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 September 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 Rule 12b-2 of the Exchange Act). Yes☒ No ☐

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

Total shares of common stock outstanding at November 13, 2003: 20,091,344

VICAL INCORPORATED

FORM 10-Q

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Item 1. Financial Statements

VICAL INCORPORATED
BALANCE SHEETS
(Unaudited)

	September 30, 2003	December 31, 2002
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 20,717,586	$ 32,608,954
Marketable securities-available-for-sale	69,450,746	76,606,286
Marketable security-restricted	2,355,700	2,298,240
Receivables and other	5,313,398	5,893,491
Total current assets	97,837,430	117,406,971
Investment	—	800,000
Property and Equipment:		
Equipment	16,831,218	10,180,279
Leasehold improvements	8,427,042	4,687,877
	25,258,260	14,868,156
Less-accumulated depreciation and amortization	(11,276,237)	(9,925,642)
	13,982,023	4,942,514
Intangible Assets, net	5,897,114	5,642,372
Other Assets	635,414	634,091
	$ 118,351,981	$ 129,425,948
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable and accrued expenses	$ 5,692,039	$ 7,369,546
Current portion of capital lease obligations	3,856,872	1,267,974
Current portion of notes payable	419,048	633,333
Current portion of deferred revenue	1,723,309	1,528,409
Total current liabilities	11,691,268	10,799,262
Long-Term Obligations:		
Long-term obligations under capital leases	7,901,530	1,976,920
Notes payable	61,904	340,476
Deferred revenue	131,130	949,315
Deferred lease credits	1,404,688	1,052,726
Total long-term obligations	9,499,252	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 September 30, 2003, and December 31, 2002	200,913	200,913
Additional paid-in capital	203,612,999	203,554,007
Accumulated other comprehensive income	1,186,514	887,068
Accumulated deficit	(107,838,965)	(90,334,739)
Total stockholders' equity	97,161,461	114,307,249
	$ 118,351,981	$ 129,425,948

See accompanying notes to financial statements.

VICAL INCORPORATED
STATEMENTS OF OPERATIONS

(Unaudited)

	Three months ended September 30,		Nine months ended September 30,	
	2003	2002	2003	2002
Revenues:				
License/royalty revenue	$ 525,846	$ 511,709	$ 1,533,348	$ 3,623,800
Contract revenue	4,347,276	2,008,260	4,849,300	2,855,221
	4,873,122	2,519,969	6,382,648	6,479,021
Operating expenses:				
Research and development	6,923,351	7,516,377	19,824,802	19,884,527
General and administrative	1,737,565	1,975,675	5,028,448	5,747,147
Write-down of investment	—	4,200,000	482,217	4,200,000
	8,660,916	13,692,052	25,335,467	29,831,674
Loss from operations	(3,787,794)	(11,172,083)	(18,952,819)	(23,352,653)
Other income (expense):				
Investment income	344,405	1,030,802	1,703,675	3,107,085
Interest expense	(113,814)	(75,003)	(255,082)	(213,647)
Net loss	$ (3,557,203)	$ (10,216,284)	$ (17,504,226)	$ (20,459,215)
Net loss per common share (basic and diluted-Note 3)	$ (0.18)	$ (0.51)	$ (0.87)	$ (1.02)
Weighted average shares used in computing net loss per common share (Note 3)	20,091,344	20,082,648	20,091,344	20,074,293

See accompanying notes to financial statements.

VICAL INCORPORATED
STATEMENTS OF CASH FLOWS
(Unaudited)

	Nine months ended September 30,	
	2003	2002
OPERATING ACTIVITIES:		
Net loss	$ (17,504,226)	$ (20,459,215)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	2,642,806	2,003,615
Write-down of investment	482,217	4,200,000
Loss on sublease	148,457	—
Compensation expense related to grant of stock options	58,992	15,911
Deferred lease credits	351,962	—
Change in operating assets and liabilities:		
Receivables and other	580,093	354,808
Other assets	(1,323)	(332,579)
Accounts payable and accrued expenses	(1,825,964)	1,559,534
Deferred revenue	(623,285)	(940,999)
Net cash used in operating activities	(15,690,271)	(13,598,925)
INVESTING ACTIVITIES:		
Sales of marketable securities	106,974,037	69,338,939
Purchases of marketable securities	(99,258,728)	(78,274,999)
Capital expenditures	(1,111,341)	(305,477)
Licensed technology expenditures	(80,000)	—
Patent expenditures	(614,969)	(460,673)
Net cash provided from (used in) investing activities	5,908,999	(9,702,210)
FINANCING ACTIVITIES:		
Issuance of common stock, net	—	8,800
Payments on notes payable	(492,857)	(492,858)
Principal payments under capital lease obligations	(1,617,239)	(719,441)
Net cash used in financing activities	(2,110,096)	(1,203,499)
Net decrease in cash and cash equivalents	(11,891,368)	(24,504,634)
Cash and cash equivalents at beginning of period	32,608,954	43,736,068
Cash and cash equivalents at end of period	$ 20,717,586	$ 19,231,434
Supplemental Disclosure of Cash Flow Information:		
Cash paid during the period for interest	$ 305,226	$ 215,891
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	$ 10,130,747	$ 1,385,566

See accompanying notes to financial statements.

VICAL INCORPORATED

NOTES TO FINANCIAL STATEMENTS

September 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 September 30, 2003, and for the three-month and nine-month periods ended September 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 periods ended March 31, 2003, and June 30, 2003, included in its Forms 10-Q filed with the Securities and Exchange Commission, or SEC.

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 September 30,		Nine months ended September 30,	
	2003	2002	2003	2002
Net loss, as reported	$ (3,557,203)	$ (10,216,284)	$ (17,504,226)	$ (20,459,215)
Add stock-based compensation expense included in reported net loss	23,025	(10,718)	58,992	15,911
Less stock-based compensation expense determined under fair value based method for all awards	(822,988)	(1,049,459)	(2,737,410)	(4,210,742)
Pro forma net loss	$ (4,357,166)	$ (11,276,461)	$ (20,182,644)	$ (24,654,046)
Net loss per common share (basic and diluted), as reported	$ (0.18)	$ (0.51)	$ (0.87)	$ (1.02)
Pro forma net loss per common share (basic and diluted)	$ (0.22)	$ (0.56)	$ (1.00)	$ (1.23)

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 2.74% and 2.52% for the three-month and nine-month periods ended September 30, 2003, respectively, and 3.3% and 3.95% for the three-month and nine-month periods ended September 30, 2002, respectively. Expected volatility was 81% for the three-month and nine-month periods ended September 30, 2003, and 82% for the same periods in the prior year. An expected option life of four years and a dividend rate of zero were assumed for the periods presented.

