VICAL INC
Form 10-Q
May 10, 2013
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

x **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the quarterly period ended March 31, 2013

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 incorporation or organization)	**(I.R.S. Employer Identification No.)**
10390 Pacific Center Court San Diego, California	**92121**
(Address of principal executive offices)	**(Zip code)**

(858) 646-1100

(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 x 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) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x No ¨

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

Large accelerated filer ¨ Accelerated filer x Non-accelerated filer ¨ Smaller reporting company ¨

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

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 22, 2013: 86,448,194

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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, 2013	December 31, 2012
ASSETS		
Current assets:		
Cash and cash equivalents	$ 47,026	$ 43,159
Marketable securities, available-for-sale	25,352	37,639
Restricted cash	3,059	3,059
Receivables and other assets	2,390	2,152
Total current assets	77,827	86,009
Long-term investments	2,197	2,225
Property and equipment, net	5,042	5,284
Intangible assets, net	2,742	2,813
Other assets	191	191
Total assets	$ 87,999	$ 96,522
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable and accrued expenses	$ 5,109	$ 5,629
Deferred revenue	167	150
Total current liabilities	5,276	5,779
Long-term liabilities:		
Deferred rent	1,569	1,657
Commitments and contingencies		
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, 86,311 and 86,136 shares issued and outstanding at March 31, 2013, and December 31, 2012, respectively	863	861
Additional paid-in capital	437,276	435,915
Accumulated deficit	(357,219)	(347,937)
Accumulated other comprehensive income	234	247
Total stockholders equity	81,154	89,086

Total liabilities and stockholders equity	$ 87,999	$ 96,522

See accompanying notes to unaudited financial statements

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VICAL INCORPORATED

STATEMENTS OF OPERATIONS

(In thousands, except per share data)

(Unaudited)

	Three Months Ended March 31,	
	2013	**2012**
Revenues:		
Contract and grant revenue	$ 1,136	$ 1,221
License and royalty revenue	438	10,239
Total revenues	1,574	11,460
Operating expenses:		
Research and development	3,650	6,428
Manufacturing and production	3,713	2,472
General and administrative	3,518	2,700
Total operating expenses	10,881	11,600
Loss from operations	(9,307)	(140)
Other income (expense):		
Investment and other income, net	25	384
Net income (loss)	$ (9,282)	$ 244
Basic net income (loss) per share	$ (0.11)	$ 0.00
Diluted net income (loss) per share	$ (0.11)	$ 0.00
Weighted average shares used in computing basic net income (loss) per share	86,638	84,519
Weighted average shares used in computing diluted net income (loss) per share	86,638	86,124

See accompanying notes to unaudited financial statements

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VICAL INCORPORATED

STATEMENTS OF COMPREHENSIVE LOSS

(In thousands)

(unaudited)

	Three Months Ended March 31,	
	2013	**2012**
Net income (loss)	$ (9,282)	$ 244
Other comprehensive loss:		
Unrealized (losses) gains on available-for-sale and long-term marketable securities:		
Unrealized (losses) gains arising during holding period	(13)	196
Less: Reversal of unrealized losses in accumulated other comprehensive loss upon the sale of long-term marketable securities included in investment and other income		(590)
Other comprehensive loss	(13)	(394)
Total comprehensive loss	$ (9,295)	$ (150)

See accompanying notes to financial statements

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VICAL INCORPORATED

STATEMENTS OF CASH FLOWS

(In thousands)

(Unaudited)

	Three Months Ended March 31,	
	2013	**2012**
Cash flows from operating activities:		
Net income (loss)	$ (9,282)	$ 244
Adjustments to reconcile net income (loss) to net cash used in operating activities:		
Depreciation and amortization	506	493
Write-off of abandoned patents	81	20
Gain on sale of property and equipment		(6)
Compensation expense related to stock options and awards	1,138	920
Changes in operating assets and liabilities:		
Receivables and other assets	(238)	(10,412)
Accounts payable and accrued expenses	(535)	889
Deferred revenue	17	(99)
Deferred rent	(72)	(57)
Net cash used in operating activities	(8,385)	(8,008)
Cash flows from investing activities:		
Proceeds from the sale of marketable securities		3,750
Maturities of marketable securities	12,594	5,261
Purchases of marketable securities	(293)	(17,659)
Purchases of property and equipment	(164)	(135)
Proceeds from the sale of property and equipment		6
Patent expenditures	(110)	(97)
Net cash provided by (used in) investing activities	12,027	(8,874)
Cash flows from financing activities:		
Net proceeds from issuance of common stock	328	48,770
Payment of withholding taxes for net settlement of restricted stock units	(103)	(109)
Net cash provided by financing activities	225	48,661
Net increase in cash and cash equivalents	3,867	31,779
Cash and cash equivalents at beginning of period	43,159	38,696
Cash and cash equivalents at end of period	$ 47,026	$ 70,475

