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, 2003

or

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

Commission File Number: 000-21088

VICAL INCORPORATED

(Exact name of registrant as specified in its charter)

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

(858) 646-1100
(Registrant's telephone number, including area code)

9373 Towne Centre Dr., Suite 100,
San Diego, CA 92121
(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 an accelerated filer (as defined in Exchange Act Rule 12b-2). 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 1, 2003
20,091,344

VICAL INCORPORATED

FORM 10-Q

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Part I. Financial Information
Item 1. Financial Statements

VICAL INCORPORATED
BALANCE SHEETS
(Unaudited)

	March 31, 2003	December 31, 2002
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 14,723,255	$ 32,608,954
Marketable securities—available-for-sale	84,581,967	76,606,286
Marketable security—restricted	2,298,240	2,298,240
Receivables and other	6,219,544	5,893,491
Total current assets	107,823,006	117,406,971
Investment	—	800,000
Property and Equipment:		
Equipment	11,253,172	10,180,279
Leasehold improvements	5,682,885	4,687,877
	16,936,057	14,868,156
Less—accumulated depreciation and amortization	(9,950,463)	(9,925,642)
	6,985,594	4,942,514
Intangible Assets, net	5,807,812	5,642,372
Other Assets	763,233	634,091
	$ 121,379,645	$ 129,425,948
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable and accrued expenses	$ 6,873,325	$ 7,369,546
Current portion of capital lease obligations	1,270,804	1,267,974
Current portion of notes payable	561,905	633,333
Current portion of deferred revenue	1,789,909	1,528,409
Total current liabilities	10,495,943	10,799,262
Long-Term Obligations:		
Long-term obligations under capital leases	1,787,716	1,976,920
Notes payable	247,619	340,476
Deferred revenue	676,588	949,315
Deferred lease credits	1,143,682	1,052,726
Total long-term obligations	3,855,605	4,319,437
Commitments and Contingencies		
Stockholders' Equity:		
Preferred stock, $0.01 par value—5,000,000 shares authorized—none outstanding	—	—
Common stock, $0.01 par value—40,000,000 shares authorized—20,091,344 shares issued and outstanding at March 31, 2003, and December 31, 2002	200,913	200,913
Additional paid-in capital	203,542,874	203,554,007
Accumulated other comprehensive income	643,946	887,068
Accumulated deficit	(97,359,636)	(90,334,739)
Total stockholders' equity	107,028,097	114,307,249
	$ 121,379,645	$ 129,425,948

See accompanying notes to financial statements.

VICAL INCORPORATED
STATEMENTS OF OPERATIONS
(Unaudited)

	Three months ended March 31,	
	2003	**2002**
Revenues:		
License/royalty revenue	$ 495,982	$ 1,033,232
Contract revenue	412,352	478,115
	908,334	1,511,347
Operating expenses:		
Research and development	6,583,390	5,999,632
General and administrative	1,540,363	1,720,180
Write-down of investment	482,217	—
	8,605,970	7,719,812
Loss from operations	(7,697,636)	(6,208,465)
Other income (expense):		
Investment income	743,740	1,054,787
Interest expense	(71,001)	(69,971)
Net loss	$ (7,024,897)	$ (5,223,649)
Net loss per common share (basic and diluted—Note 3)	$ (0.35)	$ (0.26)
Weighted average shares used in computing net loss per common share (Note 3)	20,091,344	20,059,310

See accompanying notes to financial statements.

VICAL INCORPORATED
STATEMENTS OF CASH FLOWS
(Unaudited)

	Three months ended March 31,	
	2003	**2002**
OPERATING ACTIVITIES:		
Net loss	$ (7,024,897)	$ (5,223,649)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	973,633	675,564
Write-down of investment	482,217	—
Loss on sublease	32,000	—
Compensation expense related to grant of stock options	(11,133)	30,072
Change in operating assets and liabilities:		
Receivables and other	(326,053)	371,656
Other assets	(129,142)	(323,770)
Accounts payable and accrued expenses	(528,221)	(439,396)
Deferred revenue	(11,227)	(658,045)
Deferred lease credits	90,956	—
Net cash used in operating activities	(6,451,867)	(5,567,568)
INVESTING ACTIVITIES:		
Sales of marketable securities	29,399,897	14,854,401
Purchases of marketable securities	(37,300,917)	(24,994,230)
Capital expenditures	(2,750,932)	(9,807)
Licensed technology expenditures	(80,000)	—
Patent expenditures	(227,617)	(13,681)
Net cash used in investing activities	(10,959,569)	(10,163,317)
FINANCING ACTIVITIES:		
Issuance of common stock, net	—	6,400
Payments on notes payable	(164,285)	(164,286)
Principal payments under capital lease obligations	(309,978)	(209,048)
Net cash used in financing activities	(474,263)	(366,934)
Net decrease in cash and cash equivalents	(17,885,699)	(16,097,819)
Cash and cash equivalents at beginning of period	32,608,954	43,736,068
Cash and cash equivalents at end of period	$ 14,723,255	$ 27,638,249
Interest paid	$ 71,580	$ 70,767
Supplemental Disclosure of Non-Cash Investing and Financing Activities:		
Investment accounted for on the cost method, subsequently reclassified to marketable securities available-for-sale, at quoted market value	$ 317,783	$ —

Equipment acquired under capital lease financing	$ 123,604	$ —

See accompanying notes to financial statements.

VICAL INCORPORATED

NOTES TO FINANCIAL STATEMENTS

March 31, 2003
(Unaudited)

1. ORGANIZATION AND BASIS OF PRESENTATION

Organization

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 potential biopharmaceutical products based on its patented DNA delivery technologies for the prevention and treatment of serious or life-threatening diseases.

Basis of Presentation

The information contained herein has been prepared in accordance with instructions for Form 10-Q. The information at March 31, 2003, and for the three-month periods ended March 31, 2003 and 2002, is unaudited. In the opinion of management, the information reflects all adjustments necessary to present fairly the Company's financial position and results of operations for the interim periods presented. All such adjustments are of a normal recurring nature. Interim results are not necessarily indicative of results for a full year. The preparation of financial statements in conformity with accounting principles generally accepted in the United States 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 financial statements should be read in conjunction with the Company's audited financial statements for the year ended December 31, 2002, included in its Form 10-K filed with the Securities and Exchange Commission.

