of operations. The Company adopted the new guidance effective January 1, 2019, using the modified retrospective method, and used the effective date method of adoption, as permitted by ASU 2018-11, *Leases (Topic 842): Targeted Improvements*, which the FASB issued in July 2018, clarified by ASU 2019-01, *Leases (Topic 842): Codification Improvements*, which the FASB issued in March 2019, which reduces the disclosure requirements on transition. The Company has elected the short-term lease recognition exemption for all classes of assets, which means that it will not recognize right-of-use assets or lease liabilities for leases with a duration of one year or less. Further, the Company has elected to use all of the practical expedients available on transition, whereby it has not reassessed under the new standard its prior conclusions about lease identification, lease classification and initial direct costs.

The adoption of this standard had a material effect on the Company's condensed consolidated balance sheets, the most significant effects being the recognition of new right-of-use assets and lease liabilities. The Company recognized lease liabilities of $1,229,000, $783,000 of which was current, and right-of-use assets of $953,000 based on the present value of the remaining minimum rental payments for existing operating leases, derecognized liabilities related to deferred rent and lease loss accrual of $249,000, $111,000 of which was current, and recognized an increase of $27,000 to accumulated deficit on adoption of the new accounting policy.

The increase in accumulated deficit arose because the right-of-use asset impairment charge that would have been recorded in the three months ended December 31, 2018, under Topic 842 exceeded the lease loss accrual, net of accretion, that was recorded. This impact aside, the adoption had no effect on the Company's statements of operations or cash flows, other than on related disclosures.

Recent Accounting Pronouncements

The Company has reviewed all 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. 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 short-term 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.

VAXART, INC. AND SUBSIDIARIES

Notes to the Condensed Consolidated Financial Statements (Unaudited)

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 convertible preferred stock warrant liability was classified within Level 3 of the fair value hierarchy as it was valued using inputs that were unobservable in the market.

The Company's only recurring financial assets that are measured at fair value were $15,000 held in money market funds and classified as cash equivalents as of both June 30, 2019 and December 31, 2018, with no recurring financial liabilities held at either date or in the six months ended June 30, 2019. The following table presents a reconciliation of all liabilities measured at fair value on a recurring basis using significant unobservable inputs (Level 3) for the six months ended June 30, 2018:

	Convertible Preferred Stock Warrant Liability	Total
	(in thousands)	
Balance at January 1, 2018	$ 67	$ 67
Issuances	—	—
Revaluation loss included in loss on revaluation of financial instruments, net	3	3
Settlements	(70)	(70)
Balance at June 30, 2018	$ —	$ —
Total gains included in other income and (expenses) attributable to liabilities still held as of June 30, 2018	$ —	$ —

NOTE 4. Balance Sheet Components

(a) Cash and Cash Equivalents

Cash and cash equivalents comprises the following:

	June 30, 2019	December 31, 2018
	(in thousands)	
Cash at banks	$ 16,243	$ 11,441
Restricted cash	—	50
Money market funds	15	15
Total cash and cash equivalents	$ 16,258	$ 11,506

VAXART, INC. AND SUBSIDIARIES

Notes to the Condensed Consolidated Financial Statements (Unaudited)

(b) Accounts Receivable

Accounts receivable comprises the following:

	June 30, 2019	December 31, 2018
	(in thousands)	
Royalties receivable	$ 15	$ 1,776
Government contract - billed	20	20
Accounts receivable	$ 35	$ 1,796

The Company has provided no allowance for uncollectible accounts as of June 30, 2019 or December 31, 2018.

(c) Property and Equipment, Net

Property and equipment, net consists of the following:

	June 30, 2019	December 31, 2018
	(in thousands)	
Laboratory equipment	$ 2,775	$ 2,076
Office and computer equipment	227	227
Leasehold improvements	340	333
Total property and equipment	3,342	2,636
Less: accumulated depreciation	(1,825)	(1,570)
Property and equipment, net	$ 1,517	$ 1,066

Depreciation expense was $125,000 and $121,000 for the three months ended June 30, 2019 and 2018, respectively, and $255,000 and $219,000 for the six months ended June 30, 2019 and 2018, respectively. There were no impairments of the Company's property and equipment recorded in the six months ended June 30, 2019 or 2018.

(d) Right-of-Use Assets, Net

Right-of-use assets, net consists of the following:

	June 30, 2019
	(in thousands)
Facilities	$ 557
Office equipment	8
Right-of-use assets, net	$ 565

(e) Intangible Assets

Intangible assets comprise developed technology, intellectual property and, until it was considered fully impaired, in-process research and development. Intangible assets 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. Intangible assets consist of the following:

	June 30, 2019	December 31, 2018
	(in thousands)	
Purchased technology	$ 22,100	$ 22,100
Intellectual property	80	80
Total cost	22,180	22,180
Less: accumulated amortization	(4,221)	(2,767)
Intangible assets, net	$ 17,959	$ 19,413

Intangible asset amortization expense for the three months ended June 30, 2019 and 2018, was $675,000 and $805,000 respectively, and for the six months ended June 30, 2019 and 2018, was $1,454,000 and $1,218,000, respectively. Following the results of Phase 2 trials of teslexivir in June 2018, the in-process research and development was assessed as fully impaired in the three months ended June 30, 2018, with the related $1.6 million acquired in the Merger (see Note 1) being charged to operating expenses.

VAXART, INC. AND SUBSIDIARIES

Notes to the Condensed Consolidated Financial Statements (Unaudited)

As of June 30, 2019, the estimated future amortization expense by year is as follows (in thousands):

Year Ending December 31,	Amount
2019 (six months remaining)	$ 866
2020	1,732
2021	1,732
2022	1,732
2023	1,731
Thereafter	10,166
Total	$ 17,959

(f) Accrued Liabilities

Accrued liabilities consist of the following:

	June 30, 2019	December 31, 2018
	(in thousands)	
Accrued compensation	$ 773	$ 632
Accrued clinical and manufacturing expenses	18	75
Accrued professional and consulting services	48	166
Reserve for return of royalties	339	339
Deferred rent and lease loss accrual, current portion	—	111
Other liabilities, current portion	307	195
Total	$ 1,485	$ 1,518

NOTE 5. Revenue

U.S. Government HHS BARDA Contract

In September 2015, the Department of Health and Human Services, Office of Biomedical Advanced Research and Development Authority ("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, and June 28, 2018, 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 September 30, 2018. The modified contract was a cost-plus-fixed-fee contract, which reimbursed the Company for allowable direct contract costs plus allowable indirect costs and a fixed fee, totaling $15.7 million. The Company recognized revenue of $520,000 and $1,130,000 during the three and six months ended June 30, 2018, respectively. As of December 31, 2018, the cumulative revenue recorded from inception under the HHS BARDA contract represented the maximum billable under the contract as presently modified, with no further change orders envisaged.

Billings under the contract were 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 under this contract in any period 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 marketed by GSK under the name Relenza to treat influenza. All of the Company's Relenza patents have expired, the last remaining intellectual property related to the Relenza patent portfolio, which is solely owned by the Company and exclusively licensed to GSK, having expired in July 2019 in Japan. The royalty revenue related to Relenza recognized in the three months ended June 30, 2019 and 2018, was $69,000 and $70,000, respectively, and in the six months ended June 30, 2019, and in the post-Merger period in the six months ended June 30, 2018, was $764,000 and $411,000, respectively, representing 7% of net sales in Japan.

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 Company, Limited ("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. The last patent related to Inavir is set to expire in December 2029, at which time royalty revenue will cease. The royalty revenue related to Inavir recognized in the six months ended June 30, 2019, and in the post-Merger period in the six months ended June 30, 2018, was $2,964,000 and $552,000, respectively, representing 4% of net sales in Japan. No such revenue was recognized in the three months ended June 30, 2019 or 2018, since the sums receivable, net of withholding tax, of $16,000 and $18,000, respectively, were payable to Healthcare Royalty Partners III, L.P. ("HCRP") (see Note 6). Both the royalty revenue and the non-cash royalty revenue related to the sale of future royalties have been subjected to a 5% withholding tax in Japan, for which $1,000 and $1,000 was included in income tax expense in the three months ended June 30, 2019 and 2018, respectively, and $237,000 and $29,000 was included in income tax expense in the six months ended June 30, 2019 and 2018, respectively.

The Company's royalty revenue is seasonal, in line with the flu season. The majority of the Company's royalty revenue is earned in the first and fourth fiscal quarters.

NOTE 6. Liabilities Related to Sale of Future Royalties

In April 2016, Aviragen entered into a Royalty Interest Acquisition Agreement (the "RIAA") with HCRP. Under the RIAA, 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. Per the terms of the RIAA, HCRP is entitled to the first $3.0 million plus 15% of the next $1.0 million in royalties earned in each year commencing on April 1, with any excess revenue being retained by the Company.

Under the relevant accounting guidance, due to a limit on the amount of royalties that HCRP can earn under the RIAA, this transaction is accounted for as a liability that is being 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. 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 royalties earned in each period that will be passed through to HCRP are recorded as non-cash royalty revenue related to sale of future royalties, with any excess not subject to pass-through being recorded as royalty revenue. When the pass-through royalties are paid to HCRP in the following quarter, the imputed liability related to sale of future royalties is commensurately reduced. The Company periodically assesses the expected royalty payments, and to the extent such payments are greater or less than the initial estimate, the Company adjusts 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, including the related interest, is fully amortized.

