

VICAL INC  
Form 10-Q  
May 06, 2011  
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**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

**Washington, D.C. 20549**

**FORM 10-Q**

**QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**  
For the quarterly period ended March 31, 2011

**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**  
(State or other jurisdiction of  
incorporation or organization)

**93-0948554**  
(I.R.S. Employer Identification No.)

**10390 Pacific Center Court**  
**San Diego, California**  
(Address of principal executive offices)

**92121**  
(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

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to such filing requirements for the past 90 days. Yes  No

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer or a smaller reporting company. 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  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

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

Total shares of common stock outstanding at April 30, 2011: 71,714,111

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**Table of Contents****PART I. FINANCIAL INFORMATION****ITEM 1. FINANCIAL STATEMENTS****VICAL INCORPORATED****BALANCE SHEETS****(In thousands, except par value data)****(Unaudited)**

	March 31, 2011	December 31, 2010
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 26,362	\$ 47,320
Marketable securities, available-for-sale	17,033	5,037
Restricted cash	2,911	2,911
Receivables and other	1,377	940
<b>Total current assets</b>	<b>47,683</b>	<b>56,208</b>
Long-term investments	5,401	5,434
Property and equipment, net	7,240	7,560
Intangible assets, net	3,168	3,247
Other assets	458	458
<b>Total assets</b>	<b>\$ 63,950</b>	<b>\$ 72,907</b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable and accrued expenses	\$ 5,360	\$ 6,334
Deferred revenue	76	
<b>Total current liabilities</b>	<b>5,436</b>	<b>6,334</b>
Long-term liabilities:		
Deferred rent	2,154	2,211
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, 71,696 and 71,640 shares issued and outstanding at March 31, 2011 and December 31, 2010, respectively	717	716
Additional paid-in capital	381,663	380,929
Accumulated deficit	(326,449)	(317,755)
Accumulated other comprehensive gain	429	472
<b>Total stockholders' equity</b>	<b>56,360</b>	<b>64,362</b>

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Total liabilities and stockholders' equity

\$ 63,950

\$ 72,907

See accompanying notes to unaudited financial statements

**Table of Contents****VICAL INCORPORATED****STATEMENTS OF OPERATIONS****(In thousands, except per share data)****(Unaudited)**

	<b>Three Months Ended March 31,</b>	
	<b>2011</b>	<b>2010</b>
<b>Revenues:</b>		
Contract and grant revenue	\$ 530	\$ 586
License and royalty revenue	119	877
<b>Total revenues</b>	<b>649</b>	<b>1,463</b>
<b>Operating expenses:</b>		
Research and development	4,290	5,102
Manufacturing and production	2,748	2,805
General and administrative	2,328	2,185
<b>Total operating expenses</b>	<b>9,366</b>	<b>10,092</b>
Loss from operations	(8,717)	(8,629)
<b>Other income (expense):</b>		
Investment and other income (expense), net	23	151
<b>Net loss</b>	<b>\$ (8,694)</b>	<b>\$ (8,478)</b>
Basic and diluted net loss per share	\$ (0.12)	\$ (0.15)
<b>Weighted average shares used in computing basic and diluted net loss per share</b>	<b>71,893</b>	<b>55,299</b>

See accompanying notes to unaudited financial statements

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**VICAL INCORPORATED**  
**STATEMENTS OF CASH FLOWS**

(In thousands)

(Unaudited)

	<b>Three Months Ended March 31,</b>	
	<b>2011</b>	<b>2010</b>
<b>Cash flows from operating activities:</b>		
Net loss	\$ (8,694)	\$ (8,478)
<b>Adjustments to reconcile net loss to net cash used in operating activities:</b>		
Depreciation and amortization	579	697
Compensation expense related to stock options and awards	798	599
<b>Changes in operating assets and liabilities:</b>		
Receivables and other	(437)	(452)
Accounts payable, accrued expenses and other liabilities	(996)	(2,114)
Deferred revenue	76	(60)
Deferred rent	(35)	(14)
<b>Net cash used in operating activities</b>	<b>(8,709)</b>	<b>(9,822)</b>
<b>Cash flows from investing activities:</b>		
Maturities of marketable securities including restricted	4,767	9,107
Purchases of marketable securities including restricted	(16,773)	(11,635)
Purchases of property and equipment	(78)	(27)
Patent expenditures	(102)	(86)
<b>Net cash used in investing activities</b>	<b>(12,186)</b>	<b>(2,641)</b>
<b>Cash flows from financing activities:</b>		
Net proceeds from issuance of common stock	1	4,934
Payment of withholding taxes for net settlement of restricted stock units	(64)	(53)
<b>Net cash (used in) provided by financing activities</b>	<b>(63)</b>	<b>4,881</b>
Net decrease in cash and cash equivalents	(20,958)	(7,582)
Cash and cash equivalents at beginning of period	47,320	25,873
Cash and cash equivalents at end of period	\$ 26,362	\$ 18,291

See accompanying notes to unaudited financial statements

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**VICAL INCORPORATED**

**NOTES TO FINANCIAL STATEMENTS**

**March 31, 2011**

**(Unaudited)**

**1. GENERAL**

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

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

The unaudited financial statements at March 31, 2011, and for the three months ended March 31, 2011 and 2010, have been prepared in accordance with the rules and regulations of the Securities and Exchange Commission, or SEC, and with accounting principles generally accepted in the United States applicable to interim financial statements. These unaudited financial statements have been prepared on the same basis as the audited financial statements and include all adjustments, consisting of only normal recurring accruals, which in the opinion of management are necessary to present fairly the Company's financial position as of the interim date and results of operations for the interim periods presented. Interim results are not necessarily indicative of results for a full year or future periods. The preparation of financial statements requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosures of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ materially from those estimates. These unaudited financial statements should be read in conjunction with the Company's audited financial statements for the year ended December 31, 2010, included in its Annual Report on Form 10-K filed with the SEC.

*Cash, Cash Equivalents and Marketable Securities*

Cash and cash equivalents consist of cash and highly liquid securities with original maturities at the date of acquisition of ninety days or less. Investments with an original maturity of more than ninety days are considered marketable securities and have been classified by management as available-for-sale. These investments are classified as current assets, even though the stated maturity date may be one year or more beyond the current balance sheet date. 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 reclassified out of accumulated other comprehensive income, if any, are determined on a specific identification basis.

*Restricted Cash*

The Company is required to maintain a letter of credit securing an amount equal to twelve months of the current monthly installment of base rent for the term of its primary facilities lease, which ends in August 2017. Under certain circumstances the Company may be able to eliminate the need for the letter of credit. As of March 31, 2011, and December 31, 2010, restricted cash of \$2.9 million was pledged as collateral for this letter of credit.



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### *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.