2. ACCOUNTING FOR STOCK OPTIONS

The Company accounts for stock options issued to its employees and non-employee directors using the intrinsic value method. Under this method, no compensation expense is recorded for the fair value of options issued to employees and non-employee directors. The Company has adopted the disclosure-only provisions of Statement of Financial Accounting Standards, or SFAS, No. 123, "Accounting for Stock Based Compensation," as amended by SFAS No. 148. Had compensation cost for the Company's stock option plans been determined consistent with the provisions of SFAS No. 123, the Company's net loss and net loss per common share would have increased to the pro forma amounts indicated below:

	Three Months Ended March 31,	
	2003	2002
Net loss, as reported	$ (7,024,897)	$ (5,223,649)
Stock-based compensation expense determined under fair value based method for all awards	(1,014,795)	(1,501,802)
Pro forma net loss	$ (8,039,692)	$ (6,725,451)
Net loss per common share (basic and diluted), as reported	$ (0.35)	$ (0.26)
Pro forma net loss per common share (basic and diluted)	$ (0.40)	$ (0.34)

The fair value of each option grant was estimated on the date of grant using the Black-Scholes option-pricing model with the following weighted average assumptions used for grants: risk free interest rates of 2.58%

(2003) and 3.86% (2002); and expected volatility of 81% (2003) and 82% (2002). An expected option life of four years and a dividend rate of zero are assumed for the periods presented.

3. NET LOSS PER SHARE

Net loss per share (basic and diluted) for the three-month periods ended March 31, 2003 and 2002, has been computed using the weighted average number of common shares outstanding during the respective periods. The weighted average number of shares used to compute diluted loss per share excludes any assumed exercise of stock options, as the effect would be antidilutive. The weighted average number of shares so excluded was 3,272,878 and 2,471,174 for the three-month periods ended March 31, 2003 and 2002, respectively. Options outstanding were 3,464,478 and 2,972,614 at average exercise prices of $11.32 and $14.75 at March 31, 2003 and 2002, respectively.

4. COMPREHENSIVE INCOME

Accumulated other comprehensive income represents net unrealized gains on marketable securities. For the three months ended March 31, 2002, marketable securities consisted of investments in debt instruments of financial institutions and corporations with strong credit ratings, and in U.S. government obligations. At March 31, 2003, marketable securities also included the Company's investment in common stock of Corautus Genetics Inc. See also Note 5 below. For the three-month periods ended March 31, 2003 and 2002, other comprehensive losses were $0.2 million and $0.7 million, respectively, and total comprehensive losses were $7.3 million and $5.9 million, respectively.

5. INVESTMENT IN CORAUTUS GENETICS INC.

In February 2000, the Company received shares of preferred stock in Vascular Genetics Inc., or VGI, a privately held company, in exchange for a license to Vical technology. The shares were recorded as an investment on the balance sheet at estimated fair value of $5.0 million. In September 2002, the Company wrote down the investment in VGI to $0.8 million based on objective values established as a result of a proposed merger between VGI and GenStar Therapeutics, a public company listed on the American Stock Exchange, or AMEX. The VGI shares continued to be reflected as an investment on the balance sheet at December 31, 2002.

In February 2003, the merger closed, resulting in the creation of a new entity, called Corautus Genetics Inc., or Corautus. Subsequent to the merger, the shares of VGI were exchanged for common stock of Corautus, which is listed on AMEX. These shares have a legend which restricts the number of Corautus shares the Company can sell over a period of time. The value of the Company's Corautus shares, as measured by the quoted price on AMEX on March 31, 2003, was $0.3 million. Based on this market information, the Company wrote down its investment to $0.3 million. At March 31, 2003, the Company's investment in Corautus is accounted for as an available-for-sale security.

6. LEASED FACILITY; LEASE LINE

The Company currently holds three leases at three sites for its older manufacturing, research laboratories and offices, which terminate in 2004. In March 2003, the Company relocated most of its employees to its new facility and subleased to a third party approximately half of the vacated space.

The Company has a lease line with its primary lender to provide up to $10.8 million of financing through November 30, 2003. This lease line includes approximately $8.0 million of credit for tenant improvements and equipment for the new facility. At March 31, 2003, the Company had borrowed $0.4 million against this lease line.

7. RELATED-PARTY TRANSACTIONS

R. Gordon Douglas, M.D., Chairman of the Board of Directors of the Company, also is the Director of Strategic Planning at the National Institutes of Health, Dale and Betty Bumpers Vaccine Research Center, or VRC. For the period from November 2000 to March 2003, VRC had contracted with Vical for approximately $1.8 million for the production of Human Immunodeficiency Virus, or HIV, clinical trial supplies. In April 2003, the Company and the VRC entered into a no-cost extension of the contract to June 2006. Cumulatively through March 31, 2003, the Company had recognized $1.5 million of revenue under this agreement,

including $0.0 million and $0.2 million for the three-month periods ended March 31, 2003 and 2002, respectively.

Additionally, for varying periods which commenced in February 2001 and ended in February 2003, VRC contracted with Vical for approximately $0.9 million for providing regulatory support services. Cumulatively through the contract expiration on February 28, 2003, the Company had recognized $0.6 million of revenue under this agreement, including $0.1 million and $0.0 million for the three-month periods ended March 31, 2003 and 2002, respectively.

In July 2002, the Company entered into an agreement with VRC to provide certain regulatory and manufacturing services to VRC related to the research and development of a DNA vaccine against the Ebola virus. Cumulatively through March 31, 2003, the Company has recognized $1.0 million of revenues under this agreement. No revenue was recognized under this contract for the three-month periods ended March 31, 2003 or 2002.

In May 2003, the Company entered into a contract to manufacture bulk DNA vaccines for the VRC. In support of this contract, the VRC will underwrite a portion of the capital for fermentation and purification equipment in the Company's new manufacturing facility. Under this agreement, the Company is guaranteed minimum annual production orders beginning in 2004, subject to annual extension of the agreement.

Dr. Douglas is on the Board of Directors of the International AIDS Vaccine Initiative, or IAVI, a not-for-profit entity. Vijay B. Samant, President and CEO of the Company, serves on the Project Management Subcommittee of IAVI. In 2002, the Company signed an agreement with IAVI to provide clinical trial supplies. As of March 31, 2003, IAVI had issued purchase orders under this agreement totaling approximately $1.1 million. Revenue recognized under this agreement for the three months ended March 31, 2003, was $0.2 million. No revenue was recognized in the comparable period of 2002.

The above related-party transactions were approved by a majority or more of the disinterested members of the Company's Board of Directors.

8. STOCK INCENTIVE PLAN

The Company has a stock incentive plan, under which 5,200,000 shares of common stock, subject to adjustment as provided in the plan, and including a 500,000 share increase that has been approved by the Board of Directors but remains subject to stockholder approval at the Company's 2003 Annual Meeting of Stockholders, are reserved for issuance to employees, non-employee directors and consultants of the Company.