The following table shows the activity within the liability account in the six months ended June 30, 2019 (in thousands):

Total liability related to sale of future royalties, start of period	$	17,741
Non-cash royalty revenue paid to HCRP		(3,132)
Non-cash interest expense recognized		1,060
Total liability related to sale of future royalties, end of period		15,669
Current portion		(3,150)
Long-term portion	$	12,519

VAXART, INC. AND SUBSIDIARIES

Notes to the Condensed Consolidated Financial Statements (Unaudited)

NOTE 7. Leases

The Company has obtained the right of use for office and manufacturing facilities under five operating lease agreements, one of which has been subleased, and for equipment under three operating lease agreements with initial terms exceeding one year and under three operating lease agreements with initial terms of one year or less.

The Company obtained the right of use of real estate located in South San Francisco, California, in June 2015 that terminates on April 30, 2020, with a five-year extension option. The Company also obtained, via the Merger, the right of use of facilities located in Alpharetta, Georgia, in February 2018 that terminates on February 28, 2021, with no extension option. These facilities were subleased for the remainder of the lease term effective November 30, 2018. In addition, the Company obtained the right of use of facilities located in South San Francisco, California, under three leases that terminate on August 31, 2019, with no extension options, and the right of use of equipment under three leases that terminate between July 2019 and September 2021.

As of June 30, 2019, the weighted average discount rate for operating leases with initial terms of more than one year was 10.5% and the weighted average remaining term of these leases was 1.32 years. Discount rates were determined using the Company's marginal rate of borrowing at the time each lease was executed or extended.

The following table summarizes the Company's undiscounted cash payment obligations for its operating lease liabilities with initial terms of more than twelve months as of June 30, 2019 (in thousands):

Year Ending December 31,	
2019 (excluding the six months ended June 30, 2019)	$ 361
2020	414
Thereafter	58
Undiscounted total	833
Less: imputed interest	(52)
Present value of future minimum payments	781
Current portion of operating lease liability	(565)
Operating lease liability, net of current portion	$ 216

In addition, future obligations under operating leases for equipment with initial terms of one year or less totaled $1,000. The Company presently has no finance leases.

Certain operating lease agreements include non-lease costs, such as common area maintenance, which are excluded from operating lease costs. Operating lease expenses for the three and six months ended June 30, 2019, are summarized as follows:

	Three Months Ended June 30, 2019	Six Months Ended June 30, 2019
Lease cost	*(in thousands)*	
Operating lease cost	$ 222	$ 445
Short-term lease cost	4	7
Sublease income	(55)	(109)
Total lease cost	$ 171	$ 343

Net cash outflows associated with operating leases totaled $200,000 and $399,000 in the three and six months ended June 30, 2019, respectively. Rent expense was and $222,000 and $368,000 for the three and six months ended June 30, 2018, respectively.

Future minimum payments and sublease income under operating leases as of December 31, 2018, were as follows:

Year Ending December 31,	Lease Payments	Sublease Income
	(in thousands)	
2019	$ 859	$ 213
2020	411	219
2021	56	38
Thereafter	—	—
Total	$ 1,326	$ 470

NOTE 8. 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. 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. The loan is secured by substantially all the Company's assets, except for intellectual property.

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"), expiring in December 2026. The fair value of the Warrant at the date of issuance was $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 $96,000 and $138,000 during the three months ended June 30, 2019 and 2018, respectively, of which $64,000 and $94,000 was paid, respectively, and recorded interest expense of $202,000 and $279,000 during the six months ended June 30, 2019 and 2018, respectively, of which $136,000 and $189,000 was paid, respectively.

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 antidilution 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 loss on revaluation of financial instruments line in the statements of operations and comprehensive 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 $70,000 on February 13, 2018, was transferred to equity.

NOTE 9. Commitments and Contingencies

(a) Leases

The Company's lease commitments are detailed in Note 7.

(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.

VAXART, INC. AND SUBSIDIARIES

Notes to the Condensed Consolidated Financial Statements (Unaudited)

NOTE 10. Stockholders' Equity

(a) 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 the Company's 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.

(b) Common Stock

On April 23, 2019, the Company's stockholders approved a Certificate of Amendment to the Company's Restated Certificate of Incorporation (the "Certificate"), to decrease the authorized number of shares of common stock, par value $0.10, from 200,000,000 to 100,000,000 shares. On April 23, 2019, the Certificate was filed with the Secretary of State of the State of Delaware. 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 June 30, 2019, 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:

	June 30, 2019	December 31, 2018
Options issued and outstanding	2,166,800	865,163
Available for future grants of equity awards	186,410	223,377
Common stock warrants	12,832,188	10,914
Total	15,185,398	1,099,454

(c) Warrants

The Company has the following warrants outstanding as of June 30, 2019, all of which contain standard anti-dilution protections in the event of subsequent rights offerings, stock splits, stock dividends or other extraordinary dividends, or other similar changes in the Company's common stock or capital structure, and none of which have any participating rights for any losses:

Securities into which warrants are convertible	Warrants outstanding	Exercise Price	Expiration Date
Common Stock	1,646,364	$ 0.10	April 2024
Common Stock	10,454,546	$ 1.10	April 2024
Common Stock	636,364	$ 1.375	April 2024
Common Stock	84,000	$ 3.125	March 2024
Common Stock	10,914	$ 22.99	December 2026
Total	12,832,188		

The aggregate fair value at issuance of the warrants entitling the holder to purchase one share of common stock for $3.125 that were issued to the placement agents' designees at the closing of the March 2019 Offering (see Note 1) was estimated to be $100,000, using the Black-Scholes valuation model, using a closing stock price of $2.08 and assumptions including estimated volatility of 80%, a risk-free interest rate of 2.34%, a zero dividend rate and an estimated remaining term of 5.0 years. The aggregate fair value at issuance of the warrants entitling the holder to purchase one share of common stock for $1.375 that were issued to the underwriters' designees at the closing of the April 2019 Offering (see Note 1) was estimated to be $333,000, using the Black-Scholes valuation model, using a closing stock price of $0.89 and assumptions including estimated volatility of 83%, a risk-free interest rate of 2.31%, a zero dividend rate and an estimated remaining term of 5.0 years.

In the event of a Fundamental Transaction (a transfer of ownership of the Company as defined in the warrant) within the Company's control, the holders of unexercised common stock warrants exercisable for $1.10 shall be entitled to receive cash consideration equal to a Black-Scholes valuation, as defined in the warrant. If such Fundamental Transaction is not within the Company's control, the warrantholders would only be entitled to receive the same form of consideration (and in the same proportion) as the holders of the Company's common stock, hence these warrants are classified as a component of permanent equity.

VAXART, INC. AND SUBSIDIARIES

Notes to the Condensed Consolidated Financial Statements (Unaudited)

NOTE 11. Equity Incentive Plans

Prior to the Merger, Private Vaxart issued equity awards for compensation purposes to employees, directors and consultants under its 2007 Equity Incentive Plan (the "2007 Plan"). The 2007 Plan expired in July 2017 and no further awards may be made under the 2007 Plan. Each outstanding stock option to acquire shares of Private Vaxart stock, whether vested or unvested, was assumed in the Merger after adjustment for the impact of the Conversion and the Reverse Stock Split.

In November 2016, Aviragen's stockholders approved the 2016 Equity Incentive Plan ("2016 Plan"), under which all outstanding awards under Aviragen's previous plans became available for issuance under the 2016 Plan if such awards were forfeited or otherwise terminated.

Under the 2016 Plan, Aviragen was authorized to issue incentive stock options ("ISOs"), non-qualified stock options ("NQSOs"), restricted stock ("RSAs") and restricted stock units ("RSUs"). Awards that expired or were canceled generally became available for issuance again under the 2016 Plan. Awards have a maximum term of ten years from the grant date and may vest over varying periods, as specified by the Company's Board of Directors for each grant. Following stockholder approval of the 2019 Equity Incentive Plan (the "2019 Plan"), no further awards are available for grant under the 2016 Plan.

On April 23, 2019, the Company's stockholders approved the adoption of the 2019 Plan, under which the Company is authorized to issue ISOs, NQSOs, stock appreciation rights, RSAs, RSUs, other stock awards and performance awards that may be settled in cash, stock, or other property. The 2019 Plan is designed to secure and retain the services of employees, directors and consultants, provide incentives for the Company's employees, directors and consultants to exert maximum efforts for the success of the Company and its affiliates, and provide a means by which employees, directors and consultants may be given an opportunity to benefit from increases in the value of the Company's common stock.

The aggregate number of shares of common stock that may be issued under the 2019 Plan will not exceed 1,600,000 shares, which can only be increased by stockholder approval, except that all awards are 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 that expire or are canceled generally become available for issuance again under the 2019 Plan. Awards have a maximum term of ten years from the grant date and may vest over varying periods, as specified by the Company's board of directors for each grant.

