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# UNITED STATES
# SECURITIES AND EXCHANGE COMMISSION
**Washington, D.C. 20549**

# FORM 10-Q

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

**For the quarterly period ended June 30, 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)

(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 August 5, 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)**

| | June 30, 2003 | December 31, 2002 |
|---|---|---|
| *ASSETS* | | |
| Current Assets: | | |
| Cash and cash equivalents | $ 13,386,102 | $ 32,608,954 |
| Marketable securities—available-for-sale | 82,418,566 | 76,606,286 |
| Marketable security—restricted | 2,355,700 | 2,298,240 |
| Receivables and other | 5,485,606 | 5,893,491 |
| Total current assets | 103,645,974 | 117,406,971 |
| Investment | — | 800,000 |
| Property and Equipment: | | |
| Equipment | 16,574,747 | 10,180,279 |
| Leasehold improvements | 5,839,812 | 4,687,877 |
| | 22,414,559 | 14,868,156 |
| Less—accumulated depreciation and amortization | (10,600,980) | (9,925,642) |
| | 11,813,579 | 4,942,514 |
| Intangible Assets, net | 5,906,685 | 5,642,372 |
| Other Assets | 694,933 | 634,091 |
| | $ 122,061,171 | $ 129,425,948 |
| *LIABILITIES AND STOCKHOLDERS' EQUITY* | | |
| Current Liabilities: | | |
| Accounts payable and accrued expenses | $ 7,459,851 | $ 7,369,546 |
| Current portion of capital lease obligations | 3,122,853 | 1,267,974 |
| Current portion of notes payable | 490,477 | 633,333 |
| Current portion of deferred revenue | 2,614,909 | 1,528,409 |
| Total current liabilities | 13,688,090 | 10,799,262 |
| Long-Term Obligations: | | |
| Long-term obligations under capital leases | 6,297,107 | 1,976,920 |
| Notes payable | 154,762 | 340,476 |
| Deferred revenue | 403,861 | 949,315 |
| Deferred lease credits | 1,288,669 | 1,052,726 |
| Total long-term obligations | 8,144,399 | 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 June 30, 2003, and December 31, 2002 | 200,913 | 200,913 |
| Additional paid-in capital | 203,589,974 | 203,554,007 |
| Accumulated other comprehensive income | 719,557 | 887,068 |

| | | |
|---|---|---|
| Accumulated deficit | (104,281,762) | (90,334,739) |
| Total stockholders' equity | 100,228,682 | 114,307,249 |
| | $ 122,061,171 | $ 129,425,948 |

See accompanying notes to financial statements.



**VICAL INCORPORATED**
**STATEMENTS OF OPERATIONS**
**(Unaudited)**

| | Three months ended June 30, | | Six months ended June 30, | |
|---|---|---|---|---|
| | 2003 | 2002 | 2003 | 2002 |
| Revenues: | | | | |
| License/royalty revenue | $ 511,520 | $ 2,078,859 | $ 1,007,502 | $ 3,112,091 |
| Contract revenue | 89,672 | 368,846 | 502,024 | 846,961 |
| | 601,192 | 2,447,705 | 1,509,526 | 3,959,052 |
| Operating expenses: | | | | |
| Research and development | 6,318,061 | 6,368,518 | 12,901,451 | 12,368,150 |
| General and administrative | 1,750,520 | 2,051,292 | 3,290,883 | 3,771,472 |
| Write-down of investment | — | — | 482,217 | — |
| | 8,068,581 | 8,419,810 | 16,674,551 | 16,139,622 |
| Loss from operations | (7,467,389) | (5,972,105) | (15,165,025) | (12,180,570) |
| Other income (expense): | | | | |
| Investment income | 615,530 | 1,021,495 | 1,359,270 | 2,076,283 |
| Interest expense | (70,267) | (68,672) | (141,268) | (138,644) |
| Net loss | $ (6,922,126) | $ (5,019,282) | $ (13,947,023) | $ (10,242,931) |
| Net loss per common share (basic and diluted—Note 3) | $ (0.34) | $ (0.25) | $ (0.69) | $ (0.51) |
| Weighted average shares used in computing net loss per common share (Note 3) | 20,091,344 | 20,077,333 | 20,091,344 | 20,070,046 |

See accompanying notes to financial statements.



