VICAL INC
Form 10-Q
November 03, 2014
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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 September 30, 2014

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 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes 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 October 24, 2014: 90,330,267

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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)

	September 30, 2014	December 31, 2013
ASSETS		
Current assets:		
Cash and cash equivalents	$ 22,660	$ 38,837
Marketable securities, available-for-sale	23,869	11,541
Restricted cash	3,182	3,119
Receivables and other assets	4,689	4,590
Total current assets	54,400	58,087
Long-term investments	1,937	1,980
Property and equipment, net	2,857	3,935
Intangible assets, net	1,702	1,972
Other assets	379	379
Total assets	$ 61,275	$ 66,353
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable and accrued expenses	$ 4,600	$ 3,503
Deferred revenue	38	150
Total current liabilities	4,638	3,653
Long-term liabilities:		
Deferred rent	974	1,288
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, 90,190 and 86,778 shares issued and outstanding at September 30, 2014, and December 31, 2013, respectively	902	868
Additional paid-in capital	445,843	439,708
Accumulated deficit	(391,034)	(379,175)
Accumulated other comprehensive (loss) income	(48)	11
Total stockholders equity	55,663	61,412
Total liabilities and stockholders equity	$ 61,275	$ 66,353

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 September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Revenues:				
Contract and grant revenue	$ 3,004	$ 1,311	$ 9,073	$ 3,617
License and royalty revenue	438	232	1,321	956
Total revenues	3,442	1,543	10,394	4,573
Operating expenses:				
Research and development	3,180	4,500	7,705	12,080
Manufacturing and production	2,292	3,900	7,457	11,504
General and administrative	2,366	3,123	7,176	10,119
Total operating expenses	7,838	11,523	22,338	33,703
Loss from operations	(4,396)	(9,980)	(11,944)	(29,130)
Other income:				
Investment and other income, net	32	97	85	84
Net loss	$ (4,364)	$ (9,883)	$ (11,859)	$ (29,046)
Basic and diluted net loss per share	$ (0.05)	$ (0.11)	$ (0.13)	$ (0.33)
Weighted average shares used in computing basic and diluted net loss per share	89,976	86,998	88,154	86,755

See accompanying notes to unaudited financial statements

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VICAL INCORPORATED

STATEMENTS OF COMPREHENSIVE LOSS

(In thousands)

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Net loss	$ (4,364)	$ (9,883)	$ (11,859)	$ (29,046)
Other comprehensive loss:				
Unrealized losses on available-for-sale and long-term marketable securities:				
Unrealized losses arising during holding period	(69)	(65)	(59)	(178)
Other comprehensive loss	(69)	(65)	(59)	(178)
Total comprehensive loss	$ (4,433)	$ (9,948)	$ (11,918)	$ (29,224)

See accompanying notes to unaudited financial statements

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VICAL INCORPORATED

STATEMENTS OF CASH FLOWS

(In thousands)

(Unaudited)

	Nine Months Ended September 30,	
	2014	**2013**
Cash flows from operating activities:		
Net loss	$ (11,859)	$ (29,046)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,330	1,731
Write-off of abandoned patents and licensed technology	331	778
Compensation expense related to stock options and awards	2,451	2,686
Changes in operating assets and liabilities:		
Receivables and other assets	(99)	323
Accounts payable and accrued expenses	1,050	(502)
Deferred revenue	(113)	(113)
Deferred rent	(266)	(220)
Net cash used in operating activities	(7,175)	(24,363)
Cash flows from investing activities:		
Maturities of marketable securities	8,000	25,489
Purchases of marketable securities	(20,437)	(5,137)
Purchases of property and equipment	(43)	(306)
Patent expenditures	(240)	(376)
Net cash (used in) provided by investing activities	(12,720)	19,670
Cash flows from financing activities:		
Net proceeds from issuance of common stock	3,776	815
Payment of withholding taxes for net settlement of restricted stock units	(58)	(470)
Net cash provided by financing activities	3,718	345
Net decrease in cash and cash equivalents	(16,177)	(4,348)
Cash and cash equivalents at beginning of period	38,837	43,159
Cash and cash equivalents at end of period	$ 22,660	$ 38,811

See accompanying notes to unaudited financial statements

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VICAL INCORPORATED

NOTES TO FINANCIAL STATEMENTS

September 30, 2014

(Unaudited)

1. BASIS OF PRESENTATION

Vical Incorporated, or the Company, a Delaware corporation, was incorporated in April 1987 and has devoted substantially all of its resources since that time to its research and development programs. The Company researches and develops biopharmaceutical products 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 September 30, 2014, and for the three and nine months ended September 30, 2014 and 2013, have been prepared in accordance with the rules and regulations of the Securities and Exchange Commission, or SEC, and with accounting principles generally accepted in the United States applicable to interim financial statements. These unaudited financial statements have been prepared on the same basis as the audited financial statements included in the Company s Annual Report on Form 10-K and include all adjustments, consisting of only normal recurring accruals, which in the opinion of management are necessary to present fairly the Company s financial position as of the interim date and results of operations for the interim periods presented. Interim results are not necessarily indicative of results expected for a full year or future periods. The preparation of financial statements requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosures of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ materially from those estimates. These unaudited financial statements should be read in conjunction with the Company s audited financial statements for the year ended December 31, 2013, 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 90 days or less. Investments with an original maturity of more than 90 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 September 30, 2014, and December 31, 2013, restricted cash of $3.2 million and $3.1 million, respectively, 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 license and collaboration 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.