3. NET LOSS PER SHARE

Net loss per share (basic and diluted) for the three-month and nine-month periods ended September 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 2,591,483 and 2,685,725 for the three-month and nine-month periods ended September 30, 2003, respectively. The weighted average number of shares so excluded was 3,004,412 and 2,863,615 for the three-month and nine-month periods ended September 30, 2002, respectively. Options outstanding were 3,431,089 and 3,019,923 at average exercise prices of $14.70 and $16.30 at September 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 nine-month periods ended September 30, 2003, 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 September 30, 2003 and 2002, other comprehensive income was $0.5 million and $0.3 million, respectively, and total comprehensive losses were $3.1 million and $9.9 million, respectively. For the nine-month periods ended September

30, 2003 and 2002, other comprehensive income was $0.3 million and $0.2 million, respectively, and total comprehensive losses were $17.2 million and $20.3 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 Corporation, or GenStar, 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. In connection with the merger, the shares of VGI were exchanged for common stock of Corautus, which is listed on the AMEX. The Company is restricted in the number of Corautus shares it can sell over a period of time. The value of the Company's Corautus shares, as measured by the quoted price on the 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. The market value of the Company's investment in Corautus at September 30, 2003, was approximately $1.2 million.

6. LEASED FACILITY; LEASE LINE

The Company currently holds three leases, which terminate in late 2004, at three sites for manufacturing, research and office space. 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. In May 2003 and September 2003, the Company subleased portions 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 with drawdowns through November 30, 2003. This lease line includes approximately $8.0 million of credit for tenant improvements and equipment for the new facility. At September 30, 2003, the Company had used $10.4 million of this lease line. The Company intends to pursue additional lease financing of up to $10.0 million for tenant improvements and equipment. In the event the Company is unable to obtain this additional financing, it will be required to use its existing cash resources to finance these purchases.

7. RECENT CONTRACT ACTIVITIES

In July 2003, the Company was 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 the Company's DNA vaccine against anthrax.

In February 1998, the Company entered into an exclusive license and option agreement allowing Centocor, Inc., a company subsequently acquired by Johnson & Johnson, to use Vical's DNA delivery technology to develop and commercialize certain DNA vaccines for the potential treatment of some types of cancer. During the third quarter of 2003, Centocor provided the Company with notice of termination of the agreement effective in February 2004, at which time all rights granted to Centocor under the agreement will revert to the Company.

8. CONTINGENCIES

On July 29, 2003, the Wisconsin Alumni Research Foundation, or WARF, filed a complaint against the Company in the United States District Court for the Western District of Wisconsin, seeking a declaratory judgment regarding the meaning of certain payment provisions in a license agreement the Company entered into with the WARF in 1991, as well as fees related to the Company's sublicense of certain inventions jointly owned by the Company and the WARF, the amount of which is unspecified in the WARF's complaint. The Company intends to vigorously defend the suit and has counterclaimed, likewise seeking a declaratory judgment as to the correct interpretation of the payment provisions of the agreement and a return of amounts overpaid to the WARF under this agreement in excess of $1.5 million. Based on the information presently available, the Company does not believe the WARF's claims are material to its business.

Vical's 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, the Company filed an appeal, which is still pending, seeking to overturn this initial ruling. The Company intends to vigorously defend its patent position in the European opposition proceedings. If the Company is not successful in the appeal and opposition proceedings, it may lose part or all of its proprietary protection on its product candidates in Europe. However, the Company may also use additional issued patents and patent applications that are pending in Europe to protect its core DNA delivery technology.

The Company's core DNA delivery technology is also covered by a Canadian patent that was allowed and then withdrawn after protests against its issuance were filed on behalf of an undisclosed party or parties in August and December 2001. The Company has responded to the protests and is continuing prosecution of the application in the Canadian Patent Office.

In addition, the Company's core DNA delivery technology is covered by a Japanese patent that was published in January 2002 and thereafter revoked by the examining panel at the Japanese Patent Office, or JPO, on formal and substantive grounds. The Company filed a rebuttal response to the revocation. Based on the Company's arguments and supporting evidence in that response, the JPO decided to reinstate the patent in July 2003. The Company also has received notice that four Trial for Invalidation, or TFI, requests against this patent were filed in the JPO by two companies. The Company intends to file responses to the TFI requests on or before the December 2003 deadlines.

The Company has 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 a European patent granted in March 2002. The Company has received notice from the

EPO that one company filed an opposition in December 2002 alleging both formal and substantive grounds for revocation, and that the opposition was declared admissible in February 2003. The Company has submitted a rebuttal response to the opposition.

In the ordinary course of business, the Company may become a party to lawsuits involving various matters. The Company is unaware of any such lawsuits presently pending against it, except as noted above, and none of which, individually or in the aggregate, is deemed to be material to the financial condition of the Company.

9. 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 NIH Dale and Betty Bumpers Vaccine Research Center, or VRC. For the period from November 2000 to March 2003, the 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 September 30, 2003, the Company had recognized $1.8 million of revenue under this agreement, including $0.0 million for the three-month and nine-month periods ended September 30, 2003, and $0.4 million and $0.5 million for the three-month and nine-month periods ended September 30, 2002, respectively.

Additionally, for varying periods between February 2001 and February 2003, the VRC contracted Vical to provide regulatory support services for approximately $0.9 million. Cumulatively through September 30, 2003, the Company had recognized $0.7 million of revenue under this agreement, including $0.1 million and $0.3 million for the nine-month periods ended September 30, 2003 and 2002, respectively.

In July 2002, the Company entered into an agreement with the VRC to provide certain regulatory and manufacturing services to the VRC related to the research and development of DNA vaccines against the Ebola virus. This agreement was modified in 2003 to include additional DNA vaccines against HIV, West Nile Virus and severe acute respiratory syndrome, or SARS. Cumulatively through September 30, 2003, the Company had recognized $2.8 million of revenues under this agreement, including approximately $1.8 million for the three-month and nine-month periods ended September 30, 2003, and $1.0 million for the three-month and nine-month periods ended September 30, 2002.

