

VICAL INC  
Form 10-Q  
May 15, 2017

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended March 31, 2017

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: 000-21088

VICAL INCORPORATED

(Exact name of registrant as specified in its charter)

Delaware	93-0948554
(State or other jurisdiction of	(I.R.S. Employer
incorporation or organization)	Identification No.)
10390 Pacific Center Court	
San Diego, California	92121
(Address of principal executive offices)	(Zip Code)

(858) 646-1100

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(Registrant's telephone number, including area code)

(Former name, former address and former fiscal year, if changed since last report)

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes No

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

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

Emerging growth company

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

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

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date.

Total shares of common stock outstanding at April 30, 2017: 11,096,203

VICAL INCORPORATED

FORM 10-Q

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## PART I. FINANCIAL INFORMATION

## ITEM 1. FINANCIAL STATEMENTS

## VICAL INCORPORATED

## BALANCE SHEETS

(In thousands, except par value data)

(Unaudited)

	March 31, 2017	December 31, 2016
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$4,564	\$5,069
Marketable securities, available-for-sale	29,216	30,552
Restricted cash	3,311	3,311
Deferred contract costs	7,163	5,513
Receivables and other assets	2,943	3,422
Total current assets	47,197	47,867
Long-term investments	2,108	2,046
Property and equipment, net	964	1,173
Intangible assets, net	784	810
Other assets	388	388
Total assets	\$51,441	\$52,284
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable and accrued expenses	\$3,539	\$4,127
Deferred revenue	5,316	3,018
Total current liabilities	8,855	7,145
Stockholders' equity:		
Preferred stock, \$0.01 par value, 5,000 shares authorized, none issued and outstanding	—	—
Common stock, \$0.01 par value, 160,000 shares authorized, 11,095 and 11,052 shares issued and outstanding at March 31, 2017 and December 31, 2016, respectively	111	111
Additional paid-in capital	459,017	458,881
Accumulated deficit	(416,603)	(413,878)
Accumulated other comprehensive income	61	25
Total stockholders' equity	42,586	45,139
Total liabilities and stockholders' equity	\$51,441	\$52,284

See accompanying notes to unaudited financial statements



## VICAL INCORPORATED

## STATEMENTS OF OPERATIONS

(In thousands, except per share data)

(Unaudited)

	Three Months Ended March 31,	
	2017	2016
Revenues:		
Contract revenue	\$2,901	\$4,088
License and royalty revenue	304	516
Total revenues	3,205	4,604
Operating expenses:		
Research and development	3,300	2,478
Manufacturing and production	1,309	2,846
General and administrative	1,509	1,790
Total operating expenses	6,118	7,114
Loss from operations	(2,913 )	(2,510)
Other income:		
Investment and other income, net	89	87
Net loss	\$(2,824 )	\$(2,423)
Basic and diluted net loss per share	\$(0.25 )	\$(0.26 )
Weighted average shares used in computing basic and diluted net		
loss per share	11,101	9,217

See accompanying notes to unaudited financial statements

VICAL INCORPORATED

STATEMENTS OF COMPREHENSIVE LOSS

(In thousands)

(Unaudited)

	Three Months Ended March 31,	
	2017	2016
Net loss	\$ (2,824 )	\$ (2,423 )
Other comprehensive gain:		
Unrealized gain on available-for-sale and long-term		
marketable securities:		
Unrealized gain arising during holding period, net of tax		
benefit of \$21 and \$44 for three months ended March 31,		
2017 and 2016, respectively	36	95
Other comprehensive gain	36	95
Total comprehensive loss	\$ (2,788 )	\$ (2,328 )

See accompanying notes to unaudited financial statements

## VICAL INCORPORATED

## STATEMENTS OF CASH FLOWS

(In thousands)

(Unaudited)

	Three Months Ended March 31, 2017      2016	
Cash flows from operating activities:		
Net loss	\$(2,824)	\$(2,423 )
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	267	277
Write-off of abandoned patents	—	363
Compensation expense related to stock options and awards	231	313
Changes in operating assets and liabilities:		
Deferred contract costs	(1,650)	(115 )
Receivables and other assets	479	498
Accounts payable and accrued expenses	(370 )	(315 )
Deferred revenue	2,298	(166 )
Deferred rent	(217 )	(119 )
Net cash used in operating activities	(1,786)	(1,687 )
Cash flows from investing activities:		
Maturities of marketable securities	6,479	4,296
Purchases of marketable securities	(5,187)	(10,039)
Purchases of property and equipment	(14 )	(91 )
Net cash provided by (used in) investing activities	1,278	(5,834 )
Cash flows from financing activities:		
Net proceeds from issuance of common stock	4	5
Payment of withholding taxes for net settlement of restricted stock units	(1 )	(7 )
Net cash provided by (used in) financing activities	3	(2 )
Net decrease in cash and cash equivalents	(505 )	(7,523 )
Cash and cash equivalents at beginning of period	5,069	13,450
Cash and cash equivalents at end of period	\$4,564	\$5,927

See accompanying notes to unaudited financial statements



VICAL INCORPORATED

NOTES TO FINANCIAL STATEMENTS

March 31, 2017

(Unaudited)

1. BASIS OF PRESENTATION

Vical Incorporated, or the Company, a Delaware corporation, was incorporated in April 1987 and has devoted substantially all of its resources since that time to its research and development programs. The Company researches and develops biopharmaceutical products, including those based on its patented DNA delivery technologies, for the prevention and treatment of serious or life-threatening diseases.

All of the Company's potential products are in research and development phases. No revenues have been generated from the sale of any such products, nor are any such revenues expected for at least the next several years. The Company earns revenue from research and development agreements with pharmaceutical collaborators and from contract manufacturing agreements. Most of the Company's product candidates will require significant additional research and development efforts, including extensive preclinical and clinical testing. All product candidates that advance to clinical testing will require regulatory approval prior to commercial use, and will require significant costs for commercialization. There can be no assurance that the Company's research and development efforts, or those of its collaborators, will be successful. The Company expects to continue to incur substantial losses and not generate positive cash flows from operations for at least the next several years. No assurance can be given that the Company can generate sufficient product revenue to become profitable or generate positive cash flows from operations.

The unaudited financial statements at March 31, 2017, and for the three months ended March 31, 2017 and 2016, have been prepared in accordance with the rules and regulations of the Securities and Exchange Commission, or SEC, and with accounting principles generally accepted in the United States applicable to interim financial statements. These unaudited financial statements have been prepared on the same basis as the audited financial statements included in the Company's Annual Report on Form 10-K and include all adjustments, consisting of only normal recurring accruals, which in the opinion of management are necessary to present fairly the Company's financial position as of the interim date and results of operations for the interim periods presented. Interim results are not necessarily indicative of results expected for a full year or future periods. The preparation of financial statements requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosures of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ materially from those estimates. These unaudited financial statements should be read in conjunction with the Company's audited financial statements for the year ended December 31, 2016, included in its Annual Report on Form 10-K filed with the SEC.

On May 25, 2016, the Company amended its certificate of incorporation to effect a one-for-ten (1:10) reverse stock split. This reverse stock split became effective as of the close of business on May 26, 2016. The reverse stock split had no effect on the par value of its common stock and did not reduce the number of authorized shares of common stock but reduced the number of outstanding shares of common stock by the ratio. Accordingly, the outstanding shares, stock award disclosures, net loss per share, and other per share disclosures for all periods presented have been retrospectively adjusted to reflect the impact of this reverse stock split.

The reverse stock split resulted in a proportionate adjustment to the per share exercise price and the number of shares of common stock issuable upon the exercise of outstanding stock options, the number of shares of common stock issuable upon the vesting of restricted stock units, or RSUs, and the number of shares of common stock eligible for issuance under the Company's stock incentive plan. No fractional shares were issued in connection with the reverse stock split. Each stockholder's percentage ownership and proportional voting power generally remained unchanged as a result of the reverse stock split.

#### Cash, Cash Equivalents and Marketable Securities

Cash and cash equivalents consist of cash and highly liquid securities with original maturities at the date of acquisition of ninety days or less and can be liquidated without prior notice or penalty. Investments with an original maturity of more than ninety days are considered marketable securities and have been classified by management as available-for-sale. These investments are classified as current assets, even though the stated maturity date may be one year or more beyond the current balance sheet date which reflects management's intention to use the proceeds from sales of these securities to fund its operations, as necessary. Such investments are carried at fair value, with unrealized gains and losses included as a separate component of stockholders' equity. Realized gains and losses from the sale of available-for-sale securities or the amounts, net of tax, reclassified out of accumulated other comprehensive income (loss), if any, are determined on a specific identification basis.

## Restricted Cash

The Company is required to maintain a letter of credit securing an amount equal to twelve months of the current monthly installment of base rent for the original term of the lease for its facilities, which ends on August 31, 2017. At March 31, 2017, and December 31, 2016, restricted cash of \$3.3 million was pledged as collateral for the letter of credit. In July 2016, the term of the lease was extended for 16 months through December 2018. During the extended term, the Company is required to maintain a letter of credit securing an amount equal to \$0.2 million.

## Revenue Recognition

Revenue is recognized when the four basic criteria of revenue recognition are met: (1) persuasive evidence of an arrangement exists; (2) delivery has occurred or services rendered; (3) the fee is fixed or determinable; and (4) collectability is reasonably assured. Certain portions of the Company's revenue are generated through manufacturing contracts and stand-alone license agreements.

### Contract Manufacturing Revenue

Revenue associated with contract manufacturing services is recognized once the service has been rendered and/or upon shipment (or passage of title) of the product to the customer. On occasion, the Company recognizes revenue on a "bill-and-hold" basis. Revenue is recognized for such "bill-and-hold" arrangements in accordance with the authoritative guidance, which requires, among other things, the existence of a valid business purpose for the arrangement, that the "bill-and-hold" arrangement is at the request of the customer, that title and risk of ownership pass to the customer, that the product is complete and ready for shipment, a fixed delivery date that is reasonable and consistent with the customer's business practices, that the product has been separated from the Company's inventory, and that no further performance obligations by the Company exist.

### Multiple-Element Arrangements

The Company has entered into multiple-element arrangements. In order to account for the multiple-element arrangements, the Company identifies the deliverables included within the agreement and evaluates which deliverables represent separate units of accounting. Analyzing the arrangement to identify deliverables requires the use of judgment, and each deliverable may be an obligation to deliver services, a right or license to use an asset, or another performance obligation. The delivered item(s) must have value to the customer on a standalone basis and, if the arrangement includes a general right of return relative to the delivered item, delivery or performance of the undelivered item(s) is considered probable and substantially in the Company's control.