A summary of stock option transactions in the six months ended June 30, 2019, is as follows:

	Shares Available For Grant	Number of Options Outstanding	Weighted Average Exercise Price
Balance at January 1, 2019	200,650	865,163	$ 8.13
Authorized under 2019 Plan	1,600,000	—	$ —
Removed from 2016 Plan	(223,389)	—	$ —
Granted	(1,413,590)	1,413,590	$ 0.76
Forfeited	—	(7,399)	$ 5.35
Canceled	22,739	(104,554)	$ 11.00
Balance at June 30, 2019	186,410	2,166,800	$ 3.19

The weighted average grant date fair value of options awarded in the six months ended June 30, 2019 and 2018, was $0.55 and $3.59, respectively. Fair values were estimated using the following assumptions:

	Six Months Ended June 30, 2019	2018
Risk-free interest rate	1.89% - 2.31%	2.79% - 2.80%
Expected term	5.39 - 6.08 Years	5.84 - 6.05 Years
Expected volatility	83% - 85%	78% - 80%
Dividend yield	—%	—%

The Company measures the fair value of all stock-based awards on the grant date and records the fair value of these awards, net of estimated forfeitures, to compensation expense over the service period. Total stock-based compensation recognized for options was as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
	(in thousands)		(in thousands)	
Research and development	$ 80	$ 59	$ 159	$ 103
General and administrative	100	59	185	101
Total stock-based compensation	$ 180	$ 118	$ 344	$ 204

As of June 30, 2019, the unrecognized stock-based compensation cost related to outstanding unvested stock options that are expected to vest was $1.4 million, which the Company expects to recognize over an estimated weighted average period of 2.82 years.

VAXART, INC. AND SUBSIDIARIES

Notes to the Condensed Consolidated Financial Statements (Unaudited)

NOTE 12. 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 June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Net loss	$ (5,637)	$ (8,871)	$ (6,976)	$ (6,557)
Series B and C preferred dividend	—	—	—	(339)
Net loss attributable to common stockholders – diluted calculation	$ (5,637)	$ (8,871)	$ (6,976)	$ (6,896)
Shares used to compute net loss per share – basic and diluted	14,597,446	7,141,189	10,969,473	5,477,265
Net loss per share – basic and diluted	$ (0.39)	$ (1.24)	$ (0.64)	$ (1.26)

No adjustment has been made to the net loss attributable to common stockholders as the effect would be antidilutive 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 June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Options to purchase common stock	1,561,067	878,555	1,212,654	765,702
Warrants to purchase common stock	11,802,695	10,794	5,944,948	8,230
Warrant to purchase convertible preferred stock	—	—	—	1,797
Series B and C convertible preferred stock outstanding, including cumulative dividends	—	—	—	431,064
Series A convertible preferred stock outstanding	—	—	—	24,723
Convertible promissory notes, related party (as converted)	—	—	—	373,388
Total potentially dilutive securities excluded from denominator of the diluted earnings per share computation	13,363,762	889,349	7,157,602	1,604,904

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

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our condensed consolidated financial statements and related notes included elsewhere in this in this Quarterly Report on Form 10-Q and with our audited consolidated financial statements included in our Annual Report on Form 10-K filed with the SEC on February 6, 2019. This Quarterly Report on Form 10-Q contains 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, which are subject to the "safe harbor" created by those sections. Forward-looking statements are based on our management's beliefs and assumptions and on information currently available to our management. In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "could," "goal," "would," "expect," "plan," "anticipate," "believe," "estimate," "project," "predict," "potential" and similar expressions intended to identify forward-looking statements. Our actual results could differ materially from those discussed in the forward-looking statements. Factors that could cause or contribute to these differences include those discussed below and elsewhere in this Quarterly Report on Form 10-Q, particularly in "Risk Factors." The forward-looking statements included in this Quarterly Report on Form 10-Q are made only as of the date hereof.

In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the filing date of this Quarterly Report on Form 10-Q , and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and investors are cautioned not to unduly rely upon these statements.

Company Overview and Background

We are a clinical-stage biotechnology company focused on the development of oral recombinant vaccines based on our proprietary oral vaccine platform. Our oral vaccines are designed to generate broad and durable immune responses that protect against a wide range of infectious diseases and may be useful for the treatment of chronic viral infections and cancer. Our vaccines are administered using a convenient room temperature-stable tablet, rather than by injection.

We are developing prophylactic vaccine candidates that target a range of infectious diseases. These include norovirus, a widespread cause of acute gastro-intestinal enteritis, for which two Phase 1 human studies have been completed and a Phase 1 bivalent study is in process; seasonal influenza, for which our vaccine demonstrated that it protected healthy volunteers against infection with H1 influenza in a recent Phase 2 human challenge study; and respiratory syncytial virus, or RSV, a common cause of respiratory tract infections. In addition, we are developing our first therapeutic immune-oncology vaccine targeting cervical cancer and dysplasia caused by human papillomavirus, or HPV.

Merger with Aviragen

Vaxart Biosciences, Inc. was originally incorporated in California in March 2004, under the name West Coast Biologicals, Inc. and changed its name to Vaxart, Inc., or Private Vaxart, in July 2007, and reincorporated in the state of Delaware. On February 13, 2018, Private Vaxart completed a reverse merger, or the Merger, with Aviragen Therapeutics, Inc., or Aviragen, pursuant to which Private Vaxart survived as a wholly owned subsidiary of Aviragen. Under the terms of the Merger, Aviragen changed its name to Vaxart, Inc. and Private Vaxart changed its name to Vaxart Biosciences, Inc.

Our Product Pipeline

We are developing the following tablet vaccine candidates, which are based on our proprietary platform:

- ***Norovirus Vaccine*.** We are developing an oral tablet vaccine for norovirus, a leading cause of acute gastroenteritis in the United States and Europe. Because norovirus infects the small intestine, we believe that our vaccine, which is designed to produce mucosal antibodies locally in the intestine, in addition to systemic antibodies in the blood, will better protect against norovirus infection than an injectable vaccine. Clinical evidence that vaccines based on our platform technology can protect against infection is described under "Clinical Trial Update" in the "Seasonal Influenza Vaccine" section below.

  Norovirus is the leading cause of vomiting and diarrhea from acute gastroenteritis among people of all ages in the United States. Each year, on average, norovirus causes 19 to 21 million cases of acute gastroenteritis and contributes to 56,000 to 71,000 hospitalizations and 570 to 800 deaths, mostly among young children and older adults. Typical symptoms include dehydration, vomiting, diarrhea with abdominal cramps, and nausea. In a study conducted by Pittsburg School of Medicine in 2012, the total economic burden of norovirus in the United States was estimated at $5.5 billion. In a more recent study by CDC and Johns Hopkins University, the global economic impact of norovirus disease was estimated at $60 billion, $34 billion of which occurred in high income countries including the United States, Europe and Japan. Virtually all norovirus disease is caused by norovirus GI and GII genotypes, and we are developing a bivalent vaccine designed to protect against both.

Clinical Trial Update. We have completed two Phase 1 clinical trials with our monovalent oral tablet vaccine for the GI.1 norovirus strain. The vaccine was well-tolerated and generated broad systemic and mucosal immune responses. In the clinical Phase 1b dose optimization study in healthy adults in which we evaluated four different dosing regimens, all vaccine recipients (100%) in the high dose group responded as measured by a significant increase in norovirus-specific B cells of both IgA and IgG subtypes. In the same group, there was at least a two-fold increase of norovirus-specific antibody titers in serum in more than 90% of recipients.

The bivalent norovirus Phase 1 study, designed to assess safety and immunogenicity of our norovirus GI.1 and GII.4 vaccines administered concurrently, is currently underway and we expect to announce topline results early in the fourth quarter of 2019.

Following a review of the development strategy for norovirus, Vaxart has deprioritized the monovalent GI.1 challenge study. Instead, the Company is preparing to initiate a Phase 2 safety and immunogenicity study with Vaxart's bivalent norovirus vaccine in 2020, to be followed by a Phase 3 efficacy study, assuming FDA concurrence.

- ***Seasonal Influenza Vaccine.*** Influenza is a major cause of morbidity and mortality in the U.S. and worldwide and, according to the CDC, only 42% of eligible U.S. citizens were vaccinated in 2017/2018, with particularly low vaccination rates among adults between ages 18 and 49. We believe our oral tablet vaccine has the potential to improve the protective efficacy of currently available influenza vaccines and increase flu vaccination rates.

  Influenza is one of the most common global infectious diseases, causing mild to life-threatening illness and even death. An estimated 350 million cases of seasonal influenza occur annually worldwide, of which three to five million cases are considered severe, causing 290,000 to 650,000 deaths per year globally. During the flu season of 2017 – 2018, there were 79,400 flu-related deaths in the U.S. alone, according to the CDC. Very young children and the elderly are at the greatest risk. In the United States, between 5% and 20% of the population contracts influenza, 226,000 people are hospitalized with complications of influenza, and between 3,000 and 49,000 people die from influenza and its complications each year, with up to 90% of the influenza-related deaths occurring in adults older than 65. The total economic burden of seasonal influenza has been estimated to be $87.1 billion, including medical costs which average $10.4 billion annually, while lost earnings due to illness and loss of life amount to $16.3 billion annually.

  We believe our tablet vaccine candidate has the potential to address many of the limitations of current injectable egg-based influenza vaccines, because: our tablet vaccine candidates are designed to create broad and durable immune responses, which may provide more effective immunity and protect against additional strain variants; our vaccine is delivered as a room temperature-stable tablet, which should provide a more convenient method of administration to enhance patient acceptance, and should simplify distribution and administration; and, by using recombinant methods, we believe our tablet vaccine may be manufactured more rapidly than vaccines manufactured using egg-based methods, and should eliminate the risk of allergic reactions to egg protein.