See accompanying notes to unaudited financial statements

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VICAL INCORPORATED

NOTES TO FINANCIAL STATEMENTS

March 31, 2013

(Unaudited)

1. GENERAL

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 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 grant and contract arrangements with government entities. 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, 2013, and for the three months ended March 31, 2013 and 2012, 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 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 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, 2012, included in its Annual Report on Form 10-K filed with the SEC.

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. 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, 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 term of its primary facilities lease, which ends in August 2017. Under certain circumstances, the Company may be able to eliminate the need for the letter of credit. As of March 31, 2013, and December 31, 2012, restricted cash of $3.1 million was pledged as collateral for this letter of credit.

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 of the Company s revenue is generated through manufacturing contracts and stand-alone license agreements.

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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 partnership agreements provide for milestone payments upon achievement of certain regulatory and commercial events. 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 three 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 partners incorporating the Company s licensed technology are recognized when received.

Net Income (Loss) Per Share

Basic and diluted net income (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 net loss per share excludes any assumed exercise of stock options and warrants, and any assumed issuance of common stock under restricted stock units, or RSUs, as the effect would be antidilutive. Common stock equivalents totaling 1.6 million shares for the three months ended March 31, 2013, were excluded from the calculation of diluted net loss per share because of their antidilutive effect. Common stock equivalents totaling 1.6 million shares for the three months ended March 31, 2012, were included in the calculation of diluted net income per share.

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Recent Accounting Pronouncement

Effective January 1, 2013, the Company adopted Accounting Standards Update (ASU) No. 2013-02, Reporting of Amounts Reclassified Out of Accumulated Other Comprehensive Income. The adoption of ASU No. 2013-02 concerns presentation and disclosure only and did not have an impact on the Company s financial position or results of operations. The Company elected to present the information required by ASU No. 2013-02 in the Statements of Comprehensive Loss.

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,	
	2013	**2012**
Research and development	$ 312	$ 287
Manufacturing and production	68	49
General and administrative	758	584
Total stock-based compensation expense	$ 1,138	$ 920

During the three months ended March 31, 2013 and 2012, the Company granted stock-based awards with a total estimated value of $3.1 million and $3.6 million, respectively. At March 31, 2013, total unrecognized estimated compensation expense related to unvested stock-based awards granted prior to that date was $4.3 million, which is expected to be recognized over a weighted-average period of 1.5 years. Stock-based awards granted during the three months ended March 31, 2013 and 2012, were equal to 1.8% and 1.9%, respectively, of outstanding shares of common stock at the end of the applicable period.

3. OTHER BALANCE SHEET ACCOUNTS

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

	March 31, 2013	**December 31, 2012**
Employee compensation	$ 2,392	$ 3,858
Post-termination benefit accrual	463	
Clinical trial accrual	708	660
Accounts payable	645	377
Deferred rent	322	307
Other accrued liabilities	579	427
Total accounts payable and accrued expenses	$ 5,109	$ 5,629

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4. MARKETABLE SECURITIES, AVAILABLE FOR SALE

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

March 31, 2013	Amortized Cost	Unrealized Gain	Unrealized Loss	Market Value
U.S. treasuries	$ 7,574	$ 2	$	$ 7,576
Government-sponsored enterprise securities	7,751			7,751
Corporate bonds	9,246		6	9,240
Certificates of deposit	785			785
	$ 25,356	$ 2	$ 6	$ 25,352

December 31, 2012	Amortized Cost	Unrealized Gain	Unrealized Loss	Market Value
U.S. treasuries	$ 10,135	$ 1	$	$ 10,136
Government-sponsored enterprise securities	15,507		1	15,506
Corporate bonds	11,509		8	11,501
Certificates of deposit	496			496
	$ 37,647	$ 1	$ 9	$ 37,639

At March 31, 2013, $7.8 million 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, 2013. As of March 31, 2013, none of the securities had been in a continuous unrealized loss position longer than one year.

5. LONG-TERM INVESTMENTS

In March 2012, the Company sold two auction rate securities classified as long-term investments with a par value of $4.0 million. Included in interest and other income for the three months ended March 31, 2012, is a gain of $0.3 million related to the sale.