FORWARD-LOOKING STATEMENTS

The statements incorporated by reference or contained in this report discuss our future expectations, contain projections of our results of operations or financial condition, and include other "forward-looking" information 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. Our actual results may differ materially from those expressed in forward-looking statements made or incorporated by reference in this report. Forward-looking statements that express our beliefs, plans, objectives or assumptions, or that describe future events or performance, may involve estimates, assumptions, risks and uncertainties. Therefore, our actual results and performance may differ materially from those expressed in the forward-looking statements. Forward-looking statements often, although not always, include words or phrases such as the following, or the negative of such words, or other comparable terminology:

- "Will likely result,"
- "Are expected to,"
- "Will continue,"
- "Is anticipated,"
- "Estimate,"
- "Believe,"
- "Predict,"
- "Potential,"
- "Intends,"
- "Plans,"
- "Projection," and
- "Outlook."

You should not unduly rely on forward-looking statements contained or incorporated by reference in this report. Actual results or outcomes may differ significantly and materially from those predicted in our forward-looking statements due to the risks and uncertainties inherent in our business, including risks and uncertainties related to:

- Progress of our preclinical and clinical product development programs,
- Clinical trial results,
- Obtaining and maintaining regulatory approval,
- Market acceptance of and continuing demand for our products,
- The attainment of patent protection for any of these products,
- The impact of competitive products, pricing and reimbursement policies,
- Our ability to obtain additional financing to support our operations,
- The continuation of our corporate collaborations and licenses,
- Our ability to enter into new corporate collaborations and licenses,
- Changing market conditions, and
- Other risks detailed below.

You should read and interpret any forward-looking statements together with the following documents:

- The risk factors contained in this report under the caption "Additional Business Risks,"
- Our Annual Report on Form 10-K, and
- Our other filings with the Securities and Exchange Commission.

Any forward-looking statement speaks only as of the date on which that statement is made. 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.

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

Overview

We were incorporated in Delaware in 1987. 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 for which a challenge model or accepted surrogate marker are available, and
- Cancer vaccines or immunotherapies that complement our existing programs and core expertise.

For opportunities outside these areas, we plan to continue leveraging our patented technology through licensing and collaborations. In addition, we plan to use our expertise, infrastructure, and financial strength to explore in-licensing or acquisition opportunities.

Recent Events

Cytomegalovirus

In February 2003, we announced that a DNA-based immunotherapeutic vaccine against cytomegalovirus, or CMV, will be our first independent development program focused on infectious diseases. Currently, there is no approved vaccine or even a late-stage vaccine development program for CMV. We began preclinical safety studies in animals on schedule and we expect to file our Investigational New Drug application, or IND, for this program in the second half of 2003. Our goal is to begin Phase I clinical testing of the vaccine in human subjects by year-end 2003 for an initial indication for patients at high risk of serious complications from CMV infection—patients undergoing hematopoietic cell transplants, including bone marrow transplants, or solid organ transplantation—at three of the nation's leading transplant centers.

The Institute of Medicine, or IOM, of the National Academy of Sciences has estimated the cost of treating the consequences of CMV infection in the United States at more than $4 billion per year and placed a CMV vaccine in its first priority category on the basis of cost-effectiveness. Our initial focus on the transplantation indication should allow proof of concept that could then lead to the opportunity to develop a CMV vaccine for other high-risk groups such as immunocompromised individuals and women of reproductive age.

Our CMV immunotherapeutic vaccine program is based on:

- CMV genes that encode highly immunogenic proteins associated with protective antibody and cellular immune responses,
- Our DNA vaccine technologies that have the ability to induce potent cellular immune responses and trigger production of antibodies without the safety concerns that conventional attenuated vaccines have posed for immunocompromised patients, and
- A focused clinical development plan that is designed to allow us to quickly establish proof of concept in transplant patients.

Anthrax

In March 2003, we announced our second independent infectious disease DNA vaccine development program, an anthrax DNA vaccine. Results with multiple formulations of the vaccine in mouse and rabbit immunogenicity and challenge models were presented at the American Society for Microbiology meeting, "Future Directions for Biodefense Research: Development of Countermeasures," in Baltimore, Maryland, in March, 2003, and have been encouraging. We have now completed preclinical safety studies in rabbits, in which the rabbits achieved similar levels of immune response to those achieved in our initial rabbit study. We

remain on track to file an IND and begin a safety and immunogenicity study in human subjects in the second half of 2003.

We believe that we can develop a safe and effective DNA vaccine for anthrax that will validate the potential advantages of our proprietary vaccine technologies while addressing a pressing public need, because:

- The key anthrax immunogens have been identified, and we have verified in small animal studies that nucleotide sequences encoding certain of these immunogens can be delivered effectively by formulated DNA, with resulting protective immune responses. Our technology allows us to readily produce detoxified forms of two anthrax immunogens, Protective Antigen, or PA, and Lethal Factor, or LF, that together may provide broader protection than the currently licensed anthrax vaccine or proposed single recombinant protein vaccines;

- Our cationic lipid formulated DNA delivery technology, in which positively charged lipid molecules may interact with the negatively charged DNA molecules, has established an excellent safety profile in previous clinical studies, and an important goal of this program is to extend that safety profile to vaccine applications;

- Another important goal of this program is to demonstrate that DNA vaccines can induce protective antibodies in humans and can do so with fewer injections than the currently licensed anthrax vaccine, offering a potentially shorter time to protection; and

- The potential stability of plasmid formulations may offer advantages in handling and storage, which would be important considerations for stockpiling.

We believe that the U.S. Food and Drug Administration, or FDA, would review this vaccine based on its "Animal Rule," which allows demonstration of effectiveness in two animal species in addition to safety in humans, and that development costs using this regulatory pathway should be moderate compared with conventional clinical trials.

Allovectin-7®

Allovectin-7® is a DNA/lipid complex containing the DNA sequences encoding HLA-B7 and β2 microglobulin, which together form a Major Histocompatibility Complex, or MHC, Class I antigen. This type of antigen can trigger a potent immune response against foreign tissues, such as that seen in organ transplant rejections. Allovectin-7® is injected directly into tumors, and is designed to make malignant cells more visible to the immune system. The treatment may trigger an immune response against tumor cells, both locally and systemically, by enabling the immune system to recognize other features of tumor cells.

Low-Dose Allovectin-7®. In May 1998 we began two concurrent registration trials: a Phase II clinical trial and a Phase III clinical trial, with low-dose, 10 micrograms per injection, Allovectin-7® for patients with late-stage metastatic melanoma.