Manufacturing and Production Costs

Manufacturing and production costs include expenses related to manufacturing contracts and expenses for the production of plasmid DNA for use in the Company s research and development efforts. Manufacturing expenses related to manufacturing contracts are deferred and expensed when the related revenue is recognized. Production expenses related to the Company s research and development efforts are expensed as incurred.

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Net Loss Per Share

Basic and diluted net loss per share has been computed using the weighted-average number of shares of common stock outstanding during the period. The weighted average number of shares used to compute diluted net loss per share excludes any assumed exercise of stock options and any assumed issuance of common stock under restricted stock units as the effect would be antidilutive. Common stock equivalents of 0.4 million and 0.7 million for the three months ended September 30, 2014 and 2013, respectively, were excluded from the calculation because of their antidilutive effect. Common stock equivalents of 0.5 million and 1.2 million for the nine months ended September 30, 2014 and 2013, respectively, were excluded from the calculation because of their antidilutive effect.

Stock-Based Compensation

The Company records its compensation expense associated with stock options and other share-based awards in accordance with the authoritative guidance for stock-based compensation. The cost of employee services received in exchange for an award of an equity instrument is measured at the grant date using the Black-Scholes-Merton option pricing model. Stock-based compensation includes amortization related to stock option awards based on the estimated grant date fair value. Stock-based compensation expense related to stock options includes an estimate for forfeitures and the portion that is ultimately expected to vest is recognized ratably over the vesting period of the option. In addition, the Company records expense related to restricted stock units, or RSUs, granted based on the fair value of those awards on the grant date. The fair value related to the RSUs is amortized to expense over the vesting term of those awards. Stock-based compensation expense related to RSUs includes an estimate for forfeitures and the portion expected to vest is recognized over the expected term of the award using the straight-line method. Stock-based compensation expense for a stock-based award with a performance condition is recognized when the achievement of such performance condition is determined to be probable. If the outcome of such performance condition is not determined to be probable or is not met, no compensation expense is recognized and any recognized compensation expense is reversed.

Recent Accounting Pronouncements

In May 2014, the FASB issued guidance that outlines a single comprehensive model for entities to use in accounting for revenue arising from contracts with customers and supersedes most current revenue recognition guidance, including industry-specific guidance. The guidance provides that an entity recognize revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. This guidance also requires additional disclosure about the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts, including significant judgments and changes in judgments, and assets recognized from costs incurred to obtain or fulfill a contract. The guidance allows for either full retrospective or modified retrospective adoption and will become effective for the Company in the first quarter of 2017. The Company is evaluating the alternative transition methods and the potential effects of the adoption of this update on its financial statements.

In July 2013, the FASB issued guidance on the financial statement presentation of an unrecognized tax benefit when a net operating loss carryforward, a similar tax loss, or a tax credit carryforward exists. The guidance is effective prospectively for fiscal years, and interim periods within those years, beginning after December 15, 2013. The adoption of this standard during the first quarter of 2014 did not have a material impact on the Company s consolidated financial statements.

In August 2014, the FASB issued an amendment to the accounting guidance related to the evaluation of an entity to continue as a going concern. The amendment establishes management s responsibility to evaluate whether there is substantial doubt about an entity s ability to continue as a going concern in connection with preparing financial statements for each annual and interim reporting period. The amendment also gives guidance to determine whether to disclose information about relevant conditions and events when there is substantial doubt about an entity s ability to continue as a going concern. The amended guidance is effective prospectively for fiscal years beginning after December 15, 2016. The new guidance will not have an impact on the Company s financial position, results of operations or cash flows.

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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 September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Research and development	$ 186	$ 155	$ 628	$ 709
Manufacturing and production	56	68	177	196
General and administrative	488	509	1,646	1,781
Total stock-based compensation expense	$ 730	$ 732	$ 2,451	$ 2,686

During the nine months ended September 30, 2014 and 2013, the Company granted stock-based awards with a total estimated value of $2.3 million and $4.8 million, respectively. At September 30, 2014, total unrecognized estimated compensation expense related to unvested stock-based awards granted prior to that date was $2.4 million, which is expected to be recognized over a weighted-average period of 1.3 years. Stock-based awards granted during the nine months ended September 30, 2014 and 2013, were equal to 3.0% and 3.8%, respectively, of the outstanding shares of common stock at the end of the applicable period.