  Clinical Trial Update. In September 2018, we completed a $15.7 million contract with the U.S. Government through the Department of Health and Human Services, Office of Biomedical Advanced Research and Development Authority, or HHS BARDA, under which a Phase 2 challenge study of our H1N1 flu vaccine candidate was conducted. Previously, we had announced that, in healthy volunteers immunized and then experimentally infected with H1 influenza, our H1 influenza oral tablet vaccine resulted in a 39% reduction in clinical disease relative to placebo, a result that was superior to Fluzone, the market-leading injectable quadrivalent influenza vaccine, which reduced clinical disease by only 27%. Our tablet vaccine also showed a favorable safety profile, indistinguishable from placebo. On October 4, 2018, we presented data from the study demonstrating that our vaccine elicited a significant expansion of mucosal homing receptor plasmablasts to approximately 60% of all activated B cells, while Fluzone only maintained baseline levels of 20%. We believe plasmablasts are a key indicator of a protective mucosal immune response and a unique feature of our vaccines. This data also provided evidence that our vaccines protect through mucosal immunity, the first line of defense against mucosal infections such as flu, norovirus, RSV and others, a potential key advantage over injectable vaccines for these indications.

  At this time, we aim to finance development and commercialization of our seasonal quadrivalent influenza oral tablet vaccine through third-party collaboration and licensing arrangements, and/or non-dilutive funding. In the future, we may also consider equity offerings and/or debt financings to fund the program.

  In addition to our conventional seasonal flu vaccine, we entered into a research collaboration agreement with Janssen Vaccines & Prevention B.V., or Janssen, to evaluate our proprietary oral vaccine platform for the Janssen universal influenza vaccine program. Under the agreement, we will produce an oral vaccine containing certain proprietary antigens from Janssen and test the product in a preclinical challenge model. Upon completion of the study, Janssen will have an option to negotiate an exclusive worldwide license to our technology encompassing the Janssen antigens.

- ***HPV Therapeutic Vaccine.*** Our first therapeutic oral vaccine candidate targets HPV-16 and HPV-18, the two strains responsible for 70% of cervical cancers and precancerous cervical dysplasia.

  Cervical cancer is the fourth most common cancer in women worldwide and in the United States with about 13,000 new cases diagnosed annually in the United States according to the National Cervical Cancer Coalition.

We have tested our HPV-16 vaccine candidate in two different HPV-16 solid tumor models in mice. The vaccine elicited T cell responses and promoted migration of the activated T cells into the tumors, leading to tumor cell killing. Mice that received the Vaxart HPV-16 vaccine showed a significant reduction in volume of their established tumors.

In October 2018, we filed a pre-IND meeting request for our HPV therapeutic vaccines, VXA-HPV16.1 and VXA-HPV18.1, with the FDA, and we subsequently submitted a pre-IND briefing package. We received feedback from the FDA in January 2019 providing guidance for the IND we plan to submit. Based on this feedback, we expect to be able to file an IND for this product candidate in the course of 2020.

- ***RSV Vaccine.*** RSV is a major respiratory pathogen with a significant burden of disease in the very young and in the elderly.

  Based on the positive results of our cotton rat study, we believe our proprietary oral vaccine platform is the optimal delivery system for RSV, offering important potential advantages over injectable vaccines. We aim to develop a tablet RSV vaccine by licensing one or more RSV protein antigens that have demonstrated protection against RSV infection in clinical studies, or by partnering with a third party with RSV antigens that can be delivered with our platform.

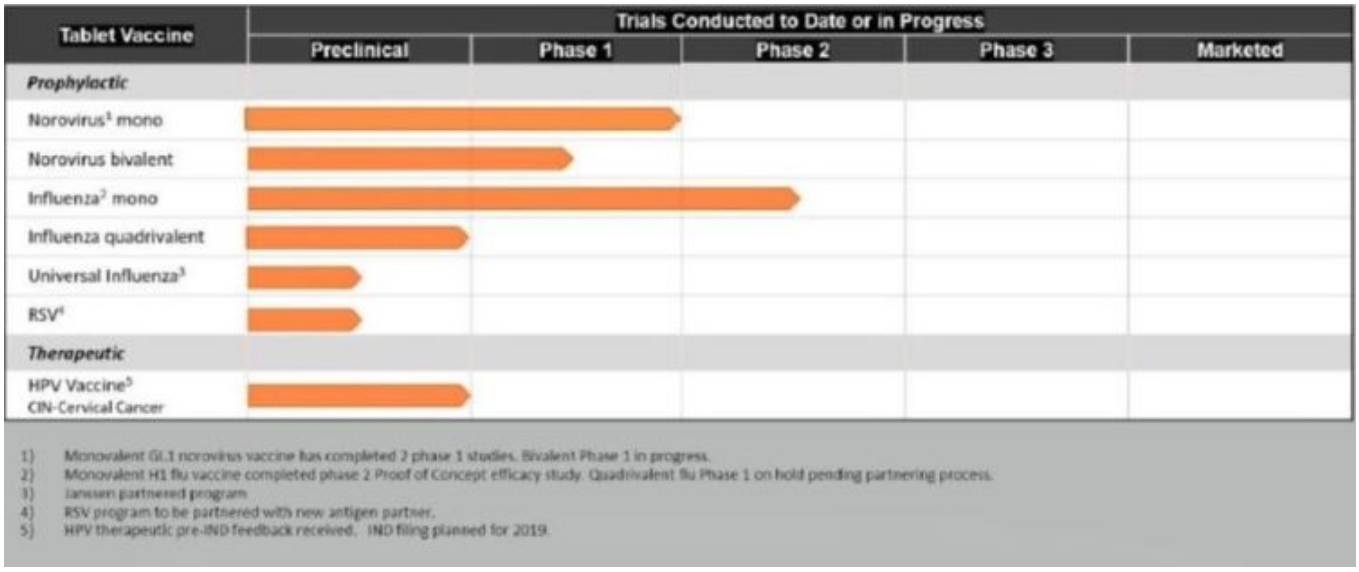
Anti-Virals

- Through the Merger, we acquired two royalty earning products, Relenza and Inavir. We also acquired three Phase 2 clinical stage antiviral compounds which we have discontinued.

- Relenza and Inavir are antivirals for the treatment of influenza that are marketed by GlaxoSmithKline, plc, or GSK, and Daiichi Sankyo Company, Limited, or Daiichi Sankyo, respectively. We have earned royalties on the net sales of Relenza and Inavir in Japan. The last patent for Relenza expired in July 2019 and the last patent for Inavir expires in December 2029. Sales of these antivirals vary significantly from quarter to quarter due to the seasonality of flu, and from one year to the next depending on the intensity of the flu season and competition from other antivirals such as Tamiflu. Importantly, on February 23, 2018, Xofluza, a new drug to treat influenza developed by Shionogi, was approved in Japan. The drug has gained significant market share, substantially reducing sales of Inavir.

Our Pipeline

The following table outlines the status of our oral vaccine development programs:



Financial Operations Overview

Revenue

Revenue from Government Contract

The government contract with HHS BARDA, as modified, was a cost-plus-fixed-fee contract, under which we were reimbursed for allowable direct contract costs plus allowable indirect costs and a fixed-fee totaling $15.7 million from September 2015 through September 30, 2018. Activities were completed in 2018 and no future revenue is expected from this contract.

Royalty Revenue

We earn royalty revenue on sales of Inavir and, until the patent expired, Relenza, both treatments for influenza, from our licensees, Daiichi Sankyo and GSK, respectively, under royalty agreements expiring in July 2019 and December 2029, respectively, based on fixed percentages of net sales of these drugs.

Non-Cash Royalty Revenue Related to the Sale of Future Royalties

In April 2016, Aviragen sold certain royalty rights related to Inavir in the Japanese market for $20.0 million to HealthCare Royalty Partners III, L.P., or HCRP. At the time of the Merger, the estimated future benefit to HCRP was remeasured at fair value and was preliminarily estimated, as of March 31, 2018, to be $16.3 million, which we account for as a liability and amortize using the effective interest method over the remaining estimated life of the arrangement. Even though we did not retain the related royalties under the transaction, as the amounts are remitted to HCRP, we will continue to record revenue related to these royalties until the amount of the associated liability and related interest is fully amortized.

Research and Development Expenses

Research and development expenses represent costs incurred to conduct research, including the development of our tablet vaccine platform, and the manufacturing, preclinical and clinical development activities of our tablet vaccine candidates. We recognize all research and development costs as they are incurred. Research and development expenses consist primarily of the following:

- employee-related expenses, which include salaries, benefits and stock-based compensation;
- expenses incurred under agreements with contract research organizations, or CROs, that conduct clinical trials on our behalf;
- manufacturing materials, analytical and release testing services required for our production of vaccine candidates used primarily in clinical trials;
- process development expenses incurred internally and externally to improve the efficiency and yield of the bulk vaccine and tablet manufacturing activities;
- laboratory supplies and vendor expenses related to its preclinical research activities;
- consultant expenses for services supporting our clinical, regulatory and manufacturing activities; and
- facilities, depreciation and allocated overhead expenses.

We do not allocate our internal expenses to specific programs. Our employees and other internal resources are not directly tied to any one research program and are typically deployed across multiple projects. Internal research and development expenses are presented as one total.

We incur significant external costs on manufacturing our tablet vaccine candidates, and on CROs that conduct clinical trials on our behalf. We capture these expenses for each vaccine program. We do not allocate external costs incurred on preclinical research or process development to specific programs.