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 the IAVI. In 2002, the Company signed an agreement with the IAVI to provide clinical trial supplies. As of September 30, 2003, the IAVI had issued purchase orders under this agreement totaling approximately $1.1 million. Revenue recognized under this agreement for the three-month and nine-month periods ended September 30, 2003, was $0.7 million and $0.9 million, respectively. For the three-month and nine-month periods ended September 30, 2002, revenue recognized under this agreement was $0.0 million and $0.2 million, respectively.

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

10. SHELF REGISTRATION STATEMENT

In August 2003, the Company filed a shelf registration statement with the SEC, which upon being declared effective by the SEC, would allow the Company to issue from time to time an aggregate of up to $50 million of common stock or preferred stock. The shelf registration is intended to provide flexibility in financing the Company's business needs. Specific terms of any offering under the shelf registration and the securities involved would be established at the time of sale.

11. 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, are reserved for issuance to employees, non-employee directors and consultants of the Company.

12. SUBSEQUENT EVENTS

In October 2003, the VRC formally notified the Company of its intention to place potentially material production orders under the bulk DNA vaccine manufacturing agreement, using the equipment being financed by the VRC, beginning in mid-2004. The terms of the agreement have a non-performance clause that could materially affect the Company's financial results, favorably or unfavorably depending on the non-performing party, in the period(s) affected.

In October 2003, the Company granted a non-exclusive license for Canada to Aqua Health Ltd. of Canada, an affiliate of the Swiss-based company Novartis Animal Health Inc., for use of Vical's patented gene delivery technology in a vaccine against an undisclosed target. Aqua Health Ltd. is investigating a vaccine based on Vical's DNA technology to combat diseases that affect both wild and farm-raised fish.

In October 2003, the Company obtained an option to secure exclusive commercialization rights for a West Nile Virus vaccine being developed in collaboration with the VRC under a Cooperative Research and Development Agreement.

In October 2003, the Company entered into an agreement with Genetronics Biomedical Corporation giving the Company an option to a worldwide exclusive license to use Genetronics' proprietary electroporation technology in combination with Vical's DNA delivery technology for undisclosed targets.

Also in October 2003, the Company secured an exclusive license from the Ohio State University to allow use of proprietary technology in the Company's anthrax vaccine.

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 for the year ended December 31, 2002, and
- Our other filings with the SEC.

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. The table below summarizes our independent, collaborative and out-licensed product development programs.

Product Area	Project Target and Indication(s)	Development Status (1)	Development Rights
INFECTIOUS DISEASES			
Infectious disease vaccines	*Plasmodium falciparum (malaria*)	Phase I/II	Vical
	Cytomegalovirus	Preclinical	Vical
	Bacillus anthracis (anthrax)	Preclinical	Vical
	Ebola	Preclinical	Vical/NIH
	West Nile Virus	Research	Vical/NIH
	HIV – preventive	Phase I	Merck & Co., Inc.
	HIV – therapeutic	Phase I	Merck & Co., Inc.
	Hepatitis B virus – preventive	Research	Merck & Co., Inc.
	Hepatitis B virus – therapeutic	Research	Merck & Co., Inc.
	Hepatitis C virus – preventive	Research	Merck & Co., Inc.
CANCER			
Immunotherapeutic vaccine	High-dose Allovectin-7® for metastatic melanoma	Phase II	Vical
Tumor-associated antigen therapeutic vaccines	Unspecified cancer(2)	Research	Aventis Pasteur
	Unspecified cancer(2)	Research	Merck & Co., Inc.
CARDIOVASCULAR			
Angiogenic growth factors	VEGF-2	Phase II	Corautus
	FGF-1	Phase II	Gencell SA, a subsidiary of Aventis Pharma SA
VETERINARY			
Preventive vaccines	Various undisclosed(2)	Research-Clinical	Merial
	Undisclosed(2)	Clinical	Aqua Health Ltd.

(1) "Research" indicates exploration and/or evaluation of a potential product candidate in a nonclinical setting. "Preclinical" indicates that a specific product candidate in a nonclinical setting has shown functional activity that is relevant to a targeted medical need, and is undergoing toxicology testing in preparation for filing an Investigational New Drug application. "Phase I" clinical trials mark the first time a new drug or treatment is administered to humans and are normally conducted to determine the safety profile of a new drug. "Phase II" clinical trials are conducted in order to determine preliminary effectiveness, or efficacy, optimal dosage, and to confirm the safety profile. At times, a single trial may incorporate elements from different phases of development. An example might be a trial designed to determine both safety and initial efficacy. Such a trial may be referred to as a "Phase I/II" clinical trial. For non-human indications, "Clinical" indicates testing in the target species.

(2) Pursuant to our collaborative agreements, we are bound by confidentiality obligations to our collaborators that prevent us from publicly disclosing these targets and indications unless such information has been made generally available to the public. Additionally, some project targets and indications cannot currently be disclosed because they have not yet been selected by our collaborators.

Recent Events

Allovectin-7®

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

In February 2001, we initiated a Phase II clinical trial evaluating a dose of Allovectin-7® of 2,000 micrograms, or 2 mg., a 200-fold increase compared with our 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.

A total of 133 patients were enrolled in this trial, including six patients in an initial dose-escalation cohort and 127 patients in the high-dose cohort. We presented unaudited data from interim analyses performed in early March 2003 with respect to the first 91 patients in the high-dose cohort at the May 2003 American Society of Clinical Oncology, or ASCO, meeting, including:

- 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 10 had partial responses; and
- One patient, or 1.1 percent, reported a drug-related Grade 3 adverse event associated with Allovectin-7®.

Based on unaudited data collected in early July 2003 on the same 91 patients:

- Estimated median duration of response was at least 6.4 months, with seven of the 12 responders still progression-free; and
- All 12 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 treatment options. We intend to review key clinical data from the full 127-patient high-dose cohort with the U.S. Food and Drug Administration, or FDA, in the first half of 2004, and evaluate the potential for the high-dose trial to support accelerated marketing approval of Allovectin-7®.

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 estimated the cost of treating the consequences of CMV infection in the United States at more than $4 billion per year in a 1999 report, 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 hematopoietic cell 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 expect to begin a safety and immunogenicity study in human subjects within the next few months.

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 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 SBIR grant from the NIAID. The grant will partially fund the development of our DNA vaccine against anthrax.

At several scientific conferences during the third quarter of 2003, we presented preclinical data from our anthrax vaccine program, including rabbit data which demonstrated protection against an aerosolized spore inhalation challenge at 7.5 months post-vaccination.

In October 2003, we secured an exclusive license from the Ohio State University to allow use of proprietary technology in our anthrax vaccine.