Our Phase II registration trial had endpoints of a 15 percent systemic clinical response rate, and a four-month median duration of response. Unadjudicated data from the investigation sites, presented at the May 2001 annual meeting of the American Society of Clinical Oncology, or ASCO, suggested that treatment with Allovectin-7® resulted in systemic clinical responses in 10.9 percent of the patients, with a median duration of response of 4.9 months. Adjudication refers to the process by which important efficacy results reported by trial investigators are reviewed to determine whether they meet protocol-specific endpoints. Estimated median survival in the Phase II registration trial was 14 months. It was determined that these data alone likely would not support FDA approval, and therefore we decided not to pursue marketing approval based solely on these data.

In our randomized, controlled Phase III registration trial for the treatment of chemotherapy-naïve patients with metastatic melanoma, half the patients received dacarbazine, the only chemotherapeutic agent approved at that time by the FDA for metastatic melanoma. The other half received dacarbazine plus low-dose Allovectin-7®. We announced in September 2002 that an initial review of investigator-determined efficacy by an external consultant indicated that our Phase III registration trial would not meet statistical significance of objective response rate, time to disease progression, or survival. As a result, we avoided prematurely embarking on the time-consuming and costly process of Biologics License Application, or BLA, filing.

High-Dose Allovectin-7®. Based on preliminary data that injected melanoma tumors appear to respond more frequently than non-injected lesions, one strategy to increase the response rate to Allovectin-7® is to inject multiple tumors rather than single tumors as in prior studies. In addition, higher doses of Allovectin-7® may increase objective response rates. In February 2001, we initiated a Phase II clinical trial evaluating a higher dose of 2,000 micrograms, a 200-fold increase compared with the registration trials. The trial also allows for the distribution of that increased dose into as many as five tumor lesions. The higher dose, with or without multiple tumor injections, may provide a relevant increase in objective response rate.

At current enrollment of 124 patients with advanced metastatic melanoma, our Phase II high-dose Allovectin-7® trial enrollment is approaching completion. We plan to present interim data from the high-dose trial at the May 2003 ASCO meeting.

Manufacturing Contract with Vaccine Research Center

In May 2003, we announced a contract to manufacture bulk DNA vaccines for the Vaccine Research Center, or VRC, part of the National Institute of Allergy and Infectious Diseases of the National Institutes of Health, or NIH. In support of this contract, the VRC will underwrite a portion of the capital for fermentation and purification equipment in Vical's new manufacturing facility. Under this agreement, Vical is guaranteed minimum annual production orders beginning in 2004, subject to annual extension of the agreement.

Management Change

In May 2003, Jon Norman, Vice President of Product Strategic Planning, resigned from Vical.

Critical Accounting Policies

Use of estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States 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. Specifically, management must make estimates in the following areas:

Investment. In February 2000, we received shares of preferred stock in Vascular Genetics Inc., or VGI, a privately held company, in exchange for a license to our technology. The shares were recorded as an investment on the balance sheet at estimated fair value of $5.0 million. In September 2002, we wrote down the investment in VGI to $0.8 million based on objective values established as a result of a proposed merger between VGI and GenStar Therapeutics, a public company listed on the American Stock Exchange, or AMEX. The VGI shares continued to be reflected as an investment on the balance sheet at December 31, 2002.

In February 2003, the merger closed, resulting in the creation of a new entity, called Corautus Genetics Inc., or Corautus. Subsequent to the merger, the shares of VGI were exchanged for common stock of Corautus, which is listed on AMEX. These shares have a legend which restricts the number of Corautus shares we can sell over a period of

time. The value of our Corautus shares, as measured by the quoted price on AMEX on March 31, 2003, was $0.3 million. Based on this market information, we wrote down our investment to $0.3 million. At March 31, 2003, our investment in Corautus is accounted for as an available-for-sale security.

Corautus still needs to raise substantial cash to complete its development plans, and there can be no assurance that its developmental therapy for angiogenesis will work or that the FDA will approve such a therapy. Corautus may not be able to raise such cash or successfully commercialize a product even if it receives FDA approval. We may incur a realized loss on sale of investment if we were to sell our shares on the open market at below the March 31, 2003, recorded value.

Loss on sublease. In 2002, we initiated activities to sublease space that would be vacated when we moved most employees to our new facility. In March 2003, we subleased to a third party approximately half of the vacated space and adjusted the accrual for loss on the subleases. If the final negotiated sublease rates or the number of months we are able to sublease the remaining vacated space are different from the amounts we assumed, we may need to adjust our estimated accrual, which in turn, could affect our results of operations and cash flow.

Intangible assets. We capitalize the license fees we pay to acquire access to proprietary technology if the technology is expected to have alternative future use in multiple research and development projects. The cost of licensed technology rights is amortized to expense over the estimated average useful life of the technology, which is generally 10 years. We also capitalize certain costs related to patent applications. Accumulated costs are amortized over the estimated economic life of the patent, which is generally 20 years and usually commences at the time the patent application is filed. Costs related to patent applications are written off to expense at the time such costs are deemed to have no continuing value. Intangible assets are amortized using the straight-line method. We review long-lived assets and intangible assets for impairment at least annually and whenever events or changes in circumstances indicate that the total amount of an asset may not be recoverable. An impairment loss is recognized when the estimated future cash flows expected from the use of the asset and the eventual disposition are less than its carrying amount. Loss of legal ownership or rights to patents or licensed technology, or significant changes in our strategic business objectives and utilization of the assets, among other things, could give rise to asset impairment.

Deferred tax assets. Deferred tax assets are recorded net of a 100% valuation allowance. This valuation allowance reduces the gross deferred tax assets to the amount that we believe is more likely than not realizable. We considered projections of future taxable income, past operating results and tax planning strategies in making this determination.

Clinical trial expenses. We account for our clinical trial costs by estimating the total cost to treat a patient in each clinical trial and amortizing this total cost for the patient over the estimated treatment period, beginning when the patient enrolls in the clinical trial. This estimated cost includes payments to the trial site and other external expenses related to the conduct of the trial. Cost per patient varies based on the type of clinical trial, the site of the clinical trial, the method of administration of the treatment, and the length of treatment period for each patient. Treatment periods vary depending on the clinical trial. As actual costs become known to us, we may need to make a material change in our estimated accrual, which could also materially affect our results of operations.

Accruals for potential disallowed costs on contracts We have contracts with agencies of the U.S. government under which we bill for direct and indirect costs incurred. These billed costs are subject to audit by government agencies. We have established accruals to provide for potential disallowed costs. In the event that the final costs allowed are different from what we have estimated, we may need to make a material change in our estimated accrual, which could also materially affect our results of operations and cash flow.