The following table shows our research and development expenses for the three and six months ended June 30, 2019 and 2018, identifying external costs that were incurred in each of our vaccine programs and, separately, on preclinical research and process development:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
	(in thousands)		*(in thousands)*	
External program costs:				
Influenza program, funded by HHS BARDA	$ —	272	$ —	$ 658
Norovirus program	1,035	372	1,900	717
RSV and HPV programs	8	—	21	26
Teslexivir and vapendavir programs	2	689	19	1,113
Preclinical research and process development	56	112	109	193
Total external costs	1,101	1,445	2,049	2,707
Internal costs	2,606	3,567	5,487	5,713
	$ 3,707	5,012	$ 7,536	$ 8,420

We expect that our research and development expenses will increase significantly over the next several years as we advance our tablet vaccine candidates into larger clinical trials, pursue regulatory approval of our tablet vaccine candidates and prepare for a possible commercial launch, all of which will also require a significant investment in manufacturing and inventory related costs.

The process of conducting clinical trials necessary to obtain regulatory approval is costly and time consuming. We may never succeed in achieving marketing approval for our tablet vaccine candidates. The probability of successful commercialization of our tablet vaccine candidates may be affected by numerous factors, including clinical data obtained in future trials, competition, manufacturing capability and commercial viability. As a result, we are unable to determine the duration and completion costs of our research and development projects or when and to what extent we will generate revenue from the commercialization and sale of any of our tablet vaccine candidates.

General and Administrative Expense

General and administrative expenses consist of personnel costs, allocated expenses and expenses for outside professional services, including legal, audit, accounting, public relations, market research and other consulting services. Personnel costs consist of salaries, benefits and stock-based compensation. Allocated expenses consist of rent, depreciation and other facilities-related expenses.

Results of Operations

The following table presents selected items in the condensed consolidated statements of operations and comprehensive loss for the three and six months ended June 30, 2019 and 2018, which include the operations of Aviragen for the six months ended June 30, 2019 and the period from February 13, 2018 to June 30, 2018:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
	(in thousands)		*(in thousands)*	
Revenue:				
Revenue from government contract	$ —	$ 520	$ —	$ 1,130
Royalty revenue	69	70	3,728	963
Non-cash royalty revenue related to sale of future royalties	16	18	1,764	18
Total revenue	85	608	5,492	2,111
Operating expenses:				
Research and development	3,707	5,012	7,536	8,420
General and administrative	1,375	1,771	3,401	3,781
Impairment of intangible assets	—	1,600	—	1,600
Total operating expenses	5,082	8,383	10,937	13,801
Operating loss	(4,997)	(7,775)	(5,445)	(11,690)
Other income and (expenses):				
Bargain purchase gain	—	(328)	—	6,660
Interest income	34	36	39	41
Interest expense	(97)	(136)	(204)	(573)
Non-cash interest expense on liability related to sale of future royalties	(516)	(468)	(1,060)	(766)
Loss on revaluation of financial instruments	—	—	—	(3)
Foreign exchange gain, net	(48)	(199)	(43)	(197)
Total other income and (expenses)	(627)	(1,095)	(1,268)	5,162
Net loss before income taxes	(5,624)	(8,870)	(6,713)	(6,528)
Provision for income taxes	13	1	263	29
Net loss	$ (5,637)	$ (8,871)	$ (6,976)	$ (6,557)

Revenue from Government Contract

The following table presents our revenue from a government contract for the three and six months ended June 30, 2019 and 2018, respectively:

Three Months Ended June 30,			Six Months Ended June 30,		
2019	2018	% Change	2019	2018	% Change
(dollars in thousands)			*(dollars in thousands)*		
$ —	$ 520	(100)%	$ —	$ 1,130	(100)%

We earned no revenue from our government contract in 2019, compared to $520,000 and $1.1 million in the three and six months, respectively, ended June 30, 2018. The active phase of the contract occurred in 2016 and 2017. In 2018 activities were wound down and completed and no future revenue is expected from this contract.

Royalty Revenue

The following table presents our royalty revenue for the three and six months ended June 30, 2019 and 2018, respectively:

Three Months Ended June 30,			Six Months Ended June 30,		
2019	2018	% Change	2019	2018	% Change
(dollars in thousands)			*(dollars in thousands)*		
$ 69	$ 70	(1)%	$ 3,728	$ 963	287%

For the three months ended June 30, 2019, royalty revenue decreased by $1,000, or 1%, compared to the three months ended June 30, 2018. This royalty revenue was earned solely from sales of Relenza, which is not significant in the second calendar quarter as influenza is not prevalent. For the six months ended June 30, 2019, royalty revenue increased by $2.8 million, or 287%, compared to the six months ended June 30, 2018. 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. Royalty revenue in the six months ended June 30, 2018, excludes comparable revenue of $3.5 million earned in the pre-Merger period.

Non-cash Royalty Revenue Related to Sale of Future Royalties

The following table presents our non-cash royalty revenue related to sale of future royalties for the three and six months ended June 30, 2019 and 2018, respectively:

Three Months Ended June 30,			Six Months Ended June 30,		
2019	2018	% Change	2019	2018	% Change
(dollars in thousands)			*(dollars in thousands)*		
$ 16	18	(11)%	$ 1,764	18	9,700%

For the three months ended June 30, 2019, non-cash royalty revenue related to sale of future royalties decreased by $2,000, or 11%, compared to the three months ended June 30, 2018. This royalty revenue was earned solely from sales of Inavir, which is not significant in the second calendar quarter as influenza is not prevalent. For the six months ended June 30, 2019, non-cash royalty revenue related to sale of future royalties increased by $1.7 million, or 9700%, compared to the six months ended June 30, 2018. Non-cash royalty revenue related to sale of future royalties in the six months ended June 30, 2018, was all earned in the pre-Merger period, so we recorded no such revenue for that fiscal quarter.

Research and Development

The following table presents our research and development expenses for the three and six months ended June 30, 2019 and 2018, respectively:

Three Months Ended June 30,			Six Months Ended June 30,		
2019	2018	% Change	2019	2018	% Change
(dollars in thousands)			*(dollars in thousands)*		
$ 3,707	$ 5,012	(26)%	$ 7,536	$ 8,420	(10)%

For the three months ended June 30, 2019, research and development expenses decreased by $1.3 million, or 26%, compared to the three months ended June 30, 2018. The decrease in the 2019 period is principally due to the absence of the teslexivir clinical trials, severance costs and costs incurred under the HHS BARDA contract, along with decreases in preclinical research, personnel costs and amortization of intangible assets acquired in the Merger, partially offset by increases in manufacturing and clinical trial costs related to our norovirus vaccine tablets.

For the six months ended June 30, 2019, research and development expenses decreased by $884,000, or 10%, compared to the six months ended June 30, 2018. The decrease in the 2019 period is principally due to the absence of the teslexivir clinical trials, costs incurred under the HHS BARDA contract and severance costs, along with decreases in preclinical research and consultancy costs, partially offset by increases in manufacturing and clinical trial costs related to our norovirus vaccine tablets, along with increased costs for personnel and amortization of intangible assets acquired in the Merger.

We expect that research and development expenses will increase in the near term as we continue to conduct clinical trials of our norovirus product candidates, which will only be partially offset by the elimination of expenses that we were formerly incurring for teslexivir trials and for work on the HHS BARDA contract.

General and Administrative

The following table presents our general and administrative expenses for the three and six months ended June 30, 2019 and 2018, respectively:

Three Months Ended June 30,			Six Months Ended June 30,		
2019	2018	% Change	2019	2018	% Change
(dollars in thousands)			*(dollars in thousands)*		
$ 1,375	$ 1,771	(22)%	$ 3,401	$ 3,781	(10)%

For the three months ended June 30, 2019, general and administrative expenses decreased by $396,000, or 22%, compared to the three months ended June 30, 2018. The decrease in the 2019 period is principally due to reductions in legal and professional costs and personnel costs.

For the six months ended June 30, 2019, general and administrative expenses decreased by $380,000, or 10%, compared to the six months ended June 30, 2018. The decrease in the 2019 period is principally due to reductions in legal costs and other costs associated with being a public company, partially offset by higher personnel costs.

Impairment of Intangible Assets

The following table presents the impairment of our intangible assets for the three and six months ended June 30, 2019 and 2018, respectively:

Three Months Ended June 30,			Six Months Ended June 30,		
2019	2018	% Change	2019	2018	% Change
(dollars in thousands)			*(dollars in thousands)*		
$ —	$ 1,600	(100)%	$ —	$ 1,600	(100)%

Impairment of intangible assets represents the write-off of the in-process research and development related to teslexivir that we acquired in the Merger. Since the Phase 2 trial completed in May 2018 did not achieve the primary efficacy endpoint and we have suspended development activities, we considered this asset to be fully impaired in the three months ended June 30, 2018.

Other Income and (Expenses)

The following table presents our non-operating income and expenses for the three and six months ended June 30, 2019 and 2018, respectively:

Three Months Ended June 30,			Six Months Ended June 30,		
2019	2018	% Change	2019	2018	% Change
(dollars in thousands)			*(dollars in thousands)*		
$ (627)	$ (1,095)	(43)%	$ (1,268)	$ 5,162	N/A

For the three months ended June 30, 2019, we recorded net non-operating expenses of $627,000, compared to net non-operating expenses of $1.1 million in the three months ended June 30, 2018. The principal reasons for the change are the non-recurrence in the 2019 period of a reduction in the bargain purchase gain of $328,000 and a reduction in the net foreign exchange loss from $199,000 to $48,000.