A delivered item is considered a separate unit of accounting when the delivered item has value to the partner on a standalone basis based on the consideration of the relevant facts and circumstances for each arrangement. Factors considered in this determination include the research capabilities of the partner and the availability of research expertise in this field in the general marketplace. Arrangement consideration is allocated at the inception of the agreement to all identified units of accounting based on their relative selling price. The relative selling price for each deliverable is determined using vendor specific objective evidence, or VSOE, of selling price or third-party evidence of selling price if VSOE does not exist. If neither VSOE nor third-party evidence of selling price exists, the Company uses its best estimate of the selling price for the deliverable. The amount of allocable arrangement consideration is limited to amounts that are fixed or determinable. The consideration received is allocated among the separate units of accounting, and the applicable revenue recognition criteria are applied to each of the separate units. Changes in the allocation of the sales price between delivered and undelivered elements can impact revenue recognition but do not change the total revenue recognized under any agreement. If facts and circumstances dictate that the license has standalone value from the undelivered items, which generally include research and development services and the

manufacture of drug products, the license is identified as a separate unit of accounting and the amounts allocated to the license are recognized upon the delivery of the license, assuming the other revenue recognition criteria have been met. However, if the amounts allocated to the license through the relative selling price allocation exceed the upfront license fee, the amount recognized upon the delivery of the license is limited to the upfront fee received. If facts and circumstances dictate that the license does not have standalone value, the transaction price, including any upfront license fee payments received, are allocated to the identified separate units of accounting and recognized as those items are delivered.

The terms of the Company's collaboration agreements provide for milestone payments upon achievement of certain regulatory and commercial events. Under the Milestone Method, the Company recognizes consideration that is contingent upon the achievement of a milestone in its entirety as revenue in the period in which the milestone is achieved only if the milestone is substantive in its entirety. A milestone is considered substantive when it meets all of the following criteria: 1) The consideration is commensurate with either the entity's performance to achieve the milestone or the enhancement of the value of the delivered item(s) as a result of a specific outcome resulting from the entity's performance to achieve the milestone, 2) The consideration relates solely to past performance, and 3) The consideration is reasonable relative to all of the deliverables and payment terms within the arrangement. A milestone is defined as an event (i) that can only be achieved based in whole or in part on either the entity's performance or on the

occurrence of a specific outcome resulting from the entity's performance, (ii) for which there is substantive uncertainty at the date the arrangement is entered into that the event will be achieved and (iii) that would result in additional payments being due to the Company.

#### Contract Services, Grant and Royalty Revenue

The Company recognizes revenues from contract services and federal government research grants during the period in which the related expenditures are incurred and related payments for those services are received or collection is reasonably assured. Royalties to be received based on sales of licensed products by the Company's collaborators incorporating the Company's licensed technology are recognized when received.

#### Manufacturing and Production Costs

Manufacturing and production costs include expenses related to manufacturing contracts and expenses for the production of plasmid DNA for use in the Company's research and development efforts. Manufacturing expenses related to manufacturing contracts are deferred and expensed when the related revenue is recognized. Deferred contract costs were \$7.2 million and \$5.5 million at March 31, 2017 and December 31, 2016, respectively. Production expenses related to the Company's research and development efforts are expensed as incurred.

#### Net Loss Per Share

Basic and diluted net loss per share has been computed using the weighted-average number of shares of common stock outstanding during the period. The weighted average number of shares used to compute diluted loss per share excludes any assumed exercise of stock options and any assumed issuance of common stock under RSUs as the effect would be antidilutive. Common stock equivalents of 476 for the three months ended March 31, 2016 were excluded from the calculation because of their antidilutive effect. There were no common stock equivalents for the three months ended March 31, 2017.

#### Stock-Based Compensation

The Company records its compensation expense associated with stock options and other forms of equity compensation based on their fair value at the date of grant using the Black-Scholes-Merton option pricing model. Stock-based compensation includes amortization related to stock option awards based on the estimated grant date fair value. Stock-based compensation expense related to stock options is recognized ratably over the vesting period of the option. In addition, the Company records expense related to RSUs granted based on the fair value of those awards on the grant date. The fair value related to the RSUs is amortized to expense over the vesting term of those awards. Forfeitures of stock options and RSUs are recognized as they occur.

Stock-based compensation expense for a stock-based award with a performance condition is recognized when the achievement of such performance condition is determined to be probable. If the outcome of such performance condition is not determined to be probable or is not met, no compensation expense is recognized and any previously recognized compensation expense is reversed.

#### Recent Accounting Pronouncements

In May 2014, the FASB issued ASU No. 2014-09, "Revenue from Contracts with Customers" which outlines a single comprehensive model for entities to use in accounting for revenue arising from contracts with customers and supersedes most current revenue recognition guidance, including industry-specific guidance. The guidance outlines a five-step process for revenue recognition that focuses on transfer of control, as opposed to transfer of risk and rewards,

and also requires enhanced disclosures regarding the nature, amount, timing and uncertainty of revenues and cash flows from contracts with customers. Major provisions include determining which goods and services are distinct and require separate accounting (performance obligations), how variable consideration (which may include change orders and claims) is recognized, whether revenue should be recognized at a point in time or over time and ensuring the time value of money is considered in the transaction price. The guidance allows for either full retrospective or modified retrospective adoption and will become effective for the Company in the first quarter of 2018.

The Company is in the process of evaluating the impact of adopting the new revenue guidance on the Company's financial position, results of operations, cash flows and related disclosures. Based on the Company's initial assessment, the Company plans to adopt this new standard using the modified retrospective method which may result in a cumulative effect adjustment as of the date of adoption. At this time, management does not expect the adoption of the new guidance to have a material impact on the revenue recognition related to contracts with remaining performance obligations upon the adoption of the standard. The impact on the Company's financial statements is not expected to be material because, based upon the preliminary analysis of material contracts under the new revenue recognition standard, management has determined the recognition and allocation of revenue upon the delivery

or completion of the Company's performance obligations are consistent with those under the current revenue recognition model. The Company expects to complete its assessment process, including finalizing a transition method for adoption, by the end of the third quarter of 2017 and expects to complete its implementation process prior to the adoption of this ASU on January 1, 2018.

In February 2016, the FASB issued ASU No. 2016-02, "Leases (Topic 842)." The new standard requires a lessee to record on the balance sheet the assets and liabilities for the rights and obligations created by leases with lease terms of more than 12 months and will require both lessees and lessors to disclose certain key information about lease transactions. The standard will be effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. The Company is evaluating the effect that the adoption of the new guidance will have on its financial statements and related disclosures.

In March 2016, the FASB issued ASU No. 2016-09, "Compensation – Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting." The amended guidance simplifies the accounting for share-based payment transactions and is effective for annual periods beginning after December 15, 2016. The Company adopted this standard during the first quarter of 2017 and elected to recognize forfeitures as they occur. The adoption of this guidance did not have a material impact on the Company's financial statements and related disclosures.

In November 2016, the FASB issued ASU No. 2016-18, "Statement of Cash Flows (Topic 230): Restricted Cash" that changes the presentation of restricted cash and cash equivalents on the statement of cash flows. Restricted cash and restricted cash equivalents will be included with cash and cash equivalents when reconciling the beginning-of-period and end-of-period total amounts shown on the statement of cash flows. This new standard is effective for fiscal years, and interim periods within those years, beginning after December 15, 2017, with early adoption permitted. The Company is currently evaluating the impact that the adoption of the new guidance will have on its financial statements.

## 2. STOCK-BASED COMPENSATION

Total stock-based compensation expense was allocated to research and development, manufacturing and production and general and administrative expense as follows (in thousands):

	Three Months Ended March 31, 2017 2016	
Research and development	\$67	\$82
Manufacturing and production	28	33
General and administrative	136	198
Total stock-based compensation expense	\$231	\$313

During the three months ended March 31, 2017 and 2016, the Company granted stock-based awards with a total estimated value of \$0.6 million and \$0.5 million, respectively. At March 31, 2017, total unrecognized estimated

compensation expense related to unvested stock-based awards granted prior to that date was \$1.0 million, which is expected to be recognized over a weighted-average period of 1.4 years. Stock-based awards granted during the three months ended March 31, 2017 and 2016, were equal to 4.4% and 3.1%, respectively, of the outstanding shares of common stock at the end of the applicable period.

### 3. MARKETABLE SECURITIES, AVAILABLE FOR SALE

The following is a summary of available-for-sale marketable securities (in thousands):

	Amortized	Unrealized	Unrealized	Market
March 31, 2017	Cost	Gain	Loss	Value
U.S. treasuries	\$ 19,778	—	23	\$19,755
Certificates of deposit	9,461	—	—	9,461
	\$ 29,239	\$	— \$ 23	\$29,216



	Amortized	Unrealized	Unrealized	Market
December 31, 2016	Cost	Gain	Loss	Value
U.S. treasuries	\$ 23,295	\$ —	\$ 18	\$23,277
Certificates of deposit	7,275	—	—	7,275
	\$ 30,570	\$ —	\$ 18	\$30,552

At March 31, 2017, none of these securities were scheduled to mature outside of one year. The Company did not realize any gains or losses on sales of available-for-sale securities for the three months ended March 31, 2017. As of March 31, 2017, none of the securities had been in a continuous material unrealized loss position longer than one year.

#### 4. OTHER BALANCE SHEET ACCOUNTS

Accounts payable and accrued expenses consisted of the following (in thousands):

	March 31, 2017	December 31, 2016
Employee compensation	\$1,501	\$ 2,518
Clinical trial accruals	931	446
Accounts payable	733	326
Deferred rent	6	223
Other accrued liabilities	368	614
Total accounts payable and accrued expenses	\$3,539	\$ 4,127

#### 5. LONG-TERM INVESTMENTS

As of March 31, 2017, the Company held an auction rate security with a par value of \$2.5 million. This auction rate security has not experienced a successful auction since the liquidity issues experienced in the global credit and capital markets in 2008. As a result, the security is classified as a long-term investment as it is scheduled to mature in 2038. The security was rated A- by Standard and Poor's as of March 31, 2017. The security continues to pay interest according to its stated terms.

The valuation of the Company's auction rate security is subject to uncertainties that are difficult to predict. The fair value of the security is estimated utilizing a discounted cash flow analysis. The key drivers of the valuation model include the expected term, collateral underlying the security investment, the creditworthiness of the counterparty, the timing of expected future cash flows, discount rates, liquidity and the expected holding period. The security was also compared, when possible, to other observable market data for securities with similar characteristics. As of March 31, 2017, the inputs used in the Company's discounted cash flow analysis assumed an interest rate of 2.46%, an estimated

redemption period of five years and a discount rate of 1.00%. Based on the valuation of the security, the Company has recognized cumulative losses of \$0.5 million as of March 31, 2017, none of which were realized during the three months ended March 31, 2017. The losses when recognized are included in investment and other income. The market value of the security has partially recovered. Included in other comprehensive income are unrealized gains of \$41,000 and \$86,000 for the three months ended March 31, 2017 and 2016, respectively. As of March 31, 2017, the Company had recorded cumulative unrealized gains of \$0.3 million. The resulting carrying value of the auction rate security at March 31, 2017, was \$2.1 million. Any future decline in market value may result in additional losses being recognized.

## 6. FAIR VALUE MEASUREMENTS

The Company measures fair value as an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability. Fair value measurements are based on a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value as follows:

Level 1: Observable inputs such as quoted prices in active markets;

Level 2: Inputs, other than the quoted prices in active markets, that are observable either directly or indirectly; and

Level 3: Unobservable inputs in which there is little or no market data, which require the reporting entity to develop its own assumptions.

