

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, 2006

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)

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

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

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 such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No

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

Large accelerated filer  Accelerated filer  Non-accelerated filer

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 May 2, 2006: 28,366,120

---

---

[Table of Contents](#)

VICAL INCORPORATED

FORM 10-Q

INDEX

PART I. FINANCIAL INFORMATION

ITEM 1. Financial Statements

[Balance Sheets \(unaudited\) as of March 31, 2006 and December 31, 2005](#) 3

[Statements of Operations \(unaudited\) for the three months ended March 31, 2006 and 2005](#) 4

[Statements of Cash Flows \(unaudited\) for the three months ended March 31, 2006 and 2005](#) 5

[Notes to Financial Statements \(unaudited\)](#) 6

[ITEM 2. Management's Discussion and Analysis of Financial Condition and Results of Operations](#) 12

[ITEM 3. Quantitative and Qualitative Disclosures About Market Risk](#) 20

[ITEM 4. Controls and Procedures](#) 21

PART II. OTHER INFORMATION

[ITEM 1A. Risk Factors](#) 22

[ITEM 6. Exhibits](#) 30

[SIGNATURE](#) 31

## PART I. FINANCIAL INFORMATION

**ITEM 1. FINANCIAL STATEMENTS****VICAL INCORPORATED  
BALANCE SHEETS  
(In thousands, except par value data)  
(Unaudited)**

	March 31, 2006	December 31, 2005
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 5,640	\$ 5,710
Marketable securities, available-for-sale	49,175	58,337
Restricted marketable securities	2,439	2,439
Receivables and other	10,002	5,778
Total current assets	67,256	72,264
Property and equipment, net	14,686	15,170
Intangible assets, net	5,364	5,481
Other assets	1,357	1,615
Total assets	<u>\$ 88,663</u>	<u>\$ 94,530</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable and accrued expenses	\$ 3,942	\$ 4,687
Current portion of equipment financing obligations	3,531	4,093
Total current liabilities	7,473	8,780
Long-term liabilities:		
Equipment financing obligations, net of current portion	2,702	3,426
Deferred rent	2,085	2,018
Total long-term liabilities	4,787	5,444
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, 40,000 shares authorized, 28,321 and 28,261 shares issued and outstanding at March 31, 2006 and December 31, 2005, respectively	283	283
Additional paid-in capital	243,467	242,991
Accumulated deficit	(167,347)	(162,874)
Accumulated other comprehensive loss	—	(94)
Total stockholders' equity	76,403	80,306
Total liabilities and stockholders' equity	<u>\$ 88,663</u>	<u>\$ 94,530</u>

See accompanying notes to unaudited financial statements

[Table of Contents](#)

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

	Three months ended	
	March 31,	
	2006	2005
Revenues:		
Contract and grant revenue	\$ 5,579	\$ 2,453
License and royalty revenue	36	231
Total revenues	5,615	2,684
Operating expenses:		
Research and development	4,644	4,473
Manufacturing and production	3,552	3,912
General and administrative	2,442	2,115
Total operating expenses	10,638	10,500
Loss from operations	(5,023)	(7,816)
Other income (expense):		
Investment income	643	384
Interest expense	(93)	(146)
Net loss	<u>\$ (4,473)</u>	<u>\$ (7,578)</u>
Basic and diluted net loss per share	<u>\$ (0.16)</u>	<u>\$ (0.32)</u>
Weighted average shares used in computing basic and diluted net loss per share	<u>28,290</u>	<u>23,509</u>

See accompanying notes to unaudited financial statements

[Table of Contents](#)

**VICAL INCORPORATED**  
**STATEMENTS OF CASH FLOWS**  
**(In thousands)**  
**(Unaudited)**

	Three months ended	
	March 31,	
	2006	2005
Cash flows from operating activities:		
Net loss	\$ (4,473)	\$ (7,578)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	840	913
Write-off of abandoned patents	—	60
Compensation expense related to stock options and awards	506	82
Changes in operating assets and liabilities:		
Receivables and other	(4,224)	(1,536)
Other assets	258	(64)
Accounts payable, accrued expenses and other liabilities	(745)	(1,595)
Deferred revenue	—	(531)
Deferred rent	67	(74)
Net cash used in operating activities	<u>(7,771)</u>	<u>(10,323)</u>
Cash flows from investing activities:		
Maturities of marketable securities – including restricted	55,777	13,999
Purchases of marketable securities – including restricted	(46,521)	(10,005)
Purchases of property and equipment	(171)	(579)
Patent expenditures	(68)	(172)
Net cash provided by investing activities	<u>9,017</u>	<u>3,243</u>
Cash flows from financing activities:		
Proceeds from issuance of common stock	51	35
Payment of withholding taxes for net settlement of restricted stock units	(81)	—
Principal payments under equipment financing obligations	(1,286)	(1,127)
Proceeds from equipment financing arrangements	—	908
Net cash used in financing activities	<u>(1,316)</u>	<u>(184)</u>
Net decrease in cash and cash equivalents	(70)	(7,264)
Cash and cash equivalents at beginning of period	5,710	17,666
Cash and cash equivalents at end of period	<u>\$ 5,640</u>	<u>\$ 10,402</u>
Supplemental information:		
Interest paid	<u>\$ 93</u>	<u>\$ 146</u>

See accompanying notes to unaudited financial statements

**VICAL INCORPORATED**  
**NOTES TO FINANCIAL STATEMENTS**  
**March 31, 2006**  
**(Unaudited)**

**1. GENERAL**

Vical Incorporated, or the Company, 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.

The unaudited financial statements at March 31, 2006, and for the three months ended March 31, 2006 and 2005, have been prepared in accordance with accounting principles generally accepted in the U.S. 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 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, 2005, included in its Form 10-K filed with the Securities and Exchange Commission, or SEC.

*Issuance of Common Stock*

In October 2005, the Company raised approximately \$21.0 million in net proceeds from the sale of approximately 4.7 million shares of its common stock at \$4.80 per share in a registered direct offering to a select group of institutional investors. All of the common stock was offered by the Company pursuant to a shelf registration statement declared effective in December 2003. This shelf registration statement allows the Company to issue from time to time up to approximately \$8.8 million of additional common or preferred stock. A second shelf registration statement was declared effective in March 2006 that allows the Company to issue from time to time an aggregate of up to \$70 million of common or preferred stock.

*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. Such investments are carried at fair value, with unrealized gains and losses included as a separate component of stockholders' equity.

*Restricted Marketable Securities*

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. At March 31, 2006, and December 31, 2005, restricted marketable securities of \$2.4 million were pledged as collateral for this letter of credit.

*Revenue Recognition*

The Company earns revenue by performing services under research and development agreements, grants, manufacturing contracts and from licensing its proprietary technology. Revenue is recognized when all of the following criteria are met: persuasive evidence of an arrangement exists, delivery has occurred or services have been rendered, the price is fixed or determined, and collection is reasonably assured.

The Company enters into fixed-price manufacturing contracts under which the primary deliverables are investigational vaccines to be used primarily for preclinical and clinical research. Under these contracts, revenue and related expenses are recognized when the product is shipped, provided all of the other revenue recognition criteria referred to above are met. Any advance payments received in excess of amounts earned are classified as deferred revenue.

---

## Table of Contents

Revenue under research and development agreements, grants, and manufacturing contracts, except for fixed-price contracts, is recognized as the research and development or manufacturing expenses for services performed are incurred, provided that all of the revenue recognition criteria noted above have been met.

Other revenues include amounts received from licensing the Company's proprietary technology, which occurs under a variety of circumstances including licenses, options and royalties. Any initial license or option payment received under a research and development agreement is recognized as revenue over the term of the research and development period. Upfront license payments are recognized as revenue upon contract signing only if the fee is nonrefundable and noncreditable, and if there are no performance obligations remaining. Payments for options to license the Company's technology are recognized as revenue over the option period. Royalty revenue is recognized when earned and when collectibility is reasonably assured.

Revenue from milestones is recognized as agreed-upon events representing the achievement of substantive steps in the development process are achieved, or as agreed-upon passages of time occur, and where the amount of the milestone payment approximates the value of achieving the milestone, and collection of payment is reasonably assured.