As of March 31, 2013, 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 BBB by Standard and Poor s as of March 31, 2013. 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, collateralization 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. Based on the valuation of the security, the Company has recognized cumulative losses of $0.5 million as of March 31, 2013, none of which were recognized during the three months ended March 31, 2013. 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 losses of $17,000 and $6,000 for the three months ended March 31, 2013 and 2012, respectively. As of March 31, 2013, the Company had recorded cumulative unrealized gains of $0.4 million. The resulting carrying value of the auction rate security at March 31, 2013, was $2.2 million. Any future decline in market value may result in additional losses being recognized.

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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			
March 31, 2013	**Level 1**	**Level 2**	**Level 3**	**Total**
Certificates of deposit	$ 785	$	$	$ 785
Money market funds	19,816			19,816
U.S. treasuries	7,576			7,576
Corporate bonds		9,240		9,240
Government-sponsored enterprise securities		7,751		7,751
Auction rate securities			2,197	2,197
	$ 28,177	$ 16,991	$ 2,197	$ 47,365

	Fair Value Measurements			
December 31, 2012	**Level 1**	**Level 2**	**Level 3**	**Total**
Certificates of deposit	$ 496	$	$	$ 496
Money market funds	18,500			18,500
U.S. treasuries	10,136			10,136
Corporate bonds		11,501		11,501
Government-sponsored enterprise securities		15,506		15,506
Auction rate securities			2,225	2,225
	$ 29,132	$ 27,007	$ 2,225	$ 58,364

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, 2013. 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. The Company did not adjust any of the valuations received from these independent third parties with respect to any of its level 2 securities at March 31, 2013. The Company did not reclassify any investments

between level categories during the three months ended March 31, 2013. The valuation of the Company s investments in auction rate securities, which includes significant unobservable inputs, is more fully described in Note 5.

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

	Three Months Ended March 31, 2013
Balance at December 31, 2012	$ 2,225
Total net unrealized losses included in other comprehensive income	(28)
Balance at March 31, 2013	$ 2,197
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

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

In the ordinary course of business, the Company may become a party to 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.

8. STOCKHOLDERS EQUITY

In January 2012, the Company sold 13,333,334 shares of its common stock in a public offering at a price to the public of $3.75 per share. In February 2012, the Company sold an additional 576,358 shares pursuant to a partial exercise of the underwriters overallotment option at a price to the public of $3.75 per share. Net proceeds from the offering, after deducting underwriting discounts and commissions and other offering expenses payable by the Company, totaled $48.7 million. All of the shares of common stock were offered pursuant to two effective shelf registration statements.

In November 2012, the Company entered into an At-The-Market Equity Offering Sales Agreement, or Sales Agreement, with Stifel, Nicolaus & Company, Incorporated, or Stifel, under which the Company may issue and sell up to $50,000,000 of shares of its common stock from time to time. Under the Sales Agreement, the Company will set the parameters for the sale of shares, including the number of shares to be issued and any minimum price below which sales may not be made. Subject to the terms and conditions of the Sales Agreement, shares may be sold through Stifel acting as sales agent or directly to Stifel acting as principal, by means of ordinary brokers transactions on the Nasdaq Global Select Market, in privately negotiated transactions or otherwise at market prices prevailing at the time of sale, at prices related to prevailing market prices or at negotiated prices.

9. ASTELLAS 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, or CMV, glycoprotein B and/or phosphoprotein 65, including TransVax but excluding CyMVectin .

Under the terms of the license agreements, Astellas paid a nonrefundable upfront license fee of $25.0 million in 2011. The Company also received a $10.0 million milestone payment in March 2012 upon finalization of the general trial design for a Phase 3 registration trial of TransVax in hematopoietic stem cell transplant recipients. The Company recognized $0.1 million and $10.1 million in license revenue under the Astellas agreements during the three months ended March 31, 2013 and 2012, respectively.

Under the terms of the agreements, the Company is also performing research and development services which are being paid for by Astellas. During the three months ended March 31, 2013 and 2012, the Company recognized $1.1 million and $1.0 million, respectively, of revenue related to these contract services.

In August 2012, the Company amended its license and supply agreements with Astellas to, among other things, extend the time period that the Company is obligated to supply licensed products for commercial use to Astellas, at Astellas expense, modify the allocation of $95.0 million of milestone payments among certain milestones through commercial launch and modify the structure of the royalties on net sales from a fixed double digit royalty to tiered double digit royalties.