Revenue recognition

We earn revenue from licensing access to our proprietary technology, and by performing services under research and development contracts and grants, and service contracts. In general, revenue is recognized when all of the following criteria are met: persuasive evidence of an arrangement exists, services have been rendered, the price is fixed or determined, and collection is reasonably assured. Any initial license or option payment received under an agreement under which we also provide research and development services is recognized as revenue over the term of the research and development period. Payments for options on a license to our technology are recognized as revenue over the option period. Fees paid to extend an option are recognized as revenue over the option extension period. Upfront license payments are recognized as revenue upon contract signing if the fee is nonrefundable and noncreditable, and if there are no significant performance obligations remaining. Revenue from milestones is recognized as the milestones are achieved and collection of payment is reasonably assured.

Revenue under research and development contracts and grants, and manufacturing and regulatory service contracts, is recognized as the services are performed. We do not recognize revenue on contract change orders until the service is performed and we have a signed modification for additional funding for the contract. Prior to that time, any costs incurred for change orders on contracts are deferred if it is probable that we will receive a signed modification increasing the funding under the contract which will allow us to recover the costs incurred. Once the signed modification for additional funding is received, the deferred costs and any related revenue are both recognized. Advance payments received in excess of amounts earned are classified as deferred revenue on the balance sheets.

Recent Accounting Pronouncements

In October 2002, the FASB revised the approach for Emerging Issues Task Force, or EITF, Issue No. 00-21, “Revenue Arrangements with Multiple Deliverables.” EITF Issue No. 00-21 addresses certain aspects of the accounting under arrangements where a company will perform multiple revenue generating activities. EITF Issue No. 00-21 provides guidance on when and how an arrangement should be divided into a separate unit of accounting, and when and how much revenue can be recognized on the different units delivered in particular to license, research and development and contract manufacturing agreements often entered into by companies in the biotechnology industry. The provisions of EITF Issue No. 00-21 will apply to revenue arrangements entered into in fiscal periods beginning after June 15, 2003. We are currently evaluating the effect that the adoption of EITF Issue No. 00-21 will have on our financial statements.

In December 2002, the FASB issued FASB Interpretation No. 45, or FIN 45, “Guarantor’s Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others.” FIN 45 would require us to record as a liability on our balance sheet any guarantees upon the issuance of such guarantees or indemnification. Additionally, FIN 45 requires disclosures about such guarantees. The initial recognition and initial measurement of guarantees is effective on a prospective basis to guarantees issued or modified after December 31, 2002. The disclosure provisions are applicable for financial statements for interim or annual periods ended after December 15, 2002. The adoption of FIN 45 did not have a material effect on our financial position or results of operations.

In December 2002, the FASB issued SFAS No. 148, “Accounting for Stock-Based Compensation—Transition and Disclosure— an amendment of FASB Statement No. 123.” This statement amends SFAS No. 123 by providing alternative methods for transition to companies who voluntarily change to the fair value method of accounting for stock options. Additionally, the statement requires expanded and more prominent disclosure in both annual and interim financial statements of the method used to account for stock options and the effect of the method used on reported results. We have provided the required disclosure in Note 2 of the Notes to Financial Statements.

Results of Operations

We recorded revenues of $0.9 million for the three months ended March 31, 2003. License/royalty revenue of $0.5 million for the three months ended March 31, 2003, represented recognition of deferred license fees from Corautus, formerly VGI, and royalty revenue. Contract revenue for the three months ended March 31, 2003, was $0.4 million and included revenues from IAVI for production of clinical trial supplies, and from the Office of Naval Research, or ONR, for development work on an investigational DNA vaccine to prevent malaria.

We recorded revenues of $1.5 million for the quarter ended March 31, 2002. License/royalty revenue of $1.0 million for the three months ended March 31, 2002, represented recognition of deferred license fees of $0.8 million from Merial and Corautus, and royalty revenue of $0.2 million. Contract revenue of $0.5 million was from the NIH for manufacturing of DNA for infectious disease vaccines, and from ONR.

Our total operating expenses for the three months ended March 31, 2003, were $8.6 million compared with $7.7 million for the same period in the prior year. Research and development expenses increased to $6.6 million for the three months ended March 31, 2003, from $6.0 million for the same period in 2002. This increase in research and development expenses was due to increased facilities costs, preclinical costs and personnel-related costs.

General and administrative expenses were $1.5 million for the three months ended March 31, 2003, and $1.7 million for the three months ended March 31, 2002. The decrease in general and administrative expenses for the three months ended March 31, 2003, compared with the same period in the prior year, was due to lower incentive-based compensation expense.

Operating expenses for the three months ended March 31, 2003, also included a write-down of investment of $0.5 million. In February 2003, GenStar Therapeutics, a public company listed on AMEX, and VGI, a private company in which we received shares of preferred stock when we licensed our technology to VGI, completed their previously announced merger and created a new entity, known as Corautus. Subsequent to the merger, the shares of VGI were exchanged for common stock of Corautus, which is listed on AMEX. The value of our shares as measured by the quoted price on AMEX on March 31, 2003, was $0.3 million compared with our

recorded value of $0.8 million. Based on this market information, we wrote down our investment to $0.3 million.

We expect research and development expense to increase for the full year 2003 compared with 2002 as a result of relocation to a new facility and expansion of our preclinical programs to broaden our future pipeline.

Investment income for the three-month period ended March 31, 2003, was $0.7 million and included realized gains on sales of investments of $0.1 million. Investment income for the three months ended March 31, 2002, was $1.1 million. The decrease in investment income in 2003 compared with 2002 is due to lower rates of return and lower investment balances. Some of our investments were purchased prior to recent reductions in interest rates, and currently are yielding higher returns than we could expect when reinvesting the proceeds upon sale or maturity. Thus, our interest yields and interest income are expected to be lower in the full year 2003 than in 2002.

Our net loss was $7.0 million, or $0.35 per common share, for the three months ended March 31, 2003, compared with a net loss of $5.2 million, or $0.26 per common share, for the same period in the prior year. We expect to incur losses throughout the remainder of 2003 and we expect our net loss for the year ending December 31, 2003, to be between $24 million and $28 million.

Liquidity and Capital Resources

Since our inception, we have financed our operations primarily through private placements of preferred and common stock, four public offerings of common stock and revenues from collaborative agreements. Cash, cash equivalents and marketable securities totaled approximately $101.6 million at March 31, 2003, compared with $111.5 million at December 31, 2002.