### *Contract and Grant Revenue*

The Company's contract manufacturing arrangements typically require the delivery of multiple lots of clinical vaccines. The Company analyzes its multiple element arrangements to determine whether the elements can be separated and accounted for individually as separate units of accounting. The evaluation is performed at the inception of the arrangement. The delivered item(s) is considered a separate unit of accounting if all of the following criteria are met: (1) the delivered item(s) has value to the customer on a standalone basis; (2) there is objective and reliable evidence of the fair value of the undelivered item(s); and (3) 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. If the delivered item does not have standalone value or the Company does not have objective or reliable evidence of the fair value of the undelivered component, the amount of revenue allocable to the delivered item is deferred.

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.

### *License and Royalty Revenue*

The Company's license and royalty revenues are generated through agreements with strategic partners. Nonrefundable, up-front license fees and milestone payments with standalone value that are not dependent on any future performance by the Company under the agreements are recognized as revenue upon the earlier of when payments are received or collection is assured, but are deferred if the Company has continuing performance obligations. If the Company has continuing involvement through contractual obligations under such agreements, such up-front fees are deferred and recognized over the period for which the Company continues to have a performance obligation.

The Company recognizes royalty revenues from licensed products when earned in accordance with the terms of the license agreements. Net sales figures used for calculating royalties include deductions for costs of returns, cash discounts, and freight and warehousing, which may vary over the course of the license agreements. Payments received related to milestones are recognized as revenue upon the achievement of the milestones as specified in the underlying agreements, which represent the culmination of the earnings process.

### *Net Loss Per Share*

Basic and diluted net loss per share has been computed using the weighted-average number of shares of common stock outstanding during the period. The weighted average number of shares used to compute diluted loss per share excludes any assumed exercise of stock options and warrants, and the assumed issuance of common stock under restricted stock units, or RSUs, as the effect would be antidilutive. Common stock equivalents of 0.7 million and 0.9 million for the three months ended March 31, 2011 and 2010, respectively, were excluded from the calculation because of their antidilutive effect.

### *Recent Accounting Pronouncements*

In March 2010, the FASB ratified the milestone method of revenue recognition. Under this new standard, an entity can recognize contingent consideration earned from the achievement of a substantive milestone in its entirety in the period in which the milestone is achieved. 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 entity. This guidance is effective for annual periods beginning after June 15, 2010, but may be adopted earlier as of the beginning of an annual period. The Company adopted these provisions as of January 1, 2011. The adoption did not have a material impact on the Company's financial position or results of operations.

In September 2009, the FASB issued authoritative guidance regarding multiple-deliverable revenue arrangements. This guidance addresses how to separate deliverables and how to measure and allocate consideration to one or more units of accounting. Specifically, the guidance requires that consideration be allocated among multiple deliverables based on relative



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selling prices. The guidance establishes a selling price hierarchy of (1) vendor-specific objective evidence, (2) third-party evidence and (3) estimated selling price. This guidance is effective for annual periods beginning after June 15, 2010, but may be adopted earlier as of the beginning of such annual period. The Company adopted these provisions as of January 1, 2011. The adoption did not have a material impact on the Company's financial position or results of operations.

**2. STOCK-BASED COMPENSATION**

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

	Three Months Ended March 31,	
	2011	2010
Research and development	\$ 258	\$ 163
Manufacturing and production	31	71
General and administrative	509	365
Total stock-based compensation expense	\$ 798	\$ 599

During the three months ended March 31, 2011 and 2010, the Company granted stock-based awards with a total estimated value of \$2.9 million and \$3.7 million, respectively. At March 31, 2011, total unrecognized estimated compensation expense related to unvested stock-based awards granted prior to that date was \$4.4 million, which is expected to be recognized over a weighted-average period of 1.5 years. Stock-based awards granted during the three months ended March 31, 2011 and 2010, were each equal to 3.1% of outstanding shares of common stock at the end of the applicable period.

**3. COMPREHENSIVE LOSS**

Comprehensive loss consists of net loss and certain changes in equity that are excluded from net loss. Accumulated other comprehensive gain (loss) represents net unrealized gain (loss) on marketable securities. For the three months ended March 31, 2011 and 2010, other comprehensive (loss) gain was \$(43,000) and \$48,000, respectively, and total accumulated comprehensive loss was \$8.7 million and \$8.4 million, respectively.

**4. OTHER BALANCE SHEET ACCOUNTS**

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

	March 31, 2011	December 31, 2010
Clinical trial accruals	\$ 2,094	\$ 2,338
Employee compensation	1,855	2,730
Accounts payable	241	752
Other accrued liabilities	1,170	514
Total accounts payable and accrued expenses	\$ 5,360	\$ 6,334

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

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

**6. SHORT-TERM MARKETABLE SECURITIES**

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

	Amortized Cost	Unrealized Gain	Unrealized Loss	Market Value
<b>March 31, 2011</b>				
U.S. treasuries	\$ 1,018	\$	\$ 1	\$ 1,017
Government-sponsored enterprise securities	10,006		9	9,997
Corporate bonds	5,154			5,154
Certificates of deposit	865			865
	\$ 17,043	\$	\$ 10	\$ 17,033

	Amortized Cost	Unrealized Gain	Unrealized Loss	Market Value
<b>December 31, 2010</b>				
U.S. treasuries	\$ 1,002	\$	\$	\$ 1,002
Government-sponsored enterprise securities	2,999	1		3,000
Certificates of deposit	1,035			1,035
	\$ 5,036	\$ 1	\$	\$ 5,037

At March 31, 2011, \$7.5 million of these securities were scheduled to mature outside of one year. The Company did not realize any gains or losses on sales of available-for-sale securities for the three months ended March 31, 2011. As of March 31, 2011, none of the securities had been in a continuous unrealized loss position longer than 12 months.

**7. LONG-TERM INVESTMENTS**

As of March 31, 2011, the Company held \$6.5 million (at par value) of auction rate securities which were classified as long-term investments. With the liquidity issues experienced in global credit and capital markets, these auction rate securities have experienced multiple failed auctions as the amount of securities submitted for sale has exceeded the amount of purchase orders, and as a result, these affected securities are currently not liquid. All of the Company's auction rate securities are secured by either student loans or municipal bonds. The student loans are backed by the full faith and credit of the federal government (up to approximately 98% of the value of the student loan). At March 31, 2011, the auction rate securities the Company held maintained Standard and Poor's credit ratings of BBB or AAA. All of these securities continue to pay interest according to their stated terms. While it is not the Company's intent to hold these securities until their stated ultimate maturity dates, these investments are scheduled to ultimately mature between 2038 and 2043.