3. MARKETABLE SECURITIES, AVAILABLE FOR SALE

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

September 30, 2014	Amortized Cost	Unrealized Gain	Unrealized Loss	Market Value
U.S. treasuries	$ 5,569	$	$	$ 5,569
Government-sponsored enterprise securities	7,999		10	7,989
Corporate bonds	2,032		4	2,028
Certificates of deposit	8,283			8,283
	$ 23,883	$	$ 14	$ 23,869

December 31, 2013	Amortized Cost	Unrealized Gain	Unrealized Loss	Market Value
U.S. treasuries	$ 1,500	$ 3	$	$ 1,503
Government-sponsored enterprise securities	4,500			4,500
Corporate bonds	4,853			4,853
Certificates of deposit	685			685
	$ 11,538	$ 3	$	$ 11,541

At September 30, 2014, $13.0 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 nine months ended September 30, 2014. As of September 30, 2014, none of the securities had been in a continuous material unrealized loss position longer than one year.

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4. OTHER BALANCE SHEET ACCOUNTS

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

	September 30, 2014	December 31, 2013
Employee compensation	$ 1,816	$ 1,587
Post-termination benefit accrual		369
Clinical trial accrual	1,049	347
Accounts payable	878	395
Deferred rent	416	369
Other accrued liabilities	441	436
Total accounts payable and accrued expenses	$ 4,600	$ 3,503

5. LONG-TERM INVESTMENTS

As of September 30, 2014, the Company held an auction rate security with a par value of $2.5 million. This auction rate security has not experienced a successful auction since the liquidity issues experienced in the global credit and capital markets in 2008. As a result, the security is classified as a long-term investment as it is scheduled to mature in 2038. The security was rated A- by Standard and Poor s as of September 30, 2014. 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 by management 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, net of tax, as of September 30, 2014. The losses when recognized are included in investment and other income. Included in other comprehensive loss are unrealized losses of $43,000 and $0.2 million for the nine months ended September 30, 2014 and 2013, respectively. As of September 30, 2014, the Company had recorded cumulative unrealized gains of $0.1 million. The resulting carrying value of the auction rate security at September 30, 2014, was $1.9 million. Any future decline in market value may result in additional losses being recognized.

6. FAIR VALUE MEASUREMENTS

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

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

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

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

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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			
September 30, 2014	**Level 1**	**Level 2**	**Level 3**	**Total**
Certificates of deposit	$ 8,283	$	$	$ 8,283
Money market funds	2,169			2,169
U.S. treasuries	5,569			5,569
Corporate bonds		2,028		2,028
Government-sponsored enterprise securities		7,989		7,989
Auction rate securities			1,937	1,937
	$ 16,021	$ 10,017	$ 1,937	$ 27,975

	Fair Value Measurements			
December 31, 2013	**Level 1**	**Level 2**	**Level 3**	**Total**
Certificates of deposit	$ 685	$	$	$ 685
Money market funds	2,275			2,275
U.S. treasuries	1,503			1,503
Corporate bonds		4,853		4,853
Government-sponsored enterprise securities		4,500		4,500
Auction rate securities			1,980	1,980
	$ 4,463	$ 9,353	$ 1,980	$ 15,796

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 September 30, 2014. 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 September 30, 2014. The Company did not transfer any investments between level categories during the nine months ended September 30, 2014. The valuation of the Company s investments in auction rate securities, which includes significant unobservable inputs, is more fully described in Note 5.

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

	Nine Months Ended September 30, 2014
Balance at December 31, 2013	$ 1,980
Total net unrealized losses, excluding tax impact, included in other comprehensive loss	(43)
Balance at September 30, 2014	$ 1,937
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	$

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7. COMMITMENTS AND CONTINGENCIES

In late October and early November 2013, following the Company s announcement of the results of its Phase 3 trial of Allovectin® and the subsequent decline of the price of its common stock, two putative securities class action complaints were filed in the U.S. District Court for the Southern District of California against the Company and certain of its current and former officers. On February 26, 2014, the two cases were consolidated into one action and a lead plaintiff and lead counsel were appointed. On April 3, 2014, the lead plaintiff filed a consolidated complaint alleging that the defendants violated Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 by making materially false and misleading statements regarding the Company s business prospects and the prospects for Allovectin®, thereby artificially inflating the price of the Company s common stock. The consolidated complaint seeks unspecified monetary damages and other relief. On April 25, 2014, the parties filed a joint motion asking the Court to permit plaintiffs to amend the consolidated complaint, which the Court granted. On May 12, 2014, lead plaintiff filed an amended complaint. On June 9, 2014, defendants filed a motion to dismiss the amended complaint. That same day, defendants also filed a motion to strike certain allegations in the amended complaint. The motions to dismiss and strike are fully briefed, but the Court has not yet issued an order. The Company plans to vigorously defend against the claims advanced. At this time, the Company is unable to estimate possible losses or ranges of losses for ongoing legal actions.

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

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

8. ASTELLAS AGREEMENTS

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

Under the terms of the 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 ASP0113 in hematopoietic stem cell transplant recipients. The Company recognized $1.1 million and $0.4 million in license revenue under the Astellas agreements during the nine months ended September 30, 2014 and 2013, respectively.

Under the terms of the agreements, the Company is also performing research and development services and manufacturing services which are being paid for by Astellas. During the three and nine months ended September 30, 2014, the Company recognized $3.0 million and $9.1 million, respectively, of revenue related to these contract services. During the three and nine months ended September 30, 2013, the Company recognized $1.2 million and $3.4 million, respectively, of revenue related to these contract services.