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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, and Section 21E of the Securities Exchange Act of 1934, as amended, including statements regarding our business, our financial position, the research and development of biopharmaceutical products based on our patented DNA delivery 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 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, 2012, and in our other filings with the SEC, and those identified in Part II, Item 1A entitled Risk Factors beginning on page 20 of this Report. 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 based on our patented DNA delivery technologies for the prevention and treatment of serious or life-threatening diseases. We believe the following areas of research offer the greatest potential for near-term commercialization for us and our partners:

- Vaccines for use in high-risk populations for infectious disease targets for which there are significant needs;
- Vaccines for general pediatric, adolescent and adult populations for infectious disease applications;
- Cancer vaccines or immunotherapies that complement our existing programs and core expertise; and
- Gene-based delivery of therapeutic proteins, such as angiogenic growth factors for treatment of cardiovascular diseases.

We currently have three active independent clinical and preclinical development programs in the areas of infectious disease and cancer including:

- A fully enrolled ongoing Phase 3 clinical trial using our Allovectin® immunotherapeutic in patients with metastatic melanoma which has been funded, up to certain limits, by AnGes MG, Inc., or AnGes, through cash payments and equity investments under a research and development agreement;
- A completed preclinical program, with an allowed investigational new drug application, or IND, using our CyMVectin prophylactic vaccine formulated with our proprietary Vaxfectin® adjuvant to prevent cytomegalovirus, or CMV, infection before and during pregnancy; and
- A preclinical program with therapeutic and prophylactic vaccines for herpes simplex virus type 2, or HSV-2, formulated with our proprietary Vaxfectin® adjuvant.

We have leveraged our patented technologies through licensing and collaboration arrangements, such as our licensing arrangements with Astellas Pharma Inc., or Astellas, Merck & Co., Inc., or Merck, Sanofi, AnGes, Aqua Health Ltd. of Canada, or Aqua Health, an affiliate of Novartis Animal Health, and Merial Limited, or Merial, a subsidiary of Sanofi, among other biopharmaceutical companies.

In addition, we have licensed complementary technologies from leading research institutions and biopharmaceutical companies. We also have granted non-exclusive, academic licenses to our DNA delivery technology patent estate to 11 leading research institutions including Stanford,

Harvard, Yale and the Massachusetts Institute of Technology. The non-exclusive academic licenses allow university researchers to use our technology free of charge for educational and internal, non-commercial research purposes. In exchange, we have the option to exclusively license from the universities potential commercial applications arising from their use of our technology on terms to be negotiated.

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Product Development

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

Product/Concept	Intended Use	Development Status[1]	Lead Developer
Independent Programs			
Allovectin® cancer immunotherapeutic	First-line treatment for metastatic melanoma	Phase 3	Vical
CyMVectin prophylactic vaccine for CMV	Prevent infection before pregnancy to preclude fetal transmission	Preclinical complete	Vical
Therapeutic and prophylactic vaccines for HSV-2	Prevent and protect against recurring flare-ups, reduce viral shedding and transmission	Preclinical	Vical
Corporate Collaborations			
TransVax therapeutic vaccine for CMV	Protect against CMV infection after stem cell transplants	Phase 3 preparation	Astellas
TransVax therapeutic vaccine for CMV	Protect against CMV infection after solid organ transplants	Phase 2 preparation	Astellas
Collategene® angiogenic therapy encoding Hepatocyte Growth Factor	Induce local growth of blood vessels to restore blood flow to limbs affected by critical limb ischemia	Phase 3 preparation	AnGes
Apex®-IHN prophylactic vaccine for infectious hematopoietic necrosis virus	Prevent infection and disease in farm-raised salmon when exposed to infected wild salmon	Marketed in Canada	Aqua Health (Novartis)
ONCEPT® therapeutic cancer vaccine encoding human tyrosinase	Adjunct treatment to increase survival time of dogs with oral melanoma	Marketed in the United States	Merial
Government Collaboration			
Tetravalent dengue vaccine	Prevent dengue disease caused by all 4 dengue serotypes	Phase 1	Naval Medical Research Center

[1] Preclinical 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.

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Recent Events

The following event has recently occurred with respect to our business and our development programs:

Effective January 2, 2013, listing of our common stock was transferred to the NASDAQ Global Select Market, the highest of the three market tiers at NASDAQ.

In February 2013, we announced the publication of a new article in the journal *Vaccine* detailing results from our completed guinea pig studies with our Vaxfectin®-formulated plasmid DNA vaccines against HSV-2. These results, along with previously published results from mouse studies, support our decision to advance toward clinical testing, which we expect to begin in the second half of 2013.