### *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 the assumed issuance of common stock under restricted stock units, or RSUs, as the effect would be antidilutive. Common stock equivalents of 0.3 million for the three months ended March 31, 2006 and 2005, were excluded from the calculation because of their antidilutive effect.

### *Recent Accounting Pronouncements*

In May 2005, the Financial Accounting Standards Board, or FASB, issued Statement of Financial Accounting Standards, or SFAS, No. 154, "Accounting Changes and Error Corrections." SFAS No. 154 establishes retrospective application as the required method for reporting a change in accounting principle in the absence of explicit transition requirements specific to the newly adopted accounting principle. SFAS No. 154 also provides guidance for determining whether retrospective application of a change in accounting principle is impracticable and for reporting a change when retrospective application is impracticable. SFAS No. 154 is effective for accounting changes and corrections of errors made in fiscal years beginning after December 15, 2005. The Company does not expect the adoption of SFAS No. 154 to significantly affect its financial condition or results of operations.

### *Change in Accounting Method for Share-Based Compensation*

Effective January 1, 2006, the Company adopted SFAS No. 123R, "Share-Based Payment", as interpreted by SEC Staff Accounting Bulletin No. 107 and began recording compensation expense associated with stock options and other forms of equity compensation based on their fair value.

## **2. EQUITY BASED COMPENSATION**

On March 31, 2006, the Company had two share based compensation plans, which are described below. Total stock-based compensation expense of \$506,000 and \$82,000 was recognized for the three months ended March 31, 2006 and 2005, respectively. Total compensation cost allocated to research and development, manufacturing and production and general and administrative expense for the three months ended March 31, 2006 was \$180,000, \$74,000 and \$252,000, respectively. Total stock-based compensation costs allocated to research and development and general and administrative expense for the three months ended March 31, 2005 was \$32,000 and \$50,000, respectively. For the three months ended March 31, 2006, the Company received a total of \$92,000 in cash from options exercised under all share-based payment arrangements.

### *Stock Incentive Plan*

The Company has a stock incentive plan, under which 5,700,000 shares of common stock, subject to adjustment as provided in the plan, are reserved for issuance to employees, non-employee directors and consultants of the Company. The plan provides for the grant of incentive and nonstatutory stock options and the direct award or sale of shares, including restricted stock. The exercise price of stock options must equal at least the fair market value of the underlying common stock on the date of grant. The maximum term of options granted under the plan is ten years. Except for annual grants to non-employee directors which vest at the next annual meeting, options generally vest 25 percent on the first anniversary of the

## Table of Contents

date of grant, with the balance vesting quarterly over the remaining three years. The plan also limits the number of options that may be granted to any plan participant in a single calendar year to 300,000 shares.

The Company has granted RSUs to executive officers, other executives, and employees under the stock incentive plan. The RSUs granted prior to 2005 vest quarterly over two years and beginning in 2005, they vest 25% on the first anniversary from the grant date, with the remaining rights vesting quarterly over the next three years. Once vested the participants have the right to acquire common stock underlying the grant at par value. The participants are not entitled to vote or receive dividends on any shares of common stock covered by RSUs prior to the acquisition of such shares. Participants are also not entitled to sell or transfer any RSUs. Granted but unvested RSUs are forfeited at termination of employment.

### *Directors' Stock Option Plan*

The Company also has a directors' stock option plan that provides for the issuance to non-employee directors of up to 210,000 shares of common stock, of which options for 202,500 shares have been granted through March 31, 2006. There will be no future grants under the directors' stock option plan as the plan expired in December of 2004. The maximum term of options granted under the plan is ten years. Grants to non-employee directors typically vest at the next annual meeting.

### *Change in Accounting Method for Share-Based Compensation*

Effective January 1, 2006, the Company adopted SFAS No. 123R, "Share-Based Payment", as interpreted by SEC Staff Accounting Bulletin No. 107 and began recording compensation expense associated with stock options and other forms of equity compensation based on their fair value. Prior to January 1, 2006, the Company accounted for stock options according to the provisions of Accounting Principles Board, or APB, Opinion No. 25, "Accounting for Stock Issued to Employees", and related interpretations, and therefore no related compensation expense was recorded for awards granted with no intrinsic value. The Company adopted the modified prospective transition method provided for under SFAS No. 123R, and consequently has not retroactively adjusted results from prior periods. Under this transition method, stock-based compensation now includes 1) amortization related to the remaining unvested portion of all stock option awards granted prior to January 1, 2006, over the remaining requisite service period based on the grant date fair value estimated in accordance with the original provisions of SFAS No. 123, "Accounting for Stock Based Compensation", adjusted for estimated forfeitures; and 2) amortization related to all stock option awards granted subsequent to January 1, 2006, based on the grant date fair value estimated in accordance with the provisions of SFAS No. 123R. In addition, the Company records expense related to RSUs granted based on the fair value of those awards on the grant date. The fair value related to the RSUs is amortized to expense over the vesting term of those awards. The stock-based compensation expense includes an estimate for forfeitures and is recognized over the expected term of the award using the straight-line method. The expected forfeiture rate of all equity based compensation is based on observed historical patterns of the Company's employees and is estimated to be 11.2% annually for the three months ended March 31, 2006.

The fair value of each option award is estimated on the date of grant using the Black-Scholes-Merton valuation model using the assumptions noted in the following table. The expected life of options is based on observed historical exercise patterns. The expected volatility of stock options is based upon the historical volatility of the Company's stock. The risk-free interest rate is based on the implied yield on a U.S. Treasury zero-coupon issue with a remaining term equal to the expected term of the option. The dividend yield reflects that the Company has not paid any cash dividends since inception and does not intend to pay any cash dividends in the foreseeable future.

	<b>Three months ended March 31, 2006</b>
Assumptions:	
Assumed risk-free interest rate	4.32%
Assumed volatility	68%
Expected option life	3 to 6 years
Expected dividend yield	—

As a result of the adoption of SFAS No. 123R, the Company's loss from operations and net loss for the three months ended March 31, 2006, was \$0.4 million, or \$0.01 per share, higher than under the Company's previous accounting method for stock-based compensation. In addition, there was no impact on the Company's cash flows for the three months ended March 31, 2006, as a result of the adoption of SFAS No. 123R.



## Table of Contents

A summary of option activity under the plans as of March 31, 2006, and changes during the three months then ended is presented below:

	Shares	Weighted Average Exercise Price
Outstanding December 31, 2005	3,790,474	\$ 9.09
Granted	274,350	\$ 4.55
Exercised	(22,019)	\$ 4.20
Forfeited	(91,322)	\$ 6.01
Outstanding March 31, 2006	<u>3,951,483</u>	<u>\$ 8.87</u>
Exercisable at March 31, 2006	2,769,040	\$ 10.61

The weighted average remaining contractual term of options outstanding and options exercisable at March 31, 2006 was 6.38 years and 5.44 years, respectively. The aggregate intrinsic value of options outstanding and options exercisable at March 31, 2006 was \$3.4 million and \$1.8 million, respectively. As of March 31, 2006, the total unrecognized compensation cost related to unvested options was \$2.2 million, which is expected to be recognized over a weighted-average period of 1.50 years. The weighted average grant-date fair values of options granted during the three months ended March 31, 2006 and 2005 were \$2.52 per share and \$3.53 per share, respectively. The total intrinsic value of options exercised during the three months ended March 31, 2006 and 2005 was \$21,000 and \$16,000, respectively.

A summary of the outstanding RSUs as of March 31, 2006 and changes during the three months then ended is presented below:

	Shares	Weighted Average Grant Date Fair Value per Share
Unvested at December 31, 2005	160,812	\$ 5.15
Granted	59,610	\$ 4.54
Vested	(48,437)	\$ 5.34
Cancelled	(540)	\$ 4.54
Unvested at March 31, 2006	<u>171,445</u>	<u>\$ 4.89</u>

The aggregate grant-date fair value of RSUs granted during the three months ended March 31, 2006 and 2005 was \$0.3 million and \$0.8 million, respectively. As of March 31, 2006, the total unrecognized compensation cost related to unvested RSUs was \$0.8 million, which is expected to be recognized over a weighted average period of 1.68 years. The total fair value of shares subject to RSUs vested during the three months ended March 31, 2006 and 2005 was \$0.3 million and \$0.1 million, respectively.