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

| | Six months ended June 30, | |
|---|---|---|
| | 2003 | 2002 |
| OPERATING ACTIVITIES: | | |
| Net loss | $ (13,947,023) | $ (10,242,931) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Depreciation and amortization | 1,774,166 | 1,307,672 |
| Write-down of investment | 482,217 | — |
| Loss on sublease | 78,402 | — |
| Compensation expense related to grant of stock options | 35,967 | 26,629 |
| Deferred lease credits | 235,943 | — |
| Change in operating assets and liabilities: | | |
| Receivables and other | 407,885 | 163,746 |

| | | |
|---|---|---|
| Other assets | (60,842) | (327,070) |
| Accounts payable and accrued expenses | 11,903 | 574,801 |
| Deferred revenue | 541,046 | (1,093,272) |
| Net cash used in operating activities | (10,440,336) | (9,590,425) |
| INVESTING ACTIVITIES: | | |
| Sales of marketable securities | 67,944,976 | 33,296,399 |
| Purchases of marketable securities | (73,664,445) | (51,609,488) |
| Capital expenditures | (1,377,934) | (105,282) |
| Licensed technology expenditures | (80,000) | — |
| Patent expenditures | (473,177) | (216,297) |
| Net cash used in investing activities | (7,650,580) | (18,634,668) |
| FINANCING ACTIVITIES: | | |
| Issuance of common stock, net | — | 7,200 |
| Payments on notes payable | (328,570) | (328,571) |
| Principal payments under capital lease obligations | (803,366) | (444,385) |
| Net cash provided from (used in) financing activities | (1,131,936) | (765,756) |
| Net decrease in cash and cash equivalents | (19,222,852) | (28,990,849) |
| Cash and cash equivalents at beginning of period | 32,608,954 | 43,736,068 |
| Cash and cash equivalents at end of period | $ 13,386,102 | $ 14,745,219 |
| Interest paid | $ 156,575 | $ 140,251 |
| 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 | $ 6,978,432 | $ 1,092,365 |

See accompanying notes to financial statements.



**VICAL INCORPORATED**

**NOTES TO FINANCIAL STATEMENTS**

**June 30, 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 June 30, 2003, and for the three-month and six-month periods ended June 30, 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 and the Company's unaudited financial statements for the three-month period ended March 31, 2003, included in its Form 10-Q 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 June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | 2003 | 2002 | 2003 | 2002 |
| Net loss, as reported | $ (6,922,126) | $ (5,019,282) | $ (13,947,023) | $ (10,242,931) |
| Add stock-based compensation expense included in reported net loss | 47,100 | (3,443) | 35,967 | 26,629 |
| Less stock-based compensation expense determined under fair value based method for all awards | (910,760) | (1,629,409) | (1,914,422) | (3,161,283) |
| Pro forma net loss | $ (7,785,786) | $ (6,652,134) | $ (15,825,478) | $ (13,377,585) |
| Net loss per common share (basic and diluted), as reported | $ (0.34) | $ (0.25) | $ (0.69) | $ (0.51) |
| Pro forma net loss per common share (basic and diluted) | $ (0.39) | $ (0.33) | $ (0.79) | $ (0.67) |

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 2.51% (2003) and 4.11% (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 and six-month periods ended June 30, 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 2,730,360 and 2,789,757 for the three-month and six-month periods ended June 30, 2003, respectively. The weighted average number of shares so excluded was 2,919,021 and 2,801,066 for the three-month and six-month periods ended June 30, 2002, respectively. Options outstanding were 3,486,984 and 2,988,554 at average exercise prices of $11.16 and $14.51 at June 30, 2003 and 2002, respectively.

**4. COMPREHENSIVE LOSS**

Comprehensive loss consists of net loss and other comprehensive income. Accumulated other comprehensive income represents net unrealized gains on marketable securities. For the three-month and six-month periods ended June 30, 2002, marketable securities consisted of investments in debt instruments of financial institutions and corporations with strong credit ratings, and in U.S. government obligations. Beginning March 31, 2003, marketable securities also included the Company's investment in common stock of Corautus Genetics Inc., or Corautus. See also Note 5 below. For the three-month periods ended June 30, 2003 and 2002, other comprehensive income was $0.1 million and other comprehensive loss was $0.6 million, respectively, and total comprehensive losses were $6.8 million and $4.4 million, respectively. For the six-month periods ended June 30, 2003 and 2002, other comprehensive losses were $0.2 million and $0.1 million, respectively, and total comprehensive losses were $14.1 million and $10.3 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 an 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, 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, on March 31, 2003, the Company wrote down its investment to $0.3 million and reclassified the investment as an available-for-sale security.