Cash equivalents, marketable securities and long-term investments measured at fair value are classified in the table below in one of the three categories described above (in thousands):

	Fair Value Measurements			
		Level 1	Level 2	Level 3
March 31, 2017		Level 1	2	3
				Total
Certificates of deposit	\$9,461	\$	—	\$—
Money market funds	3,033		—	—
U.S. treasuries	19,755		—	—
Auction rate securities	—		—	2,108
	\$32,249	\$	—	\$2,108
				\$34,357

	Fair Value Measurements			
		Level 1	Level 2	Level 3
December 31, 2016		Level 1	2	3
				Total
Certificates of deposit	\$7,275	\$	—	\$—
Money market funds	1,171		—	—
U.S. treasuries	23,277		—	—
Auction rate securities	—		—	2,046
	\$31,723	\$	—	\$2,046
				\$33,769

The Company's investments in U.S. treasury securities, certificates of deposit and money market funds are valued based on publicly available quoted market prices for identical securities as of March 31, 2017. The Company determines the fair value of corporate bonds and other government-sponsored enterprise related securities with the aid of valuations provided by third parties using proprietary valuation models and analytical tools. These valuation models and analytical tools use market pricing or similar instruments that are both objective and publicly available, including matrix pricing or reported trades, benchmark yields, broker/dealer quotes, issuer spreads, two-sided markets, benchmark securities, bids and/or offers. The Company validates the valuations received from its primary pricing vendors for its Level 2 securities by examining the inputs used in that vendor's pricing process and determines whether they are reasonable and observable. The Company also compares those valuations to recent reported trades for those securities. As of March 31, 2017 and December 31, 2016, the Company had no investments in Level 2 securities. The Company did not transfer any investments between level categories during the three months ended March 31, 2017. The valuation of the Company's investments in auction rate securities, which includes significant unobservable inputs, is more fully described in Note 5.

Activity for assets measured at fair value using significant unobservable inputs (Level 3) is presented in the table below (in thousands):

Balance at December 31, 2016	\$2,046
Total unrealized gains, excluding tax impact, included in other comprehensive gain	62
Balance at March 31, 2017	\$2,108
Total gains or losses for the period included in net loss attributable to the change in	\$—

unrealized gains or losses relating to assets still held at the reporting date

#### 7.COMMITMENTS AND CONTINGENCIES

In the ordinary course of business, the Company may become a party to additional lawsuits involving various matters. The Company is unaware of any such lawsuits presently pending against it which, individually or in the aggregate, are deemed to be material to the Company's financial condition or results of operations.

The Company prosecutes its intellectual property vigorously to obtain the broadest valid scope for its patents. Due to uncertainty of the ultimate outcome of these matters, the impact on future operating results or the Company's financial condition is not subject to reasonable estimates.

#### 8.ASTELLAS OUT-LICENSE AGREEMENTS

In July 2011, the Company entered into license agreements with Astellas Pharma Inc., or Astellas, granting Astellas exclusive, worldwide, royalty-bearing licenses under certain of the Company's know-how and intellectual property to develop and commercialize certain products containing plasmids encoding certain forms of cytomegalovirus, glycoprotein B and/or phosphoprotein 65, including ASP0113 (TransVax™) but excluding CyMVectin™.

Under the terms of the agreements, the Company is performing research and development services and manufacturing services which are being paid for by Astellas. During the three months ended March 31, 2017 and 2016, the Company recognized \$2.9 million and \$3.8 million, respectively, of revenue related to these contract services. The Company also recognized \$0.3 million and \$0.5 million in license revenue under the Astellas agreements during the three months ended March 31, 2017 and 2016, respectively.

#### 9. FACILITY LEASE

The Company leases approximately 68,400 square feet of manufacturing, research laboratory and office space at a single site in San Diego, California. In July 2016, the term of the lease was extended for 16 months through December 2018, resulting in an additional obligation of \$2.9 million.

#### 10. STOCKHOLDERS' EQUITY

On August 1, 2016, the Company entered into a stock purchase agreement with AnGes MG, Inc., or AnGes, an existing stockholder, to purchase 1,841,420 shares of the Company's common stock in a private placement. The shares were sold at a price of \$4.24 per share. Gross proceeds totaled approximately \$7.8 million. The private placement closed on August 2, 2016.

The shares are subject to a two-year lock-up period in which they may not be sold and AnGes has agreed to not increase its ownership position beyond 19.9% and to refrain from taking certain other actions with respect to the Company's stock, subject to certain conditions. AnGes is entitled to have a representative attend meetings of the Company's Board of Directors in a non-voting capacity and may in the future be entitled to have a representative appointed to the Company's Board of Directors, subject to certain conditions. AnGes has also agreed to vote its shares in accordance with the recommendations of the Company's Board of Directors for so long as it continues to hold a specified percentage of the Company's outstanding common stock. The Company also agreed under certain circumstances in the future to register the shares for resale by AnGes.

#### 11. SUBSEQUENT EVENT

On April 4, 2017, the Company entered into a research collaboration agreement with AnGes. As of the date of the transaction, AnGes held 18.6% of the outstanding stock of the Company. Pursuant to the collaboration agreement, AnGes agreed to pay the Company a total of \$750,000 and the Company agreed to conduct certain preclinical research related to a development program targeting chronic hepatitis B. In exchange for the payment, AnGes received an option to negotiate exclusive rights in Japan related to the program. The parties also agreed to share the costs of prosecuting and maintaining intellectual property rights arising from the research program after such costs reach a specified limit.



## ITEM 2.MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

This Quarterly Report on Form 10-Q, or Report, contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act, including statements regarding our business, our financial position, the research and development of biopharmaceutical products based on our patented DNA delivery and other technologies, the funding of our research and development efforts, and other statements describing our goals, expectations, intentions or beliefs. Such statements reflect our current views and assumptions and are subject to risks and uncertainties, particularly those inherent in the process of developing and commercializing biopharmaceutical products based on our patented DNA delivery and other technologies. Actual results could differ materially from those projected herein. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in our Annual Report on Form 10-K for the year ended December 31, 2016, and in our subsequent filings with the SEC, and those identified in Part II, Item 1A of this Report under the caption "Risk Factors". As a result, you are cautioned not to rely on these forward-looking statements. We disclaim any duty to update any forward-looking statement to reflect events or circumstances that occur after the date on which such statement is made.

### Overview

We research and develop biopharmaceutical products, including those based on our patented DNA delivery technologies, for the prevention and treatment of serious or life-threatening diseases. We currently have three active product development programs, independent or partnered, in the clinical testing stage in the area of infectious disease comprised of:

- An ongoing Phase 3 trial of ASP0113 for prevention of cytomegalovirus, or CMV, reactivation in hematopoietic stem cell transplant, or HCT, recipients in collaboration with Astellas Pharma Inc., or Astellas. Enrollment of the trial was completed in September 2016 with a total of 515 subjects. Dosing in the trial was completed in April of 2017 and the follow-up period is expected to be finished in September of 2017. The primary endpoint of the trial is a composite of overall mortality and CMV end organ disease which will be assessed one year after transplantation. Astellas expects top-line data to be available in the first quarter of 2018. Vical and Astellas continue to make progress towards a potential BLA filing in 2018.
- An ongoing Phase 2 trial of VCL-HB01, our Vaxfectin®-formulated therapeutic DNA vaccine for reduction of lesion recurrences caused by herpes simplex virus type 2, or HSV-2, infection. Recruitment into the Phase 2 trial of the VCL-HB01 HSV-2 therapeutic vaccine has been completed with a total of 261 subjects enrolled at 15 U.S. clinical sites. VCL-HB01 is formulated with Vaxfectin® and encodes two full-length HSV-2 antigens gD and UL46, designed to reduce recurrences in patients with symptomatic genital HSV-2 infection. Healthy adult subjects, 18 to 50 years of age, have been randomized 2:1 to receive either vaccine or placebo to evaluate in a double blinded fashion the efficacy and safety of the vaccine. The primary endpoint of the study is annualized lesion recurrence rate which is a clinically meaningful endpoint for both patients and treating physicians as it provides important information on the number of recurrences over time in this chronic disease setting. We expect to deliver top-line data during the second quarter of 2018.
- A completed first-in-human Phase 1 trial of our novel antifungal VL-2397. The randomized, double-blind, placebo-controlled trial was designed to evaluate safety, tolerability and pharmacokinetics of single and multiple ascending doses of intravenous VL-2397 in 96 healthy volunteers. Results point to a favorable safety and pharmacokinetic profile for VL-2397. The full data will be presented as one of four presentations at the ASM Microbe 2017 conference in June. Our current plan is to conduct a Phase 2 efficacy study to evaluate VL-2397 for the treatment of invasive aspergillosis and we are working with our clinical experts and the FDA towards this objective. The FDA has granted Vical QIDP, Orphan Drug and Fast Track designations to VL-2397 for the treatment of invasive aspergillosis. Under the QIDP designation we have been able to interact intensively with the FDA on the

design of the Phase 2 trial and in exploring an expedited development pathway for VL 2397.

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## Product Development

We, together with our licensees and collaborators, are developing a number of DNA-based vaccines and other therapeutics for the prevention or treatment of infectious diseases. The table below summarizes our independent programs and corporate and government collaborations.

Product/Concept	Intended Use	Development Status <sup>1</sup>	Lead Developer
<b>Independent Programs</b>			
VCL-HB01 therapeutic vaccine for HSV-2	Reduce lesion recurrence	Phase 2	Vical
VL-2397 antifungal	Treatment of invasive fungal infections	Phase 1 complete	Vical
CyMVectin™ prophylactic vaccine for CMV	Prevent fetal transmission of CMV during pregnancy	Preclinical	Vical
<b>Corporate Collaborations</b>			
ASP0113 therapeutic vaccine for CMV	Protect against reactivation of infection after HCT	Phase 3	Astellas
ONCEPT® therapeutic cancer vaccine encoding human tyrosinase	Adjunct treatment to increase survival time of dogs with oral melanoma	Marketed in the United States	Meriel

<sup>1</sup>“Preclinical” (or “nonclinical”) indicates that a specific product candidate in a nonclinical setting has shown functional activity that is relevant to a targeted medical need, and is advancing toward initial human clinical testing. “Phase 1” clinical trials are typically conducted with a small number of patients or healthy subjects to evaluate safety, determine a safe dosage range, identify side effects, and, if possible, gain early evidence of effectiveness. “Phase 2” clinical trials are conducted with a larger group of patients to evaluate effectiveness of an investigational product for a defined patient population, and to determine common short-term side effects and risks associated with the product candidate. “Phase 3” clinical trials involve large scale, multi-center, comparative trials that are conducted with patients afflicted with a target disease to evaluate the overall benefit-risk relationship of the investigational product and to provide an adequate basis for product labeling

## Research, Development and Manufacturing Programs

To date, we have not received revenues from the sale of our independently developed pharmaceutical products and have received minimal revenues from the sale of commercially marketed products by our licensees. We earn revenues by performing services under research and development and manufacturing contracts, from grants and from licensing access to our proprietary technologies. Revenues by source were as follows (in millions):

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	Three Months Ended March 31,	
Source	2017	2016
Astellas supply and services contract	\$2.9	\$3.8
Astellas license	0.3	0.5
Other contracts, licenses and royalties	—	0.3
Total revenues	\$3.2	\$4.6

Research, development, manufacturing and production costs by major program, as well as other costs, were as follows (in millions):

	Three Months Ended March 31,	
Program	2017	2016
CMV	\$2.1	\$3.8
HSV-2	1.8	0.5
VL-2397	0.4	0.8
Other research, development, manufacturing and production	0.3	0.2
Total research, development, manufacturing and production	\$4.6	\$5.3

Our current development focus includes our novel DNA vaccines for CMV and HSV-2, and our antifungal for the treatment of invasive fungal infections.