## Table of Contents

### Pro Forma Information under SFAS 123 for Periods Prior to the Adoption of SFAS 123R

For stock options granted prior to the adoption of SFAS No. 123R, if stock-based compensation expense for the Company's various stock option plans had been determined based upon estimated fair values at the grant dates in accordance with SFAS No. 123, the Company's pro forma net loss and basic and diluted net loss per share would have been as follows (in thousands, except per share data and assumptions):

	Three months ended March 31, 2005
Net loss, as reported	\$ (7,578)
Add stock-based compensation expense included in reported net loss	82
Less stock-based compensation expense determined under fair value based method	(558)
Pro forma net loss	<u>\$ (8,054)</u>
Basic and diluted net loss per share, as reported	<u>\$ (0.32)</u>
Basic and diluted pro forma net loss per share	<u>\$ (0.34)</u>
Weighted average grant-date fair value of stock options	<u>\$ 3.53</u>
Assumptions:	
Assumed risk-free interest rate	3.99%
Assumed volatility	79%
Expected option life	5 to 8 years
Expected dividend yield	—

### 3. COMPREHENSIVE LOSS

Comprehensive loss consists of net loss and other comprehensive income or loss. Accumulated other comprehensive loss represents net unrealized losses on marketable securities. For the three months ended March 31, 2006 and 2005, other comprehensive income (loss) was \$0.1 million and (\$0.1) million, respectively, and total comprehensive loss was \$4.4 million and \$7.6 million, respectively.

### 4. RECENT CONTRACT, GRANT AND LICENSE ACTIVITIES

#### NIH Vaccine Research Center

In 2002, the Company entered into a subcontract agreement, which was subsequently amended, to manufacture DNA vaccines against HIV, Ebola, West Nile Virus and severe acute respiratory syndrome, or SARS, for the Dale and Betty Bumpers Vaccine Research Center, or VRC, of the National Institutes of Health, or NIH. In 2003, the Company entered into a separate subcontract agreement to manufacture bulk DNA vaccines for the VRC. The 2003 subcontract agreement expires in July 2006. Under Federal Acquisition Regulations, or FARs, the government has the right to terminate these agreements for convenience. These subcontracts are issued and managed on behalf of the VRC by SAIC-Frederick, Inc. under the umbrella of a federally funded contract with the NIH. The Company recognized revenues under these agreements of \$3.8 million and \$1.1 million for the three months ended March 31, 2006 and 2005, respectively.

#### CMV Grants

The Company's research and development related to its cytomegalovirus, or CMV, vaccine program has been partially supported under grants from the U.S. National Institute of Allergy and Infectious Diseases, or NIAID, of the NIH. The most recent, in March 2005, was a three-year, \$3.1 million Phase II Small Business Innovation Research, or SBIR, grant from the NIAID. The grant will partially fund the ongoing development of Vical's immunotherapeutic DNA vaccine against CMV disease. Revenue recognized under these grants was \$1.0 million and \$1.1 million for the three months ended March 31, 2006 and 2005, respectively.

## Table of Contents

### 5. OTHER BALANCE SHEET ACCOUNTS

Receivables and other current assets consisted of the following (in thousands):

	March 31, 2006	December 31, 2005
Accounts receivable	\$ 4,912	\$ 502
Other current assets	5,090	5,276
	<u>\$ 10,002</u>	<u>\$ 5,778</u>

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

	March 31, 2006	December 31, 2005
Employee compensation	\$ 1,218	\$ 2,115
Accounts payable	515	298
Accrued royalty	500	500
Other accrued liabilities	1,709	1,774
	<u>\$ 3,942</u>	<u>\$ 4,687</u>

### 6. COMMITMENTS AND CONTINGENCIES

If the Company fails to satisfy its contractual obligations to deliver the DNA vaccines ordered by the VRC in the manner required by the Company's manufacturing agreements with the VRC, the applicable FARs allow the VRC to cancel the agreements in whole or in part, and the Company may be required to perform corrective actions, including but not limited to delivering to the VRC any uncompleted or partially completed work, and/or any government property in its possession, and/or paying a third-party supplier selected by the VRC to complete any uncompleted work. The performance of these corrective actions could have a material adverse impact on the Company's financial results in the period or periods affected. Government agencies may fail to perform their responsibilities under these agreements and they may terminate the agreements.

In 2003, the Wisconsin Alumni Research Foundation, or WARF, filed a complaint against the Company in the U.S. District Court for the Western District of Wisconsin, seeking a declaratory judgment regarding the meaning of certain payment provisions in a license agreement the Company entered into with the WARF in 1991. The Company counterclaimed, likewise seeking a declaratory judgment as to the correct interpretation of the payment provisions of the agreement. In May 2004, the Company settled this matter for \$1.5 million, of which \$1.0 million had been paid as of March 31, 2006, with the remaining payment due in 2006. Pursuant to the settlement and an amendment to the license agreement with the WARF, the lawsuit was dismissed.

European Patent 1026253, covering a significant portion of the Company's core DNA delivery technology, was granted in September 2004. European Patent 0465529 was granted to Vical in 1998, and was subsequently opposed by seven companies under European patent procedures. This '529 patent was revoked on formal grounds in October 2001 under an initial ruling by the Opposition Division of the European Patent Office, or EPO. In April 2002, the Company filed an appeal seeking to overturn this initial ruling. The claims that were allowed in the newly granted '253 patent cover substantially the same scope as those claims in the '529 patent which were under appeal. For this reason, the Company withdrew from the '529 appeal upon grant of the '253 patent in September 2004. In June 2005, the '253 patent was opposed by eight parties. However, the Company may also use additional issued patents and patent applications that are pending in Europe to protect its core DNA delivery technology.

In addition, the Company's core DNA delivery technology is covered by a Japanese patent that was published in January 2002 and thereafter revoked by the examining panel at the Japanese Patent Office, or JPO, on formal and substantive grounds. The Company filed a rebuttal response to the revocation. Based on the Company's arguments and supporting evidence in that response, the JPO reinstated the patent in July 2003. Four Trial for Invalidation, or TFI, requests were filed in the JPO by two companies in 2003. The Company filed responses to the TFI requests in a timely manner. The JPO combined two of the four TFI requests into a single action, and in December 2004, ruled in the Company's favor on the combined TFI requests by accepting the corrected claims and finding the demand for the trials groundless. The Company is still awaiting further action by the JPO on the other two TFI requests.

---

## Table of Contents

A European patent issued in 2003 covering a range of applications of the Company's core DNA delivery technology, including cationic lipid-formulated, gene-based immunotherapeutics such as the Company's clinical-stage Allovectin-7<sup>®</sup> treatment for melanoma, cationic lipid-formulated DNA vaccines such as the Company's investigational anthrax vaccine, and similar pharmaceutical products under development by others. This patent has been opposed by two companies. The Company responded to the oppositions in a timely manner, and defended the patent at an oral hearing in March 2006 at the EPO. The patent was maintained in amended form. The Company plans to appeal certain rulings, but the formal reasoning of the rulings leading to the amendments has yet to be provided by the EPO.

A European patent issued to the Company in 2003 with broad claims related to gene-based, extra-tumoral delivery of any cytokines for the treatment of cancer. Delivery can be either free from or formulated with transfection-facilitating materials such as cationic lipids or polymers. Cytokines are proteins such as interleukins and interferons which regulate specific cell functions, and typically are used to stimulate an immune response against cancer cells. Three companies opposed this patent. The Company responded to the oppositions in a timely manner, and will continue to vigorously defend its position in upcoming oral hearings.

The Company prosecutes its intellectual property estate vigorously to obtain the broadest valid scope for its patents. Due to the uncertainty of the ultimate outcome of these matters, the impact on future results 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, is deemed to be material to the financial condition or results of operations of the Company.

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

This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, including statements regarding our business, our financial position, the research and development of biopharmaceutical products based on our patented DNA delivery technologies, 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 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, 2005, and our other filings with the Securities and Exchange Commission, and those identified in Part II, Item 1A entitled "Risk Factors" beginning on page 20 of this Report. As a result, you are cautioned not to rely on these forward-looking statements. We disclaim any duty to update any forward-looking statement to reflect events or circumstances that occur after the date on which such statement is made.