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

NIH Vaccine Research Center

We continue to manufacture HIV, Ebola and West Nile Virus DNA vaccines for the VRC in our existing manufacturing facility under a contract awarded in July 2002 and amended most recently in July 2003. In October 2003, we received an order for clinical-grade supplies of an investigational DNA vaccine against the SARS virus for development planned by the VRC.

In May 2003, we announced a separate 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 our new manufacturing facility. Under this agreement, we are guaranteed minimum annual production orders beginning in 2004, subject to annual extension of the agreement. In October 2003, the VRC formally notified us of its intention to place production orders under the bulk DNA vaccine manufacturing agreement, using the equipment being financed by the VRC, beginning in mid-2004. Under Federal Acquisition Regulations, the government has the right to terminate this agreement for convenience.

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 the NIH.

In October 2003, we obtained an option to secure exclusive commercialization rights for a West Nile Virus vaccine being developed in collaboration with the VRC under a Cooperative Research and Development Agreement.

Other Recent Events

Also in October 2003, we entered into an agreement with Genetronics Biomedical Corporation giving us an option to a worldwide exclusive license to use Genetronics' proprietary electroporation technology in combination with our DNA delivery technology for undisclosed targets.

In August 2003, we filed a shelf registration statement with the SEC, which upon being declared effective by the SEC, would allow us to issue from time to time an aggregate of up to $50 million of common stock or preferred stock. The shelf registration is intended to provide flexibility in financing our business needs. Specific terms of any offering under the shelf registration and the securities involved would be established at the time of sale.

Merck & Co., Inc. In May 1991, we entered into a research collaboration and license agreement with Merck to develop and commercialize vaccines utilizing our DNA delivery technology to prevent infection and disease in humans. In connection with the agreement, we granted Merck a worldwide exclusive license to preventive vaccines using our technology against certain human infectious disease pathogens. In addition, Merck has rights to therapeutic uses of preventive vaccines developed under the agreement. In December 1995 and November 1997, Merck acquired additional rights from us to develop and commercialize certain therapeutic vaccines.

In August 2003, under an amendment to the research collaboration and license agreement, Merck obtained an option license for rights to use our patented non-viral gene delivery technology for three cancer targets. Exercise of the option license for each cancer target would result in an option license fee payment to us, and further development may lead to milestone and royalty payments to us. In addition, we have expanded our infectious disease portfolio by re-acquiring the rights to apply our core vaccine technology for influenza, herpes simplex virus, and human papilloma virus, previously licensed to Merck. Merck will retain rights to use the technology for HIV, hepatitis C virus, and hepatitis B virus.

Centocor, Inc. In February 1998, we entered into an exclusive license and option agreement allowing Centocor, Inc., a company subsequently acquired by Johnson & Johnson, to use our DNA delivery technology to develop and

commercialize certain DNA vaccines for the potential treatment of some types of cancer. During the third quarter of 2003, Centocor provided us with notice of termination of the agreement effective in February 2004, at which time all rights granted to Centocor under the agreement will revert to us.

Aqua Health Ltd. In October 2003, we granted a non-exclusive license for Canada to Aqua Health Ltd. of Canada, an affiliate of the Swiss-based company Novartis Animal Health Inc., for use of our patented gene delivery technology in a vaccine against an undisclosed target. Aqua Health Ltd. is investigating a vaccine based on our DNA technology to combat diseases that affect both wild and farm-raised fish.

Patents. During 2003, we announced the issuance of five European patents and one U.S. patent related to our core DNA delivery technology, enhancements of that technology, and 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 investigational anthrax vaccine, and similar pharmaceutical products under development by others.

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 us 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:

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 accruing this total cost for the patient over the estimated treatment period, which corresponds with the period over which the services are performed, 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 number of treatments for each patient. Treatment periods vary depending on the clinical trial. We make revisions to the clinical trial cost estimates as clinical trials progress. Changes to the cost estimates are charged to expense in the period that the facts giving rise to the revisions become known.

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, such as the NIH. 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 change in our estimated accrual, which could also affect our results of operations and cash flow.

Revenue Recognition

We earn revenue from licensing 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, except for fixed-price contracts, is recognized as the services are performed, provided that all of the revenue recognition criteria noted above have been met. 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 highly probable that we will receive a signed modification, or if we have received a signed modification, increasing the funding under the contract which will allow us to recover the costs incurred. Otherwise, the costs are expensed as 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 Issue No. 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. The provisions of EITF Issue No. 00-21 did not have a material effect on our financial position or results of operations for the periods ended September 30, 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 $4.9 million and $6.4 million for the three months and nine months ended September 30, 2003, respectively. License/royalty revenue for the three months and nine months ended September 30, 2003, of $0.5 million and $1.5 million, respectively, represented recognition of deferred license fees from Corautus and royalty revenue. Contract revenue of $4.3 million for the three months ended September 30, 2003, was from the NIH, the IAVI, and the VRC, and included $1.9 million of grant revenue for an anthrax SBIR grant. Contract revenue of $4.8 million for the nine months ended September 30, 2003, also included revenue from the Office of Naval Research, or ONR.

Revenues were $2.5 million for the three months ended September 30, 2002, and $6.5 million for the nine months ended September 30, 2002. License/royalty revenue of $0.5 million for the three months ended September 30, 2002, represented recognition of deferred license fees primarily from VGI, now Corautus, and royalty revenue. License/royalty revenue of $3.6 million for the nine months ended September 30, 2002, consisted of 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 nine-month periods ended September 30, 2002, of $2.0 million and $2.9 million, respectively, included revenues from the NIH, the VRC and the ONR. Contract revenue for the nine-month period ended September 30, 2002, also included revenue from the IAVI.

Our total operating expenses for the three months ended September 30, 2003, were $8.7 million compared with $13.7 million for the same period in the prior year. Our total operating expenses for the nine months ended September 30, 2003, were $25.3 million compared with $29.8 million for the same period in the prior year. Operating expenses for the nine months ended September 30, 2003, included a $0.5 million write-down of investment, and operating expenses for the three-month and nine-month periods ended September 30, 2002, included a $4.2 million write-down of investment, as more fully explained below.