The valuation of the Company's auction rate security investment portfolio is subject to uncertainties that are difficult to predict. The fair values of these securities are estimated utilizing a discounted cash flow analysis. The key drivers of the valuation model include the expected term, collateralization underlying the security investments, the creditworthiness of the counterparty, the timing of expected future cash flows, rates of

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default of the underlying assets, discount rates, and the expectation of the next time the security is expected to have a successful auction. These securities were also compared, when possible, to other observable market data for securities with similar characteristics. Based on the valuation of the individual securities, the Company has recognized cumulative losses of \$1.5 million as of March 31, 2011, none of which was realized during the three months ended March 31, 2011. The losses when incurred are included in investment and other income. The market value of these securities has partially recovered. Included in other comprehensive income are unrealized (losses) gains

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of \$(33,000) and \$0.1 million for the three months ended March 31, 2011 and 2010, respectively. As of March 31, 2011, the Company had recorded cumulative unrealized gains of \$0.4 million. The resulting carrying value of the auction rate securities at March 31, 2011, was \$5.4 million which is included in long-term investments. Any future decline in market value may result in additional losses being recognized.

At present, in the event the Company needs to liquidate its auction rate securities that are in an illiquid state, it may not be able to do so without the possible loss of principal until a future auction for these investments is successful, another secondary market evolves for these securities, they are redeemed by the issuer or they mature. If the Company is unable to sell these securities in the market or they are not redeemed, then the Company could be required to hold them to maturity. The Company does not have a need to access these funds for operational purposes in the foreseeable future. The Company will continue to monitor and evaluate these investments on an ongoing basis for impairment.

**8. FAIR VALUE MEASUREMENTS**

The current guidance related to fair value measurements, among other things, defines fair value, establishes a consistent framework for measuring fair value and expands disclosure for each major asset and liability category measured at fair value on either a recurring or nonrecurring basis. The guidance clarifies that fair value is 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. 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. As a basis for considering such assumptions, the guidance establishes a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value as follows:

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

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

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

Cash, cash equivalents, marketable securities and long-term investments measured at fair value as of March 31, 2011, are classified in the table below in one of the three categories described above (in thousands):

	Fair Value Measurements			Total
	Level 1	Level 2	Level 3	
Demand deposits	\$ 20,680	\$	\$	\$ 20,680
Certificates of deposit	865			865
Money market funds	8,593			8,593
U.S. treasury securities	1,017			1,017
Corporate bonds		5,154		5,154
Government-sponsored enterprise securities		9,997		9,997
Auction rate securities			5,401	5,401
	\$ 31,155	\$ 15,151	\$ 5,401	\$ 51,707

The Company's investments in U.S. treasury securities, certificates of deposits and money market funds are valued based on publicly available quoted market prices for identical securities as of March 31, 2011. The Company's investments in government-sponsored entities and corporate bonds are valued by a third party using proprietary valuation models and analytical tools. The inputs to these models include market pricing for similar instruments that are both objective and publicly available. The Company's investments in auction rate securities are also valued by a third party as more fully described in Note 7.



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

	<b>Three Months Ended March 31, 2011</b>
Balance at December 31, 2010	\$ 5,434
Total net unrealized losses included in earnings	
Total net unrealized losses included in other comprehensive income	(33)
Net transfers in and/out of Level 3	
<b>Balance at March 31, 2011</b>	<b>\$ 5,401</b>
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	\$

**9. STOCKHOLDERS EQUITY**

During the first quarter of 2010, certain of the Company's investors exercised warrants to purchase an aggregate of 2,365,644 shares of common stock that were issued in connection with the Company's May 2009 registered direct offering. The Company received net proceeds of \$5.0 million as a result of these exercises.



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

This Quarterly Report on Form 10-Q, or Report, contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, including statements regarding our business, our financial position, the research and development of biopharmaceutical products based on our patented DNA delivery technologies, the funding of our research and development efforts, and other statements describing our goals, expectations, intentions or beliefs. Such statements reflect our current views and assumptions and are subject to risks and uncertainties, particularly those inherent in the process of developing and commercializing biopharmaceutical products based on our patented DNA delivery technologies. Actual results could differ materially from those projected herein. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in our Annual Report on Form 10-K for the year ended December 31, 2010, 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;

Vaccines for general pediatric, adolescent and adult populations for infectious disease applications;

Cancer vaccines or immunotherapies which complement our existing programs and core expertise; and

Gene-based delivery of therapeutic proteins, such as angiogenic growth factors, for treatment of cardiovascular diseases.

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

A fully enrolled Phase 3 clinical trial using our Allovectin<sup>®</sup> immunotherapeutic in patients with metastatic melanoma which has been funded, up to certain limits, by AnGes MG, Inc., or AnGes, through cash payments and equity investments under a research and development agreement;

A recently completed Phase 2 clinical trial using TransVax<sup>®</sup>, our cytomegalovirus, or CMV, therapeutic DNA vaccine, in patients undergoing hematopoietic cell transplants. Preparation for a Phase 3 trial is ongoing;

A recently completed Phase 1 clinical trial using our H1N1 pandemic influenza DNA vaccine formulated with our proprietary Vaxfectin<sup>®</sup> adjuvant;

A completed preclinical program, with an allowed investigational new drug application, using our CyMVectin<sup>®</sup> prophylactic vaccine formulated with our proprietary Vaxfectin<sup>®</sup> adjuvant to prevent CMV infection before and during pregnancy; and

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A preclinical program with therapeutic and prophylactic vaccines for herpes simplex virus 2 formulated with our proprietary Vaxfectin® adjuvant.

We have leveraged our patented technologies through licensing and collaboration arrangements, such as our licensing arrangements with Merck & Co., Inc., or Merck, AnGes, Aqua Health Ltd. of Canada, or Aqua Health, an affiliate of Novartis Animal Health, and Merial Limited, or Merial, a subsidiary of the sanofi-aventis Group, or sanofi-aventis, among other biopharmaceutical companies. Two of the licenses have resulted in the following approvals in veterinary applications, which we believe are important steps in the validation of our DNA delivery technology:

In 2005, our licensee Aqua Health received approval from the Canadian Food Inspection Agency to sell a DNA vaccine, Apex®-IHN, to protect farm-raised salmon against a lethal infectious disease.

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In 2009, our licensee Merial received approval from the U.S. Department of Agriculture, or USDA, to market a therapeutic DNA vaccine, ONCEPT , designed to aid in extending the survival time of dogs with oral melanoma, which was launched in January 2010.

We believe that Merial s vaccine is the first cancer vaccine ever approved for therapeutic use.

In addition, we have licensed complementary technologies from leading research institutions and biopharmaceutical companies. We also have granted non-exclusive, academic licenses to our DNA delivery technology patent estate to 11 leading research institutions including Stanford, Harvard, Yale and the Massachusetts Institute of Technology. The non-exclusive academic licenses allow university researchers to use our technology free of charge for educational and internal, non-commercial research purposes. In exchange, we have the option to exclusively license from the universities potential commercial applications arising from their use of our technology on terms to be negotiated.