In July 2003, Corautus entered into a strategic alliance with Boston Scientific Corp., or BSC, to develop and commercialize a gene therapy to treat cardiovascular disease. BSC paid $9 million to Corautus in exchange for 10 percent of Corautus' equity on a fully diluted basis, paid a $1 million license fee, and committed to purchasing up to $15 million of convertible debt from Corautus based on achievement of certain milestones. BSC also holds a sublicense from Vical, under the Company's license from the University of Michigan, for catheter-based intravascular gene delivery technology that may be applicable under the Corautus strategic alliance.

**6. LEASED FACILITY; LEASE LINE**

The Company currently holds three leases at three sites for manufacturing facility, research laboratories and offices, which terminate in 2004. In March 2003, the Company relocated most of its employees to a new facility. In March 2003, the Company subleased to a third party all of the vacated research space, and in May 2003, the Company subleased a portion of the vacated office space. The Company adjusted its accrual for estimated loss on the leases after each sublease transaction.

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 June 30, 2003, the Company had used $7.3 million of this lease line.

**7. CONTINGENCIES**

On July 29, 2003, the Wisconsin Alumni Research Foundation, or WARF, filed a complaint against us in the United States District Court for the Western District of Wisconsin, seeking a declaratory judgment regarding the meaning of certain payment provisions in our agreement with WARF, as well as fees related to our sublicense of certain inventions jointly owned by us and WARF. We intend to vigorously defend the suit and we may assert counterclaims seeking to recover excess royalties we previously paid under the agreement. Based on the information presently available to us, we do not believe WARF's claims are material to our business.

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 issued patents and patent applications that are pending in Europe to protect 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. A rebuttal response to the revocation was filed with the JPO in a timely manner. The response is currently under consideration in the JPO. In addition to the Opposition proceedings, we received notice that Trial for Invalidation, or TFI, requests against Japanese Patent JP3250802 were filed in the JPO by two companies. We are currently reviewing the TFI requests. We intend to file responses to the TFI requests on or before the deadlines for each response.

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 are currently preparing a rebuttal response to the opposition.

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, except as noted above.

**8. RELATED-PARTY TRANSACTIONS**

R. Gordon Douglas, M.D., Chairman of the Board of Directors of the Company, is also 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 June 30, 2003, the Company had recognized $1.8 million of revenue under this agreement, including $0.0 million and $0.2 million for the six-month periods ended June 30, 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 June 30, 2003, the Company had recognized $0.7 million of revenue under this agreement, including $0.1 million and $0.2 million for the six-month periods ended June 30, 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 DNA vaccines against the Ebola virus. This agreement was modified in 2003 to include DNA vaccines against West Nile Virus.



Cumulatively through June 30, 2003, the Company had recognized $1.1 million of revenues under this agreement, including approximately $0.1 million and $0.0 million for the six-month periods ended June 30, 2003 and 2002, respectively.

In May 2003, the Company announced a contract to manufacture bulk DNA vaccines for the VRC. In support of this contract, the VRC has agreed to finance the purchase of a 500-liter fermenter and related 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. No revenue is expected to be recognized under this agreement in 2003.

Through June 30, 2003, Dr. Douglas was 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 June 30, 2003, IAVI had issued purchase orders under this agreement totaling approximately $1.1 million. Revenue recognized under this agreement for the three-month and six-month periods ended June 30, 2003, was $0.0 and $0.2 million, respectively. For the three-month and six-month periods ended June 30, 2002, revenue recognized under this agreement was $0.2 million.

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

**9. 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 was approved by the stockholders at the Company's 2003 Annual Meeting of Stockholders, are reserved for issuance to employees, non-employee directors and consultants of the Company.

**10. SUBSEQUENT EVENTS**

In July 2003, we were awarded a three-year, $5.7 million Phase II Small Business Innovation Research, or SBIR, grant from the U.S. National Institute of Allergy and Infectious Diseases, or NIAID, of the National Institutes of Health, or NIH. The grant will partially fund the development of our DNA vaccine against anthrax. Our continued development of the anthrax program is dependent on the continued availability of government funding.

## 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 and defense 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 our first independent development program focused on infectious diseases, a DNA-based immunotherapeutic vaccine against cytomegalovirus, or CMV. 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 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.