Research and development expenses decreased to $6.9 million for the three months ended September 30, 2003, from $7.5 million for the same period in 2002 due to lower clinical trial expenses related to the conclusion of cancer product trials and lower personnel-related costs. This decrease in expenses was partially offset by higher facilities and intellectual property-related costs. Research and development expenses decreased to $19.8 million for the nine months ended September 30, 2003, from $19.9 million for the same period in 2002. This decrease in research and development expenses for the nine months ended September 30, 2003, was due to lower clinical trial costs and the deferral of certain contract manufacturing costs until the related revenue is recognized, largely offset by higher facilities costs and personnel-related costs. We expect research and development expenses to increase for the full year 2003 compared with 2002 as a result of our 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 fourth quarter of 2003.

General and administrative expenses were $1.7 million for the three months ended September 30, 2003, and $2.0 million for the three months ended September 30, 2002. For the nine months ended September 30, 2003, general and administrative expenses were $5.0 million, compared with $5.7 million for the same period in the prior year. The decrease in general and administrative expenses for the three months ended September 30, 2003, compared with the same period in the prior year, was due to lower professional fees and lower personnel-related costs. For the nine months ended September 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, and lower professional fees.

Operating expenses for the three-month and nine-month periods ended September 30, 2002, included a $4.2 million write-down of investment.In February 2000, we received shares of preferred stock in VGI in exchange for a license to our technology. The shares were recorded as an investment on the balance sheet at an 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, a public company listed on the AMEX. The VGI shares continued to be reflected as an investment on the balance sheet at December 31, 2002. Operating expenses for the nine months ended September 30, 2003, also included a write-down of investment of $0.5 million in March 2003. In February 2003, GenStar and VGI completed their merger and created a new entity, Corautus. In connection with the merger, the shares of VGI were exchanged for common stock of Corautus, which is listed on the AMEX. The value of our Corautus shares as measured by the quoted price on the 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. The market value of our investment in Corautus at September 30, 2003, was approximately $1.2 million.

Investment income for the three-month period ended September 30, 2003, was $0.3 million and included realized losses on sales of investments of $0.1 million. Investment income for the three months ended September 30, 2002, was $1.0 million and included realized gains on sales of investments of $0.1 million. Investment income for the nine-month period ended September 30, 2003, was $1.7 million and included realized gains on investments of $0.2 million. Investment income for the nine months ended September 30, 2002, was $3.1 million and included realized gains on sales of investments of $0.1 million. The decrease in investment income in the three-month and nine-month periods ended September 30, 2003, compared with the corresponding periods in 2002, was due to lower rates of return and lower investment balances. Some of our investments 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 $3.6 million, or $0.18 per common share, for the three months ended September 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. Our net loss was $17.5 million, or $0.87 per common share, for the nine months ended September 30, 2003, compared with a net loss of $20.5 million, or $1.02 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 $92.5 million at September 30, 2003, compared with $111.5 million at

December 31, 2002. In August 2003, we filed a shelf registration statement with the SEC, which upon being declared effective by the SEC, would allow us to issue from time to time an aggregate of up to $50 million of common stock or preferred stock. The shelf registration is intended to provide flexibility in financing our business needs. Specific terms of any offering under the shelf registration and the securities involved would be established at the time of sale.

Cash used in operating activities increased to $15.7 million for the nine months ended September 30, 2003, compared with $13.6 million for the same period in 2002. The increase in cash used in operating activities for the nine months ended September 30, 2003, compared with same period in the prior year is due to cash payments resulting in a decrease in the outstanding balance of accounts payable, and an increase in deferred contract costs, which more than offset the positive cash flow impact of prepayments received on manufacturing contracts. Net loss after deducting noncash charges for depreciation and amortization, write-down of investments, loss on subleases and deferred lease credits, was slightly lower for the nine months ended September 30, 2003, than for the same period in 2002. Cash used to acquire other assets was lower in the nine months ended September 30, 2003, than in the corresponding period in 2002 because of the rent deposit we paid on our new facility in 2002. Net loss for the nine month periods ended September 30, 2003 and 2002, also included noncash write-downs of our investment in VGI, now Corautus, as more fully explained under “Results of Operations” above.

Cash provided from investing activities was $5.9 million for the nine months ended September 30, 2003, compared with cash used in investing activities of $9.7 million for the same period in 2002. In 2003, our net sales and purchases of marketable securities yielded $7.7 million of cash. In 2002, we purchased a net amount of marketable securities of $9.0 million. Capital expenditures for the nine months ended September 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 increased from the same period in the prior year.

Cash used in financing activities for the nine months ended September 30, 2003, was $2.1 million compared with cash used in financing activities of $1.2 million for the same period in 2002. Reimbursements under our capital lease line provided $10.1 million of cash for the nine months ended September 30, 2003. Payments on capital lease obligations for the nine months ended September 30, 2003, increased by $0.9 million, 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, including approximately $8.0 million of credit for tenant improvements and equipment for our new facility, with drawdowns through November 30, 2003. At September 30, 2003, we had used $10.4 million of this lease line. We intend to pursue additional lease financing of up to $10.0 million for tenant improvements and equipment. In the event we are unable to obtain this additional financing, we will be required to use our existing cash resources to finance these purchases.

In March 2003, we subleased to a third party all of the vacated research space in our older facilities. In May 2003 and September 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 were unable to sublease the remaining vacated office space, the effect on our results of operations or cash flow would not be material.

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 most significant “off balance sheet”

obligations, which are for operating leases, are disclosed in Note 8 of the Notes to Financial Statements included in our Form 10-K for the year ended December 31, 2002. We also have commitments under purchase orders and contracts for research and development.

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

None of our products has been approved for sale, and we have only one product candidate in Phase II 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, which is currently in Phase II clinical trials.

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.

Our revenues partially depend on the development and commercialization of products by others to whom we have licensed our technology. If our collaborators or licensees are not successful or if we are unable to find collaborators or licensees in the future, we may not be able to derive revenues from these

arrangements.

We have licensed our technology to corporate collaborators and licensees for the research, development and commercialization of specified product candidates. Our revenues partially depend upon the performance by these collaborators and licensees of their responsibilities under these arrangements. Some collaborators or licensees may not succeed in their product development efforts or devote sufficient time or resources to the programs covered by these arrangements, causing us to derive little or no revenue from these arrangements.

Our collaborators and licensees may breach or terminate their agreements with us, and we may be unsuccessful in entering into and maintaining other collaborative arrangements for the development and commercialization of products using our technology.