On March 15, 2013, Jill M. Broadfoot notified us that she was resigning as the Company s Senior Vice President, Chief Financial Officer and Secretary. On the same date, we entered into a separation agreement with Ms. Broadfoot. Pursuant to the terms of the separation agreement, Ms. Broadfoot s last day of employment was April 1, 2013.

The National Institute of Allergy and Infectious Diseases, or NIAID, part of the National Institutes of Health, or NIH, began a Phase 2b DNA-prime, adenovirus-boost HIV vaccine study in August 2009. In April 2013, the NIAID announced that it stopped administering injections in this clinical trial because an independent data and safety monitoring board found during a scheduled interim review that the vaccine regimen did not prevent HIV infection nor reduce viral load among vaccine recipients who became infected with HIV.

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. Since our inception, we estimate that we have received approximately $217.3 million in revenues from these sources. Revenues by source were as follows (in millions):

	Three Months Ended March 31,	
Source	**2013**	**2012**
Astellas supply and services contract	$ 1.1	$ 1.0
Other contract and grants	0.1	0.2
Total contract and grant revenues	1.2	1.2
Astellas license	$ 0.1	$ 10.1
Other royalties and licenses	0.3	0.2
Total royalty and license revenues	0.4	10.3
Total revenues	$ 1.6	$ 11.5

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

Program	Three Months Ended March 31, 2013	2012
Allovectin®	$ 5.0	$ 4.0
CMV	1.3	3.8
Other research, development, manufacturing and production	1.1	1.1
Total research, development, manufacturing and production	$ 7.4	$ 8.9

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Since our inception through March 31, 2013, we estimate that we have spent approximately $480 million on research, development, manufacturing and production. Our current independent development focus is on our cancer immunotherapeutic Allovectin®, novel DNA vaccines for CMV and HSV-2, and other clinical and preclinical targets.

We are conducting a Phase 3 clinical trial using Allovectin® in patients with recurrent metastatic melanoma which has been funded, up to certain limits, by AnGes through cash payments and equity investments under a research and development agreement. We are also developing TransVax , CyMVectin , and HSV-2 vaccine candidates, and these programs, excluding TransVax which we licensed to Astellas, will require significant additional funds to advance through development to commercialization. From inception through March 31, 2013, we have spent approximately $171 million on our Allovectin® program and $75 million on our CMV programs.

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 U.S. Food and Drug Administration, or FDA, or comparable foreign agencies. The outcome of the research is unknown until each stage of the testing is completed, up through and including the registration of 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 discussed in our Annual Report on Form 10-K for the fiscal year ended December 31, 2012.

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, 2013, Compared with Three Months Ended March 31, 2012

Total Revenues. Total revenues decreased $9.9 million to $1.6 million for the three months ended March 31, 2013, from $11.5 million for the three months ended March 31, 2012. This decrease was primarily the result of the recognition of $10.1 million of license revenue during the three months ended March 31, 2012 related to our TransVax license agreements with Astellas.

Research and Development Expenses. Research and development expenses decreased $2.8 million, or 43.2%, to $3.7 million for the three months ended March 31, 2013, from $6.4 million for the three months ended March 31, 2012. This decrease was primarily due to a sub-license payment we made to the City of Hope related to the license of our TransVax program to Astellas during the three months ended March 31, 2012.

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Manufacturing and Production Expenses. Manufacturing and production expenses increased $1.2 million, or 50.2%, to $3.7 million for the three months ended March 31, 2013, from $2.5 million for the three months ended March 31, 2012. This increase was primarily the result of an increase in contract manufacturing expenses and a decrease in capitalized manufacturing costs associated with our license agreements with Astellas during the three months ended March 31, 2013.

General and Administrative Expenses. General and administrative expenses increased $0.8 million, or 30.3%, to $3.5 million for the three months ended March 31, 2013, from $2.7 million for the three months ended March 31, 2012. This increase was primarily the result of post-termination benefit costs accrued related to the resignation of our Chief Financial Officer and higher employee related compensation costs.

Investment and Other Income, Net. Investment and other income, net decreased $359,000 to $25,000 for the three months ended March 31, 2013, from $384,000 for the three months ended March 31, 2012. This decrease was primarily the result of a gain recognized on the sale of auction rate securities during the three months ended March 31, 2012.