The initial clinical development plan includes vaccination of both donors and recipients in bone marrow transplants.



***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 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 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.

In July 2003, we were awarded a three-year, $5.7 million Phase II Small Business Innovation Research, or SBIR, grant from the U.S. National Institute of Allergy and Infectious Diseases, or NIAID, of the National Institutes of Health, or NIH. The grant will partially fund the development of our DNA vaccine against anthrax. Our continued

development of the anthrax program is dependent on the continued availability of government funding.

***Allovectin-7®***

Allovectin-7® is a DNA/lipid complex containing the DNA sequences encoding HLA-B7 and b2 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 III clinical trial and a Phase II clinical trial, with low-dose, 10 micrograms per injection, Allovectin-7® for patients with late-stage metastatic melanoma. Following analysis of unadjudicated data from the Phase II registration trial, as previously reported, we decided not to pursue marketing approval based solely on these data. Adjudication refers to the process by which efficacy results reported by trial investigators are independently reviewed to determine whether they meet protocol-specific endpoints. 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.

One strategy to increase the response rate to Allovectin-7® is to increase the dose of Allovectin-7®. We implemented this strategy in our high-dose Allovectin-7® trial, described below.

*High-Dose Allovectin-7®.* In February 2001, we initiated a Phase II clinical trial evaluating a higher dose of 2,000 micrograms, or 2 mg., a 200-fold increase compared with the two prior registration trials. The trial also allows for the injection of a total dose of 2 mg. 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, duration of response, and/or survival.

We presented unaudited data from interim analyses performed in early March 2003 with respect to the first 91 of 127 patients ultimately enrolled in the high-dose Allovectin-7® portion of the trial at the May 2003 American Society of Clinical Oncology, or ASCO, meeting, including objective response rate, duration of response, safety, and preliminary survival, as follows:

- Twelve of the first 91 high-dose patients, or 13 percent, had objective responses; this compares favorably with recently published response rates of 10 percent to 12 percent for dacarbazine in metastatic melanoma;
- Two of the 12 responders had complete responses, and ten had partial responses;
- Nine of the 12 responders had stage IV disease, and three had stage III disease;
- Twenty-two patients, or 24 percent, achieved stable disease, for a total of 37 percent of the patients deriving potential clinical benefit; and
- The safety profile continued to be excellent, with less than two percent of the more than 600 patients treated with Allovectin-7® at various doses experiencing product-related serious adverse events.

At the time of the presentation, only one of the twelve responders had experienced progressive disease; therefore, the estimated median duration of response of 3.5 months was expected to increase as the data matured.

Subsequent to the ASCO meeting, trial enrollment was completed, reflecting strong interest by patients and physicians. Based on unaudited data on the same 91 patients collected in early July 2003, estimated median duration of response increased to at least 6.4 months, with 7 of the 12 responders still progression-free. All twelve of the responders were still alive.

Data from this and our low-dose Phase II trial suggest that Allovectin-7® may offer a well-tolerated alternative for patients with stage III or IV melanoma, who have few other options. We intend to review the data with the FDA and evaluate the development and commercialization opportunities for Allovectin-7®, either independently or through partnerships.

***Manufacturing Contracts with Vaccine Research Center***

We continue to manufacture Ebola DNA vaccines for the VRC in our existing manufacturing facility under a contract awarded in July 2002. In July 2003, we announced an order for clinical-grade



supplies of an investigational DNA vaccine against the West Nile Virus, for development planned by the VRC. In May 2003, we announced a separate contract to manufacture bulk DNA vaccines for the Vaccine Research Center, or VRC, part of the NIAID of the NIH. In support of this contract, the VRC has agreed to finance the purchase of a 500-liter fermenter and related purification equipment in our new manufacturing facility. Under this agreement, we are guaranteed minimum annual production orders beginning in 2004, subject to annual extension of the agreement. These contracts are issued and managed on behalf of the VRC by SAIC Frederick, Inc. under the umbrella of a federally funded prime contract with NIH.

***Other Recent Events***

In the last several months, we announced the issuance of five European patents and one U.S. patent related to our core DNA delivery technology, enhancements of that technology, or applications of that technology.