9. RESTRUCTURING COSTS

In August 2013, the Company announced that its Phase 3 clinical trial of Allovectin®, the Company s investigational cancer immunotherapy, failed to meet the pre-established endpoints. As a result, the Company restructured its operations to conserve capital, which included a staff reduction of 47 employees and the write-off of certain intangible assets. The Company recorded charges for employee termination benefits of $2.2 million and for asset impairments of $0.7 million in August of 2013.

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The following table sets forth activity in the restructuring liability for the nine months ended September 30, 2014, which is wholly comprised of employee severance costs (in thousands):

	Accrued Severance
Balance at December 31, 2013	$ 281
Accruals	
Payments	$ (281)
Balance at September 30, 2014	$

The balance of the accrued severance liability at December 31, 2013 has been fully distributed as of September 30, 2014.

10. STOCKHOLDERS EQUITY

In April 2014, the Company entered into an At-The-Market Issuance Sales Agreement, or Sales Agreement, with Meyers Associates, L.P. (doing business as Brinson Patrick, a division of Meyers Associates, L.P.), or Brinson Patrick, under which the Company may issue and sell up to $25,000,000 of shares of its common stock from time to time. Under the Sales Agreement, the Company may deliver placement notices that will set the parameters for the sale of shares, including the number of shares to be issued, the time period during which sales are requested to be made, any limitation on the number of shares that may be sold in any one trading day and any minimum price below which sales may not be made. Subject to the terms and conditions of the Sales Agreement, Brinson Patrick may sell the shares only by methods deemed to be an at the market offering as defined in Rule 415 promulgated under the Securities Act of 1933, as amended, including without limitation sales made directly through the Nasdaq Global Market, on any other existing trading market for the Company s common stock or to or through a market maker. The Sales Agreement may be terminated by the Company upon prior notice to Brinson Patrick or by Brinson Patrick upon prior notice to the Company, or at any time under certain circumstances, including but not limited to the occurrence of a material adverse effect on the Company. During the three months ended September 30, 2014, the Company sold 2,186,870 shares under the sales agreement and received gross proceeds of $2,741,718. During the nine months ended September 30, 2014, the Company sold 3,168,886 shares under the sales agreement and received gross proceeds of $3,914,400.

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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, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act, including statements regarding our business, our financial position, the research and development of biopharmaceutical products based on our patented DNA delivery 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, 2013, and in our other filings with the SEC, and those identified in Part II, Item 1A entitled Risk Factors beginning on page 22 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; and
- Vaccines for general pediatric, adolescent and adult populations for infectious disease applications.

We currently have three active, independent or partnered, development programs in the area of infectious disease comprised of:

- An ongoing Phase 3 clinical trial of ASP0113 for prevention of cytomegalovirus, or CMV, reactivation in stem cell transplant recipients and an ongoing Phase 2 clinical trial of ASP0113 for prevention of CMV infection in kidney transplant recipients, both in collaboration with Astellas Pharma Inc., or Astellas;
- An ongoing Phase 1/2 clinical trial using our Vaxfectin®-formulated therapeutic vaccine for herpes simplex virus type 2, or HSV-2, a cause of recurrent genital herpes; and
- 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 CMV infection before and during pregnancy.

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, or MIT. 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. The table below summarizes our independent programs and corporate and government collaborations.

Product/Concept	Intended Use	Development Status[1]	Lead Developer
Independent Programs			
Therapeutic and prophylactic vaccines for HSV-2	Prevent and protect against recurring flare-ups, reduce viral shedding and transmission	Phase 1/2	Vical
CyMVectin prophylactic vaccine for CMV	Prevent infection during pregnancy to preclude fetal transmission	Preclinical complete	Vical
Corporate Collaborations			
ASP0113 therapeutic vaccine for CMV	Protect against infection after stem cell transplants	Phase 3	Astellas
ASP0113 therapeutic vaccine for CMV	Protect against infection after solid organ transplants	Phase 2	Astellas
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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Research, Development and Manufacturing Programs

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
Source	**2014**	**2013**	**2014**	**2013**
Astellas supply and services contract	$ 3.0	$ 1.2	$ 9.1	$ 3.4
Other contract and grants		0.1		0.2
Total contract and grant revenues	3.0	1.3	9.1	3.6
Astellas license	$ 0.4	$ 0.2	$ 1.1	$ 0.4
Other royalties and licenses			0.2	0.6
Total royalty and license revenues	0.4	0.2	1.3	1.0
Total revenues	$ 3.4	$ 1.5	$ 10.4	$ 4.6

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
Program	**2014**	**2013**	**2014**	**2013**
Allovectin®	$	$ 4.0	$ 0.1	$ 14.4
CMV	3.3	2.0	10.5	4.6
HSV-2	1.2	1.9	2.9	2.8
Other research, development, manufacturing and production	1.0	0.5	1.7	1.8
Total research, development, manufacturing and production	$ 5.5	$ 8.4	$ 15.2	$ 23.6

Our current independent development focus is on our novel DNA vaccines for HSV-2 and CMV, and other targets. We are developing HSV-2 and CyMVectin vaccine candidates, and these programs will require significant additional funds to advance through development to commercialization. From inception through September 30, 2014, we have spent approximately $11.9 million on our HSV-2 program and $90.3 million on our CMV programs including ASP0113.