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. From our inception through March 31, 2013, we have received approximately $217.3 million in revenues from performing services under research and development and manufacturing contracts, from grants and from licensing access to our proprietary technologies, and we have raised net proceeds of approximately $420.3 million from the sale of equity securities. Cash, cash equivalents, marketable securities, and long-term investments, including restricted cash, totaled $77.6 million at March 31, 2013, compared with $86.1 million at December 31, 2012. The decrease in our cash, cash equivalents and marketable securities for the three months ended March 31, 2013, was primarily the result of the use of cash to fund our operations.

Net cash used in operating activities was $8.4 million and $8.0 million for the three months ended March 31, 2013 and 2012, respectively. The increase in net cash used in operating activities for the three months ended March 31, 2013, compared with the prior year period, was primarily the result of a $10.0 million decrease in license revenue related to our TransVax license agreements, which was partially offset by a $10.2 million decrease in accounts receivable related to our TransVax license agreements.

Net cash provided by (used in) investing activities was $12.0 million and $(8.9) million for the three months ended March 31, 2013 and 2012, respectively. The increase in net cash provided by investing activities for the three months ended March 31, 2013, compared with the prior year period, was primarily the result of an increase in net maturities of marketable securities.

Net cash provided by financing activities was $0.2 million and $48.7 million for the three months ended March 31, 2013 and 2012, respectively. The decrease in net cash provided by financing activities for the three months ended March 31, 2013, compared with the prior year period, was the result of net proceeds received from the sale of our common stock in a public offering during the three months ended March 31, 2012.

A discussion of our exposure to auction rate securities is included in Part 1, Item 3 of this Report under the heading Quantitative and Qualitative Disclosures About Market Risk.

We expect to incur substantial additional research and development expenses, manufacturing and production expenses, and general and administrative expenses, including continued 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. We currently have on file an effective shelf registration statement that allows us to raise up to $150.0 million from the sale of common stock, preferred stock, debt securities and/or warrants. However, additional financing 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, 2014.

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In November 2012, we entered into an At-The-Market Equity Offering Sales Agreement, or Sales Agreement, with Stifel, Nicolaus & Company, Incorporated, or Stifel, under which we may issue and sell up to $50,000,000 of shares of our common stock from time to time. Under the Sales Agreement, we will set the parameters for the sale of shares, including the number of shares to be issued and any minimum price below which sales may not be made. Subject to the terms and conditions of the Sales Agreement, shares may be sold through Stifel acting as sales agent or directly to Stifel acting as principal, by means of ordinary brokers transactions on the Nasdaq Global Select Market, in privately negotiated transactions or otherwise at market prices prevailing at the time of sale, at prices related to prevailing market prices or at negotiated prices. Any sales other than by methods deemed to be an at the market offering as defined in Rule 415 promulgated under the Securities Act of 1933, as amended, or the Securities Act, will require our prior consent. Stifel is obligated to use commercially reasonable efforts in conducting sales activities consistent with its normal trading and sales practices. The Sales Agreement may be terminated by us upon prior notice to Stifel or by Stifel upon prior notice to us, or at any time under certain circumstances, including but not limited to the occurrence of a material adverse change in the company.

The Sales Agreement provides that Stifel will be entitled to compensation for its services in an amount of 2.5% of the gross proceeds from the sale of shares sold through Stifel under the Sales Agreement. We have no obligation to sell any shares under the Sales Agreement, and may at any time suspend offers under the Sales Agreement. We agreed in the Sales Agreement to provide indemnification and contribution to Stifel against certain liabilities, including liabilities under the Securities Act, and to reimburse Stifel for certain legal expenses incurred in connection with the Sales Agreement.

Contractual Obligations

Under our Merck, Sanofi, AnGes, Merial and Aqua Health agreements, we are required to pay up to 10% of certain initial upfront monetary payments, and a small percentage of some royalty payments, to the Wisconsin Alumni Research Foundation and/or the University of Michigan. Under our license agreements with Astellas, we are required to make certain payments to the City of Hope and CytRx Corporation 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. 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 all of our in-license agreements in place at March 31, 2013, is approximately $14.9 million, of which approximately $7.1 million is related to our independent programs and corporate and government collaborations which are currently in clinical development. 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 each of our two executive officers and four of our other executives. Under the agreements with the executive officers, we are obligated to pay severance if we terminate the executive officer s employment without cause, or if the executive officer resigns for good reason, as defined in the agreements, within the periods set forth therein. The severance for the executive officers consists of continued base salary payments at the then-current rate, including the payment of health insurance premiums, for the period specified in each agreement, which ranges from 12 to 18 months, plus a payment equal to between one and one and a half times the executive s cash bonus in the previous year. In addition, the executive officers receive accelerated vesting on all their