These programs will require significant additional funds to advance through development to commercialization. From inception through March 31, 2017, we had spent approximately \$22.3 million on our HSV-2 program, \$119.2 million on our CMV programs and \$7.2 million on our VL-2397 program.

We have other product candidates in the research stage. It can take many years to develop product candidates from the initial decision to screen product candidates, perform preclinical and safety studies, and perform clinical trials leading up to possible approval of a product by the FDA or comparable foreign agencies. The outcome of the research is unknown until each stage of the testing is completed, up through and including registration-enabling clinical trials. Accordingly, we are unable to predict which potential product candidates we may proceed with, the time and cost to complete development, and ultimately whether we will have a product approved by the FDA or comparable foreign agencies.

As a result, we expect to incur substantial operating losses for at least the next several years, due primarily to the advancement of our research and development programs, the cost of preclinical studies and clinical trials, spending for outside services, costs related to maintaining our intellectual property portfolio, costs due to manufacturing activities, costs related to our facilities, and possible advancement toward commercialization activities.

#### Critical Accounting Policies and Estimates

The preparation and presentation of financial statements in accordance with accounting principles generally accepted in the United States requires that management make a number of assumptions and estimates that affect the reported amounts of assets, liabilities, revenues and expenses in our financial statements and accompanying notes. Management bases its estimates on historical information and assumptions believed to be reasonable. Although these estimates are based on management's best knowledge of current events and circumstances that may impact us in the future, they are inherently uncertain and actual results may differ materially from these estimates.

Our critical accounting policies are those that affect our financial statements materially and involve a significant level of judgment by management. Our critical accounting policies regarding revenue recognition are in the following areas: license and royalty agreements, manufacturing contracts, contract services and grant revenues. Our critical accounting policies also include recognition of research and development expenses and the valuation of long-lived and intangible assets.

There have been no material changes to our critical accounting policies and estimates as compared to those discussed in our Annual Report on Form 10-K for the fiscal year ended December 31, 2016.

#### Recent Accounting Pronouncements

For information on the recent accounting pronouncements which may impact our business, see Note 1 of the Notes to Financial Statements included in this Report.

#### Results of Operations

##### Three Months Ended March 31, 2017, Compared with Three Months Ended March 31, 2016

**Total Revenues.** Total revenues decreased \$1.4 million, or 30.4%, to \$3.2 million for the three months ended March 31, 2017, from \$4.6 million for the three months ended March 31, 2016. This decrease was primarily due to a decrease

in the delivery of ASP0113 material under our license agreements with Astellas.

**Research and Development Expenses.** Research and development expenses increased \$0.8 million, or 33.2%, to \$3.3 million for the three months ended March 31, 2017, from \$2.5 million for the three months ended March 31, 2016. This increase was primarily due to costs related to our ongoing HSV-2 Phase 2 clinical trial which was initiated in September 2016.

**Manufacturing and Production Expenses.** Manufacturing and production expenses decreased \$1.5 million, or 54.0%, to \$1.3 million for the three months ended March 31, 2017, from \$2.8 million for the three months ended March 31, 2016. This decrease was primarily due to a net increase in deferred costs capitalized during the three months ended March 31, 2017 related to materials manufactured under our supply agreement with Astellas.

**General and Administrative Expenses.** General and administrative expenses decreased \$0.3 million, or 15.7%, to \$1.5 million for the three months ended March 31, 2017, from \$1.8 million for the three months ended March 31, 2016. This decrease was primarily due to a decrease in employee expenses, audit fees and facility related costs.

**Investment and Other Income, Net.** Investment and other income, net, increased \$2,000 to \$89,000 for the three months ended March 31, 2017, from \$87,000 for the three months ended March 31, 2016.

#### Liquidity and Capital Resources

Since our inception, we have financed our operations primarily through private placements and public offerings of equity securities, and revenues from our operations. Cash, cash equivalents, marketable securities, and long-term investments, including restricted cash, totaled \$39.2 million at March 31, 2017, compared with \$41.0 million at December 31, 2016. The decrease in our cash, cash equivalents and marketable securities for the three months ended March 31, 2017, was primarily the result of the use of cash to fund our operations.

Net cash used in operating activities was \$1.8 million and \$1.7 million for the three months ended March 31, 2017 and 2016, respectively. The increase in net cash used in operating activities for the three months ended March 31, 2017, compared with the prior year period, was primarily the result of an increase in our net loss offset by an increase in deferred revenue under our collaboration agreement with Astellas.

Net cash provided by (used in) investing activities was \$1.3 million and \$(5.8) million for the three months ended March 31, 2017 and 2016, respectively. The increase in net cash provided by investing activities for the three months ended March 31, 2017, compared with the prior year period, was primarily the result of a net increase in the maturities of marketable securities.

Net cash provided by (used in) financing activities was \$3,000 and \$(2,000) for the three months ended March 31, 2017 and 2016, respectively.

A discussion of our exposure to auction rate securities is included in Part I, Item 3 of this Report under the heading “Quantitative and Qualitative Disclosures About Market Risk.”

In the long-term, we expect to incur substantial additional research and development expenses, manufacturing and production expenses, and general and administrative expenses, including increases in costs related to personnel, preclinical and clinical testing, outside services, facilities, intellectual property and possible commercialization. Our future capital requirements will depend on many factors, including continued scientific progress in our research and development programs, the scope and results of preclinical testing and clinical trials, the time and costs involved in obtaining regulatory approvals, the costs involved in filing, prosecuting, enforcing and defending patent claims, the impact of competing technological and market developments, the cost of manufacturing scale-up and validation, and possible commercialization activities and arrangements. We may seek additional funding through research and development relationships with suitable potential corporate collaborators. We may also seek additional funding through public or private financings. For example, in August 2016, we sold 1,841,420 shares of our common stock to AnGes in a private placement for gross proceeds of approximately \$7.8 million. We currently have on file an effective shelf registration statement that allows us to raise up to \$100.0 million from the sale of common stock, preferred stock, debt securities and/or warrants. In October 2016, we also entered into an At-The-Market Issuance Sales Agreement, or the ATM Agreement, with IFS Securities, Inc. (doing business as Brinson Patrick, a division of IFS Securities, Inc.), or BP, under which we may issue and sell up to \$10.0 million of shares of our common stock from time to time. Under the ATM Agreement, we may deliver placement notices that will set the parameters for the sale of shares, including the number of shares to be issued, the time period during which sales are requested to be made, any limitation on the number of shares that may be sold in any one trading day and any minimum price below which sales

may not be made. Subject to the terms and conditions of the ATM Agreement, BP may sell the shares only by methods deemed to be an “at the market” offering as defined in Rule 415 promulgated under the Securities Act of 1933, as amended, including without limitation sales made directly through the Nasdaq Capital Market, on any other existing trading market for our common stock or to or through a market maker. BP will use commercially reasonable efforts consistent with its normal trading and sales practices to sell the shares in accordance with the terms of the ATM Agreement and any applicable placement notice. The ATM Agreement may be terminated by us upon prior notice to BP or by BP upon prior notice to us, or at any time under certain circumstances, including but not limited to the occurrence of a material adverse effect on our Company. We have no obligation to sell any shares under the ATM Agreement, and both we and BP may at any time suspend the sale of shares under the ATM Agreement. To date we have not sold any shares of our common stock under the ATM Agreement.

Despite our current shelf registration statement and the ATM Agreement, additional financing through these or other means may not be available on favorable terms or at all. If additional financing is not available, we anticipate that our available cash and existing sources of funding will be adequate to satisfy our cash needs at least through December 31, 2018.

## Contractual Obligations

Under our pre-existing license agreements, we are required to make certain payments to the City of Hope and CytRx in connection with the development and commercialization of our products licensed by Astellas. In addition, certain technology license agreements require us to make other payments if we or our sublicensees advance products through clinical development. For programs developed with the support of U.S. government funding, the U.S. government may have rights to resulting products without payment of royalties to us.

We may be required to make future payments to our licensors based on the achievement of milestones set forth in various in-licensing agreements, including our in-license agreement with Astellas related to VL-2397. In most cases, these milestone payments are based on the achievement of development or regulatory milestones, including the exercise of options to obtain licenses related to specific disease targets, commencement of various phases of clinical trials, filing of product license applications, approval of product licenses from the FDA or a foreign regulatory agency, and the first commercial sale of a related product. Payment for the achievement of milestones under our in-license agreements is highly speculative and subject to a number of contingencies.

The aggregate amount of additional milestone payments that we could be required to pay under our active in-license agreements in place at March 31, 2017, is approximately \$106.0 million. These amounts assume that all remaining milestones associated with the milestone payments are met. In the event that product license approval for any of the related products is obtained, we may be required to make royalty payments in addition to these milestone payments. Although we believe that some of the milestones contained in our in-license agreements may be achieved, it is highly unlikely that a significant number of them will be achieved. Because the milestones are contingent, we are not in a position to reasonably estimate how much, if any, of the potential milestone payments will ultimately be paid, or when. Additionally, under the in-license agreements, many of the milestone events are related to progress in clinical trials which will take several years to achieve.

In addition, we have undertaken certain commitments under license agreements with collaborators, and under indemnification agreements with our officers and directors. Under the license agreements with our collaborators, we have agreed to continue to maintain and defend the patent rights licensed to the collaborators and, in the case of our agreements with Astellas, have agreed to undertake certain development and manufacturing activities. Under the indemnification agreements with our officers and directors, we have agreed to indemnify those individuals for any expenses and liabilities in the event of a threatened, pending or actual investigation, lawsuit, or criminal or investigative proceeding.

We have employment agreements that contain severance arrangements with our chief executive officer, or CEO, and our four other executives. Under the agreement with our CEO, we are obligated to pay severance if we terminate the CEO's employment without "cause," or if the CEO resigns for "good reason," as defined in the agreement, within the periods set forth therein. The severance for the CEO consists of continued base salary payments at the then-current rate, including the payment of health insurance premiums for 18 months, plus a payment equal to one and one-half times the CEO's cash bonus in the previous year. In addition, the CEO receives accelerated vesting on all his unvested stock awards as if he had remained employed by us for 18 months from the date of termination. In the event that the termination occurs within 24 months of a "change in control," as defined in the agreement, the severance for the CEO consists of a lump sum payment equal to 24 months of base salary at the then-current rate, the payment of health insurance premiums for 18 months, plus a payment equal to one and one-half times the CEO's cash bonus in the previous year. In addition, all outstanding unvested stock awards will vest immediately. Under the agreements with our other four executives, we are obligated to pay severance if we terminate the executive's employment without "cause," or if the executive resigns for "good reason," as defined in the agreements, within the periods set forth therein. The severance for the other executives consists of a lump-sum payment equal to 12 months of base salary at the then-current rate, including the payment of health insurance premiums for 12 months, plus a payment equal to the

executive's cash bonus in the previous year. In addition, the executive receives accelerated vesting on all his unvested stock awards as if he had remained employed by us for 12 months from the date of termination. In the event that the termination occurs within 12 months of a "change in control," as defined in the agreements, the severance for the other executives consists of a lump sum payment equal to 18 months of base salary at the then-current rate, the payment of health insurance premiums for 12 months, plus a payment equal to the executive's cash bonus in the previous year. In addition, all outstanding unvested stock awards will vest immediately. The maximum payments due under these employment agreements would have been \$3.6 million if each such officer was terminated at March 31, 2017.