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 September 30, 2003, we have incurred cumulative net losses totaling approximately $107.8 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. For example, in August 2003, we filed a shelf registration statement with the SEC seeking to register an aggregate of up to $50 million of common stock or preferred stock. However, we may not be able to raise additional funds on favorable terms, or at all. If we are unable to obtain additional funds, we may have to 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 the 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 gain 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 investigational CMV vaccine to patients who are at risk of CMV reactivation. Likewise, our investigational 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.

As of September 1, 2003, we had 21 patents issued in the U.S., seven patents issued in Europe, one of which was revoked and is under appeal, and two patents issued in Japan, one of which was opposed and maintained in amended form after opposition. We also had two patents issued in the U.S. directed to vaccines for Lyme disease for which we were a co-assignee with Aventis Pasteur, successor to Pasteur Mérieux Sérums & Vaccins, the named assignee, and the University of Texas. We also had 15 patents issued in foreign countries related to influenza vaccines for which we were a co-assignee with Merck & Co., Inc., and one patent issued in a foreign country related to vaccines against Lyme disease

for which we were a co-assignee with Aventis Pasteur and the University of Texas. In addition, we had 26 pending patent applications in the U.S. and 41 pending patent applications in foreign venues for which we were the sole assignee. Finally, we had four patent applications pending in the U.S. and 17 patent applications pending in foreign venues related to influenza vaccines for which we were a co-assignee with Merck, as well as five patent applications pending in foreign venues related to applications directed to vaccines against Lyme disease for which we were a co-assignee with Aventis Pasteur and the University of Texas.

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.

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

For example, our core DNA delivery technology is covered by a patent that has been issued and revoked as a result of an opposition in Europe. We are currently appealing the European revocation, responding to requests for TFIs in Japan, and continuing prosecution in Canada, but if our actions do not succeed, 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.

We are currently engaged in several legal proceedings involving our intellectual property rights. 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 EPO. In April 2002, we filed an appeal, which is still pending, seeking to overturn this initial ruling. Our core DNA delivery technology is also covered by a Canadian patent that was allowed and then withdrawn after protests against its issuance were filed on behalf of an undisclosed party or parties in August and December 2001. We have responded to the protests and are continuing prosecution of the application in the Canadian Patent Office.

In addition, our core DNA delivery technology is covered by a Japanese patent that was published in January 2002 and thereafter revoked by the examining panel at the JPO on formal and substantive grounds. We filed a rebuttal response to the revocation. Based on our arguments and supporting evidence in that response, the JPO decided to reinstate the patent in July 2003. We have also received notice that four TFI requests against this patent were filed in the JPO by two companies. 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 a European patent granted in March 2002. We have received notice from the EPO that one company filed an opposition in December 2002 alleging both formal and substantive grounds for revocation, and that the opposition was declared admissible in February 2003. We have submitted a rebuttal response to the opposition.

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, including Vijay B. Samant, our President and Chief Executive Officer, and David C. Kaslow, our Chief

Scientific Officer. The loss of the services of these individuals might significantly delay or prevent the achievement of our objectives. We do not maintain "key person" life insurance on any of our personnel. We depend on our continued ability to attract, retain and motivate highly qualified management and scientific personnel. We face competition for qualified individuals from other companies, academic institutions, government entities and other organizations in attracting and retaining personnel. To pursue our product development plans, we may need to hire additional management personnel and additional scientific personnel to perform research and development, as well as personnel with expertise in clinical trials, government regulation and manufacturing. We have not had any problem attracting and retaining key personnel and qualified staff in the recent past. Also, to our knowledge, no key personnel or qualified staff plans to retire or leave us in the near future. However, due to the reasons noted above, 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 how much, if any, reimbursement for our products and related treatments will be available from:

- Government health administration authorities,
- Government agencies procuring biodefense products for military or public use, including some for which we may become a sole-source vendor,
- Private health coverage insurers,
- Managed care organizations, and
- Other organizations.

If we fail to obtain appropriate reimbursement, we could be prevented from successfully commercializing our potential products. There are efforts by governmental and third-party payers to contain or reduce the costs of healthcare through various means. 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 andminor amounts of low-level radioactive compounds. Our hazardous materials include certain compressed gasses, flammable liquids, acids and bases, and other toxic compounds.We are subject to federal, state and local regulations governing the use, manufacture, storage, handling and disposal of materials and waste products. Although we believe that our safety procedures for handling and disposing of these hazardous materials comply with the standards prescribed by law and regulation, the risk of accidental contamination or injury from hazardous materials cannot be completely eliminated. In the event of an accident, we could be held liable for any damages that result. We have insurance that covers our use of hazardous materials with the following coverage limits: up to $25,000 per occurrence for losses related to the release of bio-contaminants, $10,000 per occurrence for losses from refrigerant contamination and $25,000 per occurrence for losses from radioactive contamination. Any liability could exceed the limits or fall outside the coverage of our insurance. We could 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 in the amount of $10 million in the aggregate, this insurance coverage may not be sufficient, and we may not be able to obtain sufficient insurance coverage in the future at a reasonable cost. Our inability to obtain product liability insurance at an acceptable cost or to otherwise protect against potential product liability claims could prevent or inhibit the commercialization of any products developed by us or our collaborators, or our ability to manufacture products for third parties. To date, no product liability claims have been filed

against us. However, 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 volatileDuring the three-year period ended October 31, 2003, our stock price has ranged from $2.12 to $25.875. 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. To date, we have not been subject to class action litigation. However, we may in the future become subject to this litigation. Securities litigation could result in substantial costs and divert our management's attention and resources, and could seriously harm our business.

The ability of our investors to seek remedies against Arthur Andersen LLP, who audited some of the financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2002, may be significantly limited.

Our annual financial statements for the years ended December 31, 2001 and 2000, which are included in our Annual Report on Form 10-K for the year ended December 31, 2002, were audited by Arthur Andersen LLP. We dismissed Arthur Andersen as our independent public accountants effective April 16, 2002. After reasonable efforts, we were unable to obtain Arthur Andersen's written consent to incorporate by reference its report dated February 1, 2002, with respect to these audited financial statements. The absence of this consent may limit the ability of investors to seek remedies against Arthur Andersen for any untrue statement of a material fact contained in these financial statements, or any omission of a material fact required to be stated in these financial statements. In addition, as a practical matter, any claims that may be available under federal securities laws against auditing firms may not be available against Arthur

Andersen due to the diminished amount of assets of Arthur Andersen that are or in the future may be available for claims.