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

<b>Product/Concept</b>	<b>Intended Use</b>	<b>Development Status<sup>1</sup></b>	<b>Lead Developer</b>
<b>Independent Programs</b>			
Allovectin <sup>®</sup> cancer immunotherapeutic	First-line treatment for metastatic melanoma	Phase 3	Vical
TransVax therapeutic vaccine for cytomegalovirus	Protect against viral reactivation after transplant	Phase 3 preparation	Vical
Prophylactic vaccine for H5N1 pandemic influenza virus	Prevent infection, disease, and/or viral shedding	Phase 1 complete	Vical
Prophylactic vaccine for H1N1 pandemic influenza virus	Prevent infection, disease, and/or viral shedding	Phase 1 complete	Vical
CyMVectin prophylactic vaccine for cytomegalovirus	Prevent infection before pregnancy to preclude fetal transmission	Preclinical complete	Vical
Therapeutic vaccine for herpes simplex type 2 virus	Protect against recurring flare-ups, reduce viral shedding and transmission	Preclinical	Vical
<b>Corporate Collaborations</b>			
Collatogene angiogenic therapy encoding Hepatocyte Growth Factor	Induce local growth of blood vessels to restore blood flow to limbs affected by critical limb ischemia	Phase 3 preparation	AnGes
Therapeutic vaccine encoding human telomerase reverse transcriptase	Treat non-small cell lung, breast or prostate cancer, melanoma, or carcinomas of the upper GI tract, colon, kidney, or bladder	Phase 1	Merck
Prophylactic and/or therapeutic hepatitis C vaccine	Prevent and/or treat infection, disease, and/or viral shedding	Research	Merck
Apex <sup>®</sup> -IHN prophylactic vaccine for infectious hematopoietic necrosis virus	Prevent infection and disease in farm-raised salmon when exposed to infected wild salmon	Approved in Canada	Aqua Health (Novartis)
ONCEPT therapeutic cancer vaccine encoding human tyrosinase	Adjunct treatment to increase survival time of dogs with oral melanoma	Approved in the United States	Merial
<b>Government Collaboration</b>			
Prophylactic and/or therapeutic HIV vaccine	Prevent and/or treat infection, disease, and/or viral shedding	Phase 2b	NIH

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

benefit-risk relationship of the investigational product and to provide an adequate basis for product labeling.

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### **Recent Events**

The following events have recently occurred with respect to our business and our independent programs:

#### *Continued Progress in our CMV Program*

We are currently preparing for a pivotal Phase 3 trial of our TransVax™ therapeutic CMV vaccine. At a recent End-of-Phase 2 meeting, the U.S. Food and Drug Administration, or FDA, was open to considering a clinically relevant CMV viremia endpoint or a combined endpoint that also includes use of antiviral therapy.

We received Scientific Advice from the European Medicines Agency, or EMA, recommending practical efficacy endpoints for a Phase 3 trial of our TransVax therapeutic CMV vaccine. Because the incidence of CMV disease is low with the use of preemptive antiviral therapy and the target population is small, the EMA agreed with our position that a CMV disease endpoint is not practical. The EMA also provided what we believe to be positive comments on important features of the proposed trial design and overall product development pathway. We are currently preparing for a pivotal Phase 3 trial with the FDA.

#### *Continued Progress in our Melanoma Program*

An independent Safety Monitoring Board for our Phase 3 trial of Allovectin® in patients with metastatic melanoma completed the trial's fifth scheduled safety analysis and the safety monitoring board recommended that the trial continue per the protocol.

#### *Pandemic Influenza Program*

We completed the Phase 1 trial of our Vaxfectin®-adjuvanted DNA vaccine for H1N1 influenza and found that more than half of the subjects in the trial generated neutralizing antibodies of the type expected to provide protection against the disease.

#### *Extension of NMRC Collaboration*

We extended our relationship with the U.S. Naval Medical Research Center, or NMRC, to develop our platform technology for the rapid development and production of vaccines against emerging infectious diseases. We received funding from the Defense Threat Reduction Agency and NMRC in 2010 to support development of our Vaxfectin®-formulated DNA vaccine against H1N1 pandemic influenza. With the additional funding under the extended relationship, we plan to work with the NMRC to establish systems and procedures for the application of our DNA delivery technology, with the goal of protecting military personnel from the threat of new pathogens in the early stages of outbreaks.

#### *Patent Update*

We were issued U.S. Patent No. 7,879,339 and U.S. Patent No. 7,935,352, assigned to us and the University of Washington, covering DNA vaccines for HSV-2. We are collaborating with the University of Washington School of Medicine and the Sealy Center for Vaccine Development under a previously disclosed grant on the preclinical development of an HSV-2 vaccine. The initial focus will be for people already infected with HSV-2, with the goal of reducing or eliminating periodic viral flare-ups and the associated viral shedding and transmission.

We were issued U.S. Patent No. 7,888,112 covering DNA vaccines for CMV containing specific gene sequences and formulated with our Vaxfectin® adjuvant. The patent covers DNA vaccines containing codon-optimized versions of genes encoding gB and CMV phosphoprotein 65 antigens, formulated with our Vaxfectin® adjuvant. It adds to our family of patents in the United States and

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other key regions based on our discovery that administering genetic sequences such as DNA or RNA into the body, without the use of viral delivery vehicles, may cause expression of the proteins encoded by the genetic sequences.

We were issued European Patent EP1587816, which extends coverage for TransVax™, our first-in-class therapeutic DNA vaccine designed to prevent reactivation of latent cytomegalovirus or introduction of CMV through donor cells or tissues in transplant recipients.

**Table of Contents****Research, Development and Manufacturing Programs**

To date, we have not received revenues from the sale of our independently developed pharmaceutical products and have received minimal revenues from the sale of commercially marketed products by our licensees. We earn revenues by performing services under research and development and manufacturing contracts, from grants and from licensing access to our proprietary technologies. Since our inception, we estimate that we have received approximately \$168.8 million in revenues from these sources. Revenues by source were as follows (in millions):

Source	Three Months Ended March 31,	
	2011	2010
RapidResponse DNA manufacturing grant	\$ 0.4	\$ 0.4
Navy H1N1 contract		0.1
HSV grant	0.1	0.1
Total contract and grant revenues	0.5	0.6
AnGes licenses		0.8
Other royalties and licenses	0.1	0.1
Total royalty and license revenues	0.1	0.9
Total revenues	\$ 0.6	\$ 1.5

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

Program	Three Months Ended March 31,	
	2011	2010
Allovectin®	\$ 4.6	\$ 4.7
CMV	1.4	1.8
Pandemic influenza	0.1	0.3
Other research, development, manufacturing and production	0.9	1.1
Total research, development, manufacturing and production	\$ 7.0	\$ 7.9

Since our inception through March 31, 2011, we estimate that we have spent approximately \$421 million on research, development, manufacturing and production. Our current independent development focus is on our cancer immunotherapeutic Allovectin®, novel DNA vaccines for CMV and pandemic influenza, and other clinical and preclinical targets.

We are conducting a Phase 3 clinical trial using Allovectin® in patients with recurrent metastatic melanoma which has been funded, up to certain limits, by AnGes through cash payments and equity investments under a research and development agreement. We are also in the early stages of clinical development of vaccine candidates for CMV and pandemic influenza and these programs will require significant additional funds to advance through development to commercialization. From inception through March 31, 2011, we have spent approximately \$137 million on our Allovectin® program, \$58 million on our CMV programs, and \$25 million on our pandemic influenza programs.