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.

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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, 2013.

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 September 30, 2014, Compared with Three Months Ended September 30, 2013

Total Revenues. Total revenues increased $1.9 million to $3.4 million for the three months ended September 30, 2014, from $1.5 million for the three months ended September 30, 2013. This increase was primarily due to an increase in contract revenue recognized related to our ASP0113 license agreements with Astellas.

Research and Development Expenses. Research and development expenses decreased $1.3 million, or 29.3%, to $3.2 million for the three months ended September 30, 2014, from $4.5 million for the three months ended September 30, 2013. This decrease was primarily due to a $1.9 million restructuring charge recognized in August 2013 combined with a decrease in employee-related expenses. These decreases were partially offset by an increase in clinical trial costs during the three months ended September 30, 2014.

Manufacturing and Production Expenses. Manufacturing and production expenses decreased $1.6 million, or 41.2%, to $2.3 million for the three months ended September 30, 2014, from $3.9 million for the three months ended September 30, 2013. This decrease was primarily due to a $0.6 million restructuring charge recognized in August 2013 combined with a reduction in employee-related expenses, scientific supplies, contract services and deferred contract costs.

General and Administrative Expenses. General and administrative expenses decreased $0.7 million, or 24.2%, to $2.4 million for the three months ended September 30, 2014, from $3.1 million for the three months ended September 30, 2013. This decrease was primarily due to a $0.4 million restructuring charge recognized in August 2013 combined with a reduction in employee-related expenses and consulting costs.

Investment and Other Income, Net. Investment and other income, net, decreased $65,000 to $32,000 for the three months ended September 30, 2014, from $97,000 for the three months ended September 30, 2013.

Nine Months Ended September 30, 2014, Compared with Nine Months Ended September 30, 2013

Total Revenues. Total revenues increased $5.8 million to $10.4 million for the nine months ended September 30, 2014, from $4.6 million for the nine months ended September 30, 2013. This increase was primarily due to an increase in contract revenue recognized related to our ASP0113 license agreements with Astellas.

Research and Development Expenses. Research and development expenses decreased $4.4 million, or 36.2%, to $7.7 million for the nine months ended September 30, 2014, from $12.1 million for the nine months ended September 30, 2013. This decrease was primarily due to a $1.9 million restructuring charge recognized in August 2013 combined with a decrease in employee-related expenses, scientific supplies and contract services. These decreases were partially offset by an increase in clinical trial costs.

Manufacturing and Production Expenses. Manufacturing and production expenses decreased $4.0 million, or 35.2%, to $7.5 million for the nine months ended September 30, 2014, from $11.5 million for the nine months ended September 30, 2013. This decrease was primarily due to a reduction in employee-related expenses as a result of our August 2013 restructuring combined with a reduction in the purchase of scientific supplies.

General and Administrative Expenses. General and administrative expenses decreased $2.9 million, or 29.1%, to $7.2 million for the nine months ended September 30, 2014, from $10.1 million for the nine months ended September 30, 2013. This decrease was primarily due to a decrease in employee-related expenses as a result of our August 2013 restructuring.

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Investment and Other Income, Net. Investment and other income net, increased $1,000 to $85,000 for the nine months ended September 30, 2014, from $84,000 for the nine months ended September 30, 2013.

Liquidity and Capital Resources

Since our inception, we have financed our operations primarily through private placements and public offerings of equity securities, and revenues from our operations. Cash, cash equivalents, marketable securities, and long-term investments, including restricted cash, totaled $51.6 million at September 30, 2014, compared with $55.5 million at December 31, 2013. The decrease in our cash, cash equivalents and marketable securities for the nine months ended September 30, 2014, was primarily the result of the use of cash to fund our operations, partially offset by the receipt of proceeds from sales of our common stock.

Net cash used in operating activities was $7.2 million and $24.4 million for the nine months ended September 30, 2014 and 2013, respectively. The decrease in net cash used in operating activities for the nine months ended September 30, 2014, compared with the prior year period, was primarily the result of a $17.2 million decrease in our net loss which was primarily the result of our August 2013 restructuring.

Net cash (used in) provided by investing activities was $(12.7) million and $19.7 million for the nine months ended September 30, 2014 and 2013, respectively. The decrease in net cash provided by investing activities for the nine months ended September 30, 2014, compared with the prior year period, was primarily the result of an increase in net purchases of marketable securities.

Net cash provided by financing activities was $3.7 million and $0.3 million for the nine months ended September 30, 2014 and 2013, respectively. The increase in net cash provided by financing activities for the nine months ended September 30, 2014, compared with the prior year period, was primarily the result of receiving gross proceeds of $3,914,400 from the sale of 3,168,886 common shares in an At-The-Market offering during the nine months ended September 30, 2014.

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.