#### Off-Balance Sheet Arrangements

As of March 31, 2017, we did not have any off-balance sheet arrangements.



### ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are subject to interest rate risk. Our investment portfolio is maintained in accordance with our investment policy which defines allowable investments, specifies credit quality standards and limits the credit exposure of any single issuer. Our investment portfolio consists of cash equivalents, both restricted and non-restricted, marketable securities and long-term investments. The average maturity of our investments, excluding our auction rate securities, is approximately five months. Our investments are classified as available-for-sale securities.

To assess our interest rate risk, we performed a sensitivity analysis projecting an ending fair value of our cash equivalents and current marketable securities using the following assumptions: a five month average maturity and a 150-basis point increase in interest rates. This pro forma fair value would have been \$0.2 million lower than the reported fair value of our investments at March 31, 2017.

Our investment securities consist of auction rate securities, corporate debt securities and government agency securities. As of March 31, 2017, our long-term investments included a (at par value) \$2.5 million auction rate security secured by municipal bonds. At March 31, 2017, the auction rate security we held maintained a Standard and Poor's credit rating of A-. The auction rate security is a debt instrument with a long-term maturity and with an interest rate that is reset in short intervals through auctions. The conditions in the global credit markets have prevented some investors from liquidating their holdings of auction rate securities because the amount of securities submitted for sale has exceeded the amount of purchase orders for such securities. If there is insufficient demand for the securities at the time of an auction, the auction may not be completed and the interest rates may be reset to predetermined higher rates. When auctions for these securities fail, the investments may not be readily convertible to cash until a future auction of these investments is successful or they are redeemed or mature.

Since February 2008, there has been insufficient demand at auction for our auction rate security held at March 31, 2017. As a result, this security is currently not liquid, and we could be required to hold it until it is redeemed by the issuer or to maturity. As of March 31, 2017, we had recognized \$0.5 million of losses related to the auction rate security by adjusting its carrying value. The market value of the security has partially recovered from the lows that created the losses. As of March 31, 2017, we had recorded cumulative unrealized gains of \$0.3 million. Any future decline in market value may result in additional losses being recognized.

The valuation of our auction rate security is subject to uncertainties that are difficult to predict. The fair value of the security is estimated utilizing a discounted cash flow analysis or other type of valuation model as of March 31, 2017. The key drivers of the valuation model include the expected term, collateralization underlying the security investment, the creditworthiness of the counterparty, the timing of expected future cash flows, discount rates, and the expected holding period. This security was also compared, when possible, to other observable market data for securities with similar characteristics.

In the event we need to access the funds that are not currently liquid, we will not be able to do so without the possible loss of principal, until a future auction for these investments is successful or they are redeemed by the issuer or they mature. If we are unable to sell these securities in the market or they are not redeemed, then we may be required to hold them until 2038 when they mature. We do not anticipate a need to access these funds for operational purposes for the foreseeable future. We will continue to monitor and evaluate these investments on an ongoing basis for impairment. Based on our ability to access our cash and other short-term investments, our expected operating cash flows, and our other sources of cash, we do not anticipate that the potential illiquidity of these investments will affect our ability to execute our current business plan.

### ITEM 4. CONTROLS AND PROCEDURES

## Conclusion Regarding the Effectiveness of Disclosure Controls and Procedures

Under the supervision and with the participation of our management, including our principal executive and financial officer, we conducted an evaluation of the design and operation of our disclosure controls and procedures, as such term is defined in Rule 13a-15(e) promulgated under the Exchange Act as of the end of the period covered by this Report. Based on this evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective and were operating at a reasonable assurance level as of March 31, 2017.

## Changes in Internal Control over Financial Reporting

Management has determined that there were no significant changes in our internal control over financial reporting that occurred during the three months ended March 31, 2017, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

## PART II. OTHER INFORMATION

### ITEM 1A. RISK FACTORS

You should consider carefully the risks described below, together with all of the other information included in this Report, and in our other filings with the SEC, before deciding whether to invest in or continue to hold our common stock. The risks described below are all material risks currently known, expected or reasonably foreseeable by us. If any of these risks actually occur, our business, financial condition, results of operations or cash flow could be seriously harmed. This could cause the trading price of our common stock to decline, resulting in a loss of all or part of your investment.

The risk factors set forth below with an asterisk (\*) next to the title are new risk factors or risk factors containing changes, including any material changes, from the risk factors previously disclosed in Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2016, as filed with the SEC.

(\*)None of our independently developed product candidates has been approved for sale, and we have a limited number of independently developed product candidates in clinical trials. If we do not develop commercially successful products, we may be forced to curtail or cease operations.

All of our independently developed product candidates are either in research or development. We must conduct a substantial amount of additional research and development before any U.S. or foreign regulatory authority will approve any of our product candidates. Limited data exist regarding the efficacy of DNA vaccines or therapeutics compared with conventional vaccines or therapeutics. Results of our research and development activities may indicate that our product candidates are unsafe or ineffective. In this case, we may stop development and regulatory authorities will not approve them. For example, in 2013 we ceased development of Allovectin®, an investigational intratumoral cancer immunotherapy, following negative results from a Phase 3 trial.

We initiated a Phase 2 clinical trial of VCL-HB01, our HSV-2 vaccine in September 2016, but the results of the Phase 2 clinical trial may not be positive and the favorable results or trends observed in our previously completed Phase 1/2 clinical trial may not continue in the Phase 2 clinical trial. The Phase 2 clinical trial of VCL-HB01 and any future trials, if any, may not demonstrate sufficient safety or efficacy to support further product development. Because we have a limited number of independent clinical-stage product candidates, if we experience a significant delay, set-back or failure in the development of any of our product candidates, it could have a material adverse impact on our business prospects.

All of the product candidates we are developing independently will require significant costs to advance through the development stages. If such product candidates are advanced through clinical trials, the results of such trials may not support approval by the FDA or comparable foreign agencies. Even if approved, our products may not be commercially successful, particularly if they do not gain market acceptance among physicians, patients, healthcare payers and relevant medical communities. If we fail to develop and commercialize our product candidates, we may be forced to curtail or cease operations.

Our clinical trials or those of our partners may fail to demonstrate adequately the safety and efficacy of any of our product candidates, which would prevent or delay regulatory approval and commercialization.

Before obtaining regulatory approvals for the commercial sale of our product candidates, we must demonstrate through lengthy, complex and expensive preclinical testing and clinical trials that our product candidates are both safe and effective for use in each target indication. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. The results of

preclinical studies and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. There is typically an extremely high rate of attrition from the failure of product candidates proceeding through clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy profile despite having progressed through preclinical studies and initial clinical trials. We and our licensees have in the past suffered significant setbacks in advanced clinical trials due to lack of efficacy, notwithstanding promising results in earlier trials. For example, in 2013 we ceased development of Allovectin®, an investigational intratumoral cancer immunotherapy, following negative results from a Phase 3 trial. In June 2015, we announced that our HSV-2 product candidates did not meet the primary endpoint in a Phase 1/2 clinical study. In September 2016, we and Astellas announced ASP0113 did not meet its primary endpoint in a Phase 2 clinical study evaluating the safety and efficacy of ASP0113 versus placebo in kidney transplant patients receiving an organ from a CMV-seropositive donor. Most product candidates that commence clinical trials are never approved as products.

There are a number of factors that could cause a clinical study to fail or be delayed, including:

- the clinical study may produce negative or inconclusive results;
- regulators, monitoring boards or other entities may require that we hold, suspend or terminate clinical research for safety, ethical or regulatory reasons, including adverse events reported during the trial;
- we may decide, or regulators may require us, to conduct additional preclinical testing or clinical studies;
- enrollment in our clinical studies may be slower than we anticipate;
- the cost of our clinical studies may be greater than we anticipate; and
- the supply or quality of our product candidates or other materials necessary to conduct our clinical studies may be insufficient, inadequate or delayed.

In addition, even if clinical trials are successfully completed, we cannot guarantee that the FDA or foreign regulatory authorities will interpret the results as sufficient to demonstrate that a product is safe and efficacious, and more trials could be required before we submit our product candidates for approval. To the extent that the results of the trials are not satisfactory to the FDA or foreign regulatory authorities for support of a marketing application, approval of our product candidates may be significantly delayed, or we may be required to expend significant additional resources, which may not be available to us, to conduct additional trials in support of potential approval of our product candidates.

We are dependent on our out-license agreements with Astellas to further develop and commercialize ASP0113. The failure to maintain these agreements, or the failure of Astellas to perform its obligations under these agreements, could negatively impact our business.

Pursuant to the terms of our out-license agreements with Astellas, we granted to Astellas exclusive worldwide rights to develop and commercialize certain products, including ASP0113 but excluding CyMVectin™, for the control and prevention of CMV infection in immunocompromised patients, including transplant recipients and transplant donors, and pursuant to the terms of our supply and services agreement with Astellas, we are obligated to perform certain development activities and supply Astellas with its product requirements for development and initial commercialization activities. Consequently, our ability to generate any revenues from ASP0113 depends on Astellas' ability to develop, obtain regulatory approvals for and successfully commercialize ASP0113. We have limited control over the amount and timing of resources that Astellas will dedicate to these efforts. For example, based on the results of the Phase 2 clinical trial evaluating ASP0113 in kidney transplant patients, Astellas has informed us that they do not plan to pursue further clinical development of ASP0113 in solid organ transplant indications.

We are subject to a number of other risks associated with our dependence on our out-license agreements with Astellas, including:

- Astellas may not comply with applicable regulatory guidelines with respect to developing or commercializing ASP0113, which could adversely impact sales or future development of ASP0113;
- We and Astellas could disagree as to future development plans and Astellas may delay, fail to commence or stop future clinical trials or other development;
- There may be disputes between us and Astellas, including disagreements regarding the license agreements or supply agreement, that may result in (1) the delay of or failure to achieve developmental, regulatory and commercial objectives that would result in milestone or royalty payments, (2) the delay or termination of any future development or commercialization of ASP0113, and/or (3) costly litigation or arbitration that diverts our management's attention and resources;
- Astellas may not provide us with timely and accurate information regarding development, sales and marketing activities or supply forecasts, which could adversely impact our ability to comply with our service and supply obligations to Astellas and manage our own inventory of ASP0113, as well as our ability to generate accurate financial forecasts;

Business combinations or significant changes in Astellas' business strategy may adversely affect Astellas' ability or willingness to perform its obligations under our license agreements;

Astellas may not properly defend our intellectual property rights, or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property rights or expose us to potential litigation;

The royalties we are eligible to receive from Astellas may be reduced based upon Astellas' and our ability to maintain or defend our intellectual property rights and the presence of generic competitors;

Limitations on our or an acquirer's ability to maintain or pursue development or commercialization of products that are competitive with ASP0113 could deter a potential acquisition of us that our stockholders may otherwise view as beneficial; and

If Astellas is unsuccessful in developing, obtaining regulatory approvals for or commercializing ASP0113, we may not receive any additional milestone or royalty payments under the license agreements and our business prospects and financial results may be materially harmed.