European Patent EP0737750, entitled "Expression of Exogenous Polynucleotide Sequences in a Vertebrate," is part of a family of patents based on our discovery that tissues can take up polynucleotides, such as DNA or RNA, without the use of viral delivery vehicles, and subsequently express the proteins encoded by the polynucleotides. The new patent claims medicinal compositions which contain cationic lipids and polynucleotides and which elicit an immune response against the proteins encoded by the polynucleotides. The new patent covers a range of applications of our core DNA delivery technology, including cationic lipid-formulated, gene-based immunotherapeutics such as our clinical-stage Allovectin-7® treatment for melanoma, cationic lipid-formulated DNA vaccines such as our developmental anthrax vaccine, and similar pharmaceutical products under development by others. We hold multiple issued U.S. patents covering various aspects of our core technology.

European Patent EP1032428, "Treatment of Cancer Using Cytokine-Expressing Polynucleotides and Compositions Therefor," broadly claims gene-based, extra-tumoral delivery of any cytokines for the treatment of cancer. Delivery can be either free from or formulated with transfection-facilitating materials such as cationic lipids or polymers. Cytokines are proteins such as interleukins and interferons which regulate specific cell functions, and typically are used to stimulate an immune response against cancer cells.

European Patent EP0795015, "Plasmids Suitable for IL-2 Expression," specifically claims the composition, manufacture and application of gene-based cancer treatments delivering the cytokine interleukin-2.

European Patents EP0742820, "Production of Pharmaceutical-Grade Plasmid DNA," and EP0802975, "Process for Reducing RNA Concentration in a Mixture of Biological Material Using Diatomaceous Earth," claim specific processes developed by Vical for the manufacture and purification of DNA.

U.S. Patent No. 6,586,409 covers DNA vaccination with a novel adjuvant, Vaxfectin™. Specific claims include compositions and methods for gene-based vaccination using immunogen-encoding polynucleotides plus the Vaxfectin™ cationic lipid/co-lipid formulation.

**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, on March 31, 2003, we wrote down our investment to $0.3 million and reclassified the investment as an available-for-sale security.

In July 2003, Corautus entered into a strategic alliance with Boston Scientific Corp., or BSC, to develop and commercialize a gene therapy to treat cardiovascular disease. BSC paid $9 million to Corautus in exchange for 10 percent of Corautus' equity on a fully diluted basis, paid a $1 million license fee, and committed to purchasing up to $15 million of convertible debt from Corautus based on achievement of certain milestones. BSC also holds a sublicense from Vical, under our license from the University of Michigan, for catheter-based intravascular gene delivery technology that may be applicable under the Corautus strategic alliance.

There can be no assurance that Corautus' developmental therapy for angiogenesis will work or that the FDA will approve such a therapy. Corautus may not be able to 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 of $0.3 million.

*Loss on leases.* 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 all of the vacated research space and adjusted the accrual for loss on our leases. In May 2003, we subleased a portion of our vacated office space and adjusted our accrual for loss on our leases. If the final negotiated sublease rates or the number of months we are able to sublease the remaining vacated office 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.

We also have entered into fixed price manufacturing contracts under which the primary deliverables are investigational vaccines to be used for preclinical and clinical research. Generally, under these contracts, revenue is recognized when the product is shipped. At that time, the revenue is recognized and any deferred manufacturing costs are recognized as expense.



***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. We anticipate entering into fixed price manufacturing contracts which we believe would qualify for multiple element accounting under EITF 00-21. In certain cases, this might allow us to recognize a portion of the revenue before all of the multiple elements are delivered. The provisions of EITF Issue No. 00-21 apply to revenue arrangements entered into in fiscal periods beginning after June 15, 2003.

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**

Revenues were $0.6 million and $1.5 million for the three and six months ended June 30, 2003, respectively. License/royalty revenue for the three months and six months ended June 30, 2003, of $0.5 million and $1.0 million, respectively, represented recognition of deferred license fees from Corautus and royalty revenue. Contract revenue of $0.1 million for the three months ended June 30, 2003, was from the NIH. Contract revenue of $0.5 million for the six months ended June 30, 2003, also included revenue from IAVI, and the Office of Naval Research, or ONR.

Revenues were $2.4 million and $4.0 million for the three and six months ended June 30, 2002, respectively. License/royalty revenue of $2.1 million and of $3.1 million for the three months and six months ended June 30, 2002, respectively, represented recognition of license payments from Merial and Centocor, recognition of deferred license fees primarily from Merial and VGI, and royalty revenue. Contract revenue for the three-month and six-month periods ended June 30, 2002, of $0.4 million and $0.8 million, respectively, included revenues from IAVI and the NIH for manufacturing of DNA for infectious disease vaccines, and from ONR.