For the six months ended June 30, 2019, we recorded net non-operating expenses of $1.3 million, compared to net non-operating income of $5.2 million in the six months ended June 30, 2018. The principal source of non-operating income in the six months ended June 30, 2018, was a bargain purchase gain of $6.7 million, representing the excess of our preliminary valuation 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 $204,000 in the 2019 period, decreasing from $573,000 in the 2018 period principally due to the absence of an expense of $295,000 related to Private Vaxart's convertible promissory notes being outstanding for the 43 days prior to the Merger. Non-cash interest expense on liability related to sale of future royalties, which relates to accounting for sums that will become payable to HCRP for royalty revenue earned from Inavir as debt, was $1.1 million in the 2019 period, compared to $766,000 related to the shorter post-Merger period in 2018.

Provision for income taxes

The following table presents our provision for income taxes for the three and six months ended June 30, 2019 and 2018, respectively:

Three Months Ended June 30,			Six Months Ended June 30,		
2019	2018	% Change	2019	2018	% Change
(dollars in thousands)			*(dollars in thousands)*		
$ 13	$ 1	1,200%	$ 263	$ 29	807%

The provision for income taxes comprises $13,000 and $1,000 in the three months ended June 30, 2019 and 2018, respectively. For the three months ended June 30, 2019, $12,000 relates to foreign taxes payable on intercompany interest, with $1,000 in both the 2019 and 2018 periods relating to 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.

The provision for income taxes comprises $263,000 and $29,000 in the six months ended June 30, 2019 and 2018, respectively. For the six months ended June 30, 2019, $26,000 relates to foreign taxes payable on intercompany interest. The remaining $237,000 in the 2019 period and the full $29,000 in the 2018 period represent the Japanese withholding tax on royalty revenue. The increase arose principally because the majority of Inavir sales in the first calendar quarter arise in the first six weeks, so most of the revenue in the 2018 period was earned pre-Merger.

Liquidity and Capital Resources

From its inception until the Merger, Vaxart's operations were 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 Aviragen's Merger-related costs. Since the Merger, we have received net proceeds of $2.5 million from the sale of common stock in March 2019, and in April 2019 we received net proceeds of $8.7 million from the sale of common stock, pre-funded warrants and common stock warrants, plus the exercise of pre-funded warrants (see Note 1 to the Condensed Consolidated Financial Statements in Part I, Item 1 for further information regarding our March 2019 Offering and April 2019 Offering).

As of June 30, 2019, we had $16.3 million of cash and cash equivalents. Our independent registered public accounting firm included an explanatory paragraph in their report on our financial statements as of and for the year ended December 31, 2018, indicating that, because we have experienced losses and negative cash flows from operations and have an accumulated deficit and debt obligations, there is substantial doubt about our ability to continue as a going concern.

We believe our existing funds are sufficient to fund us into, but probably not beyond, the first quarter of 2020. To continue operations thereafter, we will need to raise further capital, through the sale of additional securities or otherwise. Our operating needs include the planned costs to operate our business, including amounts required to fund working capital and capital expenditures. As of June 30, 2019, we had no material commitments for capital expenditures. Our future capital requirements and the adequacy of our available funds will depend on many factors, most notably our ability to successfully develop and commercialize our products.

We plan to continue to fund our operations and capital funding needs through equity and/or debt financing. We may also enter into government funding programs and consider partnering for clinical development and commercialization. The sale of additional equity would result in additional dilution to our 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 our operations. If we are unable to raise additional capital in sufficient amounts or 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 vaccine candidates that we would otherwise prefer to develop and market ourselves. Any of these actions could harm our business, results of operations and prospects.

Our future funding requirements will depend on many factors, including the following:

- the timing and costs of our planned clinical trials for our product candidates;
- the timing and costs of our planned preclinical studies of our product candidates;
- our success in establishing and scaling commercial manufacturing capabilities;
- the amount and timing of royalties received on sales of Inavir;
- the number and characteristics of product candidates that we pursue;
- the outcome, timing and costs of seeking regulatory approvals;
- revenue received from commercial sales of our future products, which will be subject to receipt of regulatory approval;
- the terms and timing of any future collaborations, licensing, consulting or other arrangements that we 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 we in-license or acquire other products and technologies.

Cash Flows

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

	Six Months Ended June 30,	
	2019	**2018**
	(in thousands)	
Net cash used in operating activities	$ (4,970)	$ (3,488)
Net cash (used in) provided by investing activities	(711)	26,580
Net cash provided by (used in) financing activities	10,433	(742)
Net increase in cash and cash equivalents	$ 4,752	$ 22,350

Net Cash Used in Operating Activities

We experienced negative cash flow from operating activities for the six months ended June 30, 2019 and 2018, in the amounts of $5.0 million and $3.5 million, respectively. The cash used in operating activities in the six months ended June 30, 2019, was due to cash used to fund a net loss of $7.0 million, partially offset by a decrease in working capital of $1.6 million and net non-cash expenses related to depreciation and amortization, stock-based compensation, non-cash interest expense, non-cash interest expense related to sale of future royalties and non-cash revenue related to sale of future royalties totaling $433,000. The cash used in operating activities in the six months ended June 30, 2018, was due to cash used to fund a net loss of $6.6 million and $2.2 million of net non-cash income related to the bargain purchase gain, depreciation and amortization, impairment of intangible assets, 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, partially offset by a decrease in working capital of $5.3 million.

Net Cash (Used in) Provided by Investing Activities

In the six months ended June 30, 2019, we used $711,000 to purchase property and equipment. In the six months ended June 30, 2018, we received cash of $25.5 million in the Merger and $1.4 million from maturities of short-term investments, net of purchases. This was partially offset by $339,000 to purchase property and equipment and $21,000 to pay for fractional shares of common stock in the Merger.

Net Cash Provided by (Used in) Financing Activities

In the six months ended June 30, 2019, we received $2.5 million from the sale of common stock in a registered direct offering, $8.1 million from the sale of common stock, pre-funded warrants and common stock warrants in an underwritten offering and $652,000 from the exercise of pre-funded warrants, partially offset by repayment of principal of $833,000 on the secured promissory note payable to Oxford Finance. In the six months ended June 30, 2018, we used $694,000 in repayment of principal on the secured promissory note payable to Oxford Finance and $61,000 to repay principal on a short-term note, partially offset by $13,000 received for the exercise of stock options.

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 third-party service providers, which include the conduct of clinical and contract formulation and contract manufacturing activities. We record the estimated costs of research and development activities based upon the estimated amount of services provided and include the costs incurred but not yet invoiced within accrued liabilities in the condensed consolidated balance sheets and within research and development expense in the condensed consolidated statement of operations and comprehensive loss. These costs can be a significant component our research and development expenses.

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 were recorded at preliminary estimates of their fair values of $20.6 million (subsequently adjusted to $20.3 million when estimates were refined) 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 was indefinite-lived until it was assessed as impaired in the three months ended June 30, 2018. 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 had no off-balance sheet arrangements in the periods presented.

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 2019, 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 President and Chief Executive Officer (who serves as our principal executive officer and principal 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 management has concluded that as of June 30, 2019, our disclosure controls and procedures were not effective at a 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 June 30, 2019:

> We lacked consistent processes to appropriately perform effective and timely review of account reconciliations and non-routine 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 have taken certain steps to remediate this material weakness, including increasing the depth and experience within our accounting and finance organization and 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

During 2018, we hired a full-time Corporate Controller and a full-time Associate Director of SEC Reporting, both Certified Public Accountants with active licenses. Since then, we have implemented procedures in our finance department including formal approval procedures for all journal entries and account reconciliations, and increased management oversight of financial reporting. This was done to address a material weakness relating to our lack of sufficient qualified resources and adequate processes to appropriately segregate duties and perform effective and timely review of account reconciliations and nonroutine transactions that was originally identified in the audit of our financial statements for the year ended December 31, 2015 and was previously reported in Item 9A in our Annual Report on Form 10-K for the year ended December 31, 2018. While we believe these procedures will be effective in remediating the material weakness, they were not yet fully operational as of June 30, 2019.

Other than the implementation of these new procedures, there was no material change in our internal control over financial reporting that occurred during the quarter ended June 30, 2019, that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitations on Effectiveness of Controls

Our management, including our President and Chief Executive Officer, does not expect that our disclosure controls and procedures or our internal controls will prevent all error and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within Vaxart have been detected.

PART II OTHER INFORMATION

Item 1. 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

You should carefully consider the following risk factors, as well as the other information in this Quarterly Report on Form 10-Q, including our financial statements and the related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations", as well as 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.

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 our Annual Report on Form 10-K for the year ended December 31, 2018.

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 are at an early stage in our clinical development process and have not yet successfully completed a large-scale, pivotal clinical trial, obtained marketing approval, manufactured our tablet vaccine 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 we 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 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 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 our financial position and working capital. As of June 30, 2019, we had an accumulated deficit of $105.0 million.

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 norovirus tablet vaccine candidate. As a result, we have not submitted a 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 a BLA is an extensive, lengthy, expensive and inherently uncertain process, and the FDA may delay, limit or deny approval of our norovirus 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.

We believe that there is substantial doubt about our ability to continue as a going concern.

We have concluded that there is substantial doubt about our ability to continue as a going concern within one year after the date that the financial statements are issued. Our independent registered public accounting firm included an explanatory paragraph in their report on our financial statements as of and for the year ended December 31, 2018, indicating that, because we have experienced losses and negative cash flows from operations and have an accumulated deficit and debt obligations, there is substantial doubt about our ability to continue as a going concern. We do not believe that this substantial doubt has been alleviated. As of June 30, 2019, we had $16.3 million of cash and cash equivalents. We believe these funds are sufficient to fund our operations into, but probably not beyond, the first quarter of 2020. 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. 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.