---

## [Table of Contents](#)

### 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. In addition, we have gained access to enhancing technologies through licensing and collaborative agreements. We believe the following areas of research offer the greatest potential for our product development efforts:

- Vaccines for use in high-risk populations for infectious disease targets for which there are significant U.S. needs;
- Vaccines for general pediatric or adult populations for infectious disease applications; and
- Cancer vaccines or immunotherapies which complement our existing programs and core expertise.

In 2005, the first product utilizing our patented DNA delivery technology received approval for use in animals. Our licensee, Aqua Health Ltd. of Canada, or Aqua Health, an affiliate of Novartis Animal Health, received approval from the Canadian Food Inspection Agency to sell a DNA vaccine to protect farm-raised salmon against an infectious disease. We believe this approval is an important step in the validation of our DNA delivery technology. We plan to continue leveraging our patented technologies through licensing and collaborations. We also plan to use our expertise, infrastructure, and financial strength to explore both in-licensing and acquisition opportunities.

We have licensed our technologies to:

- Merck & Co., Inc., or Merck;
- Two divisions of the Sanofi-Aventis Group, or Sanofi-Aventis:
  - *Sanofi Pasteur; and*
  - *Centelion SAS, or Centelion, a wholly-owned subsidiary of Aventis Pharmaceuticals S.A.;*
- Merial Ltd., or Merial, a joint venture between Merck and Sanofi-Aventis;
- Corautus Genetics Inc., or Corautus;
- Aqua Health;
- Invitrogen Corporation, or Invitrogen;
- AnGes MG, Inc., or AnGes;
- Stanford University, or Stanford;
- Harvard University, or Harvard;
- Massachusetts Institute of Technology, or MIT; and
- Yale University, or Yale.

We have also licensed complementary technologies from:

- WARF;
- The University of Michigan;
- Inovio Biomedical Corporation, or Inovio (formerly Genetronics Biomedical Corporation);
- CytRx Corporation, or CytRx;
- The National Institutes of Health, or NIH; and
- The U.S. Centers for Disease Control and Prevention, or CDC.

## Table of Contents

### Product Development

We, together with our licensees and collaborators, are currently developing a number of DNA-based vaccines and therapeutics for the prevention or treatment of infectious diseases, cardiovascular diseases and cancer. Our current independent development focus is on our novel pDNA vaccines for cytomegalovirus, or CMV, and avian influenza, as well as our cancer immunotherapeutic, IL-2 EP. The table below summarizes our independent, collaborative and out-licensed product development programs.

Product Area	Project Target and Indication(s)	Development Status <sup>1</sup>	Development Rights
<b>Infectious Disease</b>			
Infectious disease vaccine	Cytomegalovirus	Phase 2	Vical
”	<i>Bacillus anthracis</i> (anthrax)	Phase 1	Vical
”	Influenza	Research	Vical
”	Ebola virus	Phase 1	Vical/NIH
”	West Nile virus	Phase 1	Vical/NIH
”	HIV EP	Research	Vical/NIH
”	SARS coronavirus	Phase 1	NIH
”	HIV	Phase 2	NIH
”	HIV	Phase 1	Merck
”	Hepatitis B virus	Research	Merck
”	Hepatitis C virus	Research	Merck
<b>Cardiovascular</b>			
Angiogenic growth factor	HGF, peripheral arterial disease	Phase 3	AnGes/Daiichi Pharma
”	HGF, ischemic heart disease	Phase 1	AnGes/Daiichi Pharma
”	VEGF-2, peripheral arterial disease	Phase 1	Coratutis
”	FGF-1, peripheral arterial disease	Phase 2	Centelion
<b>Cancer</b>			
Immunotherapeutic	IL-2/EP for metastatic melanoma	Phase 1	Vical
”	High-dose Allovectin-7 <sup>®</sup> for metastatic melanoma	Phase 2	Vical
Tumor-associated antigen therapeutic vaccines	HER-2 and CEA for breast, colorectal, ovarian or non-small cell lung cancer	Phase 1	Merck
”	Unspecified cancer <sup>2</sup>	Research	Merck
<b>Veterinary</b>			
Preventive infectious disease vaccine(s)	Infectious Haematopoietic Necrosis Virus	Marketed in Canada	Aqua Health
”	Various undisclosed <sup>2</sup>	Research-Clinical	Merial
Protective cancer vaccine	Melanoma in dogs	Conditional U.S. license expected in 2006	Merial

<sup>1</sup> “Research” indicates exploration and/or evaluation of a potential product candidate in a nonclinical laboratory setting. “Phase 1” clinical trials include the first use of an investigational new drug in humans and are conducted in a small group of patients or normal volunteer subjects (20-80) to evaluate safety, determine a safe dosage range, and identify side effects, and, if possible, gain early evidence on effectiveness. “Phase 2” clinical trials are typically well controlled and conducted in a larger group of subjects (no more than several hundred) to evaluate effectiveness of an investigational drug for a defined patient population, and to determine common short-term side effects and risks associated with the drug. “Phase 3” clinical trials are conducted in an even larger group of subjects (several hundred to thousands) to evaluate the overall benefit-risk relationship of the investigational drug and to provide an adequate basis for product labeling. For veterinary products, “Clinical” indicates testing in the target species.

<sup>2</sup> Pursuant to our collaborative agreements, we are bound by confidentiality obligations to our collaborators that prevent us from publicly disclosing these targets and indications. Additionally, some project targets and indications cannot currently be disclosed because they have not yet been selected by our collaborators.

See the section entitled “Business” in our Annual Report on Form 10-K for the year ended December 31, 2005 for a detailed discussion of our independent, collaborative and out-licensed product development programs.

---

## [Table of Contents](#)

### Recent Events

The following events have recently occurred with respect to our technologies and applications:

- In May 2006, we announced that our lead three-component influenza (flu) DNA vaccine candidate provided 100% protection in mice and ferrets against lethal challenges with a highly virulent H5N1 avian influenza virus in studies conducted by Richard J. Webby, Ph.D., at St. Jude Children's Research Hospital. Additionally, in these and earlier studies in mice, simplified versions of our vaccine candidate using only two of the three components provided high levels of protection against multiple human flu strains and against the H5N1 avian flu strain. Based on the results, we are continuing to advance toward human testing of the pandemic flu DNA vaccine candidate.
- In March 2006, we announced that our licensee, Sanofi-Aventis, presented encouraging data from a Phase 2b trial of its angiogenesis product candidate NV1FGF, using our patented DNA delivery technology. Sanofi-Aventis has separately disclosed plans to advance to Phase 3 testing of the product candidate in the fourth quarter of 2006.
- In March 2006, the SEC declared our recently filed shelf registration statement effective, which allows us to issue from time to time an aggregate of up to \$70 million of common stock, preferred stock or a combination of these securities. The shelf registration is intended to provide flexibility in financing our business needs. Specific terms of any offering under the shelf registration and the securities involved would be established at the time of sale.
- In February 2006, we announced that an Ebola vaccine candidate administered in a Phase 1 trial sponsored by the NIAID and conducted at the NIH Clinical Center, using our proprietary DNA delivery technology was safe and well tolerated, and produced both antibody and T-cell Ebola-specific responses in all healthy volunteers who received the full 3 doses of vaccine. The DNA vaccine used in the Phase 1 trial incorporates genetic material encoding core and surface proteins from two strains of Ebola. We have secured a nonexclusive license from the NIH to proprietary gene sequences used in the vaccine.
- In February 2006, we announced that enrollment has opened in our novel Phase 2 trial of a DNA vaccine against CMV. The Phase 2 trial will be conducted at leading U.S. transplant centers in donors and patients undergoing hematopoietic stem cell transplants. Success in this patient population would support the expansion of studies of our CMV vaccine into other transplant settings and, possibly, the general population.
- In January 2006, we granted non-exclusive, academic licenses to our DNA delivery technology patent estate to four of the nation's top research institutions: Stanford, Harvard, Yale and MIT. The academic licenses are intended to encourage widespread commercial use of our innovative DNA delivery technologies in the development of new antibodies, vaccines, therapeutic proteins, and diagnostics. 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 stemming from their use of the technology on terms to be negotiated.
- In April 2006, our licensee, Corautus, announced that it had terminated a Phase 2b angiogenesis trial involving pDNA-based delivery of VEGF-2 based on the recommendation of an independent data monitoring committee.