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unvested stock awards as if they had remained employed by us for between 12 and 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 agreements, the severance for the executive officers consists of lump sum payments equal to between 18 and 24 months of base salary at the then-current rate, the payment of health insurance premiums for the period specified in each agreement, which ranges from 12 to 18 months, plus a payment equal to between one and one and a half times the executive s cash bonus in the previous year. In addition, all outstanding unvested stock awards will vest immediately. The severance for the other executives consists of continued payments at the then-current base compensation rate for a period of six months. All of the agreements specify that any earnings from employment or consulting during this period will offset any salary continuation payments due from us. The maximum payments due under these employment agreements would have been $2.8 million if each such executive officer and other executive were terminated at March 31, 2013.

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 six 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 12-month time horizon, a 9-month average maturity and a 150-basis-point increase in interest rates. This pro forma fair value would have been $0.1 million lower than the reported fair value of our investments at March 31, 2013.

Our investment securities consist of auction rate securities, corporate debt securities and government agency securities. As of March 31, 2013, our long-term investments included a (at par value) $2.5 million auction rate security secured by municipal bonds. At March 31, 2013, the auction rate security we held maintained a Standard and Poor s credit rating of BBB. 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, 2013. 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, 2013, 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, 2013, we had recorded cumulative unrealized gains of $0.4 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, 2013. 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 this investment is successful or it is redeemed by the issuer or it matures. If we are unable to sell this security in the market or it is not redeemed, then we may be required to hold it to maturity. We do not anticipate a need to access the funds for operational purposes for the foreseeable future. We will continue to monitor and evaluate this investment 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 this investment will affect our ability to execute our current business plan.

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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 officer and principal 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 Securities Exchange Act of 1934, as amended, 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 the reasonable assurance level as of March 31, 2013.

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, 2013, 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 occurs, 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, 2012, 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, regulatory authorities will not approve them.

Our independently developed product candidates currently in clinical development include Allovectin®, for which we announced the completion of enrollment of a Phase 3 clinical trial in 2010. We have an allowed Investigational New Drug Application for CyMVectin and have begun preclinical work on a HSV-2 vaccine. We may not conduct Phase 1 CyMVectin or HSV-2 vaccine trials, and the future trials, if any, may not demonstrate sufficient 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 these product candidates, it could have a material adverse impact on our business prospects. In particular, we believe that our near-term prospects are substantially dependent on the results of our Phase 3 clinical trial for Allovectin. If we do not meet our pre-specified endpoints of the trial or the results are otherwise negative or are perceived negatively, our stock price could decline significantly.

Additionally, we are in early stages of development with other product candidates. These product candidates 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 products, we may be forced to curtail or cease operations.

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We are dependent on our license agreements with Astellas to further develop and commercialize TransVax . 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 license agreements with Astellas, we granted to Astellas exclusive worldwide rights to develop and commercialize certain products, including TransVax 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 TransVax depends on Astellas ability to develop, obtain regulatory approvals for and successfully commercialize TransVax . We have limited control over the amount and timing of resources that Astellas will dedicate to these efforts.

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

- Astellas may not comply with applicable regulatory guidelines with respect to developing or commercializing TransVax , which could adversely impact sales or future development of TransVax ;
- 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, 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 TransVax , 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 TransVax , 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 acquiror s ability to maintain or pursue development or commercialization of products that are competitive with TransVax 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 TransVax , 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 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 TransVax on acceptable terms, or at all, and we may be unable to pursue continued development or commercialization of TransVax on our own.

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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 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 licensees Astellas and AnGes have product candidates in advanced stage 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 AnGes or any of our other 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. In September 2010, AnGes announced that after a series of extensive consultations with the Japanese Pharmaceuticals and Medical Devices Agency, it would be withdrawing its New Drug Application, or NDA, in Japan. Also in September 2010, another one of our licensees, Sanofi, announced that NV1FGF, an angiogenic growth factor therapeutic for which Sanofi had licensed our DNA delivery technology, did not meet the primary endpoint in a global Phase 3 trial. 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 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 $22.9 million, $7.3 million and $30.4 million for the years ended December 31, 2012, 2011 and 2010, respectively. As of March 31, 2013, we had incurred cumulative net losses totaling approximately $357.2 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. 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.