In the long-term, we expect to incur substantial additional research and development expenses, manufacturing and production expenses, and general and administrative expenses, including increases in costs related to personnel, preclinical and clinical testing, outside services, facilities, intellectual property and possible commercialization. Our future capital requirements will depend on many factors, including continued scientific progress in our research and development programs, the scope and results of preclinical testing and clinical trials, the time and costs involved in obtaining regulatory approvals, the costs involved in filing, prosecuting, enforcing and defending patent claims, the impact of competing technological and market developments, the cost of manufacturing scale-up and validation, and possible commercialization activities and arrangements. We may seek additional funding through research and development relationships with suitable potential corporate collaborators. We may also seek additional funding through public or private financings. We currently have on file an effective shelf registration statement that allows us to raise up to $146.1 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, 2015.

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 $50.0 million 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 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 our Company.

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The Sales Agreement provides that Stifel will be entitled to compensation for its services in an amount equal to 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.

In April 2014, we entered into an At-the-Market Issuance Sales Agreement, or ATM Agreement, with Meyers Associates, L.P. (doing business as Brinson Patrick, a division of Meyers Associates, L.P.), or Brinson Patrick, under which we may issue and sell up to $25.0 million of shares of our common stock from time to time. Under the ATM Agreement, we may deliver placement notices that will set the parameters for the sale of shares, including the number of shares to be issued, the time period during which sales are requested to be made, any limitation on the number of shares that may be sold in any one trading day and any minimum price below which sales may not be made. Subject to the terms and conditions of the ATM Agreement, Brinson Patrick may sell the shares only by methods deemed to be an at the market offering as defined in Rule 415 promulgated under the Securities Act of 1933, as amended, including without limitation sales made directly through the Nasdaq Global Market, on any other existing trading market for our common stock or to or through a market maker. Brinson Patrick will use commercially reasonable efforts consistent with its normal trading and sales practices to sell the shares in accordance with the terms of the ATM Agreement and any applicable placement notice. The ATM Agreement may be terminated by us upon prior notice to Brinson Patrick or by Brinson Patrick upon prior notice to us, or at any time under certain circumstances, including but not limited to the occurrence of a material adverse effect on our Company.

The ATM Agreement provides that Brinson Patrick will be entitled to compensation for its services in an amount up to 2.5% of the gross proceeds from the sale of shares sold through Brinson Patrick under the ATM Agreement. We have no obligation to sell any shares under the ATM Agreement, and both we and Brinson Patrick may at any time suspend the sale of shares under the ATM Agreement. We have also agreed to provide indemnification and contribution to Brinson Patrick against certain liabilities. During the three months ended September 30, 2014, we sold 2,186,870 shares under the sales agreement and received gross proceeds of $2,741,718. During the nine months ended September 30, 2014, we sold 3,168,886 shares under the sales agreement and received gross proceeds of $3,914,400.

Contractual Obligations

Under our Sanofi and Merial 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 September 30, 2014, is approximately $11.8 million, of which approximately $7.5 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.

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We have employment agreements that contain severance arrangements with our Chief Executive Officer, or CEO, and three of our other executives. If our executive officers, other than our CEO, are terminated without cause or they resign for good reason (as defined in their employment agreements), they will be entitled to severance consisting of continued base salary payments at the then-current rate for a period of 6 months. In addition, our Senior Vice President, Corporate Development receives the payment of health insurance premiums for 6 months and accelerated vesting on all his unvested stock awards if his employment is terminated without cause or if he resigns for good reason (as defined in his employment agreement). Our CEO s employment agreement provides for severance consisting of 18 months of continued base salary, including the payment of health insurance premiums, plus a payment equal to one and one half times any cash bonus paid in the prior year, if his employment is terminated without cause or if he resigns for good reason (as defined in his employment agreement). In addition, our CEO receives accelerated vesting on all his unvested stock awards as if he had remained employed by us for 18 months from the date of termination. In the event that the termination occurs within 24 months of a change in control (as defined in his employment agreement), the employment agreement for our CEO provides for severance of a lump sum equal to 24 months of base salary at the then-current rate, the payment of health insurance premiums for 18 months, plus a payment equal to one and one half times any cash bonus paid in the prior year. In addition, all outstanding unvested stock awards held by our CEO will vest immediately. 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 $1.5 million if our CEO and other executives were terminated at September 30, 2014.

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 eight 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 three month average maturity and a 150-basis-point increase in interest rates. This pro forma fair value would have been $0.4 million lower than the reported fair value of our investments at September 30, 2014.

Our investment securities consist of auction rate securities, corporate debt securities and government agency securities. As of September 30, 2014, our long-term investments included a (at par value) $2.5 million auction rate security secured by municipal bonds. At September 30, 2014, the auction rate security we held maintained a Standard and Poor s credit rating of A-. The auction rate security is a debt instrument with a long-term maturity and with an interest rate that is reset in short intervals through auctions. The conditions in the global credit markets have prevented some investors from liquidating their holdings of auction rate securities because the amount of securities submitted for sale has exceeded the amount of purchase orders for such securities. If there is insufficient demand for the securities at the time of an auction, the auction may not be completed and the interest rates may be reset to predetermined higher rates. When auctions for these securities fail, the investments may not be readily convertible to cash until a future auction of these investments is successful or they are redeemed or mature.

Since February 2008, there has been insufficient demand at auction for our auction rate security held at September 30, 2014. 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 September 30, 2014, 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 September 30, 2014, we had recorded cumulative unrealized gains of $0.1 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 September 30, 2014. 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.