We have other product candidates in the research stage. It can take many years to develop product candidates from the initial decision to screen product candidates, perform preclinical and safety studies, and perform clinical trials leading up to possible approval of a product by the 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 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.



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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.

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### **Critical Accounting Policies and Estimates**

The preparation 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, actual results may differ from these estimates.

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

#### ***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.

*Contract Manufacturing Revenue.* Our contract manufacturing arrangements typically require the delivery of multiple lots of clinical vaccines. We analyze our multiple element arrangements to determine whether the elements can be separated and accounted for individually as separate units of accounting. The evaluation is performed at the inception of the arrangement. The delivered item(s) is considered a separate unit of accounting if all of the following criteria are met: (1) the delivered item(s) have standalone value to the customer; (2) there is objective and reliable evidence of the fair value of the undelivered item(s); and (3) 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 our control. If the delivered item does not have standalone value or we do not have objective or reliable evidence of the fair value of the undelivered component, the amount of revenue allocable to the delivered item is deferred.

*License and Royalty Revenue.* Our license and royalty revenues are generated through agreements with strategic partners. Nonrefundable, up-front license fees and milestone payments with standalone value that are not dependent on any future performance by us under the arrangements are recognized as revenue upon the earlier of when payments are received or collection is assured, but are deferred if we have continuing performance obligations. If we have continuing involvement through contractual obligations under such agreement, such up-front fees are deferred and recognized over the period for which we continue to have a performance obligation, unless all of the following criteria exist: (1) the delivered item(s) have standalone value to the customer; (2) there is objective and reliable evidence of the fair value of the undelivered item(s); and (3) 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 our control. If the delivered item does not have standalone value or we do not have objective or reliable evidence of the fair value of the undelivered component, the amount of revenue allocable to the delivered item is deferred.

We recognize royalty revenues from licensed products when earned in accordance with the terms of the license agreements. Net sales figures used for calculating royalties include deductions for costs of returns, cash discounts, and costs of freight and warehousing, which may vary over the course of the license agreement. Payments received related to milestones are recognized as revenue upon the achievement of the milestones as specified in the underlying agreements, which represent the culmination of the earnings process.

*Contract Services and Government Research Grant Revenue.* We recognize revenue 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.

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### ***Research and Development Expenses***

Research and development expenses consist of expenses incurred in performing research and development activities including salaries and benefits, facilities and other overhead expenses, clinical trials, contract services and other outside expenses. Research and development expenses are charged to operations as they are incurred.

We assess our obligations to make milestone payments that may become due for licensed or acquired technology to determine whether the payments should be expensed or capitalized. We charge milestone payments to research and development expense when:

The technology is in the early stage of development and has no alternative uses;

There is substantial uncertainty of the technology or product being successful;

There will be difficulty in completing the remaining development; and

There is substantial cost to complete the work.

### ***Capitalization and Valuation of Long-Lived and Intangible Assets***

Intangible assets with finite useful lives consist of capitalized legal costs incurred in connection with patents, patent applications pending and technology license agreements. Payments to acquire a license to use a proprietary technology are capitalized if the technology is expected to have alternative future use in multiple research and development projects. We amortize costs of approved patents, patent applications pending and license agreements over their estimated useful lives, or terms of the agreements, whichever are shorter.

For patents pending, we amortize the costs over the shorter of a period of twenty years from the date of filing the application or, if licensed, the term of the license agreement. We re-assess the useful lives of patents when they are issued, or whenever events or changes in circumstances indicate the useful lives may have changed. For patents and patent applications pending that we abandon, we charge the remaining unamortized accumulated costs to expense.

Intangible assets and long-lived assets are evaluated for impairment at least annually or whenever events or changes in circumstances indicate that their carrying value may not be recoverable. If the review indicates that intangible assets or long-lived assets are not recoverable, their carrying amount would be reduced to fair value. Factors we consider important that could trigger an impairment review include the following:

A significant change in the manner of our use of the acquired asset or the strategy for our overall business; and/or

A significant negative industry or economic trend.

In the event we determine that the carrying value of intangible assets or long-lived assets is not recoverable based upon the existence of one or more of the above indicators of impairment, we may be required to record impairment charges for these assets. As of March 31, 2011, our largest group of intangible assets with finite lives includes patents and patents pending for our DNA delivery technology, consisting of intangible assets with a net carrying value of approximately \$2.8 million.

### **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**

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### *Three Months Ended March 31, 2011, Compared with Three Months Ended March 31, 2010*

*Total Revenues.* Total revenues decreased \$0.9 million, or 55.6%, to \$0.6 million for the three months ended March 31, 2011, from \$1.5 million for the three months ended March 31, 2010. Our license and royalty revenue decreased by \$0.8 million which was primarily the result of a decrease in the recognition of revenue related to our Allovectin<sup>®</sup> license agreement with AnGes.

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*Research and Development Expenses.* Research and development expenses decreased \$0.8 million, or 15.9%, to \$4.3 million for the three months ended March 31, 2011, from \$5.1 million for the three months ended March 31, 2010. This decrease was primarily the result of lower costs related to our clinical trials for Allovectin® and TransVax .

*Manufacturing and Production Expenses.* Manufacturing and production expenses decreased \$0.1 million, or 2.0%, to \$2.7 million for the three months ended March 31, 2011, from \$2.8 million for the three months ended March 31, 2010. This decrease was primarily the result of lower employee related costs.

*General and Administrative Expenses.* General and administrative expenses increased \$0.1 million, or 6.5%, to \$2.3 million for the three months ended March 31, 2011, from \$2.2 million for the three months ended March 31, 2010. This increase was primarily the result of higher consulting costs and higher stock-based compensation expense.

## **Liquidity and Capital Resources**

Since our inception, we have financed our operations primarily through private placements of preferred and common stock, public offerings of common stock, and revenues from our operations. From our inception through March 31, 2011, we have received approximately \$168.8 million in revenues from performing services under research and development and manufacturing contracts, from grants and from licensing access to our proprietary technologies, and we have raised net proceeds of approximately \$370.8 million from the sale of equity securities. Cash, cash equivalents, marketable securities, and long-term investments, including restricted cash, totaled \$51.7 million at March 31, 2011, compared with \$60.7 million at December 31, 2010. The decrease in our cash, cash equivalents and marketable securities for the three months ended March 31, 2011, was primarily the result of the use of cash to fund our operations.

Net cash used in operating activities was \$8.7 million and \$9.8 million for the three months ended March 31, 2011 and 2010, respectively. The decrease in net cash used in operating activities for the three months ended March 31, 2011, compared with the prior year period, was primarily the result of a decrease in payments for accounts payable.