The out-license agreements and supply and services agreement are subject to early termination, including through Astellas' right to terminate upon advance notice to us if Astellas reasonably determines that further development and/or commercialization will not be beneficial for Astellas. If the agreements are terminated early, we may not be able to find another collaborator for the commercialization and further development of ASP0113 on acceptable terms, or at all, and we may be unable to pursue continued development or commercialization of ASP0113 on our own.

Our revenues partially depend on the development and commercialization of products in collaboration with others to whom we have licensed our technologies. If our other collaborators or licensees do not successfully develop and commercialize products covered by these arrangements, or if we are unable to find collaborators or licensees in the future, we may not be able to derive revenues from these arrangements, we may lose opportunities to validate our DNA delivery technologies, or we may be forced to curtail our development and commercialization efforts in these areas.

In addition to our out-license agreements with Astellas, we have licensed, and may continue to license, our technologies to corporate collaborators and licensees for the research, development and commercialization of specified product candidates. Our revenues partially depend upon the ability of these collaborators and licensees to successfully develop and commercialize products covered by these arrangements. In addition, our licensee Astellas has product candidates in advanced stages of clinical development, for which we believe regulatory approval would provide important further validation of our DNA delivery technologies. The development and commercialization efforts of our collaborators and licensees are subject to the same risks and uncertainties described above with respect to our independently developed product candidates.

Some collaborators or licensees may not succeed in their product development efforts. It is possible that our collaborators or licensees may be unable to obtain regulatory approval of product candidates using our technologies or successfully market and commercialize any such products for which regulatory approval is obtained. Other collaborators or licensees may not devote sufficient time or resources to the programs covered by these arrangements, and we may have limited or no control over the time or resources allocated by these collaborators or licensees to these programs. The occurrence of any of these events may cause us to derive little or no revenue from these arrangements, lose opportunities to validate our DNA delivery technologies, or force us to curtail or cease our development and commercialization efforts in these areas.

Our collaborators and licensees may breach or terminate their agreements with us, including some that may terminate their agreements without cause at any time subject to certain prior written notice requirements, and we may be unsuccessful in entering into and maintaining other collaborative arrangements for the development and commercialization of products using our technologies. If we are unable to maintain existing collaboration arrangements or enter into new ones, our ability to generate licensing, milestone or royalty revenues would be materially impaired.

Some of our independent product candidates and some of those under development by our sublicensees incorporate technologies we have licensed from others. If we are unable to retain rights to use these technologies, we or our sublicensees may not be able to market products incorporating these technologies on a commercially feasible basis, if at all.

We have licensed certain technologies from corporate collaborators and research institutions, and sublicensed certain of such technologies to others, for use in the research, development and commercialization of product candidates. Our product development efforts and those of our sublicensees partially depend upon continued access to these technologies. For example, we or our licensors may breach or terminate our agreements, or disagree on interpretations of those agreements, which could prevent continued access to these technologies. If we were unable to resolve such matters on satisfactory terms, or at all, we or our sublicensees may be unable to develop and commercialize our products, and we may be forced to curtail or cease operations.

We licensed rights to patents and know-how for VL-2397 from Astellas pursuant to an in-license agreement that contains obligations to pay Astellas regulatory and sales milestone payments relating to VL-2397, as well as royalties on net sales of VL-2397. If we fail to make a required payment to Astellas or otherwise materially breach our in-license agreement with Astellas and do not cure the failure within the required time period, Astellas may be able to terminate the license to the VL-2397 patents and know-how, which would have a material adverse effect on our business, financial condition and results of operations.



(\*)We have a history of net losses. We expect to continue to incur net losses and we may not achieve or maintain profitability.

To date, we have not sold, or received approval to sell, any pharmaceutical products. We do not expect to sell any pharmaceutical products for at least the next several years. Our net losses were approximately \$9.0 million, \$9.2 million and \$16.5 million for the years ended December 31, 2016, 2015 and 2014, respectively. As of March 31, 2017, we had incurred cumulative net losses totaling approximately \$416.6 million. Moreover, we expect that our net losses will continue and may increase for the foreseeable future. We may not be able to achieve projected results if we generate lower revenues or receive lower investment income than expected, or we incur greater expenses than expected, or all of the above. Currently our revenues are largely dependent on manufacturing and research services performed under our license agreement with Astellas. That revenue may decrease once the ASP0113 trials are complete or in the event that the development of the ASP0113 program ceases. We may never generate sufficient product revenue to become profitable. We also expect to have quarter-to-quarter fluctuations in revenues, expenses, and losses, some of which could be significant.

We may need additional capital in the future. If additional capital is not available, we may have to curtail or cease operations.

We may need to raise more money to continue the research and development necessary to bring our products to market and to establish marketing and additional manufacturing capabilities. We may seek additional funds through public and private stock offerings, government contracts and grants, arrangements with corporate collaborators, borrowings under lines of credit or other sources. We currently have on file a shelf registration statement that allows us to raise up to an aggregate of \$100.0 million from the sale of common stock, preferred stock, debt securities and/or warrants. However, we may not be able to raise additional funds on favorable terms, or at all. Conditions in the credit markets and the financial services industry may make equity and debt financing more difficult to obtain, and may negatively impact our ability to complete financing transactions. To the extent that we raise additional funds by issuing equity securities, our stockholders may experience significant dilution. Any debt financing, if available, may involve restrictive covenants, such as limitations on our ability to incur additional indebtedness and other operating restrictions that could adversely impact our ability to conduct our business.

In October 2016, we also entered into an At-The-Market Issuance Sales Agreement, or the ATM Agreement, with IFS Securities, Inc. (doing business as Brinson Patrick, a division of IFS Securities, Inc.), or BP, under which we may issue and sell up to \$10.0 million of shares of our common stock from time to time. To date we have not sold any shares of our common stock under the ATM Agreement. However, BP is not obligated to sell any shares that we may request to be sold, and any attempt to sell shares under this facility, if made, may not be successful or generate sufficient proceeds to meet our capital requirements.

If we are unable to obtain additional funds, we may have to scale back our development of new products, reduce our workforce or license to others products or technologies that we otherwise would seek to commercialize ourselves. The amount of money we may need would depend on many factors, including:

- The progress of our research and development programs;
- The scope and results of our preclinical studies and clinical trials;
- The amount of our legal expenses and any settlement or damages payments associated with litigation; and
- The time and costs involved in: obtaining necessary regulatory approvals; filing, prosecuting and enforcing patent claims; scaling up our manufacturing capabilities; and the commercial arrangements we may establish.

The regulatory approval process is expensive, time consuming and uncertain, which may prevent us and our collaborators and licensees from obtaining required approvals for the commercialization of our products.

Our product candidates under development and those of our collaborators and licensees, including Astellas, are subject to extensive and rigorous regulations by numerous governmental authorities in the United States and other countries. The regulatory approval process takes many years and will require us to expend substantial resources.

U.S. or foreign regulations evolve and could prevent or delay regulatory approval of our products or limit our and our collaborators and licensees' ability to develop and commercialize our products. Delays could:

- Impose costly procedures on our activities and those of our collaborators and licensees;
- Delay or prevent our receipt of developmental or commercial milestones from our collaborators and licensees;

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- Diminish any competitive advantages that we or our products attain; or

• Otherwise negatively affect our results of operations and cash flows.

We have no experience in filing a BLA or an NDA with the FDA. Because these applications must be submitted to and approved by the FDA before any of our product candidates may be commercialized, our lack of experience may impede our ability to obtain FDA approval in a timely manner, if at all, which in turn would delay or prevent us from commercializing those products. Similarly, our lack of experience with respect to obtaining regulatory approvals in countries other than the United States may impede our ability to commercialize our products in those countries.

The FDA and comparable foreign regulatory bodies will regulate separately each product containing a particular gene depending on its intended use. Presently, to commercialize any product we and our collaborators and licensees must file a regulatory application for each proposed use. We and our collaborators and licensees must conduct clinical studies to demonstrate the safety and efficacy of the product necessary to obtain FDA or foreign regulatory authority approval. The results obtained so far in our clinical trials and those of our collaborators and licensees may not be replicated in ongoing or future trials, or the results may be subject to varying interpretation on whether they are sufficient to support approval for commercialization. This may prevent any of our product candidates from receiving approval for commercial sale.

We anticipate that we would commercially manufacture the drug substance for the ASP0113 program if it is approved for marketing. Therefore, our manufacturing facilities will have to be approved by the FDA pursuant to inspections conducted after we submit an application for regulatory approval. If we cannot successfully manufacture material that conforms to applicable specifications and the strict regulatory requirements of the FDA, we will not be able to secure and/or maintain regulatory approval for our manufacturing facilities. If the FDA does not approve our facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, our ability to develop, obtain regulatory approval for or market our product candidates will be adversely affected.

If any of our product candidates receive regulatory approval, the FDA or other foreign regulatory agencies may still impose significant restrictions on the indicated uses or marketing of our product candidates or impose ongoing requirements for potentially costly post-approval studies. In addition, regulatory agencies subject a product, its manufacturer and the manufacturer's facilities to continual review and periodic inspections. If a regulatory agency discovers previously unknown problems with a product or a product class, including adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions on that product or product class, our collaborators and licensees or us, including requiring withdrawal of a product from the market. Our product candidates will also be subject to ongoing FDA and other foreign regulatory agency requirements for the labeling, packaging, storage, advertising, promotion, record-keeping and submission of safety and other post-market information on the product. If we or our collaborators and licensees fail to maintain regulatory compliance after receiving marketing approval, we or our collaborators and licensees may be unable to market our products and our business could suffer.

Adverse events or the perception of adverse events in the field of gene therapy, or with respect to our product candidates, may negatively impact regulatory approval or public perception of our products.

The commercial success of some of our product candidates will depend in part on public acceptance of the use of gene therapy for preventing or treating human diseases. Serious adverse events, including patient deaths, have occurred in clinical trials utilizing viral delivery systems to deliver therapeutic genes to the patient's targeted cells. Although none of our current products or studies utilize viral delivery systems, these adverse events, as well as any other adverse events in the field of gene therapy that may occur in the future, may negatively influence public perception of gene therapy in general. If public perception is influenced by claims that gene therapy is unsafe, our product candidates may not be accepted by the general public or the medical community.