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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 lease 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 $150.0 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 November 2012, we entered into a Sales Agreement with Stifel, under which we may issue and sell up to $50.0 million of our common stock from time to time. However, Stifel 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 result in 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; 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. For example, the FDA has provided only limited guidelines concerning the size and scope of clinical trials required for gene-based therapeutic and vaccine products.

Therefore, U.S. or foreign regulations 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;

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 Biologics License Application, or BLA, or NDA with the FDA. Because a BLA or NDA 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.

We believe that 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

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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 any of our product candidates that are 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 effected.

We use recombinant DNA molecules in our product candidates, and therefore we and our collaborators and licensees also must comply with guidelines instituted by the NIH and its Office of Biotechnology Activities. The NIH could restrict or delay the development of our product candidates.

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. For example, one patient in our Allovectin® Phase 2 trial conducted in 2000, died from progressive disease more than two months after receiving Allovectin® and other cancer therapies. The death was originally reported as unrelated to the treatment. Following an autopsy, the death was reclassified as probably related to the treatment because the possibility could not be ruled out. We do not believe Allovectin® was a significant factor in the patient s death. 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, in our TransVax Phase 2 trial, we administered TransVax to patients who were at risk of CMV reactivation. 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.

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(*)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, 2013, we were the assignee or co-assignee of 85 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, 2013, we were also prosecuting 56 pending patent applications 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.

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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 NIH and the FDA jointly developed the Genetic Modification Clinical Research Information System, or GeMCRIS, an Internet-based database of human gene transfer trials. GeMCRIS enables individuals to easily view information on particular characteristics of clinical gene transfer trials. Although GeMCRIS includes special security features designed to protect patient privacy and confidential commercial information, these security features may be inadequately designed or enforced, potentially resulting in disclosure of confidential commercial information. In addition, the NIH, in collaboration with the FDA, has developed an Internet site, ClinicalTrials.gov, which 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 current Good Manufacturing Practices, or 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.

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Noncompliance with the cGMP regulations, the inability to complete the installation or validation of additional large-scale equipment, 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, or CROs, 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.

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.

If we fail to obtain appropriate 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 in 2010. Many of the details regarding the implementation of this legislation are yet to be determined and we currently cannot predict whether or to what extent such implementation or adoption of reforms may impair our business.

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Additionally, 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.

(*)Negative conditions in the global credit markets may impair the liquidity of a portion of our investment portfolio.

Our investment securities consist of auction rate securities, corporate debt securities and government agency securities. As of March 31, 2013, our long-term investments included a (at par value) $2.5 million auction rate security secured by municipal bonds. At March 31, 2013, the auction rate security we held maintained a Standard and Poor s credit rating of BBB. Our 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, 2013. 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, 2013, 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, 2013, we had recorded cumulative unrealized gains of $0.4 million. Any future decline in market value may result in additional losses being recognized.

In the event we need to access the funds that are in an illiquid state, we will not be able to do so without the possible loss of principal, until a future auction for this investment is successful or it is redeemed by the issuer or it matures. If we are unable to sell this security in the market or it is not redeemed, then we may be required to hold it to maturity.

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(*)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, 2010, to March 31, 2013, our stock price has ranged from $1.70 to $5.30. 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;
- 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 securities class action litigation due to our 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. To date, we have not been subject to class action litigation. However, we may in the future be the target of this litigation. Securities litigation could result in substantial costs and divert our management s attention and resources, and could seriously harm our business.

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.

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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 $150.0 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.

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ITEM 6. EXHIBITS

Exhibit Number	Description of Document
3.1(i)(1)	Restated Certificate of Incorporation.
3.2(ii)(2)	Amended and Restated Bylaws.
3.3(i)(2)	Certificate of Amendment to Restated Certificate of Incorporation.
4.1(1)	Specimen Common Stock Certificate.
10.1(3)[a]	Separation Letter Agreement between Vical Incorporated and Jill M. Broadfoot dated March 15, 2013.
31.1	Certification of Vijay B. Samant, Chief Executive Officer and acting Chief Financial Officer, 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 Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS*	XBRL Instance Document.
101.SCH*	XBRL Taxonomy Extension Schema Document.
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF*	XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB*	XBRL Taxonomy Extension Label Linkbase Document.
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document.

(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 the exhibit of the same number filed with the Company s Current Report on Form 8-K filed on March 15, 2013.

[a] Indicates management contract or compensatory plan or arrangement.

* Furnished herewith and not filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended.

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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 10, 2013

By: /s/ ANTHONY A. RAMOS
Anthony A. Ramos
Chief Accounting Officer (on behalf of the registrant

and as the registrant s Principal Accounting Officer)