Net cash used in investing activities was \$12.2 million and \$2.6 million for the three months ended March 31, 2011 and 2010, respectively. The increase in cash used in investing activities for the three months ended March 31, 2011, compared with the prior year period, was primarily the result of an increase in net purchases of investments.

Net cash (used in) provided by financing activities was \$(0.1) million and \$4.9 million for the three months ended March 31, 2011 and 2010, respectively. The decrease in cash provided by financing activities for the three months ended March 31, 2011, compared with the prior year period, was the result of net proceeds received from the exercise of warrants during the three months ended March 31, 2010.

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

We expect to incur substantial additional research and development expenses, manufacturing and production expenses, and general and administrative expenses, including continued increases in costs related to personnel, preclinical and clinical testing, outside services, facilities, intellectual property and possible commercialization. Our future capital requirements will depend on many factors, including continued scientific progress in our research and development programs, the scope and results of preclinical testing and clinical trials, the time and costs involved in obtaining regulatory approvals, the costs involved in filing, prosecuting, enforcing and defending patent claims, the impact of competing technological and market developments, the cost of manufacturing scale-up and validation, and possible commercialization activities and arrangements. We may seek additional funding through research and development relationships with suitable potential corporate collaborators. We may also seek additional funding through public or private financings. We have on file two effective shelf registration statements that collectively allow us to raise up to an additional \$105.6 million from the sale of common stock, preferred stock, debt securities and/or warrants and we have also entered into an equity line of credit with Azimuth pursuant to which we may sell up to \$25.0 million of our common stock, subject to certain conditions. However, additional financing may not be available on favorable terms or at all. If additional funding 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, 2012.

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***Contractual Obligations***

Under our Merck, sanofi-aventis, AnGes, Merial and Aqua Health agreements, we are required to pay up to 10% of certain initial upfront monetary payments, and a small percentage of some royalty payments, to the Wisconsin Alumni Research Foundation and/or the University of Michigan. In addition, certain technology license agreements require us to make payments if we or our sublicensees advance products through clinical development. For programs developed with the support of U.S. government funding, the U.S. government may have rights to resulting products without payment of royalties to us.

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

The aggregate amount of additional milestone payments that we could be required to pay under all of our in-license agreements in place at March 31, 2011, is approximately \$13.8 million, of which approximately \$7.1 million is related to our independent programs and corporate and government collaborations which are currently in clinical development. These amounts assume that all remaining milestones associated with the milestone payments are met. In the event that product license approval for any of the related products is obtained, we may be required to make royalty payments in addition to these milestone payments. Although we believe that some of the milestones contained in our in-license agreements may be achieved, it is highly unlikely that a significant number of them will be achieved. Because the milestones are highly contingent and we have limited control over whether the development and regulatory milestones will be achieved, 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. Under the indemnification agreements with our officers and directors, we have agreed to indemnify those individuals for any expenses and liabilities in the event of a threatened, pending or actual investigation, lawsuit, or criminal or investigative proceeding.

We have employment agreements that contain severance arrangements with each of our three executive officers and three of our other executives. Under the agreements with the executive officers we are obligated to pay severance if we terminate the executive officer's employment without cause, or if the executive officer resigns for good reason, as defined in the agreements, within the periods set forth therein. The severance for the executive officers consists of continued base salary payments at the then-current rate, including the payment of health insurance premiums, for the period specified in each agreement, which ranges from 12 to 18 months, plus a payment equal to between one and one and a half times the executive's cash bonus in the previous year. In addition, the executive officers receive accelerated vesting on all their unvested stock awards as if they had remained employed by us for between 12 and 18 months from the date of termination. In the event that the termination occurs within 24 months of a change in control, as defined in the agreements, the severance for the executive officers consists of lump sum payments equal to between 18 and 24 months of base salary at the then-current rate, the payment of health insurance premiums for the period specified in each agreement, which ranges from 12 to 18 months, plus a payment equal to between one and one and a half times the executive's cash bonus in the previous year. In addition, all outstanding unvested stock awards will vest immediately. The severance for the other executive consists of continued payments at the then-current base compensation rate for a period of six months. All of the agreements specify that any earnings from employment or consulting during this period will offset any salary continuation payments due from us. The maximum payments due under these employment agreements would have been \$3.1 million if each such executive officer and other executive were terminated at March 31, 2011.

**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



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investments. The average maturity of our investments, excluding our auction rate securities, is approximately five months. Our investments are classified as available-for-sale securities.

To assess our interest rate risk, we performed a sensitivity analysis projecting an ending fair value of our cash equivalents and current marketable securities using the following assumptions: a 12-month time horizon, a 9-month average maturity and a 150-basis-point increase in interest rates. This pro forma fair value would have been \$0.2 million lower than the reported fair value of our investments at March 31, 2011.

All of our investment securities are classified as available-for-sale and therefore reported on the balance sheet at market value. Our investment securities consist of high-grade auction rate securities, corporate debt securities and government agency securities. As of March 31, 2011, our long-term investments included (at par value) \$6.5 million of auction rate securities secured by municipal bonds and student loans. At March 31, 2011, the auction rate securities we held maintained Standard and Poor's credit ratings of BBB or AAA. Our auction rate securities are debt instruments with a long-term maturity and with an interest rate that is reset in short intervals through auctions. The recent 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 all of our auction rate securities held at March 31, 2011. As a result, these affected securities are currently not liquid, and we could be required to hold them until they are redeemed by the issuer or to maturity. As of March 31, 2011, we had recognized \$1.5 million of losses related to those auction rate securities by adjusting their carrying value. The market value of these securities has partially recovered from the lows that created the losses. As of March 31, 2011, we had recorded cumulative unrealized gains of \$0.4 million. Any future decline in market value may result in additional losses being recognized.

The valuation of our auction rate security investment portfolio is subject to uncertainties that are difficult to predict. The fair values of these securities are estimated utilizing a discounted cash flow analysis or other type of valuation model as of March 31, 2011. The key drivers of the valuation model include the expected term, collateralization underlying the security investments, the creditworthiness of the counterparty, the timing of expected future cash flows, rates of default of the underlying assets, discount rates, and the expectation of the next time the security is expected to have a successful auction. These securities were also compared, when possible, to other observable market data with similar characteristics to the securities held by us.

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

## **ITEM 4. CONTROLS AND PROCEDURES**

### **Conclusion Regarding the Effectiveness of Disclosure Controls and Procedures**

Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of our disclosure controls and procedures, as such term is defined in Rule 13a-15(e) promulgated under the Securities Exchange Act of 1934, as amended, as of the end of the period covered by this Report. Based on this evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective as of March 31, 2011.

### **Changes in Internal Control over Financial Reporting**

There has been no change in our internal control over financial reporting during the three months ended March 31, 2011, that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.



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**PART II. OTHER INFORMATION**

**ITEM 1A. RISK FACTORS**

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

The risk factors set forth below with an asterisk (\*) next to the title are new risk factors or risk factors containing changes, including any material changes, from the risk factors previously disclosed in Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2010, as filed with the SEC.