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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.

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 Exchange Act as of the end of the period covered by this Report. Based on this evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective and were operating at a reasonable assurance level as of September 30, 2014.

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 September 30, 2014, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

In late October and early November 2013, following our announcement of the results of our Phase 3 trial of Allovectin® and the subsequent decline of the price of our common stock, two putative, securities class action complaints were filed in the U.S. District Court for the Southern District of California against us and certain of our current and former officers. On February 26, 2014, the two cases were consolidated into one action and a lead plaintiff and lead counsel were appointed. On April 3, 2014, the lead plaintiff filed a consolidated complaint alleging that the defendants violated Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 by making materially false and misleading statements regarding our business prospects and the prospects for Allovectin®, thereby artificially inflating the price of our common stock. The consolidated complaint seeks unspecified monetary damages and other relief. On April 25, 2014, the parties filed a joint motion asking the Court to permit plaintiffs to amend the consolidated complaint, which the Court granted. On May 12, 2014, lead plaintiff filed an amended complaint. On June 9, 2014, defendants filed a motion to dismiss the amended complaint. That same day, defendants also filed a motion to strike certain allegations in the amended complaint. The motions to dismiss and strike are fully briefed, but the Court has not yet issued an order. We plan to vigorously defend against the claims advanced. At this time, we unable to estimate possible losses or ranges of losses for ongoing legal actions.

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, 2013, as filed with the SEC.

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

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

We have an allowed IND for our CyMVectin vaccine candidate. However, we may not conduct Phase 1 CyMVectin vaccine trials, and 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 our product candidates, it could have a material adverse impact on our business prospects.

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.

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

Before obtaining regulatory approvals for the commercial sale of our product candidates, we must demonstrate through lengthy, complex and expensive preclinical testing and clinical trials that our product candidates are both safe and effective for use in each target indication. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. The results of preclinical studies and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. There is typically an extremely high rate of attrition from the failure of product candidates proceeding through clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy profile despite having progressed through preclinical studies and initial clinical trials. We and our licensees have in the past suffered significant setbacks in advanced clinical trials due to lack of efficacy, notwithstanding promising results in earlier trials. For example, in 2013 we ceased development of Allovectin®, an investigational intratumoral cancer immunotherapy, following negative results from a Phase 3 trial. Most product candidates that commence clinical trials are never approved as products.

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

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

the supply or quality of our product candidates or other materials necessary to conduct our clinical studies may be insufficient, inadequate or delayed.

In addition, even if clinical trials are successfully completed, we cannot guarantee that the FDA or foreign regulatory authorities will interpret the results as we do, and more trials could be required before we submit our product

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candidates for approval. To the extent that the results of the trials are not satisfactory to the FDA or foreign regulatory authorities for support of a marketing application, approval of our product candidates may be significantly delayed, or we may be required to expend significant additional resources, which may not be available to us, to conduct additional trials in support of potential approval of our product candidates.

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

Pursuant to the terms of our license agreements with Astellas, we granted to Astellas exclusive worldwide rights to develop and commercialize certain products, including ASP0113 but excluding CyMVectin , for the control and prevention of CMV infection in immunocompromised patients, including transplant recipients and transplant donors, and pursuant to the terms of our supply and services agreement with Astellas, we are obligated to perform certain development activities and supply Astellas with its product requirements for development and initial commercialization activities. Consequently, our ability to generate any revenues from ASP0113 depends on Astellas ability to develop, obtain regulatory approvals for and successfully commercialize ASP0113. We have limited control over the amount and timing of resources that Astellas will dedicate to these efforts.

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 ASP0113, which could adversely impact sales or future development of ASP0113;
- We and Astellas could disagree as to future development plans and Astellas may delay, fail to commence or stop future clinical trials or other development;
- There may be disputes between us and Astellas, including disagreements regarding the license agreements, that may result in (1) the delay of or failure to achieve developmental, regulatory and commercial objectives that would result in milestone or royalty payments, (2) the delay or termination of any future development or commercialization of ASP0113, and/or (3) costly litigation or arbitration that diverts our management s attention and resources;
- Astellas may not provide us with timely and accurate information regarding development, sales and marketing activities or supply forecasts, which could adversely impact our ability to comply with our service and supply obligations to Astellas and manage our own inventory of ASP0113, as well as our ability to generate accurate financial forecasts;
- Business combinations or significant changes in Astellas business strategy may adversely affect Astellas ability or willingness to perform its obligations under our license agreements;
- Astellas may not properly defend our intellectual property rights, or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property rights or expose us to potential litigation;
- The royalties we are eligible to receive from Astellas may be reduced based upon Astellas and our ability to maintain or defend our intellectual property rights and the presence of generic competitors;
- Limitations on our or an acquiror s ability to maintain or pursue development or commercialization of products that are competitive with ASP0113 could deter a potential acquisition of us that our stockholders may otherwise view as beneficial; and

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

The 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

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commercialization will not be beneficial for Astellas. If the agreements are terminated early, we may not be able to find another collaborator for the commercialization and further development of ASP0113 on acceptable terms, or at all, and we may be unable to pursue continued development or commercialization of ASP0113 on our own.