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

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

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

In August 2003, we filed a shelf registration statement with the SEC, which upon being declared effective by the SEC, would allow us to issue from time to time an aggregate of up to $50 million of common stock or preferred stock. The issuance of preferred stock could adversely affect the voting power of holders of our common stock, and reduce the likelihood that our common stockholders will receive dividend payments and payments upon liquidation. The issuance of preferred stock could also decrease the market price of our common stock, or have terms and conditions that could discourage a takeover or other transaction that might involve a premium price for our shares or that our stockholders might believe to be in their best interests.

ITEM 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. At September 30, 2003, the unrealized gain on this investment was $0.9 million. 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 $0.8 million lower than the reported fair value of our non-equity investments at September 30, 2003. At September 30, 2003, our unrealized gain on marketable securities was $1.2 million, including an unrealized gain of $0.9 million on our investment in Corautus.

Some of our investments 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 September 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 SEC'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 our 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 a license agreement we entered into with the WARF in 1991, as well as fees related to our sublicense of certain inventions jointly owned by us and the WARF, the amount of which is unspecified in the WARF's complaint. We intend to vigorously defend the suit and we have counterclaimed, likewise seeking a declaratory judgment as to the correct interpretation of the payment provisions of the agreement and a return of amounts overpaid to the WARF under this agreement in excess of $1.5 million. Based on the information presently available to us, we do not believe the 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 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 a Canadian patent that was allowed and then withdrawn after protests against its issuance were filed on behalf of an undisclosed party or parties in August and December 2001. We have responded to the protests and are continuing prosecution of the application in the Canadian Patent Office.

In addition, our core DNA delivery technology is covered by a Japanese patent that was published in January 2002 and thereafter revoked by the examining panel at the JPO, on formal and substantive grounds. We filed a rebuttal response to the revocation. Based on our arguments and supporting evidence in that response, the JPO decided to reinstate the patent in July 2003. We have also received notice that four TFI requests against this patent were filed in the JPO by two companies. 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 a European patent granted in March 2002. We have received notice from the EPO that one company filed an opposition in December 2002 alleging both formal and substantive grounds for revocation, and that the opposition was declared admissible in February 2003. We have submitted 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, and none of which, individually or in the aggregate, is deemed to be material to our financial condition.

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.
10.32*	Fourth Amendment dated August 20, 2003, to Research Collaboration and License Agreement dated May 31, 1991, between the Company and Merck & Co., Inc.
31.1	Certification of Vijay B. Samant, Chief Executive Officer, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of 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).

* The Company has requested confidential treatment of certain portions of this agreement which have been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 under the Securities Exchange Act of 1934.

(b) Reports on Form 8-K

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: November 13, 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)

***** Text Omitted and Filed Separately**
Confidential Treatment Requested
Under 17 C.F.R §§ 200.80(b)(4)
and 240.24b-2

Exhibit 10.32

FOURTH AMENDMENT TO RESEARCH COLLABORATION AND LICENSE AGREEMENT DATED MAY 31, 1991

This Fourth Amendment ("Fourth Amendment"), entered into this 20th day of August, 2003 ("Amendment Effective Date"), between Merck & Co., Inc. ("MERCK") and Vical Incorporated ("VICAL"), amends the Research Collaboration and License Agreement between MERCK and VICAL dated May 31, 1991, as previously amended on April 27, 1994, December 13, 1995, and November 3, 1997 (collectively the "Agreement").

RECITALS:

WHEREAS, pursuant to the Agreement, MERCK obtained an exclusive license under VICAL PATENT RIGHTS and VICAL KNOW-HOW to develop, make, have made, use and sell LICENSED PRODUCTS in the TERRITORY upon the terms and conditions set forth therein; and

WHEREAS, INFLUENZA VACCINE is a LICENSED PRODUCT; and

WHEREAS, on April 27, 1995, MERCK exercised its option to pursuant to Section 8.3(c) of the Agreement to obtain an exclusive license under the VICAL PATENT RIGHTS and VICAL KNOW-HOW for vaccines used for the prevention of herpes simplex virus (hereinafter "HSV VACCINE"), making such a vaccine a LICENSED PRODUCT under the Agreement; and

WHEREAS, in April 1994, MERCK exercised its option to pursuant to Section 8.3(c) of the Agreement to obtain an exclusive license under the VICAL PATENT RIGHTS and VICAL KNOW-HOW for vaccines for human papilloma virus; and

WHEREAS, on December 13, 1995, the parties amended the Agreement to define any vaccine for the treatment, prevention, or prevention and treatment of clinical diseases caused by or associated with human papilloma virus ("HPV VACCINE") as a LICENSED PRODUCT under the Agreement; and

WHEREAS, the parties wish to amend the Agreement to provide for the reversion of rights to VICAL under the VICAL PATENT RIGHTS and VICAL KNOW-HOW for INFLUENZA VACCINE, HPV VACCINE and HSV VACCINE; and

WHEREAS, VICAL and MERCK have held discussions regarding the exclusivity of the license granted to MERCK in Article 3.1 of the Agreement as it applies to TREATMENT VACCINES which the parties wish to address; and

WHEREAS, VICAL and MERCK have also held discussions regarding the determination of royalty rates for TREATMENT VACCINES which are covered by VALID PATENT RIGHTS pursuant to Article 8.4(b)(i)(A) of the Agreement which the parties wish to address; and

WHEREAS, VICAL and MERCK have agreed that MERCK shall have an option to obtain a license under the VICAL Patent Rights and VICAL Know-How to vaccines for the prevention, treatment, and prevention and treatment of diseases and medical conditions associated with certain oncological targets upon the same terms and conditions as set forth in the Agreement for LICENSED PRODUCTS;

NOW, THEREFORE, in consideration of the premises and covenants set forth herein, the parties hereto agree as follows:

1. This Fourth Amendment shall be effective as of the date set forth above (the "Amendment Effective Date").

2. Reversion of Rights to VICAL. As of the Amendment Effective Date, the license granted to MERCK pursuant to Article 3.1 of the Agreement, and the rights and obligations of MERCK and VICAL arising therefrom, other than the obligations provided under Articles 21.1, 21.2, 21.3 and Article 6 shall no longer apply to INFLUENZA VACCINE, HPV VACCINE and HSV VACCINE, and INFLUENZA VACCINE, HPV VACCINE and HSV VACCINE shall no longer be deemed to be LICENSED PRODUCTS under the Agreement. Accordingly, the following provisions of the Agreement shall be amended:

   (a) Article 1.3 "LICENSED PRODUCT", shall be amended by deleting "or INFLUENZA VACCINE" in the first and second lines thereof, as more fully set forth in paragraph 8(b) below; and

   (b) Article 1.4 "COMBINATION PRODUCT" shall be amended by deleting "or INFLUENZA VACCINE" from the third line thereof; and

   (c) Article 12.3 shall be amended by deleting "and human INFLUENZA VACCINE" at the end of the second sentence thereof.