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

All of our independently developed product candidates are either in research or development. We must conduct a substantial amount of additional research and development before any U.S. or foreign regulatory authority will approve any of our product candidates. Limited data exist regarding the efficacy of DNA vaccines or therapeutics compared with conventional vaccines or therapeutics. Results of our research and development activities may indicate that our product candidates are unsafe or ineffective. In this case, regulatory authorities will not approve them.

For example, our independently developed product candidates currently in clinical development include Allovectin<sup>®</sup>, for which we announced the completion of enrollment of a Phase 3 clinical trial in 2010, a completed Phase 2 clinical study of our TransVax therapeutic vaccine and a completed Phase 1 clinical study of our H1N1 pandemic influenza vaccine. We may not meet the primary endpoint of the Allovectin<sup>®</sup> trial for which a Special Protocol Assessment agreement is in place with the FDA. We may not conduct additional TransVax or H1N1 pandemic influenza vaccine trials, and the future trials, if any, may not demonstrate sufficient efficacy to support further product development.

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 revenues partially depend on the development and commercialization of products in collaboration with others to whom we have licensed our technologies. If our 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.*

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 AnGes has a product candidate in advanced stage of clinical development, for which we believe regulatory approval would provide important further validation of our DNA delivery technologies. The development and commercialization efforts of our collaborators and licensees are subject to the same risks and uncertainties described above with respect to our independently developed product candidates.

Some collaborators or licensees may not succeed in their product development efforts. It is possible that AnGes or any of our other collaborators or licensees may be unable to obtain regulatory approval of product candidates using our technologies or successfully market and commercialize any such products for which regulatory approval is obtained. In September 2010, AnGes announced that after a series of extensive consultations with the Japanese Pharmaceuticals and Medical Devices Agency, it would be withdrawing its NDA in Japan. Also in September 2010 another one of our licensees, sanofi-aventis announced that NV1FGF, an angiogenic growth factor therapeutic for which sanofi-aventis had licensed our DNA delivery technology, did not meet the primary endpoint in a global Phase 3 trial. Other collaborators or licensees may



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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.

***A significant portion of our revenue is derived from agreements with government agencies, which are subject to termination and uncertain future funding.***

We have entered into agreements with government agencies, such as the NIH and Navy Medical Research Center, and we intend to continue entering into these agreements in the future. For example, we receive grants from governmental agencies and have in the past entered into agreements to manufacture vaccines for such agencies. Our business is partially dependent on the continued performance by these government agencies of their responsibilities under these agreements, including adequate continued funding of the agencies and their programs. We have no control over the resources and funding that government agencies may devote to these agreements, which may be subject to annual renewal and which generally may be terminated by the government agencies at any time.

Government agencies may fail to perform their responsibilities under these agreements, which may cause them to be terminated by the government agencies. In addition, we may fail to perform our responsibilities under these agreements. Many of our government agreements are subject to audits which may occur several years after the period to which the audit relates. If an audit identifies significant unallowable costs, we could incur a material charge to our earnings or reduction in our cash position. As a result, we may be unsuccessful entering or ineligible to enter into future government agreements.

We apply for and have received funding from various government agencies. Eligibility of public companies to receive grants, such as Small Business Technology Transfer and Small Business Innovation Research grants, may be based on size and ownership criteria which are under review by the Small Business Administration, or SBA. As a result, our eligibility may change in the future, and additional funding from these sources may not be available.

***(\*)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 \$30.4 million, \$28.6 million and \$36.9 million for the years ended December 31, 2010, 2009 and 2008, respectively. As of March 31, 2011, we had incurred cumulative net losses totaling approximately \$326.4 million. Moreover, we expect that our net losses will continue and may increase for the foreseeable future. We may not be able to achieve projected results if we generate lower revenues or receive lower investment income than expected, or we incur greater expenses than expected, or all of the above. We may never generate sufficient product revenue to become profitable. We also expect to have quarter-to-quarter fluctuations in revenues, expenses, and losses, some of which could be significant.

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

We may need to raise more money to continue the research and development necessary to bring our products to market and to establish marketing and additional manufacturing capabilities. We may seek additional funds through public and private stock offerings, government contracts and grants, arrangements with corporate collaborators, borrowings under lease lines of credit or other sources. We have on file two effective shelf registration statements that collectively allow us to raise up to an additional \$105.6 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 January 2010, we entered into a committed equity line of credit with Azimuth, under which we may sell to Azimuth, subject to certain limitations, up to \$25.0 million of our common stock over a 24-month period. Azimuth will not be obligated to purchase shares under the equity line of credit unless specified conditions are met, which include a minimum price of \$1.50 for our common stock. If we are unable to meet the specified conditions with respect to any sale of shares under the Azimuth equity line of credit, we may be unable to access this source of financing. Azimuth is also permitted to terminate the equity line of credit under certain circumstances.

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

The progress of our research and development programs;

The scope and results of our preclinical studies and clinical trials; and

The time and costs involved in: obtaining necessary regulatory approvals; filing, prosecuting and enforcing patent claims; scaling up our manufacturing capabilities; and the commercial arrangements we may establish.

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

Our product candidates under development and those of our collaborators and licensees are subject to extensive and rigorous regulations by numerous governmental authorities in the United States and other countries. The regulatory approval process takes many years and will require us to expend substantial resources. For example, the FDA has provided only limited guidelines concerning the size and scope of clinical trials required for gene-based therapeutic and vaccine products.

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

Impose costly procedures on our activities and those of our collaborators and licensees;

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

Negatively affect our results of operations and cash flows.

We have no experience in filing a Biologics License Application, or BLA, or NDA, with the FDA. Because a BLA or NDA must be submitted to and approved by the FDA before any of our product candidates may be commercialized, our lack of experience may impede our ability to

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obtain FDA approval in a timely manner, if at all, which in turn would delay or prevent us from commercializing those products. Similarly, our lack of experience with respect to obtaining regulatory approvals in countries other than the United States may impede our ability to commercialize our products in those countries.

We believe that the FDA and comparable foreign regulatory bodies will regulate separately each product containing a particular gene depending on its intended use. Presently, to commercialize any product we and our collaborators and licensees must file a regulatory application for each proposed use. We and our collaborators and licensees must conduct

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clinical studies to demonstrate the safety and efficacy of the product necessary to obtain FDA or foreign regulatory authority approval. The results obtained so far in our clinical trials and those of our collaborators and licensees may not be replicated in ongoing or future trials, or the results may be subject to varying interpretation on whether they are sufficient to support approval for commercialization. This may prevent any of our product candidates from receiving approval for commercial sale.