Our total operating expenses for the three months ended June 30, 2003, were $8.1 million compared with $8.4 million for the same period in the prior year. Our total operating expenses for the six months ended June 30, 2003, were $16.7 million compared with $16.1 million for the same period in the prior year.



Research and development expenses decreased to $6.3 million for the three months ended June 30, 2003, from $6.4 million for the same period in 2002 due to the deferral of certain contract manufacturing costs until the related revenue is recognized, and lower clinical trial expenses. These lower expenses were partially offset by higher facilities and personnel-related expenses, and higher preclinical expenses for our anthrax and CMV vaccine development programs. Research and development expenses increased to $12.9 million for the six months ended June 30, 2003, from $12.4 million for the same period in 2002. This increase in research and development expenses for the six months ended June 30, 2003, was due to increased facilities costs, preclinical costs and personnel-related costs, partially offset by lower clinical trial costs related to the conclusion of cancer product trials and the deferral of certain contract manufacturing costs until the related revenue is recognized. We expect research and development expenses to increase for the full year 2003 compared with 2002 as a result of relocation to a new facility, expansion of our preclinical programs to broaden our future pipeline, and recognition of certain deferred manufacturing costs when the related revenue is recognized in the second half of 2003.

General and administrative expenses were $1.8 million for the three months ended June 30, 2003, and $2.1 million for the three months ended June 30, 2002. For the six months ended June 30, 2003, general and administrative expenses were $3.3 million compared with $3.8 million in the same period in the prior year. The decrease in general and administrative expenses for the three months ended June 30, 2003, compared with the same period in the prior year, was due to lower personnel-related costs and lower professional fees. For the six months ended June 30, 2003, the decrease in general and administrative expenses, compared with the same period in the prior year, was due to lower personnel-related costs, including lower incentive-based compensation expense.

Operating expenses for the six months ended June 30, 2003, also included a write-down of investment of $0.5 million in March 2003. In February 2003, GenStar Therapeutics and VGI completed their previously announced merger and created a new entity, 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 Corautus 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 in March 2003.

Investment income for the three-month period ended June 30, 2003, was $0.6 million and included realized gains on sales of investments of $0.1 million. Investment income for the three months ended June 30, 2002, was $1.0 million. Investment income for the six-month period ended June 30, 2003, was $1.4 million and included realized gains on investments of $0.2 million. Investment income for the six months ended June 30, 2002, was $2.1 million. The decrease in investment income in the three-month and six-month periods ended June 30, 2003, compared with the corresponding periods in 2002, was 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 $6.9 million, or $0.34 per common share, for the three months ended June 30, 2003, compared with a net loss of $5.0 million, or $0.25 per common share, for the same period in the prior year. Our net loss was $13.9 million, or $0.69 per common share, for the six months ended June 30, 2003, compared with a net loss of $10.2 million, or $0.51 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 $98.2 million at June 30, 2003, compared with $111.5 million at December 31, 2002.

Cash used in operating activities increased to $10.4 million for the six months ended June 30, 2003, compared with $9.6 million for the same period in 2002. The increase in cash used in operating activities was due to an increased net loss, a decrease in the outstanding balance and related collections of accounts receivable, and an increase in deferred contract costs. Cash used to acquire other assets was lower in the six months ended June 30, 2003, than in the corresponding period in 2002 because of the rent deposit last year on our new facility. These changes were partially offset by the positive cash flow impact of prepayments received on manufacturing contracts and increases in noncash charges such as depreciation and amortization. Net loss for the six months ended June 30, 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 $14.5 million for the six months ended June 30, 2003, compared with $18.6 million for the same period in 2002. Capital expenditures for the six months ended June 30, 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, our new facility. Additionally, spending for licensed technology and patents contributed to the increase in cash used in investing activities.

Cash provided by financing activities for the six months ended June 30, 2003, was $5.7 million compared with cash used in financing activities of $0.8 million for the same period in 2002. Reimbursements under our capital lease line provided $6.9 million of cash for the six months ended June 30, 2003. Payments on capital lease obligations for the six months ended June 30, 2003, increased, compared with the same period in 2002, due to greater capital lease obligations.

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 our new facility. At June 30, 2003, we had used $7.3 million of this lease line.