Raising finance via the issuance of securities to the public generally entails filing documents with the SEC and, in the normal course of business, obtaining regulatory approval. The process is time-consuming and can result in delays in seeking potential investors. Further, the recent partial shutdown of the government means that SEC staff were furloughed and were not available to review registration statements. This caused a delay in one potential source of financing via a registration statement that we filed with the SEC on December 27, 2018, and any future government shutdown impacting the SEC may have a similar impact in preventing or delaying our ability to obtain additional capital.

As of June 30, 2019, we had $16.3 million of cash and cash equivalents. We believe these funds are sufficient to fund our operations under our current operating plan into, but probably not beyond, the first quarter of 2020. 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, royalties, 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 debt 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, as amended, under which we borrowed $5 million. Our outstanding debt facility with Oxford is collateralized by substantially all of our assets, except for intellectual property, which is subject to a negative pledge, 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 from 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 when due 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 or insolvency proceedings, or attachments;
- we are unable to pay our debts as they become due; or
- we default on certain 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 to Oxford 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 as the secured lender. 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 our 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.

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, the trading price of our common stock could decline. Sales of a substantial number of shares of our common stock in the public market, or the perception that the sales might occur, could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. We are unable to predict the effect that sales may have on the prevailing market price of our common stock.

**** One stockholder owns a significant percentage of our stock and may be able to exert significant control over matters subject to stockholder approval.***

As of June 30, 2019, entities affiliated with Care Capital, a venture capital fund, owned 17.7% of our common stock and have significant ability to influence decisions through their ownership position. For example, this concentration of ownership may enable entities affiliated with Care Capital 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.

Because the Merger in February 2018 resulted in an ownership change under Section 382 of the Code for Vaxart, Inc. (formerly Aviragen), our 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 Vaxart, Inc. (formerly Aviragen), and probably Vaxart Biosciences; accordingly, our U.S. net operating loss carryforwards and certain other tax attributes are subject to limitations on their use. Annual usage may be restricted to 1.97% of the combined organization'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 in the future, 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 reimbursement and insurance coverage 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, M.D. and our Chief Scientific Officer, Sean N. Tucker, Ph.D. 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 June 30, 2019, we had 33 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 2018, 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 consistent processes to appropriately perform effective and timely review of account reconciliations and non-routine transactions.

We have already taken steps to remediate this material weakness. We have increased the depth and experience within our accounting and finance organization, in part by hiring a Corporate Controller and an SEC Reporting Director. We are also 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 furnish a quarterly report by management on, among other things, the effectiveness of our internal control over financial reporting. This assessment needs to include disclosure of any material weaknesses identified by our management in our internal control over financial reporting. Our independent registered public accounting firm will be required to attest annually to the effectiveness of our internal control over financial reporting in the future should our public float exceed $75 million. We are required to disclose changes made in our internal control over financial reporting on a quarterly basis.

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.

**** Our outstanding warrants to purchase common stock are speculative in nature and there is no public market for such warrants.***

There is no established public trading market for our outstanding warrants to purchase common stock and we do not expect a market to develop. In addition, we do not intend to apply to list our warrants on any securities exchange or nationally recognized trading system, including the Nasdaq Capital Market. Without an active market, the liquidity of our outstanding warrants is limited. Our warrants do not confer any rights of common stock ownership on their holders, such as voting rights or the right to receive dividends, but rather merely represent the right to acquire shares of common stock at a fixed price. The market value of our warrants is uncertain and there can be no assurance that that the market price of the common stock will ever equal or exceed the exercise price such warrants, and consequently, whether it will ever be profitable for holders of the such warrants to exercise such warrants.

**** Our failure to meet the continued listing requirements of The Nasdaq Capital Market could result in a delisting of our common stock.***

Our common stock is listed on The Nasdaq Capital Market, which imposes, among other requirements a minimum bid requirement. Our common stock traded for less than $1.00 for 30 consecutive trading days, and we received notice of this from the Listing Qualifications Staff of The Nasdaq Stock Market LLC on May 22, 2019. Under Nasdaq Listing Rule 5810(c)(3)(A), we were granted a 180 calendar day grace period, or until November 18, 2019, to regain compliance with the minimum bid price requirement. The minimum bid price requirement will be met if our common stock has a minimum closing bid price of at least $1.00 per share for a minimum of 10 consecutive business days during the 180 calendar day grace period. If we do not regain compliance with the Rule by November 18, 2019 but we meet the Nasdaq Capital Market initial inclusion criteria set forth in Nasdaq Listing Rule 5505, except for the minimum $1.00 per share bid price requirement, we will be granted an additional 180-calendar day compliance period. If we do not regain compliance with the Rule by November 18, 2019 and are not eligible for an additional compliance period at that time, the Nasdaq staff will provide written notification to us that our common stock will be delisted. At that time, we may appeal the Nasdaq staff's delisting determination to a Nasdaq Listing Qualifications Panel pursuant to the procedures set forth in the applicable Nasdaq Listing Rules. There can be no assurance that we will be able to regain compliance or that Nasdaq will grant us a further extension of time to regain compliance, if necessary.

The delisting of our common stock from Nasdaq may make it more difficult for us to raise capital on favorable terms in the future, or at all. Such a delisting would likely have a negative effect on the price of our common stock and would impair your ability to sell or purchase our common stock when you wish to do so. Further, if our common stock were to be delisted from The Nasdaq Capital Market, our common stock would cease to be recognized as a covered security and we would be subject to additional regulation in each state in which we offer our securities. Moreover, there is no assurance that any actions that we take to restore our compliance with the Nasdaq minimum bid requirement would stabilize the market price or improve the liquidity of our common stock, prevent our common stock from falling below the Nasdaq minimum bid price required for continued listing again, or prevent future non-compliance with Nasdaq's listing requirements.

There can be no assurance that we will continue to meet the minimum bid price requirement, or any other requirement in the future. If we fail to meet the minimum bid price requirement, or other applicable Nasdaq listing requirements, including maintaining minimum levels of stockholders' equity or market values of our common stock, our common stock could be delisted. If our common stock were to be delisted, the liquidity of our common stock would be adversely affected, and the market price of our common stock could decrease.

**** Unless our common stock continues to be listed on a national securities exchange it will become subject to the so-called "penny stock" rules that impose restrictive sales practice requirements.***

If we are unable to maintain the listing of our common stock on Nasdaq or another national securities exchange, our common stock could become subject to the so-called "penny stock" rules if the shares have a market value of less than $5.00 per share. The SEC has adopted regulations that define a penny stock to include any stock that has a market price of less than $5.00 per share, subject to certain exceptions, including an exception for stock traded on a national securities exchange. The SEC regulations impose restrictive sales practice requirements on broker-dealers who sell penny stocks to persons other than established customers and accredited investors. An accredited investor generally is a person whose individual annual income exceeded $200,000, or whose joint annual income with a spouse exceeded $300,000 during the past two years and who expects their annual income to exceed the applicable level during the current year, or a person with net worth in excess of $1.0 million, not including the value of the investor's principal residence and excluding mortgage debt secured by the investor's principal residence up to the estimated fair market value of the home, except that any mortgage debt incurred by the investor within 60 days prior to the date of the transaction shall not be excluded from the determination of the investor's net worth unless the mortgage debt was incurred to acquire the residence. For transactions covered by this rule, the broker-dealer must make a special suitability determination for the purchaser and must have received the purchaser's written consent to the transaction prior to sale. This means that if we are unable maintain the listing of our common stock on a national securities exchange, the ability of stockholders to sell their common stock in the secondary market could be adversely affected.

If a transaction involving a penny stock is not exempt from the SEC's rule, a broker-dealer must deliver a disclosure schedule relating to the penny stock market to each investor prior to a transaction. The broker-dealer also must disclose the commissions payable to both the broker-dealer and its registered representative, current quotations for the penny stock, and, if the broker-dealer is the sole market-maker, the broker-dealer must disclose this fact and the broker-dealer's presumed control over the market. Finally, monthly statements must be sent disclosing recent price information for the penny stock held in the customer's account and information on the limited market in penny stocks.

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 x 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 x 10^{11} IU, the target dose for this trial. We believe that in order to fully capture the commercial success of our seasonal influenza vaccine candidate, 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. 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. 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 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. Our 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. Also, the results of early clinical trials of the tablet vaccine candidates for seasonal influenza, norovirus and RSV may not be predictive of the results of subsequent clinical trials. Furthermore, the FDA may impose additional requirements to conduct preclinical studies to advance the HPV therapeutic vaccine candidates which could delay initiation of Phase 1 studies. 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 current tablet vaccine candidates, including for norovirus, include a novel adjuvant, and future vaccine candidates may also 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. 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. In particular, our influenza vaccine candidate would compete 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 the diseases we are targeting.

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 diseases, 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 our 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 their 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 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 that several companies are in various stages of developing an RSV vaccine including Pfizer, Merck, 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 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 their 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 our tablet vaccine candidates; and
- our reputation may suffer.

Any of these events could prevent us 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 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 a tablet vaccine candidate receives marketing approval, the accompanying label may limit the approved use of that 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 candidate 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 we would otherwise plan.

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 (containing three strains) or quadrivalent (containing 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, and competition from new products 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 earn royalty revenue from the net sales of Inavir and, until the royalty agreement expired in July 2019, Relenza, 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, including generic copies of Relenza and Inavir, which could adversely affect our royalty income. The last patent related to Inavir is set to expire in December 2029 in Japan, at which time royalty revenue will cease. However, the patent covering the laninamivir octanoate compound expires in 2024, at which time generic competition may enter the market, potentially decreasing or eliminating the royalties received. On February 23, 2018, Osaka-based drug maker 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 would significantly decrease the royalty payments we receive from Daiichi Sankyo Company, Limited.