Cash used in operating activities increased to $6.5 million for the three months ended March 31, 2003, compared with $5.6 million for the same period in 2002. The increase in cash used in operating activities was due to an increased net loss, lower interest payments received on investments, an increase in deferred contract costs, and a decrease in accounts payable and accrued expenses. Cash used to acquire other assets was higher in the three months ended March 31, 2002, than in the corresponding period in 2003 because of the rent deposit on the new facility. These changes were partially offset by the positive cash flow impact of a prepayment received on a contract and increases in noncash charges such as depreciation and amortization. Net loss for the three months ended March 31, 2003 also included a noncash write-down of our investment in Corautus, as more fully explained under “Results of Operations” above.

Cash used in investing activities was $11.0 million for the three months ended March 31, 2003, compared with $10.2 million for the same period in 2002. Capital expenditures for the three months ended March 31, 2003, increased from the same period in the prior year, and are expected to be higher for the full year as we make additional capital purchases for, and improvements to, the new facility. Additionally, spending for licensed technology and patents contributed to the increase in cash used in investing activities.

Cash used in financing activities for the three months ended March 31, 2003, was $0.5 million compared with $0.4 million for the same period in 2002. The increased use of cash was a result of an increase in payments on capital lease obligations for the three months ended March 31, 2003, compared with the same period in 2002.

In November 2002, we entered into a new lease line with our primary lender to provide up to $10.8 million of financing through November 30, 2003. This financing replaced a previous capital equipment line which was renewed in January 2002. The new lease line includes approximately $8.0 million of credit for tenant improvements and equipment for the new leased facility. At March 31, 2003, we had borrowed $0.4 million against this lease line.

We are attempting to sublease vacated space in our older facilities in order to recover some or all of our existing rent payments plus a portion of our amortization of leasehold improvements. In March 2003, we subleased approximately half of the vacant space. However, if we are unable to sublease the remaining space on acceptable terms, if at all, our net loss and cash outlays will continue to include the full amounts of rent payments on vacant space until the leases terminate in 2004.

We expect to incur substantial additional research and development expenses and general and administrative expenses, including continued increases in personnel costs, costs related to preclinical testing and clinical trials, costs related to outside services and facilities, and costs to maintain and enhance our intellectual property. 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 and enforcing patent claims, competing technological and market developments, the cost of manufacturing scale-up, and construction costs of the new facility. We intend to seek additional funding through research and development relationships with suitable potential corporate collaborators. We may also seek additional funding through public or private financings, or an increase in our credit facilities. We cannot assure that additional financing will 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 2004.

We do not utilize “special purpose entities” for any transactions. Our only “off balance sheet” obligations are for operating leases that are disclosed in Note 8 of the Notes to Financial Statements included in our Form 10-K for the year ended December 31, 2002.

Additional Business Risks

You should carefully consider the risks described below, together with all of the other information included in this report, before deciding whether to invest in or continue to hold our common stock. The risks and uncertainties described below are not the only ones facing us, because we are also subject to additional risks and uncertainties not presently known to us. If any of these known or unknown 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 products has been approved for sale, and we have only one product candidate in clinical trials. If we do not develop commercially successful products, we may be forced to curtail or cease operations.

All of our potential products 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. Very little data exists regarding the safety and efficacy of DNA-based vaccines or therapies. 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, in 2002 we announced that the efficacy data from our low-dose Phase III registration trial with Allovectin-7® in patients with metastatic melanoma would not support a registration submission with the FDA. We also announced in 2002 that further independent development of Allovectin-7® for head and neck cancer, and of Leuvectin® for kidney cancer and prostate cancer, was not justified in light of our other priorities. As a result, our only product candidate currently in clinical trials is high-dose Allovectin-7® for metastatic melanoma.

Additionally, we are in the early stages of research and development of vaccine candidates for infectious diseases such as CMV and anthrax. These vaccine candidates will require significant costs to advance through the development stages. If such vaccine candidates are advanced to clinical trials, the results of such trials may not support FDA approval. 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.

Commercialization of some of our potential products depends on collaborations with others. If our collaborators are not successful or if we are unable to find collaborators in the future, we may not be able to develop these products.

Our strategy for the research, development and commercialization of some of our product candidates requires us to enter into contractual arrangements with corporate collaborators, licensors, licensees and others. Our success depends upon the performance by these collaborators of their responsibilities under

these arrangements. Some collaborators may not perform their obligations as we expect or we may not derive any revenue from these arrangements.

We have collaborative agreements with several pharmaceutical companies. We do not know whether these companies will successfully develop and market any products under their respective agreements. Moreover, some of our collaborators are also researching competing technologies to treat the diseases targeted by our collaborative programs. We may be unsuccessful in entering into and maintaining other collaborative arrangements to develop and commercialize our products.

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 products and do not expect to sell any products for the next several years. Our net losses were approximately $27.9 million, $9.2 million and $8.5 million for 2002, 2001 and 2000, respectively. As of March 31, 2003, we have incurred cumulative net losses totaling approximately $97.4 million. Moreover, we expect that our negative cash flow and losses from operations will continue and may increase for the foreseeable future. For 2003, we have forecast a net loss of between $24 million and $28 million. We may not be able to achieve our projected results, either because we generate lower revenues or 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.

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 manufacturing and marketing capabilities. We may seek additional funds through public and private stock offerings, arrangements with corporate collaborators, borrowings under lease lines of credit or other sources. 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 reduce our capital expenditures, 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 will 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 are subject to extensive and rigorous regulations by numerous governmental authorities in the United States 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 products,
- The FDA has not indicated how many patients it will require to be enrolled in clinical trials to establish the safety and efficacy of gene-based products, and
- Current regulations 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 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 then 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 on-going or future trials. This may prevent any of our potential products from receiving FDA approval.

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.

We understand that both the FDA and NIH are considering rules and regulations that would require public disclosure of commercial development data that is presently confidential. This potential disclosure of commercial confidential information, if implemented, may result in loss of advantage of competitive secrets.

A rule published in 2002 by the FDA, known commonly as the "Animal Rule," attempts to establish 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 DNA-based products designed to treat or prevent a disease for which clinical efficacy trials in humans are neither feasible nor ethical, such as our DNA vaccine for anthrax. At the moment, however, we cannot guarantee that the Animal Rule will 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 and January 2003, two children in France who received retroviral-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. The FDA responded to these events in France by temporarily halting all U.S. clinical trials using retroviral vectors to transduce hematopoietic stem cells. Following public advisory committee review by experts in the field, the FDA allowed these trials in the U.S. to continue under careful scrutiny, because the potential benefit of the investigational gene therapy in patients with this life-threatening condition was believed to justify the risk.

Some of our potential products may be administered to patients who are suffering from or vulnerable to diseases which can themselves be life-threatening. For example, one patient who had undergone treatment with Allovectin-7® 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® was a significant factor in the patient's death.