### Research, Development and Manufacturing Programs

To date, we have not received revenues from the sale of our independently developed pharmaceutical products. We earn revenue by performing services under research and development contracts, grants, and manufacturing contracts, and from licensing access to our proprietary technologies. Since our inception, we estimate that we have received approximately \$124.2 million in revenue under these types of agreements.

## Table of Contents

Revenues by source were as follows (in millions):

Source	Three months ended March 31,	
	2006	2005
NIH contracts	\$ 3.8	\$ 1.3
CMV grants	1.0	1.1
Anthrax grant	0.4	—
Other contracts and grants	0.4	0.1
Total contract and grant revenues	5.6	2.5
Invitrogen royalties	—	0.2
Total royalty and license revenues	0.0	0.2
Total revenues	<u>\$ 5.6</u>	<u>\$ 2.7</u>

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,	
	2006	2005
CMV	\$ 1.8	\$ 2.2
Allovectin-7 <sup>®</sup>	1.2	1.1
Anthrax	0.4	0.5
IL-2/EP	0.6	0.8
Other research, development, manufacturing and production	4.2	3.8
Total research, development, manufacturing and production	<u>\$ 8.2</u>	<u>\$ 8.4</u>

Since our inception, we estimate that we have spent approximately \$252 million on research, development, manufacturing and production. Our current independent development focus is on novel DNA vaccines for CMV and our cancer immunotherapeutic IL-2/EP, as well as other preclinical targets such as influenza. We are in the early stages of clinical development of vaccine candidates for CMV and our IL-2/EP program for solid tumors with an initial indication for metastatic melanoma and these programs will require significant additional costs to advance through development to commercialization. From inception, we have spent approximately \$27 million on our CMV program, and approximately \$6 million on our IL-2 EP program.

We are currently performing research testing of vaccine candidates for human and avian influenza under separate grants. We have several other product candidates in the research stage. It can take many years from the initial decision to screen product candidates, perform preclinical and safety studies, and perform clinical trials leading up to possible approval of a product by the U.S. Food and Drug Administration, or FDA, or comparable foreign agencies. The outcome of the research is unknown until each stage of the testing is completed, up through and including the registration clinical trials. Accordingly, we are unable to predict which potential product candidates we may seek to develop, the time and cost to complete development, and ultimately whether we will have a product approved by the FDA or comparable foreign agencies.

For instance, we have spent approximately \$63 million from inception on our Allovectin-7<sup>®</sup> program. We have successfully completed a Special Protocol Assessment, or SPA, with the FDA for a Phase 3 trial of Allovectin-7<sup>®</sup> that would be needed to support submission of a Biologics License Application, or BLA. We are currently in discussions with potential partners for the further development and commercialization of Allovectin-7<sup>®</sup>, and do not expect to conduct the Phase 3 trial independently.

In addition, we are in the early stages of clinical development of an anthrax vaccine candidate, however, due to the lack of additional government funding, we do not intend to pursue further development of our anthrax vaccine candidate at this time except for the ongoing non-clinical development supported by an SBIR grant.

As a result, we expect to incur substantial operating losses for at least the next several years, due primarily to the expansion 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 increased contract manufacturing activities, increased costs of our facilities, and possible advancement toward commercialization activities.



---

## [Table of Contents](#)

### **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 consolidated 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, 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***

We recognize revenue in accordance with SEC Staff Accounting Bulletin Topic 13, "Revenue Recognition" and Emerging Issues Task Force No. 00-21, or EITF No. 00-21, "Accounting for Revenue Arrangements with Multiple Deliverables." 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. In accordance with EITF No. 00-21, 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) 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 our control. If the delivered item does not have standalone value or if 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 agreements, 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) there is no general right to return the delivered item(s).

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 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.

*Government Research Grant Revenue.* We recognize revenues from federal government research grants during the period in which the related expenditures are incurred.

#### ***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.

---

## **Table of Contents**

We assess our obligations to make milestone payments that may become due under 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 whenever events or changes in circumstances indicate that their carrying value may not be recoverable. If the review indicates that the carrying value of 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.

When we determine that the carrying value of intangible assets or long-lived assets are 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, 2006, our largest group of intangible assets with finite lives was patents and patents pending for our DNA delivery technology, consisting of intangible assets with a net carrying value of approximately \$3.2 million.

### **Recent Accounting Pronouncements**

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

### **Change in Accounting Method for Share-Based Compensation**

As a result of the adoption of SFAS No. 123R, as discussed in Note 2 to the notes to the financial statements, the Company's loss from operations and net loss for the three months ended March 31, 2006, was \$0.4 million, or \$0.01 per share, higher than under the Company's previous accounting method for stock-based compensation.

### **Results of Operations**

#### ***Three Months Ended March 31, 2006 Compared with Three Months Ended March 31, 2005***

*Total Revenues.* Total revenues increased \$2.9 million, or 109.2%, to \$5.6 million for the three months ended March 31, 2006, from \$2.7 million for the three months ended March 31, 2005. Revenues from our contracts and grants were \$5.6 million for the three months ended March 31, 2006, compared with \$2.5 million for the three months ended March 31, 2005. Contract and grant revenue for the three months ended March 31, 2006, included revenues of \$3.8 million related to

---

## Table of Contents

production orders for clinical lots of DNA vaccines against HIV for the VRC and \$1.0 million related to our NIAID CMV SBIR grant. Contract and grant revenue for the three months ended March 31, 2005, included revenues of \$1.0 million related to production orders for clinical lots of DNA vaccines against HIV for the VRC and \$1.1 million related to our NIAID CMV SBIR grant.

License and royalty revenue was \$36,000 for the three months ended March 31, 2006, compared with \$0.2 million for the three months ended March 31, 2005. The decrease in license and royalty revenue was primarily related to a \$0.2 million decrease in license fees from Invitrogen.

*Research and Development Expenses.* Research and development expenses increased \$0.1 million, or 3.8%, to \$4.6 million for the three months ended March 31, 2006, from \$4.5 million for the three months ended March 31, 2005. The increase was primarily the result of the increase in costs associated with clinical trials and contract services as a result of the initiation of our CMV Phase 2 trial, stock compensation and facility-related costs offset by a decrease in employee costs as a result of a lower average headcount.

*Manufacturing and Production Expenses.* Manufacturing and production expenses decreased \$0.3 million, or 9.2%, to \$3.6 million for the three months ended March 31, 2006, from \$3.9 million for the three months ended March 31, 2005. The decrease was primarily the result of a decrease in facility related costs of \$0.3 million as a result of the shut-down of our previous manufacturing facility.

*General and Administrative Expenses.* General and administrative expenses increased \$0.3 million, or 15.5%, to \$2.4 million for the three months ended March 31, 2006, from \$2.1 million for the three months ended March 31, 2005. The increase was primarily the result of increased stock compensation expense of \$0.2 million related to the implementation of SFAS No. 123R.

*Investment Income.* Investment income increased \$259,000, or 67.4%, to \$643,000 for the three months ended March 31, 2006, from \$384,000 for the three months ended March 31, 2005. This increase was primarily the result of higher rates of return on our investments during the three months ended March 31, 2006, partially offset by lower average cash and short-term investment balances.

*Interest Expense.* Interest expense decreased \$53,000, or 36.3%, to \$93,000 for the three months ended March 31, 2006, from \$146,000 for the three months ended March 31, 2005. The decrease was the result of lower interest rates and lower principal amounts outstanding on our equipment financing obligations.

### **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 collaborative agreements. From our inception through March 31, 2006, we have received approximately \$124.2 million in revenues from performing services under research and development contracts, grants, and manufacturing contracts, and from licensing access to our proprietary technologies, and we have raised net proceeds of approximately \$241.2 million from the sale of equity securities. As of March 31, 2006, we had working capital of approximately \$59.8 million, compared with \$63.4 million at December 31, 2005. Cash, cash equivalents and marketable securities, including restricted securities, totaled approximately \$57.3 million at March 31, 2006, compared with \$66.5 million at December 31, 2005. The decline in our cash, cash equivalents and marketable securities in the three months ended March 31, 2006, were due primarily to cash used to fund our operations and to pay our long-term debt obligations.