In March 2003, we subleased to a third party all of the vacated research space in our older facilities, and in May 2003, we subleased a portion of our vacated office space in those facilities. We adjusted our accrual for estimated loss on our leases after each sublease transaction. If we are unable to sublease the remaining office 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 personnel-related 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 government contracts and grants, and 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.

We anticipate that our available cash and existing sources of funding will be adequate to satisfy our operating needs through at least 2005.

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, and in our other filings with the Securities and Exchange Commission, 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. We 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 June 30, 2003, we have incurred cumulative net losses totaling approximately $104.3 million. Moreover, we expect that our net losses 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 marketing and additional manufacturing capabilities. We may seek additional funds through public and private stock offerings, government contracts and grants, arrangements with corporate collaborators, borrowings under lease lines of credit or other sources. We 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 and licensees 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 provided only limited guidance on 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 ongoing 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 and 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 are not 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 products may not gain market acceptance among physicians, patients, healthcare payers and the medical communities. If any of our products do not achieve market acceptance, we may lose our investment in that product, which could have a material adverse impact on our operations.

***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 Allovectin-7®, attending physicians have punctured patients' lungs in less than one percent of procedures, requiring hospitalization. In addition, a physician administering Allovectin-7® 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 our principal 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.

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

We have entered into agreements with government agencies, such as the NIH, and we intend to continue entering into these agreements in the future. Our business is partially dependent on the continued performance by these government agencies of their responsibilities under these agreements, including adequate continued funding of the agencies and their programs. We have no control over the resources and funding that government agencies may devote to these agreements, which may be subject to annual renewal and which generally may be terminated by the government agencies at any time. Government agencies may fail to perform their responsibilities under these agreements. We may also be unsuccessful in entering into additional agreements with government agencies.

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

The commercial manufacturing of vaccines and other biological products is a time-consuming and complex process, which must be performed in compliance with the FDA's current Good Manufacturing Practices, or GMP, regulations. Our experience in manufacturing our product candidates and the products of others has been limited to production of research and clinical trial supplies under less rigorous clinical GMP, or cGMP regulations. We may not be able to comply with the GMP regulations, and our manufacturing process may be subject to delays, disruptions or quality control problems. In addition, we must complete the installation and validation of a large-scale fermenter and related purification equipment in order to produce the quantities of product expected to be required under certain contract manufacturing agreements or for commercial purposes. We do not have any experience in manufacturing at this scale. Noncompliance with the GMP regulations, the inability to complete the installation or validation of our large-scale equipment, or other problems with our manufacturing process may limit or delay the development or commercialization of our product candidates, and cause us to breach our contract manufacturing arrangements.

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

We may initially depend on collaborators, licensees or other third parties to manufacture our product candidates in commercial quantities. We may be unable to enter into any arrangement for the commercial manufacture of our product candidates, and any arrangement we secure may not meet our requirements for manufacturing quality or quantity. Our dependence on third parties for the



commercial manufacture of our product candidates may also reduce our profit margins and our ability to develop and deliver products in a timely manner.

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

Our current strategy is to market our proprietary products directly in the United States, but we currently do not possess pharmaceutical marketing or sales capabilities. 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, became effective in 2003 and may complicate 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. We also have potential liability for products manufactured by us on a contract basis for third parties. These risks are inherent in the development and manufacture 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, or our ability to manufacture products for third parties. If we are sued for any injury caused by our technology or products, or by third-party products that we manufacture, our liability could exceed our insurance coverage and total assets.

***Our stock price could continue to be highly volatile and you may not be able to resell your shares at or above the price you 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, licensees or competitors or for gene therapies in general,
- Evidence or lack of evidence of the safety or efficacy of our potential products or those of our collaborators, licensees or competitors,
- The announcement by us or our collaborators, licensees or competitors of technological innovations or new products,
- Developments concerning our patent or other proprietary rights or those of our collaborators, licensees or competitors, including litigation and challenges to our proprietary rights,
- Other developments with our collaborators or licensees,
- 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,
- 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.***

Pursuant to the terms of our stockholder rights plan adopted in March 1995, we have distributed a dividend of one preferred stock purchase 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. In addition to our stockholder rights plan, some provisions of our certificate of incorporation and bylaws could have anti-takeover effects, such as provisions requiring a classified board of directors with staggered terms, and supermajority voting requirements for specified actions.