As another example, we may administer our developmental CMV vaccine to patients who are at risk of CMV reactivation. Likewise, our developmental anthrax vaccine may eventually be administered to patients who have been exposed to anthrax. 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.

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 may not receive any patents from our current patent applications. Moreover, if patents are issued to us, governmental authorities may not allow claims sufficient to protect our technology 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 technology or to provide any commercial advantage.

Our core DNA delivery technology is covered by patents that have been issued and revoked as a result of oppositions in Europe and Japan. In addition, our core DNA delivery technology is covered by a patent that was withdrawn from issuance as a result of a protest procedure in Canada. If we are not successful in appealing the revocation or withdrawal from issuance of our patents in Europe, Japan or Canada, we may lose all or part of our proprietary protection on our product candidates in these countries or 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 United States and in other countries. The patent positions of biotechnology and pharmaceutical companies, however, can be highly uncertain and involve complex legal and factual questions. Therefore, it is difficult to predict the breadth of claims allowed in the biotechnology and pharmaceutical fields.

We also rely on confidentiality agreements with our corporate collaborators, employees, consultants and certain contractors to protect our proprietary technology. 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 will 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 United States 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 technology. 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 technology.

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 may not be able to redesign our products or processes to avoid infringement.

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 technology 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. Other companies may succeed in developing products and obtaining FDA approval faster than we do, or in developing products that are more effective than ours. While we will seek to expand our technological capabilities to remain competitive, research and development by others will seek to render our technology or products obsolete or noncompetitive or result in treatments or cures superior to any therapeutics developed by us. Additionally, even if our product development efforts are successful, and even if the requisite regulatory approvals are obtained, our product may not gain market acceptance among physicians, patients, healthcare payers and the medical communities. If any of our product candidates do not achieve market acceptance, we may lose our investment in that product, which could have a material adverse impact on our operations.

The method of administration of some of our product candidates can cause adverse events in patients, including death.

Some of our potential products are designed to be injected directly into malignant tumors. There are medical risks inherent in direct tumor injections. For example, in clinical trials of our potential products, attending physicians have punctured patients' lungs in less than one percent of procedures, requiring hospitalization. In addition, a physician administering our product in an investigator-sponsored clinical trial inadvertently damaged tissue near the heart of a patient, which may have precipitated the patient's death. These events are reported as adverse events in our clinical trials. These risks may adversely impact market acceptance of some of our product candidates.

If we lose our key personnel or are unable to attract and retain additional personnel, we may not be able to pursue collaborations or develop our own products.

We are highly dependent on the principal members of our scientific, manufacturing, clinical, regulatory and management personnel, the loss of whose services might significantly delay or prevent the achievement of our objectives. 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 personnel with expertise in clinical trials, government regulation and manufacturing. We may not be successful in hiring or retaining qualified personnel.

We may not be able to manufacture products on a commercial scale.

We have limited experience in manufacturing our product candidates in commercial quantities. We may be dependent initially on corporate collaborators, licensees or others to manufacture our products commercially. We also will be required to comply with extensive regulations applicable to manufacturing facilities. We may be unable to enter into any arrangement for the manufacture of our products.

We may not be able to sublease vacated space in our older office site.

We currently hold three leases at three sites for our older manufacturing, research laboratories and offices, which terminate in 2004. In March 2003, we subleased to a third party approximately half of the vacated space. Currently there is excess office space available for rent or sublease in San Diego. This condition may continue or worsen before we are able

to sublease the remaining vacated space. If we are unable to sublease this remaining space, or if the final negotiated sublease rates, or the number of months we are able to sublease the remaining vacated space, are different from the amounts we assumed in our net loss calculations for this space, we may need to adjust our estimated accrual, which in turn could affect our results of operations or cash flows.

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

Our current strategy is to market our proprietary products directly in the United States, but we currently do not possess pharmaceutical marketing or sales capabilities. In order 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, our business will be harmed.

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 the extent to which 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. We expect that there will continue to be a number of legislative proposals to implement government controls. The announcement of proposals or reforms could impair our ability to raise capital. The adoption of proposals or reforms could impair our business.

Certain portions of the Health Insurance Portability and Accountability Act of 1996, or HIPAA, that become effective this year are expected to lengthen the process by which clinical trials may be initiated, however the specific nature and degree of impact are not yet 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 radioactive compounds. We are subject to federal, state and local regulations governing the use, manufacture, storage, handling and disposal of materials and waste products. Although we believe that our safety procedures for handling and disposing of these hazardous materials comply with the standards prescribed by law and regulation, the risk of accidental contamination or injury from hazardous materials cannot be completely eliminated. In the event of an accident, we could be held liable for any damages that result, and any liability could exceed the limits or fall outside the coverage of our insurance. We may not be able to maintain insurance on acceptable terms, or at all. We could be required to 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. These risks are inherent in the development of chemical and pharmaceutical products. Although we currently maintain product liability insurance, we may not have sufficient insurance coverage and we may not be able to obtain sufficient coverage 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. We also have potential liability for products manufactured by us on a contract basis for third parties. If we are sued for any injury caused by our technology or products, 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 paid 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. 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 those of our collaborators or competitors or for gene therapies in general,
- Evidence or lack of evidence of the safety or efficacy of our potential products or the products of our competitors,
- The announcement by us or our competitors of technological innovations or new products,
- 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,
- Developments with our collaborators,
- Developments concerning our patent or other proprietary rights or those of our competitors, including litigation and challenges to our proprietary rights,
- Concern as to the safety of our potential products,
- 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. We may in the future be the target of similar litigation. Securities litigation could result in substantial costs and divert our management's attention and resources, and could seriously harm our business.

Our anti-takeover provisions could discourage potential takeover attempts and make attempts by stockholders to change management more difficult.

The approval of two-thirds of our voting stock is required to approve some transactions and to take some stockholder actions, including the calling of a special meeting of stockholders and the amendment of any of the anti-takeover provisions contained in our certificate of incorporation. Further, pursuant to the terms of our stockholder rights plan adopted in March 1995, we have distributed a dividend of one right for each

outstanding share of common stock. These rights will cause substantial dilution to the ownership of a person or group that attempts to acquire us on terms not approved by our Board of Directors and may have the effect of deterring hostile takeover attempts.

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 and marketable securities. The average maturity of our non-equity investments is approximately nine months. Our investments are all classified as available-for-sale securities.

At March 31, 2003, marketable securities also included our investment in common stock of Corautus. Any subsequent change in the fair value of the Corautus shares we own, based on the market price of the listed shares, is expected to be reflected as an unrealized gain or loss in the stockholders' equity section of our balance sheet at the end of each quarter, provided any reduction in value is not due to impairment which is other than temporary. See Note 5 of the Notes to Financial Statements for further details.