Net cash used in operating activities was \$7.8 million and \$10.3 million for the three months ended March 31, 2006 and 2005, respectively. The decrease in net cash used in operating activities for the three months ended March 31, 2006 compared with the same period in the prior year, was primarily the result of a decrease in our net loss combined with a relative decrease in accounts payable, accrued expense and other liabilities balances offset by an increase in accounts receivable balances related to the VRC production orders.

Net cash provided by investing activities was \$9.0 million and \$3.2 million for the three months ended March 31, 2006 and 2005, respectively. The increase in cash provided by investing activities for the three months ended March 31, 2006, compared with the same period in the prior year, was primarily the result of an increase in net maturities of investments.

---

## Table of Contents

Net cash used in financing activities was \$1.3 million and \$0.2 million for the three months ended March 31, 2006 and 2005, respectively. The increase in cash used in financing activities for the three months ended March 31, 2006, compared with the same period in the prior year, was primarily the result of an increase in the net principal payments related to our equipment financing arrangements.

We expect to incur substantial additional research and development expenses, manufacturing and production expenses, and general and administrative expenses, including continued personnel costs, costs related to preclinical and clinical testing, outside services, facilities, intellectual property and possible commercialization costs. 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 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 a shelf registration statement, which was declared effective in March 2006, that allows us to raise up to \$70 million from the sale of common or preferred stock. We also have on file a shelf registration statement, which was declared effective in December 2003, that allows us to raise up to an additional \$8.8 million from the sale of common or preferred stock. 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 operating needs through at least December 31, 2007.

### ***Contractual Obligations***

In December 2004, we modified an equipment financing agreement which provided for \$5.3 million of financing, with interest rates ranging from 3.0% to 3.2%, with payments of principal and interest due through 2009. A portion of the financing was used to repay outstanding debt of approximately \$2.2 million under another credit facility. Additional amounts were used to finance equipment purchases. The draw down period for this equipment financing arrangement ended in October 2005. The agreement requires a non-interest-bearing cash security deposit in the amount of 60.0% of the amount of each draw down, which amounts are included in current and long-term other assets. This financing involves restrictive financial covenants, including a requirement that we maintain unrestricted cash and marketable securities of at least \$25.0 million or obtain a letter of credit from another lender in the amount of outstanding borrowings.

Under certain licensing agreements with collaborators, we are required to pay up to 10% of certain initial upfront monetary payments, and a small percentage of some royalty payments, to the WARF. Pursuant to certain agreements whereby we have licensed technology from others, we may be required 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.

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.

As of March 31, 2006, we have employment agreements that contain severance arrangements with each of our three executive officers and three other executives. Under these agreements, we are obligated to pay severance if we terminate an executive officer's or other executive's employment other than for "cause" or "disability," or if an executive officer or other executive resigns for "good reason," as defined in the agreements, within the periods set forth therein. The severance would consist of continued payments at the current base compensation rate, or current base compensation rate plus the prior year's cash bonus in the case of the CEO, for the period specified in each agreement, which ranges from six to twelve months. These agreements also specify that any earnings from employment or consulting during this period will offset any salary continuation payments due from us. The maximum payments due under these employment agreements would have been \$1.4 million if each executive officer and other executive was terminated at March 31, 2006.

### **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, and marketable securities. The

---

[Table of Contents](#)

average maturity of our non-equity investments is approximately nine 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 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 non-equity investments at March 31, 2006. At March 31, 2006, our unrealized loss on non-equity investments was \$0.1 million. We expect lower investment income for the full year 2006 compared with 2005 due to lower investment balances.

**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 under 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, 2006.

**Changes in Internal Controls**

There has been no change in our internal control over financial reporting during the three months ended March 31, 2006 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

## PART II. OTHER INFORMATION

### **ITEM 1A. RISK FACTORS**

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

***None of our independently developed products has been approved for sale, and we have a limited number of independent 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 independent 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 products. Limited data exist regarding the safety and efficacy of DNA vaccines or therapeutics compared with conventional vaccines or therapeutics. Results of our research and development activities may indicate that our potential products are unsafe or ineffective. In this case, regulatory authorities will not approve them.

For example, our independent product candidates currently in clinical evaluation include our CMV vaccine, for which we initiated Phase 2 clinical testing in early 2006, and our IL-2 EP program, which is currently in Phase 1 clinical testing. We may not conduct additional CMV vaccine trials, leading transplant centers may not participate or sufficiently enroll patients in our trials, and our CMV vaccine may not elicit sufficient immune responses in humans. We may not conduct additional IL-2 EP trials, and our IL-2 EP program may not demonstrate sufficient safety and efficacy to support product approval.

Additionally, we are in various stages of development with several 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. If we fail to develop and commercialize our products, we may be forced to curtail or cease operations.

***We may not be able to identify and reach agreement with a potential partner for the further development and commercialization of Allovectin-7<sup>®</sup>.***

We are currently seeking a partner for Allovectin-7<sup>®</sup> and do not expect to pursue further development of Allovectin-7<sup>®</sup> until such time, if any, as we identify and reach agreement with a partner. We may not be able to reach agreement with a potential partner on acceptable terms, if at all. Failure to reach agreement with a partner in a timely manner will prevent or delay continued development and potential commercialization of Allovectin-7<sup>®</sup>. Even if approved, Allovectin-7<sup>®</sup> may not be commercially successful.

***Our revenues partially depend on the development and commercialization of products by others to whom we have licensed our technologies. If our collaborators or licensees are not successful 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 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 performance by these collaborators and licensees of their responsibilities under these arrangements. Some collaborators or licensees may not succeed in their product development efforts, such as Corautus which terminated their Phase 2b angiogenesis trial, or devote sufficient time or resources to the programs covered by these arrangements, causing us to derive little or no revenue from these arrangements.

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.

---

## Table of Contents

*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 we intend to continue entering into these agreements in the future. For example, we have entered into an agreement to manufacture bulk DNA vaccines for the VRC. 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. If we fail to satisfy our contractual obligations to deliver the vaccines ordered by the VRC in the manner required by the agreement, the applicable FARs allow the VRC to cancel the agreement in whole or in part, and we may be required to perform corrective actions, including but not limited to delivering to the VRC any uncompleted or partially completed work, or other government property in our possession, or paying a third-party supplier selected by the VRC to complete any uncompleted work. The performance of these corrective actions could have a material adverse impact on our financial results in the period or periods affected. 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 or ineligible to enter into future government agreements.

There are only a limited number of other contractors that could manufacture bulk DNA in the unlikely event that we were unable to perform our responsibilities under these agreements. The price these other contractors might charge could be more than what we would charge based on their capacity, utilization, size of order and other factors. Accordingly, we are unable to estimate a range of potential cost that we could be required to pay if the VRC were to engage a substitute contractor to meet any performance obligations that we were unable to meet.

We apply for and have received funding from various government agencies. Eligibility of public companies to receive grants, such as Small business Technology Transfer, or STTR, and SBIR 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 this source 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 \$24.4 million, \$23.7 million and \$24.5 million for the years ended December 31, 2005, 2004 and 2003, respectively. As of March 31, 2006, we had incurred cumulative net losses totaling approximately \$167.3 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.

---

## Table of Contents

*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 a shelf registration statement, which was declared effective in March 2006, that allows us to raise up to \$70 million from the sale of common or preferred stock. We also have on file a shelf registration statement, which was declared effective in December 2003, that allows us to raise up to an additional \$8.8 million from the sale of common or preferred stock. However, we may not be able to raise additional funds on favorable terms, or at all.

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 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 U.S. and other countries. The regulations are evolving and uncertain. The regulatory process can take many years and require us to expend substantial resources. For example:

- The FDA has not established guidelines concerning the scope of clinical trials required for gene-based therapeutic and vaccine products;
- The FDA has provided only limited guidance on how many subjects it will require to be enrolled in clinical trials to establish the safety and efficacy of gene-based products; and
- Current regulations and guidances are subject to substantial review by various governmental agencies.

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

- Impose costly procedures on our activities;
- Diminish any competitive advantages that we attain; or
- Negatively affect our results of operations and cash flows.