Future adverse events in gene therapy or the biotechnology industry could also result in greater governmental regulation, stricter labeling requirements and potential regulatory delays in the testing or approval of our potential products. Any increased scrutiny could delay or increase the costs of our product development efforts or clinical trials. In addition, any adverse events that may occur in our clinical trials and any resulting publicity may cause regulatory delays or otherwise affect our product development efforts or clinical trials.

Some of our potential products may be administered to patients who are suffering from, or are vulnerable to, serious diseases or other conditions which can themselves be life-threatening and often result in the death of the patient. Patient deaths in our clinical trials, even if caused by pre-existing diseases or conditions, could negatively affect the perception of our product candidates. In addition, although we do not believe our vaccine candidates could cause the diseases they are designed to protect against, a temporal relationship between vaccination and disease onset could be perceived as causal. Some of our products are designed to stimulate

immune responses, and those responses, if particularly strong or uncontrolled, could result in local or systemic adverse events, including latent adverse events.

(\*)Our patents and proprietary rights may not provide us with any benefit and the patents of others may prevent us from commercializing our products.

As of March 31, 2017, we were the assignee or co-assignee of 53 issued U.S. and foreign patents. We maintain our issued patents by paying maintenance fees to the patent office in each country when due. Where appropriate, we participate in legal proceedings to vigorously defend against the revocation or withdrawal of our patents. The scope and nature of these proceedings generally differ depending on the country in which they are initiated. If we are not successful in defending our patents, we may lose all or part of our proprietary rights related to those patents in these geographic regions.

As of March 31, 2017, we were also prosecuting one pending patent application in the United States and in foreign countries that cover various aspects of our proprietary technologies, not including patent applications for which we are a co-assignee and that are being prosecuted by our partners.

We may not receive any patents from our current patent applications. Issued patents provide exclusivity for only a limited time period, after which they no longer serve to protect proprietary technologies or to provide any commercial advantage. Moreover, if patents are issued to us, governmental authorities may not allow claims sufficient to protect our technologies and products. Others may also challenge or seek to circumvent or invalidate our patents. In that event, the rights granted under our patents may be inadequate to protect our proprietary technologies or to provide any commercial advantage.

In addition, the Leahy-Smith America Invents Act, or AIA, was signed into law on September 16, 2011, and significantly changed certain aspects of the United States patent laws. These changes include, but are not limited to, authorizing fee setting authority to the United States Patent Office, transitioning the United States to a first-inventor-to-file patent system, expanding the scope of prior art that may be utilized against a pending patent application, and adding post-patent grant proceedings before the Patent Office in which third parties may challenge the validity of the granted patent. It is not clear, what, if any, impact the AIA will have on the cost of prosecuting our patent applications, our ability to obtain patents based on our patent applications, and our ability to enforce or defend our issued or granted United States patents. An inability to obtain, enforce, and defend patents covering our proprietary technologies would materially and adversely affect our business prospects and financial condition.

Some components of our gene-based product candidates are, or may become, patented by others. As a result, we may be required to obtain licenses to conduct research, to manufacture, or to market such products. Licenses may not be available on commercially reasonable terms, or at all, which may impede our ability to commercialize our products.

The legal proceedings to obtain and defend patents, and litigation of third-party claims of intellectual property infringement, could require us to spend money and could impair our operations.

Our and our collaborators', including Astellas', success will depend in part on our, or our collaborators', ability to obtain patent protection for our products and processes, both in the United States and in other countries. The patent positions of biotechnology and pharmaceutical companies, however, can be highly uncertain and involve complex legal and factual questions. Therefore, it is difficult to predict the breadth of claims allowed in the biotechnology and pharmaceutical fields.

We also rely on confidentiality agreements with our corporate collaborators, employees, consultants and certain contractors to protect our proprietary technologies. However, these agreements may be breached and we may not have

adequate remedies for such breaches. In addition, our trade secrets may otherwise become known or independently discovered by our competitors.

Protecting intellectual property rights can be very expensive. Litigation may be necessary to enforce patents issued to us or to determine the scope and validity of third-party proprietary rights. If we or, as applicable, our commercialization partners, including Astellas pursuant to its first right to enforce patents licensed to it under our license agreements, choose to go to court to stop someone else from using our inventions, that individual or company has the right to ask the court to rule that the underlying patents are invalid and/or should not be enforced against that third party. Moreover, if a competitor were to file a patent application claiming technology also invented by us or our collaborators or licensees, we would have to participate in an interference proceeding before the U.S. Patent and Trademark Office to determine the priority of the invention. We or our collaborators or licensees may be drawn into interferences with third parties or may have to provoke interferences ourselves to unblock third-party patent rights to allow us or our collaborators or licensees to commercialize products based on our technologies. Litigation could result in substantial costs and the diversion of management's efforts regardless of the results of the litigation. An unfavorable result in litigation could subject us to significant liabilities to third parties, require disputed rights to be licensed or require us to cease using some technologies.

Our products and processes may infringe, or be found to infringe, patents not owned or controlled by us. Patents held by others may require us to alter our products or processes, obtain licenses, or stop activities. If relevant claims of third-party patents are upheld as valid and enforceable, we or our collaborators or licensees could be prevented from practicing the subject matter claimed in the patents, or may be required to obtain licenses or redesign our products or processes to avoid infringement. In addition, we or our collaborators or licensees could be required to pay money damages. A number of genetic sequences or proteins encoded by genetic sequences that we are investigating are, or may become, patented by others. As a result, we or our collaborators or licensees may have to obtain licenses to test, use or market these products. Our business will suffer if we or our collaborators or licensees are not able to obtain licenses at all or on terms commercially reasonable to us or them and we or they are not able to redesign our products or processes to avoid infringement.

We have incurred costs in several legal proceedings involving our intellectual property rights in Europe, Japan and Canada. We may continue to incur costs to defend and prosecute patents and patent applications in these and other regions.

Competition and technological change may make our product candidates and technologies less attractive or obsolete.

We compete with companies, including major pharmaceutical and biotechnology firms that are pursuing other forms of treatment or prevention for diseases that we target. We also may experience competition from companies that have acquired or may acquire technologies from universities and other research institutions. As these companies develop their technologies, they may develop proprietary positions which may prevent us from successfully commercializing products.

Some of our competitors are established companies with greater financial and other resources than we have. Other companies may succeed in developing products and obtaining regulatory approval from the FDA or comparable foreign agencies faster than we do, or in developing products that are more effective than ours. Research and development by others may seek to render our technologies or products obsolete or noncompetitive or result in treatments or cures superior to any therapeutics developed by us.

The internet site [ClinicalTrials.gov](http://ClinicalTrials.gov) provides public access to information on clinical trials and their results for a wide range of diseases and conditions. Future disclosures of such confidential commercial information may result in loss of advantage of competitive secrets.

If we lose our key personnel or are unable to attract and retain additional personnel, we may not be able to achieve our business objectives.

We are highly dependent on our principal scientific, manufacturing, clinical, regulatory and management personnel, including Vijay B. Samant, our President and Chief Executive Officer. The loss of the services of these individuals might significantly delay or prevent the achievement of our objectives. We do not maintain “key person” life insurance on any of our personnel. We depend on our continued ability to attract, retain and motivate highly qualified management and scientific personnel. We face competition for qualified individuals from other companies, academic institutions, government entities and other organizations in attracting and retaining personnel. To pursue our product development plans, we may need to hire additional management personnel and additional scientific personnel to perform research and development, as well as additional personnel with expertise in clinical trials, government regulation and manufacturing. However, due to the reasons noted above, we may not be successful in hiring or retaining qualified personnel and therefore we may not be able to achieve our business objectives.

We have limited experience in manufacturing our product candidates in commercial quantities. We may not be able to comply with applicable manufacturing regulations or produce sufficient product for contract or commercial purposes.

The commercial manufacturing of vaccines and other biological products is a time-consuming and complex process, which must be performed in compliance with the FDA's cGMP regulations. We may not be able to comply with the cGMP regulations, and we have in the past encountered and may in the future encounter delays, disruptions or quality control problems in our manufacturing process. In addition, we may need to complete the installation and validation of additional large-scale fermentation and related purification equipment to produce the quantities of product expected to be required for commercial purposes. We have limited experience in manufacturing at this scale. We will also depend on third parties for any commercial scale filling of product vials. Moreover, our manufacturing processes may be disrupted if we do not extend the lease for our existing facility or find adequate replacement space sufficiently in advance of the expiration of our current lease term in December 2018. Noncompliance with the cGMP regulations, the inability to complete the installation or validation of additional large-scale equipment, the inability to secure adequate space to conduct our manufacturing activities or other problems with our manufacturing process may limit or delay the development or commercialization of our product candidates, and cause us to breach our contract manufacturing service arrangements or our obligations under our agreements with collaborators, including our obligations under our supply and services agreement with Astellas.



We currently depend on third parties to conduct our clinical trials and may initially depend on third parties to manufacture our product candidates commercially.

We rely on third parties, including clinical research organizations, medical institutions and contract laboratories, to perform critical services for us in connection with our clinical trials. These third parties are responsible for many aspects of the trials, including finding and enrolling subjects for testing and administering the trials. Although we rely on these third parties to conduct our clinical trials, we are responsible for ensuring that each of our clinical trials is conducted in accordance with its protocol and applicable regulations, including good clinical practices established by the FDA and foreign regulatory authorities, which govern the conduct, monitoring, recording and reporting the results of clinical trials to ensure that the data and results are scientifically credible and accurate, and that trial subjects are adequately informed of the potential risks associated with participating in clinical trials. Our reliance on third parties does not relieve us of the responsibility to ensure these requirements are met. These third parties may not comply with all regulatory and contractual requirements or may not otherwise perform their services in a timely or acceptable manner, and we may need to enter into new arrangements with alternative third parties and our clinical trials may be extended, delayed or terminated. In addition, if such third parties fail to perform their obligations in compliance with our clinical trial protocols or applicable good clinical practice regulations, our clinical trials may not meet regulatory requirements or may need to be repeated, and we may not be able to obtain regulatory approval for or commercialize the product candidate being tested in such trials. These risks also apply to the development activities of our collaborators and licensees, and we do not control our collaborators' and licensees' research and development, clinical trials or regulatory activities.

We may also initially depend on collaborators, licensees or other third parties to manufacture our product candidates in commercial quantities. There are a limited number of third parties that could manufacture our product candidates. We may be unable to enter into any arrangement for the commercial manufacture of our product candidates, and any arrangement we secure may not meet our requirements for manufacturing quality or quantity. Our dependence on third parties for the commercial manufacture of our product candidates may also reduce our profit margins and our ability to develop and deliver products in a timely manner.

We have no marketing or sales experience, and if we are unable to develop our own sales and marketing capability, we may not be successful in commercializing our products.

Our current strategy is to market our proprietary products directly in the United States, but we currently do not possess pharmaceutical marketing or sales capabilities. To market and sell our proprietary products, we will need to develop a sales force and a marketing group with relevant pharmaceutical industry experience, or make appropriate arrangements with strategic partners to market and sell these products. Developing a marketing and sales force is expensive and time-consuming and could delay any product launch. If we are unable to successfully employ qualified marketing and sales personnel or develop other sales and marketing capabilities, we may not be able to generate sufficient product revenue to become profitable.