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 $0.9 million lower than the reported fair value of our nonequity investments at March 31, 2003. At March 31, 2003, our unrealized gain on marketable securities was $0.6 million.

Some of our investments currently are yielding higher returns than we could expect when reinvesting the proceeds upon sale or maturity. Thus, our interest yields and investment income are expected to be lower in 2003 than in 2002.

The fair market value of floating interest rate debt is subject to interest rate risk. Generally, the fair market value of floating interest rate debt will vary as interest rates increase or decrease. Based on our market-risk-sensitive instruments outstanding at March 31, 2003, and December 31, 2002, we believe that there were no material market risk exposures to our financial position, results of operations or cash flows as of such dates.

ITEM 4. CONTROLS AND PROCEDURES

Within the 90 days prior to the filing of this report, we carried out an evaluation, under the supervision and with the participation of our President and Chief Executive Officer and our Vice President and Chief Financial Officer, of the effectiveness of our disclosure controls and procedures. Disclosure controls and procedures are designed to ensure that information required to be disclosed in our periodic reports filed or submitted under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Commission's rules and forms. Based upon that evaluation, our President and Chief Executive Officer and Vice President and Chief Financial Officer concluded that our disclosure controls and procedures are effective. There have been no significant changes in our internal controls or other factors that could significantly affect internal controls subsequent to the date we carried out this evaluation.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

Our core DNA delivery technology was covered by a patent issued in Europe in 1998, which was subsequently opposed by seven companies under European patent procedures. This patent was revoked on formal grounds in October 2001 under an initial ruling by the Opposition Division of the European Patent Office, or EPO. The Opposition Division ruled that, as a result of amendments to the claims made during the process of obtaining the European patent and during the opposition process, the claims did not comply with European patent laws. In April 2002, we filed an appeal, which is still pending, seeking to overturn this initial ruling. We intend to vigorously defend our patent position in the European opposition proceedings. If we are not successful in the appeal and opposition proceedings, we may lose part or all of our proprietary protection on our product candidates in Europe. However, we may also use additional patent applications that are pending in Europe to secure patent protection for our core DNA delivery technology.

Our core DNA delivery technology is also covered by patent applications filed in Canada. A Canadian patent was issued and then withdrawn from issuance and returned to the examiner for further consideration after protests against the issuance of the patent were filed on behalf of an undisclosed party or parties on August 10 and December 5, 2001. We have responded to the protests and are awaiting further action by the Canadian Patent Office.

Our core DNA delivery technology is also covered by patent applications filed in Japan. On January 2, 2002,Japanese Patent 3250802 was published, and simultaneously opened for third party opposition. We received an Office Action from the Japanese Patent Office, or JPO, notifying us that the patent had been revoked by the examining panel at the JPO. Both formal and substantive grounds for the revocation were given. We intend to file a rebuttal response on or before May 28, 2003.

We have licensed from the University of Michigan rights to various U.S. and international patents related to injection of DNA-based therapeutics into tumors that, for example, provide additional protection for Allovectin-7® and Leuvectin®. Included in this license is European Patent Number 0591385, which was granted, and simultaneously opened for opposition, on March 20, 2002. We have received notice from the EPO that one company filed an opposition on December 19, 2002, alleging both formal and substantive grounds for revocation, and that the opposition was declared admissible on February 13, 2003. We intend to file a rebuttal response on or before the due date of June 13, 2003, or, if we are granted a six-month extension, on or before the extended due date of December 13, 2003.

In the ordinary course of business, we may become a party to lawsuits involving various matters. We are unaware of any such lawsuits presently pending against us.

ITEM 6. EXHIBITS AND REPORTS ON FORM 8-K

(a) Exhibits

Exhibit Number	Description of Document
3.1(i)(1)	Restated Certificate of Incorporation.
3.1(ii)(1)	Amended and Restated Bylaws.
4.1(1)	Specimen Common Stock Certificate.
4.2(2)	Rights Agreement dated as of March 20, 1995, between the Company and First Interstate Bank of California.
99.1	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.
99.2	Certification of Martha J. Demski, 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.

(2) Incorporated by reference to the exhibit of the same number to the Company's Report on Form 10-K for the fiscal year ended December 31, 1994 (No. 0-21088).

(b) Reports on Form 8-K

On May 6, 2003, we filed a Form 8-K to disclose our press release of financial results for the three months ended March 31, 2003.

SIGNATURES

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

Vical Incorporated

Date: May 15, 2003

By: /s/ MARTHA J. DEMSKI
Martha J. Demski
Vice President and Chief Financial Officer
(on behalf of the registrant and as the registrant's Principal Financial and Accounting Officer)

CERTIFICATIONS UNDER SECTION 302 OF THE SARBANES-OXLEY ACT

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 quarterly 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 quarterly report;

3. Based on my knowledge, the financial statements, and other financial information included in this quarterly 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 quarterly report;

4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and we have:

a) designed such disclosure controls and procedures 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 quarterly report is being prepared;

b) evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this quarterly report (the "Evaluation Date"); and

c) presented in this quarterly report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;

5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent function):

a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and

b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and

6. The registrant's other certifying officers and I have indicated in this quarterly report whether there were significant changes in internal controls or in other factors that could

significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: May 15, 2003 By: /s/ VIJAY B. SAMANT
Vijay B. Samant
President and Chief Executive Officer

CERTIFICATIONS UNDER SECTION 302 OF THE SARBANES-OXLEY ACT (CONT'D.)

I, Martha J. Demski, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Vical Incorporated;

2. Based on my knowledge, this quarterly 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 quarterly report;

3. Based on my knowledge, the financial statements, and other financial information included in this quarterly 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 quarterly report;

4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and we have:

a) designed such disclosure controls and procedures 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 quarterly report is being prepared;

b) evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this quarterly report (the "Evaluation Date"); and

c) presented in this quarterly report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;

5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the
equivalent function):

a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and

b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and

6. The registrant's other certifying officers and I have indicated in this quarterly report whether there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: May 15, 2003 By: /s/ MARTHA J. DEMSKI
Martha J. Demski
Vice President and Chief Financial Officer

Exhibit 99.1

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, 2003, to which this Certification is attached as Exhibit 99.1 (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 15, 2003

/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.

Exhibit 99.2

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), Martha J. Demski, 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, 2003, to which this Certification is attached as Exhibit 99.2 (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 15, 2003

/s/ MARTHA J. DEMSKI
Martha J. Demski
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.