We have no experience in filing BLAs with the FDA. Because a BLA must be filed with and approved by the FDA before a biologic product may be commercialized, our lack of experience may impede our ability to obtain FDA approval in a timely manner, if at all, for our products, 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 U.S. 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 must sponsor and file a regulatory application for each proposed use. We must conduct clinical studies to demonstrate the safety and efficacy of the product necessary to obtain FDA approval. The results obtained so far in our clinical trials may not be replicated in our ongoing or future trials. This may prevent any of our potential products from receiving FDA approval.



---

## Table of Contents

We use recombinant DNA molecules in our product candidates, and therefore we 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.

In March 2004, the NIH Office of Biotechnology Activities and the FDA Center for Biologics Evaluation and Research launched the jointly developed Genetic Modification Clinical Research Information System, or GeMCRIS, an Internet-based database of human gene transfer trials. In its current form, GeMCRIS enables individuals to easily view information on particular characteristics of clinical gene transfer trials, and includes special security features designed to protect patient privacy and confidential commercial information. These security features may be inadequate in design or enforcement, potentially resulting in disclosure of confidential commercial information. We understand that both the FDA and the NIH are considering rules and regulations that would require public disclosure of additional commercial development data that is presently confidential. 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 for a wide range of diseases and conditions. Such disclosures of confidential commercial information, whether by implementation of new rules or regulations, by inadequacy of GeMCRIS security features, or by intentional posting on the Internet, may result in loss of advantage of competitive secrets.

A rule published in 2002 by the FDA, known commonly as the “Animal Rule,” established requirements for demonstrating effectiveness of drugs and biological products in settings where human clinical trials for efficacy are not feasible or ethical. The rule requires as conditions for market approval the demonstration of safety and biological activity in humans, and the demonstration of effectiveness under rigorous test conditions in up to two appropriate species of animal. We believe that with appropriate guidance from the FDA, we may seek and win market approval under the Animal Rule for certain DNA-based products for which human clinical efficacy trials are not feasible or ethical. At the moment, however, we cannot determine whether the Animal Rule would be applied to any of our products, or if applied, that its application would result in expedited development time or regulatory review.

***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 death in 1999 of a patient undergoing a viral-delivered gene therapy at the University of Pennsylvania in an investigator-sponsored trial was widely publicized. In October 2002, January 2003, and January 2005, three children in France who received viral-delivered ex vivo gene transfer for the treatment of X-linked Severe Combined Immunodeficiency Disease, called X-SCID or “bubble boy” syndrome, were diagnosed with leukemia that was caused by the integration of the viral delivery vehicle in or near a cancer-causing region of the children’s genome. Certain gene therapy clinical trials were placed on clinical hold following the second child’s death, and the trial in which the children had been enrolled was again placed on hold following the third child’s death. In October 2004, the FDA requested that clinical trials of another company’s viral-delivered gene therapy product candidate be placed on clinical hold pending review of information pertaining to potential adverse events. A portion of one of the trials was subsequently allowed to resume.

In 2003, the FDA proposed a new rule on “Safety Reporting Requirements for Human Drug and Biological Products” that would change the reporting requirements for drugs and biological products, such that any serious adverse event that cannot be definitely excluded as related to the product will be reported in an expedited manner. At present, sponsors of clinical research typically report on an annual basis all serious adverse events that have been deemed to be “unlikely” or “improbable.” The effect of this proposed rule will likely be to increase the number of expedited reports of serious adverse events to the FDA, which may create a perception of increased adverse events and higher risk profiles, despite no change in the actual severity or the actual number of adverse events that occur in the course of a product’s development.

Some of our potential products may be administered to patients who are suffering from, or are vulnerable to, diseases which can themselves be life-threatening. For example, one patient who had undergone treatment with Allovectin-7<sup>®</sup> for advanced metastatic melanoma died more than two months later of progressive disease and numerous other factors after receiving multiple 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-7<sup>®</sup> was a significant factor in the patient’s death. As another example, in our Phase 2 trial, we plan to administer our investigational CMV vaccine to patients who are 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.

---

## Table of Contents

These adverse events, and real or perceived risks, could result in greater government regulation and stricter labeling requirements for DNA-based vaccines or therapies, and may adversely impact market acceptance of some of our product candidates. Increased scrutiny in the field of gene therapy also may cause regulatory delays or otherwise affect our product development efforts or clinical trials.

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

We are the assignee of 43 issued U.S. and foreign patents. We are also co-assignee, together with Sanofi Pasteur and the University of Texas Health Science Center, of two issued U.S. patents related to vaccines against Lyme disease. In addition, we have been granted a Japanese patent related to our core DNA delivery technology that is subject to Trials for Invalidation, or TFIs; a recently granted patent in Europe related to our core DNA delivery technology has been opposed by eight parties; a patent granted in Europe covering a range of applications of our core DNA delivery technology using cationic lipid formulations has been opposed; and a patent granted in Europe covering gene-based, extra-tumoral delivery of any cytokine for the treatment of cancer has also been opposed.

We are also prosecuting 62 pending patent applications in the U.S. 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. Three of the pending foreign patent applications are international patent applications under the PCT, each of which preserves our right to pursue national-phase patent applications in a large number of foreign countries. In addition, we are co-assignee, together with Merck, of U.S. and foreign patent applications related to DNA-based vaccines against influenza that are being prosecuted by Merck.

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.

Once issued, we maintain our patents by paying maintenance fees to the patent office in each country when due. Where appropriate, we participate in legal proceedings to vigorously defend against the revocation or withdrawal of our patents. The scope and nature of these proceedings generally differ depending on the country in which they are initiated.

For example: in Europe, four patents granted to us have been opposed and one was revoked as a consequence of opposition; in Japan, one patent granted to us was opposed and subsequently subjected to TFIs; and in Canada, a protest was lodged against a patent application filed by us. 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.

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

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

Our success will depend in part on our ability to obtain patent protection for our products and processes, both in the U.S. 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

---

## **Table of Contents**

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.

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. Further our products may not gain market acceptance among physicians, patients, healthcare payers and the medical communities. If any of our products do not achieve market acceptance, we may lose our investment in that product, which could have a material adverse impact on our operations.

### ***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, and David C. Kaslow, our Chief Scientific 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

---

## Table of Contents

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 may initially depend on third parties to manufacture our product candidates commercially.***

We may 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 U.S., 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 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 efforts by governmental and third-party payers to contain or reduce the costs of healthcare through various means, including the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, which provides a new Medicare prescription drug benefit that was recently implemented and mandates other reforms. We expect that there will continue to be a number of legislative proposals to implement government controls. The adoption of such proposals or reforms could impair our business.

Certain portions of the Health Insurance Portability and Accountability Act of 1996, or HIPAA, have become effective and may complicate the process by which clinical trials may be initiated. We believe we have taken the necessary action to ensure compliance with HIPAA; however, the specific nature and degree of impact are not yet fully known.

Additionally, third-party payers are increasingly challenging the price of medical products and services. If purchasers or users of our products are not able to obtain adequate reimbursement for the cost of using our products, they may forego or reduce their use. Significant uncertainty exists as to the reimbursement status of newly approved healthcare products, and whether adequate third-party coverage will be available.

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

Our research and development processes involve the controlled storage, use and disposal of hazardous materials, biological hazardous materials and minor amounts of low-level radioactive compounds. 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

---

## **Table of Contents**

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 \$25,000 per occurrence for losses related to the release of bio-contaminants, \$1 million per occurrence for losses from refrigerant contamination and \$25,000 per occurrence for losses from radioactive contamination. Any liability could exceed 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, this insurance coverage may not be sufficient, and we may not be able to obtain sufficient coverage in the future at a reasonable cost. Our inability to obtain product liability insurance at an acceptable cost or to otherwise protect against potential product liability claims could prevent or inhibit the commercialization of any products developed by us or our collaborators, or our ability to manufacture products for third parties. If we are sued for any injury caused by our technologies or products, or by third-party products that we manufacture, our liability could exceed our insurance coverage and total assets.