(\*)If we fail to comply with federal and state healthcare laws, including fraud and abuse, transparency, and health information privacy and security laws, we could face substantial penalties and our business, results of operations, financial condition and prospects could be adversely affected.

Our business operations and current and future arrangements with investigators, healthcare professionals, consultants, third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations. These laws may constrain the business or financial arrangements and relationships through which we conduct our operations, including how we research, market, sell and distribute any product for which we obtain marketing approval. Such laws include:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward, or in return for, 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 a federal healthcare program, such as Medicare or Medicaid;
- the federal false claims and civil monetary penalties laws, including the civil False Claims Act and its qui tam or whistleblower provisions, which impose criminal and civil penalties against individuals or entities for, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal and civil liability for, among other things, executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;

HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and its implementing regulations, which imposes obligations, including mandatory contractual terms, on certain types of individuals and entities and their respective business associates with respect to safeguarding the privacy, security and transmission of individually identifiable health information;

the federal Physician Payments Sunshine Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to report annually to the Centers for Medicare & Medicaid Services, or CMS, information related to payments or other transfers of value made to physicians and teaching hospitals, and applicable manufacturers and applicable group purchasing organizations to report annually to CMS ownership and investment interests held by the physicians and their immediate family members; and

analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by third-party payors, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government; state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians, other healthcare providers, and healthcare entities, or marketing expenditures; and state and foreign laws governing the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Efforts to ensure that our current and future business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, agency guidance or case law involving applicable healthcare laws. If our operations are found to be in violation of any of these or any other health regulatory laws that may apply to us, we may be subject to significant penalties, including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgement, individual imprisonment, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, additional integrity obligations, such as additional reporting and/or oversight requirements if we become subject to a corporate integrity agreement or similar agreement with a governmental authority, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations. Defending against any such actions can be costly, time-consuming and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired.

(\*)Healthcare reform and restrictions on reimbursement may limit our returns on potential products.

Our ability to earn sufficient returns on our products will depend in part on how much, if any, reimbursement for our products and related treatments will be available from:

- Government health administration authorities;
- Government agencies procuring biodefense products for military or public use, including some for which we may become a sole-source vendor;
- Private health coverage insurers;
- Managed care organizations; and
- Other organizations.

Such third-party payers decide which drugs and treatments they will cover and the amount of reimbursement, and no uniform policy exists. Therefore, coverage and reimbursement for products can differ significantly from payer to payer. Further, the coverage determination process is a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payer separately. Patients rely on third-party payers to reimburse all or part of the cost associated with treatment. If we fail to obtain adequate reimbursement, we

could be prevented from successfully commercializing our potential products.

There are ongoing efforts by governmental and third-party payers to contain or reduce the costs of healthcare through various reform measures. In the United States, the Federal government passed comprehensive healthcare reform legislation, the ACA, in 2010, which Congress may consider legislation to repeal or replace. In January 2017, President Trump signed an Executive Order directing federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal or regulatory burden on states, individuals, healthcare

providers, health insurers, or manufacturers of pharmaceuticals or medical devices. In March 2017, following the passage of the budget resolution for fiscal year 2017, the U.S. House of Representatives introduced legislation known as the American Health Care Act, which, if enacted, would have amended or repealed significant portions of the ACA. However, consensus over the scope of the American Health Care Act could not be reached by its proponents in the U.S. House of Representatives. Thus, the proposed legislation has been withdrawn and the prospects for legislative action on this bill are uncertain. Congress could consider other legislation to repeal or replace certain elements of the ACA. We continue to evaluate the effect that the ACA and its possible repeal and replacement has on our business.

In addition, drug pricing by pharmaceutical companies has recently come under increased scrutiny. Specifically, there have been several recent U.S. Congressional inquiries and proposed federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the out-of-pocket cost of prescription drugs, review the relationship between pricing and manufacturer patient programs, reduce the cost of drugs under Medicare, and reform government program reimbursement methodologies. Further, third-party payers are increasingly challenging the price of medical products and services. If purchasers or users of our products are not able to obtain adequate reimbursement for the cost of using our products, they may forego or reduce their use. Significant uncertainty exists as to the reimbursement status of newly approved healthcare products, and whether adequate third-party coverage will be available.

We use hazardous materials in our business. Any claims relating to improper handling, storage or disposal of these materials could be time consuming and costly.

Our research and development processes involve the controlled storage, use and disposal of hazardous materials and biological materials. Our hazardous materials include certain compressed gases, flammable liquids, acids and bases, and other toxic compounds. We are subject to federal, state and local regulations governing the use, manufacture, storage, handling and disposal of materials and waste products. Although we believe that our safety procedures for handling and disposing of these hazardous materials comply with the standards prescribed by law and regulation, the risk of accidental contamination or injury from hazardous materials cannot be completely eliminated. In the event of an accident, we could be held liable for any damages that result. We could incur significant costs to comply with current or future environmental laws and regulations.

We may have significant product liability exposure.

We face an inherent business risk of exposure to product liability and other claims in the event that our technologies or products are alleged to have caused harm. We also have potential liability for products manufactured by us on a contract basis for third parties. Although we currently maintain product liability insurance in the amount of \$10 million in the aggregate plus additional coverage specific to the foreign countries where our clinical trials are being conducted, this insurance coverage may not be sufficient, and we may not be able to obtain sufficient coverage in the future at a reasonable cost. Our inability to obtain product liability insurance at an acceptable cost or to otherwise protect against potential product liability claims could prevent or inhibit the commercialization of any products developed by us or our collaborators, or our ability to manufacture products for third parties. If we are sued for any injury caused by our technologies or products, or by third-party products that we manufacture, our liability could exceed our insurance coverage and total assets.

(\*)Our stock price could continue to be highly volatile and you may not be able to resell your shares at or above the price you pay for them.

The market price of our common stock, like that of many other life sciences companies, has been and is likely to continue to be highly volatile. From January 1, 2014, to March 31, 2017, our stock price has ranged from \$2.05 to \$17.90. The following factors, among others, could have a significant impact on the market price of our common

stock:

- The results of our preclinical studies and clinical trials or announcements regarding our plans for future studies or trials, or those of our collaborators, licensees or competitors;
- Evidence or lack of evidence of the safety or efficacy of our potential products or those of our collaborators, licensees or competitors;
- The success of our collaborators and licensees, including Astellas, in the development or commercialization of our product candidates;
- The announcement by us or our collaborators, licensees or competitors of technological innovations or new products;
- Developments concerning our patent or other proprietary rights or those of our collaborators, licensees or competitors, including litigation and challenges to our proprietary rights;

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- Other developments with our collaborators or licensees, including our entry into new collaborative or licensing arrangements;
- Geopolitical developments, natural or man-made disease threats, or other events beyond our control;
- U.S. and foreign governmental regulatory actions;
- Changes or announcements in reimbursement policies;
- Period-to-period fluctuations in our operating results;
- Market conditions for life science stocks in general;
- Changes in the collective short interest in our stock;
- Changes in estimates of our performance by securities analysts; and
- Our cash balances, need for additional capital, and access to capital.

We are at risk of future securities class action litigation due to our past and expected stock price volatility.

In the past, stockholders have brought securities class action litigation against a company following a decline in the market price of its securities. This risk is especially acute for us because life science companies have experienced greater than average stock price volatility in recent years and, as a result, have been subject to, on average, a greater number of securities class action claims than companies in other industries. Even if such claims are not successful, any litigation could result in substantial costs and divert our management's attention and resources, which could have a material adverse effect on our business, operating results or financial condition.

Anti-takeover provisions in our charter documents and under Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.

Our certificate of incorporation and bylaws include anti-takeover provisions, such as a classified board of directors, a prohibition on stockholder actions by written consent, the authority of our board of directors to issue preferred stock without stockholder approval, and supermajority voting requirements for specified actions. In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which generally prohibits stockholders owning in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years. These provisions may delay or prevent an acquisition of us, even if the acquisition may be considered beneficial by some stockholders. In addition, they may discourage or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, which is responsible for appointing the members of our management.

In addition, we recently completed a private placement of common stock to AnGes, immediately following which AnGes owned approximately 18.6% of our outstanding shares. In connection with the private placement, AnGes agreed to vote all of its shares in accordance with the recommendations of our board of directors on any matter brought before our stockholders for a vote, subject to certain limitations. This voting provision may also discourage or prevent attempts by other stockholders to replace members of our board of directors or engage in acquisition activities that our board of directors does not determine to be in the best interests of our stockholders.

The issuance of preferred stock could adversely affect our common stockholders.

We currently have on file a shelf registration statement that allows us to raise up to an aggregate of \$100.0 million from the sale of common stock, preferred stock, debt securities and/or warrants and our restated certificate of incorporation authorizes us to issue up to 5,000,000 shares of preferred stock. The issuance of preferred stock could adversely affect the voting power of holders of our common stock, and reduce the likelihood that our common stockholders will receive dividend payments and payments upon liquidation. The issuance of preferred stock could also decrease the market price of our common stock, or have terms and conditions that could discourage a takeover or

other transaction that might involve a premium price for our shares or that our stockholders might believe to be in their best interests.



ITEM 6. EXHIBITS

Exhibit

Number Description of Document

- 3.1(1) Restated Certificate of Incorporation.
- 3.2(2) Amended and Restated Bylaws.
- 3.3(3) Certificate of Amendment to Restated Certificate of Incorporation.
- 3.4(4) Certificate of Amendment to Restated Certificate of Incorporation.
- 3.5(5) Certificate of Amendment to Restated Certificate of Incorporation.
- 4.1(1) Specimen Common Stock Certificate.
- 31.1 Certification of Vijay B. Samant, Chief Executive Officer and acting Chief Financial Officer, pursuant to Rules 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- 32.1 Certification of Vijay B. Samant, Chief Executive Officer and acting Chief Financial Officer, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
- 101.INS XBRL Instance Document.
- 101.SCH XBRL Taxonomy Extension Schema Document.
- 101.CAL XBRL Taxonomy Extension Calculation Linkbase Document.
- 101.DEF XBRL Taxonomy Extension Definition Linkbase.
- 101.LAB XBRL Taxonomy Extension Label Linkbase Document.
- 101.PRE XBRL Taxonomy Extension Presentation Linkbase Document.

- (1) Incorporated by reference to the exhibit of the same number filed with the Company's Registration Statement on Form S-3 (No. 33-95812) filed on August 15, 1995.
- (2) Incorporated by reference to the exhibit of the same number filed with the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2010.
- (3) Incorporated by reference to exhibit 3.1 to the Company's Current Report on Form 8-K filed on May 25, 2016.
- (4) Incorporated by reference to exhibit 3.3(i) filed with the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2010.
- (5) Incorporated by reference to exhibit 4.2 filed with the Company's Registration Statement on Form S-8 (No. 333-135266) filed on June 23, 2006.

SIGNATURE

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.

Vical Incorporated

Date: May 15,  
2017

By: /s/ ANTHONY A. RAMOS

Anthony A. Ramos

VP Finance, Chief Accounting Officer (on behalf of the registrant and as the registrant's  
Principal Accounting Officer)