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

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

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

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

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

Some of our potential products may be administered to patients who are suffering from, or are vulnerable to, serious diseases or other conditions which can themselves be life-threatening and often result in the death of the patient. For example, one patient in our Allovectin® Phase 2 trial conducted in 2000, died from progressive disease more than two months after receiving Allovectin® and other cancer therapies. The death was originally reported as unrelated to the treatment. Following an autopsy, the death was reclassified as probably related to the treatment because the possibility could not be ruled out. We do not believe Allovectin® was a significant factor in the patient's death. Patient deaths in our clinical trials, even if caused by pre-existing diseases or conditions, could negatively affect the perception of our product candidates. In addition, in our TransVax Phase 2 trial, we administered TransVax to patients who were at risk of CMV reactivation. Although we do not believe our vaccine candidates could cause the diseases they are designed to protect against, a temporal relationship between vaccination and disease onset could be perceived as causal. Some of our products are designed to stimulate immune responses, and those responses, if particularly strong or uncontrolled, could result in local or systemic adverse events, including latent adverse events.

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

As of March 31, 2011, we were the assignee or co-assignee of 67 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

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proceedings generally differ depending on the country in which they are initiated. If we are not successful in defending our patents, we may lose all or part of our proprietary rights related to those patents in these geographic regions.

As of March 31, 2011, we were also prosecuting 74 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. Finally, others may 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.

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 NIH and the FDA jointly developed the Genetic Modification Clinical Research Information System, or GeMCRIS, an Internet-based database of human gene transfer trials. GeMCRIS enables individuals to easily view information on particular characteristics of clinical gene transfer trials. Although GeMCRIS includes special security features designed to protect patient privacy and confidential commercial information, these security features may be inadequately designed or enforced, potentially resulting in disclosure of confidential commercial information. In addition, the NIH, in collaboration with the FDA, has developed an Internet site, ClinicalTrials.gov, which provides public access to information on clinical trials and their results for a wide range of diseases and conditions. Future disclosures of such confidential commercial information may result in loss of advantage of competitive secrets.

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

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

Protecting intellectual property rights can be very expensive. Litigation may be necessary to enforce patents issued to us or to determine the scope and validity of third-party proprietary rights. Moreover, if a competitor were to file a patent application claiming technology also invented by us, 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 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 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 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 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 may have to obtain licenses to test, use or market these products. Our business will suffer if we are not able to obtain licenses at all or on terms commercially reasonable to us and we are not able to redesign our products or processes to avoid infringement.

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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.

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

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

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

The commercial manufacturing of vaccines and other biological products is a time-consuming and complex process, which must be performed in compliance with the FDA's current Good Manufacturing Practices, or cGMP, regulations. We may not be able to comply with the cGMP regulations, and our manufacturing process may be subject to delays, disruptions or quality control problems. 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. 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.

***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 currently rely on third parties, including clinical research organizations, to perform critical services for us in connection with our clinical trials. Clinical research organizations 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. Our reliance on third parties does not relieve us of these responsibilities and requirements. 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 regulations, our clinical trials may not meet regulatory requirements or may need to be repeated. These risks also apply to the development activities of our



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collaborators and licensees, and we do not control our collaborators and licensees' research and development, clinical trials or regulatory activities.

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

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

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

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

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

Government health administration authorities;

Government agencies procuring biodefense products for military or public use, including some for which we may become a sole-source vendor;

Private health coverage insurers;

Managed care organizations; and

Other organizations.

If we fail to obtain appropriate reimbursement, we could be prevented from successfully commercializing our potential products. There are ongoing efforts by governmental and third-party payers to contain or reduce the costs of healthcare through various reform measures. In the United States, the Federal government passed comprehensive healthcare reform legislation in 2010. Many of the details regarding the implementation of this legislation are yet to be determined and we currently cannot predict whether or to what extent such implementation or adoption of reforms may impair our business.

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.***

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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 have insurance that covers our use of hazardous materials with the following coverage limits: up to \$250,000 per occurrence for losses related to the release of bio-contaminants, \$250,000 per occurrence for losses from refrigerant contamination and \$250,000 per occurrence for losses from radioactive contamination. Any liability could exceed

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the limits or fall outside the coverage of our insurance. 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 high-grade auction rate securities, corporate debt securities and government agency securities. As of March 31, 2011, our long-term investments included (at par value) \$6.5 million of auction rate securities secured by municipal bonds and student loans. At March 31, 2011, the auction rate securities we held had Standard and Poor's credit ratings of BBB or AAA. Our auction rate securities are debt instruments with a long-term maturity and with an interest rate that is reset in short intervals through auctions. Ongoing 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 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 all of our auction rate securities held at March 31, 2011. As a result, these affected securities are currently not liquid, and we could be required to hold them until they are redeemed by the issuer or to maturity. As of March 31, 2011, we had recognized \$1.5 million of losses related to those auction rate securities by adjusting their carrying value. The market value of these securities has partially recovered from the lows that created the loss. As of March 31, 2011, we had recorded cumulative unrealized gains of \$0.4 million. Any future decline in market value may result in additional losses being recognized.

In the event we need to access the funds that are in an illiquid state, we will not be able to do so without the possible loss of principal, until a future auction for these investments is successful or they are redeemed by the issuer or they mature. If we are unable to sell these securities in the market or they are not redeemed, then we may be required to hold them 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, 2007, to March 31, 2011, our stock price has ranged from \$1.04 to \$6.99. 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 announcement by us or our collaborators, licensees or competitors of technological innovations or new products;

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Developments concerning our patent or other proprietary rights or those of our collaborators, licensees or competitors, including litigation and challenges to our proprietary rights;

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Other developments with our collaborators or licensees, including our entry into new collaborative or licensing arrangements;

Geopolitical developments, natural or man-made disease threats, or other events beyond our control;

U.S. and foreign governmental regulatory actions;

Changes or announcements in reimbursement policies;

Period-to-period fluctuations in our operating results;

Market conditions for life science stocks in general;

Changes in the collective short interest in our stock;

Changes in estimates of our performance by securities analysts; and

Our cash balances, need for additional capital, and access to capital.

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

In the past, stockholders have brought securities class action litigation against a company following a decline in the market price of its securities. This risk is especially acute for us because life science companies have experienced greater than average stock price volatility in recent years and, as a result, have been subject to, on average, a greater number of securities class action claims than companies in other industries. To date, we have not been subject to class action litigation. However, we may in the future be the target of this litigation. Securities litigation could result in substantial costs and divert our management's attention and resources, and could seriously harm our business.

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

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

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

We have on file two effective shelf registration statements that collectively allow us to raise up to an additional \$105.6 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**

<b>Exhibit Number</b>	<b>Description of Document</b>
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, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Jill M. Broadfoot, Chief Financial Officer, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of Vijay B. Samant, Chief Executive Officer, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of Jill M. Broadfoot, Chief Financial Officer, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

- (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.

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**SIGNATURE**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this Report to be signed on its behalf by the undersigned thereunto duly authorized.

Vical Incorporated

Date: May 6, 2011

By: /s/ JILL M. BROADFOOT  
Jill M. Broadfoot  
Senior Vice President, Chief Financial Officer and  
Secretary (on behalf of the registrant and as the registrant's  
Principal Financial and Accounting Officer)