## 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.

Beginning 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 non-equity investments at June 30, 2003. At June 30, 2003, our unrealized gain on marketable securities was $0.7 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 June 30, 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

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 as of the end of the period covered by this report. 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 our Vice President and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of the end of the period covered by this report. 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

On July 29, 2003, the Wisconsin Alumni Research Foundation, or WARF, filed a complaint against us in the United States District Court for the Western District of Wisconsin, seeking a declaratory judgment regarding the meaning of certain payment provisions in our agreement with WARF, as well as fees related to our sublicense of certain inventions jointly owned by us and WARF. We intend to vigorously defend the suit and we may assert counterclaims seeking to recover excess royalties we previously paid under the agreement. Based on the information presently available to us, we do not believe WARF's claims are material to our business.

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 issued patents and patent applications that are pending in Europe to protect 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. A rebuttal response to the revocation was filed with the JPO in a timely manner. The response is currently under consideration in the JPO. In addition to the Opposition proceedings, we received notice that Trial for Invalidation, or TFI, requests against Japanese Patent JP3250802 were filed in the JPO by two companies. We are currently reviewing the TFI requests. We intend to file responses to the TFI requests on or before the deadlines for each response.

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 are currently preparing a rebuttal response to the opposition.

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, except as noted above.



**ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS**

On May 21, 2003, we held our Annual Meeting of Stockholders. As of March 28, 2003, the record date for the meeting, 20,091,344 shares of our common stock were outstanding and entitled to vote. The following actions were taken at the meeting:

(a) The following Class II directors were elected:

R. Gordon Douglas, M.D.—16,794,313 shares voted in favor of the nominee; 1,485,620 withheld their vote.

M. Blake Ingle, Ph.D.—17,899,449 shares voted in favor of the nominee; 386,484 withheld their vote.

Our Class III directors, Patrick F. Latterell and Gary A. Lyons, continue in office until the 2004 Annual Meeting. Our Class I directors, Vijay B. Samant and Robert C. Merton, continue in office until the 2005 Annual Meeting.

(b) The amendment and restatement of the Stock Incentive Plan of Vical Incorporated was approved. The number of shares of common stock reserved for issuance under the plan was increased to 5,200,000 from 4,700,000, subject to adjustment as provided in the plan. Shares voted for the proposal were 13,018,433, with 5,220,112 shares voted against the proposal and 41,088 shares abstained.

(c) The selection of KPMG LLP as the Company's independent auditors for the year ending December 31, 2003, was ratified. Shares voted in favor of the proposal were 18,183,074, with 39,706 shares voted against the proposal and 57,153 shares abstained.

**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. |
| 31.1 | Certification of Vijay B. Samant, Chief Executive Officer, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. |
| 31.2 | Certification of Martha J. Demski, Chief Financial Officer, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. |
| 32.1 | Certification of Vijay B. Samant, Chief Executive Officer, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. |
| 32.2 | Certification of 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. 000-21088).

**(b) Reports on Form 8-K**

On May 16, 2003, we filed a Form 8-K to disclose our press release of revised financial results for the three months ended March 31, 2003.

On July 31, 2003, we filed a Form 8-K to disclose our press release of financial results for the three months and six months ended June 30, 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: August 12, 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)



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SIGNATURES

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**Exhibit 31.1**

**CERTIFICATION**

I, Vijay B. Samant, certify that:

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

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

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

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 12, 2003

/s/ VIJAY B. SAMANT

Vijay B. Samant
President and Chief Executive Officer

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Exhibit 31.1

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**Exhibit 31.2**

**CERTIFICATION**

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 report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

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

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 12, 2003

/s/ MARTHA J. DEMSKI

Martha J. Demski
Vice President and Chief Financial Officer

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**Exhibit 32.1**

**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 June 30, 2003, to which this Certification is attached as Exhibit 32.1 (the "Periodic Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934, as amended; and

2. The information contained in the Periodic Report fairly presents, in all material respects, the financial condition of the Company at the end of the period covered by the Periodic Report and results of operations of the Company for the period covered by the Periodic Report.

Dated: August 12, 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.

QuickLinks

Exhibit 32.1

QuickLinks -- Click here to rapidly navigate through this document

**Exhibit 32.2**

**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 June 30, 2003, to which this Certification is attached as Exhibit 32.2 (the "Periodic Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934, as amended; and

2. The information contained in the Periodic Report fairly presents, in all material respects, the financial condition of the Company at the end of the period covered by the Periodic Report and results of operations of the Company for the period covered by the Periodic Report.

Dated: August 12, 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.

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Exhibit 32.2