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

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

Some collaborators or licensees may not succeed in their product development efforts. It is possible that our collaborators or licensees may be unable to obtain regulatory approval of product candidates using our technologies or successfully market and commercialize any such products for which regulatory approval is obtained. 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, for Collategene® 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 $31.2 million, $22.9 million and $7.3 million for the years ended December 31, 2013, 2012 and 2011, respectively. As of September 30, 2014, we had incurred cumulative net losses totaling approximately $391.0 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 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 $146.1 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. In April 2014, we entered into an ATM Agreement with Brinson Patrick, under which we may issue and sell up to $25.0 million of our common stock from time to time. As of September 30, 2014 there was $21.1 million of our common stock available to be sold under the Brinson Patrick ATM. However, neither Stifel nor Brinson Patrick are obligated to sell any shares that we may request to be sold, and any attempt to sell shares under these facilities, 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;
- The amount of our legal expenses, including those expenses associated with the shareholder class action filed against us and certain of our current and former officers and any settlement or damages payments associated with litigation; and
- The time and costs involved in: obtaining necessary regulatory approvals; filing, prosecuting and enforcing patent claims; scaling up our manufacturing capabilities; and the commercial arrangements we may establish.

(*)If we do not continue to realize the expected benefits and successfully manage the transition from the restructuring that we announced in August 2013, our operations and financial condition may be negatively impacted.

In August 2013, we implemented a restructuring designed to conserve capital and focus our development activities on our infectious disease vaccine candidates. If we are unable to continue to realize the expected operational efficiencies and cost savings from our restructuring, our operating results and financial condition would be adversely affected. We cannot guarantee that we will not have to undertake additional restructuring activities or that any of our restructuring efforts will be successful in the long-term.

We will also need to effectively manage our operations and facilities in order to advance our drug development programs and support our collaboration arrangements. Following our August 2013 restructuring, it is possible that our infrastructure may be inadequate to support our future efforts and business strategy or to maintain effective operational, financial and management controls and reporting systems and procedures. If we cannot successfully manage the transition of our restructured operations, we may be unsuccessful in executing our business strategy.

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

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

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

- Impose costly procedures on our activities and those of our collaborators and licensees;
- Delay or prevent our receipt of developmental or commercial milestones from our collaborators and licensees;
- 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, with the FDA. Because a BLA 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 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 affected.

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

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

The commercial success of some of our product candidates will depend in part on public acceptance of the use of gene therapy for preventing or treating human diseases. Serious adverse events, including patient deaths, have occurred in clinical trials utilizing viral delivery systems to deliver therapeutic genes to the patient s targeted cells. Although none of our current products or studies utilize viral delivery systems, these adverse events, as well as any other adverse events in the field

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of gene therapy that may occur in the future, may negatively influence public perception of gene therapy in general. If public perception is influenced by claims that gene therapy is unsafe, our product candidates may not be accepted by the general public or the medical community.

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

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

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

As of September 30, 2014, we were the assignee or co-assignee of 70 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 September 30, 2014, we were also prosecuting 20 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.

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We also rely on confidentiality agreements with our corporate collaborators, employees, consultants and certain contractors to protect our proprietary technologies. However, these agreements may be breached and we may not have adequate remedies for such breaches. In addition, our trade secrets may otherwise become known or independently discovered by our competitors.

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

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

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

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

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

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

The internet site ClinicalTrials.gov 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.

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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. We will also depend on third parties for any commercial scale filling of product vials. 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, 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.

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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.

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 September 30, 2014, our long-term investments included a (at par value) $2.5 million auction rate security secured by municipal bonds. At September 30, 2014, the auction rate security we held maintained a Standard and Poor s credit rating of A-. 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

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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 September 30, 2014. 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 September 30, 2014, we had recognized $0.5 million of losses related to the auction rate security. The market value of the security has partially recovered from the lows that created the losses. As of September 30, 2014, we had recorded cumulative unrealized gains of $0.1 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.

(*)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, 2011, to September 30, 2014, our stock price has ranged from $1.01 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.

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We and certain of our current and former officers have been named as defendants in two recently initiated securities class action lawsuits and are at risk of future securities class action litigation due to our past and expected stock price volatility.

In the past, stockholders have brought securities class action litigation against a company following a decline in the market price of its securities. This risk is especially acute for us because life science companies have experienced greater than average stock price volatility in recent years and, as a result, have been subject to, on average, a greater number of securities class action claims than companies in other industries. For example, we and certain of our current and former officers have been the target of class action litigation relating to the decline in our stock price following our announcement that our Phase 3 clinical trial with Allovectin® failed to achieve its pre-established endpoints. Even if such claims are not successful, the litigation could result in substantial costs and divert our management s attention and resources, which could have a material adverse effect on our business, operating results or financial condition.

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

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

(*)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 $146.1 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.
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.
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.
* 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: November 3, 2014

By: /s/ ANTHONY A. RAMOS
Anthony A. Ramos
VP Finance, Chief Accounting Officer (on behalf of the registrant and as the registrant s Principal Accounting Officer)