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

The market price of our common stock, like that of many other life sciences companies, has been and is likely to continue to be highly volatile. From January 1, 2002 to March 31, 2006, our stock price has ranged from \$2.12 to \$12.48. 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;
- Developments concerning our patent or other proprietary rights or those of our collaborators, licensees or competitors, including litigation and challenges to our proprietary rights;
- Other developments with our collaborators or licensees, including our entry into new collaborative or licensing arrangements;
- Geopolitical developments, natural or man-made disease threats, or other events beyond our control;
- U.S. and foreign governmental regulatory actions;
- Changes or announcements in reimbursement policies;
- Period-to-period fluctuations in our operating results;
- Market conditions for life science stocks in general;
- Changes in the collective short interest in our stock;
- Changes in estimates of our performance by securities analysts; and
- Our cash balances, need for additional capital, and access to capital.

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

In the past, stockholders have brought securities class action litigation against a company following a decline in the market price of its securities. This risk is especially acute for us because life science companies have experienced greater than average stock price volatility in recent years and, as a result, have been subject to, on average, a greater number of securities class action claims than companies in other industries. To date, we have not been subject to class action litigation. However,

## Table of Contents

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 prohibits stockholders owning in excess of 15% of our outstanding voting stock from merging or combining with us. 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 frustrate 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 an effective shelf registration statement that allows us to raise up to \$70 million from the sale of common or preferred stock. We also have on file an effective shelf registration statement that allows us to raise up to an additional \$8.8 million from the sale of common or preferred stock. The issuance of preferred stock could adversely affect the voting power of holders of our common stock, and reduce the likelihood that our common stockholders will receive dividend payments and payments upon liquidation. The issuance of preferred stock could also decrease the market price of our common stock, or have terms and conditions that could discourage a takeover or other transaction that might involve a premium price for our shares or that our stockholders might believe to be in their best interests.

## **ITEM 6. EXHIBITS**

<u>Exhibit Number</u>	<u>Description of Document</u>
3.1(i)(1)	Restated Certificate of Incorporation.
3.1(ii)(1)	Amended and Restated Bylaws.
4.1(1)	Specimen Common Stock Certificate.
10.47(a)	Amendment dated February 20, 2006, to License Agreement dated May 24, 2005, between the Company and AnGes MG, Inc.
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. Church, 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 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of Jill M. Church, Chief Financial Officer, pursuant to 18 U.S.C. Section 1350, as adopted 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.
- (a) The Company has requested confidential treatment for certain portions of this amendment which have been omitted and filed separately with the SEC pursuant to Rule 24b-2 under the Securities Exchange Act of 1934.

**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.

Date: May 8, 2006

Vical Incorporated

By: /s/ JILL M. CHURCH

Jill M. Church  
Vice President, Chief Financial Officer and Secretary  
(on behalf of the registrant and as the registrant's Principal Financial and Accounting Officer)

\*\*\* Text Omitted and Filed Separately  
with the Securities and Exchange Commission.  
Confidential Treatment Requested  
under 17 C.F.R. Sections 200.800(b)(4)  
and 240.24b-2.

Amendment to License Agreement

This Amendment made this 20th day of February 2006 (the "Effective Date") is by and between AnGes MG, Inc., a corporation with its principal executive offices located at 7-7-15, Saito-Asagi, Ibaraki, Osaka, 567-0085, Japan ("Anges"), and VICAL Incorporated, a Delaware corporation having its principal place of business at 10390 Pacific Center Court, San Diego, California 92121, USA ("VICAL").

WHEREAS, VICAL and Anges entered into a License Agreement ("Agreement") dated May 24, 2005; and

WHEREAS, the parties now wish to revise certain provision of the Agreement as provided below to eliminate a patent application [\*\*\*] from, and to add two patent applications [\*\*\*] and [\*\*\*] to, the Patent Rights.

NOW THEREFORE, the parties agree as follow:

- 1. VICAL and Anges agree to amend Exhibit A of the Agreement as described in Exhibit A attached hereto, pursuant to Section 10.1 of the Agreement.

IN WITNESS WHEREOF, both VICAL and Anges have executed this Amendment by their respective and duly authorized officers on the day and year written. This Amendment is effective as of the Effective Date.

Vical Incorporated

AnGes MG, Inc.

By: /s/ Vijay B. Samant

By: /s/ Ei Yamada, Ph. D.

Date: February 20, 2006

Date: February 20, 2006

Name: Vijay B. Samant

Name: Ei Yamada, Ph. D.

Title: President and Chief Executive Officer

Title: CEO

\*\*\* Confidential Treatment Requested



---

**Exhibit A****United States**

---

[\*\*\*]

[\*\*\*]

[\*\*\*]

[\*\*\*]

[\*\*\*]

US [\*\*\*] is specifically excluded, but the continuations [\*\*\*] and [\*\*\*] are included.

**Japan**

---

[\*\*\*]

**Europe**

---

[\*\*\*]

**Canada**

---

[\*\*\*]

\*\*\* Confidential Treatment Requested

## CERTIFICATION

I, Vijay B. Samant, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Vical Incorporated;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 8, 2006

By: /s/ VIJAY B. SAMANT

Vijay B. Samant  
Chief Executive Officer

## CERTIFICATION

I, Jill M. Church, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Vical Incorporated;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 8, 2006

By: /s/ JILL M. CHURCH

Jill M. Church  
Chief Financial Officer

**CERTIFICATION PURSUANT TO  
18 U.S.C. SECTION 1350,  
AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. § 1350, as adopted), Vijay B. Samant, the Chief Executive Officer of Vical Incorporated (the "Company"), hereby certifies that, to the best of his knowledge:

1. The Company's Quarterly Report on Form 10-Q for the period ended March 31, 2006, to which this Certification is attached as Exhibit 32.1 (the "Periodic Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934, as amended; and
2. The information contained in the Periodic Report fairly presents, in all material respects, the financial condition of the Company at the end of the period covered by the Periodic Report and results of operations of the Company for the period covered by the Periodic Report.

Dated: May 8, 2006

/s/ VIJAY B. SAMANT

\_\_\_\_\_  
Vijay B. Samant

Chief Executive Officer

THIS CERTIFICATION "ACCOMPANIES" THE FORM 10-Q TO WHICH IT RELATES, IS NOT DEEMED FILED WITH THE SEC AND IS NOT TO BE INCORPORATED BY REFERENCE INTO ANY FILING OF THE COMPANY UNDER THE SECURITIES ACT OF 1933, AS AMENDED, OR THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED (WHETHER MADE BEFORE OR AFTER THE DATE OF THE FORM 10-Q), IRRESPECTIVE OF ANY GENERAL INCORPORATION LANGUAGE CONTAINED IN SUCH FILING. A SIGNED ORIGINAL OF THIS CERTIFICATION HAS BEEN PROVIDED TO THE COMPANY AND WILL BE RETAINED BY THE COMPANY AND FURNISHED TO THE SECURITIES AND EXCHANGE COMMISSION OR ITS STAFF UPON REQUEST.

**CERTIFICATION PURSUANT TO  
18 U.S.C. SECTION 1350,  
AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. § 1350, as adopted), Jill M. Church, the Chief Financial Officer of Vical Incorporated (the "Company"), hereby certifies that, to the best of her knowledge:

1. The Company's Quarterly Report on Form 10-Q for the period ended March 31, 2006, to which this Certification is attached as Exhibit 32.2 (the "Periodic Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934, as amended; and
2. The information contained in the Periodic Report fairly presents, in all material respects, the financial condition of the Company at the end of the period covered by the Periodic Report and results of operations of the Company for the period covered by the Periodic Report.

Dated: May 8, 2006

/s/ JILL M. CHURCH

\_\_\_\_\_  
Jill M. Church

Chief Financial Officer

THIS CERTIFICATION "ACCOMPANIES" THE FORM 10-Q TO WHICH IT RELATES, IS NOT DEEMED FILED WITH THE SEC AND IS NOT TO BE INCORPORATED BY REFERENCE INTO ANY FILING OF THE COMPANY UNDER THE SECURITIES ACT OF 1933, AS AMENDED, OR THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED (WHETHER MADE BEFORE OR AFTER THE DATE OF THE FORM 10-Q), IRRESPECTIVE OF ANY GENERAL INCORPORATION LANGUAGE CONTAINED IN SUCH FILING. A SIGNED ORIGINAL OF THIS CERTIFICATION HAS BEEN PROVIDED TO THE COMPANY AND WILL BE RETAINED BY THE COMPANY AND FURNISHED TO THE SECURITIES AND EXCHANGE COMMISSION OR ITS STAFF UPON REQUEST.