In addition, all of our Relenza patents have expired, with the last substantial intellectual property related to the Relenza patent portfolio having expired in July 2019 in Japan. Further, we sold a portion of our Inavir royalties to HealthCare Royalty Partners III, L.P. 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, competing products 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, or competing products may be introduced and limit the market penetration of our product candidates. If serious safety, tolerability, resistance, drug-drug interaction, efficacy, competing products, or any other concerns or issues arise with respect to Relenza and Inavir, 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. For example, the Phase 2 trial of teslexivir, a product acquired through the merger with Aviragen, was costly and diverted resources from our other product candidates, did not achieve the primary efficacy endpoint. 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 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.

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 our 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 bulk vaccine for our Phase 1 and Phase 2a clinical studies for the foreseeable future at our own facility. In addition, we intend to manufacture the vaccine tablets for all our Phase 1 and Phase 2 clinical studies, including the larger Phase 2b studies using bulk vaccine manufactured by a third-party contract manufacturer, 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 for the bulk vaccine or any other components of our vaccine tablets, 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., or Lonza, 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. We have developed and continue to develop manufacturing processes under cGMP, which we are currently using to manufacture bulk product and vaccine tablets, for future Phase 1 and Phase 2a clinical trials, at our own facility in South San Francisco, California. This transition has resulted in unanticipated delays and lower yields, may result in further unanticipated delays or lower yields or both and may cost more than expected due to a number of factors, including regulatory requirements. If we are unable to manufacture sufficient quantities of our tablet vaccine candidates in a timely manner, our development activities would be impaired and we may need to partner with a third-party supplier.

Our manufacturing facility is 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.

If we encounter any of these problems or are otherwise delayed, or if the cost of manufacturing at our South San Francisco facility is not economically feasible and we cannot find a third-party contract manufacturer, we may not be able to produce our tablet vaccine candidates in a sufficient quantity to conduct our planned clinical trials and commercialize our vaccine tablet candidates, if approved.

**** In the event that a third-party contract manufacturer cannot timely supply sufficient bulk vaccine to allow us to manufacture our vaccine tablets, our preclinical studies or our clinical trials and the commercialization of our product candidates could be delayed, adversely affected or terminated, or may result in the need for us to incur significantly higher costs, which could materially harm our business.***

Our manufacturing facility and equipment is sized to support manufacturing of cGMP product for our Phase 1 and Phase 2a trials, but is not adequate to support larger Phase 2b and Phase 3 trials. Accordingly, in July 2019, we executed a contract with Lonza, an established CMO that we have used previously, for large scale bulk vaccine production capabilities adequate to support larger trials. This CMO may fail to supply adequate product or have limited capacity in the future, which may cause significant delays in starting clinical studies.

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 a contract manufacturer may be difficult and could be extremely costly and time consuming, which could result in our inability to manufacture our product candidates for an extended period of time and a delay in the development of our product candidates. Further, in order to maintain our 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.

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.

Changes in funding for the FDA, the SEC and other government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, including most recently on December 22, 2018, the U.S. government has shut down, at least partially, several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions which could have a material adverse effect on our business. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

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.

To the extent that we rely on third-party contract manufacturers, which in some cases may be sole sourced, we are exposed 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 potential contract manufacturers failing to develop an acceptable formulation to support late-stage clinical trials for, or the commercialization of, our product candidates;

- our potential 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 potential 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 potential 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 potential contract manufacturers placing a priority on the manufacture of other customers' or their own products, rather than our products;

- our potential contract manufacturers failing to perform as agreed or exiting from the contract manufacturing business; and

- our potential 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 a third-party contract manufacturer, our preclinical studies or our clinical trials, and 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 a contract manufacturer may be difficult and could be extremely costly and time-consuming, which could result in our inability to manufacture our product candidates for an extended period of time and a delay, as well as an increase in costs, in the development of 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 oral vaccine 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.

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, or maintain and enforce any patents that may issue from such 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 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 our 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. Even if our patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our patents by developing similar or alternative product candidates in a non-infringing manner. 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 our 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 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 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 harmed.

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 our 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, or NI, approved for the treatment and prevention of influenza A and B, is marketed worldwide as Relenza by GSK. All of our Relenza patents have expired, the last remaining intellectual property related to the Relenza patent portfolio, which we own and have exclusively licensed to GSK, having expired in July 2019 in Japan.

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." However, our research, development and commercialization activities may be subject to claims that we infringe or otherwise violate patents or other intellectual property rights owned or controlled by third parties. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are pursuing development candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our current or future product candidates may be subject to claims of infringement of the patent rights of third parties. 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, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties or 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 universities or 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.

Patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time.

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired for a product candidate, we may be open to competition from competitive vaccines and medications, including generic medications. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such product candidates might expire before or shortly after such product 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.

Depending upon the timing, duration and conditions of any FDA marketing approval of our product candidates, one or more of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments, and similar legislation in the European Union. The Hatch-Waxman Amendments permit a patent term extension of up to five years for a patent covering an approved product as compensation for effective patent term lost during product development and the FDA regulatory review process. However, we may not receive an extension if we fail to exercise due diligence during the testing phase or regulatory review process, fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Moreover, the length of the extension could be less than we request. Only one patent per approved product can be extended, the extension cannot extend the total patent term beyond 14 years from approval and only those claims covering the approved drug, a method for using it or a method for manufacturing it may be extended. If we are unable to obtain patent term extension or the term of any such extension is less than we request, the period during which we can enforce our patent rights for the applicable product candidate will be shortened and our competitors may obtain approval to market competing products sooner. As a result, our revenue from applicable products could be reduced. Further, if this occurs, our competitors may take advantage of our investment in development and trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case, and our competitive position, business, financial condition, results of operations and prospects could be materially harmed.

We may be subject to claims challenging the inventorship of our patents and other intellectual property.

We or our licensors may be subject to claims that former employees, collaborators or other third parties have an interest in our patents, trade secrets, or other intellectual property as an inventor or co-inventor. For example, we or our licensors may have inventorship disputes arise from conflicting obligations of employees, consultants or others who are involved in developing our product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship or our or our licensors' ownership of our patents, trade secrets or other intellectual property. If we or our licensors fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, intellectual property that is important to our product candidates. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

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

Not applicable.

Item 3. Defaults Upon Senior Securities

Not applicable.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

Not applicable.

Item 6. Exhibits

Exhibit Number	Description of Document	Incorporated by Reference			
		Schedule/Form	File Number	Exhibit	Filing Date
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	Certificate of Amendment to Restated Certificate of Incorporation of Vaxart, Inc.	Form 8-K	001-35285	3.1	April 24, 2019
3.5	Restated By-laws of Aviragen Therapeutics, Inc.	Form 10-K	001-35285	3.2	September 13, 2016
4.1	Reference is made to Exhibits 3.1 to 3.5				
4.2	Specimen Common Stock Certificate	Form S-3	333-228910	4.2	December 20, 2018
4.3	Form of Pre-Funded Warrant	Form S-1	333-229536	10.25	February 6, 2019
4.4	Form of Common Stock Warrant	Form S-1/A	333-229536	4.4	April 8, 2019
4.5	Form of Representative Warrant	Form S-1/A	333-229536	4.5	April 8, 2019
10.1 #	2019 Equity Incentive Plan	Form 8-K	001-35285	10.1	April 24, 2019
10.2 #	Form of Stock Option Grant Notice, Stock Option Agreement and Notice of Exercise under the 2019 Equity Incentive Plan	Form 8-K	001-35285	10.2	April 24, 2019
10.3 #	Form of Restricted Stock Unit Grant Notice and Restricted Stock Unit Award Agreement and Notice of Exercise under the 2019 Equity Incentive Plan	Form 8-K	001-35285	10.3	April 24, 2019
31.1 *	Certification of Principal Executive and 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				

Exhibit Number	Description of Document	Incorporated by Reference			
		Schedule/Form	File Number	Exhibit	Filing Date
32.1 *§	Certification of Principal Executive and 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 June 30, 2019, formatted in Extensible Business Reporting Language (XBRL): (i) the Condensed Consolidated Balance Sheets as of June 30, 2019 and December 31, 2018, (ii) the Condensed Consolidated Statements of Operations and Comprehensive Loss for the three and six months ended June 30, 2019 and 2018, (iii) the Condensed Consolidated Statements of Stockholders' Equity (Deficit) for the three and six months ended June 30, 2019 and 2018, (iv) the Condensed Consolidated Statements of Cash Flows for the six months ended June 30, 2019 and 2018, and (v) Notes to the Condensed Consolidated Financial Statements				

* Filed herewith

\# Management contract or compensation plan or arrangement

§ 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 certification furnished in Exhibit 32.1 hereto is 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 certification 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: August 8, 2019

By: /s/ WOUTER W. LATOUR, M.D.
Wouter W. Latour, M.D.
President and Chief Executive Officer
(Principal Executive Officer and 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) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

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

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

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

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

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

Date: August 8, 2019

By: /s/ WOUTER W. LATOUR, M.D.

Wouter W. Latour, M.D.
President and Chief Executive Officer
(Principal Executive Officer and 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., 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 June 30, 2019, 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: August 8, 2019

By: /s/ WOUTER W. LATOUR, M.D.

Wouter W. Latour, M.D.
President and Chief Executive Officer
(Principal Executive Officer and 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.