3. No Obligation to Provide Data. MERCK shall have no obligation to provide any MERCK KNOW-HOW or any other materials, data or other information to VICAL in connection with the reversion to VICAL of MERCK's rights to INFLUENZA VACCINE, HPV VACCINE and HSV VACCINE.

4. Freedom to Operate – INFLUENZA VACCINE. In the event the making, having made, use, offer for sale, sale or import by VICAL of INFLUENZA VACCINE utilizing the Technology ("DNA INFLUENZA VACCINE") would infringe during the term of this Agreement any claim of issued patents claiming the composition of matter, methods of treatment or use of DNA INFLUENZA VACCINES owned by MERCK or an AFFILIATE OF MERCK, MERCK hereby covenants not to sue VICAL for such infringement, provided, however, that such covenant not to sue shall not apply to methods of treatment or use of vaccines utilizing the Technology that: (i) are discovered by MERCK or its AFFILIATES after the Amendment Effective Date, or (ii) are or have been licensed by MERCK or its AFFILIATES from third parties, either before or after the Amendment Effective Date.

5. Release of Claims Related to INFLUENZA VACCINE, HPV VACCINE and HSV VACCINE. VICAL, on behalf of itself, its agents, AFFILIATES, employees, officers, directors, shareholders, attorneys, assigns, licensees and other representatives each a "Releasing Party"), hereby releases and forever discharges MERCK and MERCK's agents, AFFILIATES, employees, officers, directors, shareholders, attorneys, assigns, licensees and other representatives (each a "Released Party"), from any and all actions, causes of action, suits, charges, complaints, arbitrations, claims, judgments, demands, obligations or liabilities, damages, rights, costs, loans, debts and expenses (including attorneys' fees and expenses), in law or equity, whether now known or unknown, determined or determinable, by or to any Releasing Party arising out of or in any way related to any acts or omissions by MERCK or the Released Parties in the conduct of research and development related to INFLUENZA VACCINE, HPV VACCINE and HSV VACCINE under the Agreement (each a "Released Claim"). Each Releasing Party agrees that neither it, nor any other Releasing Party, nor any other person acting by, through, or under, any Releasing Party, shall institute, pursue, solicit, encourage or assist any action or actions, cause or causes of action (in law or at equity), suits, arbitration proceedings or claims in any court (including state, federal or foreign) or other tribunal or forum against or adverse to any Released Party arising out of or in any way related to the Released Claims. Nothing herein shall release MERCK from its obligation to perform the terms, conditions, and promises of all other provisions of this Agreement.

6. Exclusive License Relating to TREATMENT VACCINES. MERCK and VICAL hereby agree to amend Section 3.1 for the purpose of clarifying that MERCK has exclusive rights, even as to

VICAL, as it relates to TREATMENT VACCINES. Accordingly, the following provisions of the Agreement shall be amended:

(a) Article 3.1 is hereby amended to be replaced in its entirety as follows:

> VICAL grants to MERCK an exclusive license (even as to VICAL) under VICAL KNOW-HOW and VICAL PATENT RIGHTS to develop, make, have made, use and sell LICENSED PRODUCTS in the TERRITORY with the right to grant sublicenses to AFFILIATES of MERCK and those persons or entities through whom MERCK, in the normal course of its business collaborates in the manufacture and sale of its products; provided however, that nothing in this Agreement shall prohibit VICAL from utilizing the VICAL KNOW-HOW and/or VICAL PATENT RIGHTS, exclusive of MERCK KNOW-HOW, to develop, make, have made, use and sell, either by itself or with one or more third parties, products for the treatment of infectious diseases; provided, further, notwithstanding the preceding proviso, that VICAL shall not have any right to develop, make, have made, use, or sell, either by itself or with one or more third parties, TREATMENT VACCINES.

7. Royalty Rates for TREATMENT VACCINES. MERCK and VICAL hereby agree that Article 8.4(b)(i)(A) shall be amended to state as follows:

> the sale of which is covered by VALID PATENT RIGHTS in the country of sale, for the term of the relevant VALID PATENT RIGHTS in the following amounts:
>
> | | |
> |---|---|
> | For annual cumulative NET SALES for all countries of the world outside the United States (and its territories and possessions) the sale of which is covered by VALID PATENT RIGHTS less than or equal to **[…***…]** | **[…***…]** of NET SALES |
> | For annual cumulative NET SALES greater than **[…***…]** for all countries of the world outside the United States (and its territories and possessions) the sale of which is covered by VALID PATENT RIGHTS, for that portion of such NET SALES greater that **[…***…]** | **[…***…]** of NET SALES |

8. Amended Definitions Relating to CANCER TARGETS.

(a) The Agreement is amended by adding to Article 1 new provisions as follows:

1.15 CANCER INDICATION means an oncological disease or diseases in humans, and/or diseases or medical conditions associated with such an oncological disease in humans.

1.16 CANCER TARGET means a TARGET against which a host-mediated humoral or cellular immune response is intended to or would prevent, treat, or prevent and treat a CANCER INDICATION.

1.17 CANCER VACCINE means a preparation for administration to humans: (i) which contains an antigenically-active component or components that facilitate a host-mediated cellular and/or humoral immune response for a CANCER TARGET; and (ii) which is intended to or would prevent, treat, or prevent and treat one or more CANCER INDICATIONS; and (iii) the manufacture and/or sale of which preparation would infringe the VICAL PATENT RIGHTS or would utilize VICAL KNOW-HOW,

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provided, however, that no CANCER VACCINE shall include components that encode for the HLA-B7 complex or parts thereof.

1.18 TARGET means (i) DNA and all post-transcriptional material encoded by such DNA, including all naturally occurring or disease-associated truncations, mutations, variants, fragments and post-transcriptional modifications thereof (including but not limited to splice variants and polysaccharides) and all material encoded by such post-transcriptional material including but not limited to proteins; (ii) the DNA encoding a polypeptide or protein, as identified by a sequence of amino acids, and all post-translational variants thereof including but not limited to glycosylation and phosphorylation modifications.

(b) The following provisions of Article 1 are hereby amended, as follows:

1.3 LICENSED PRODUCT means (i) a bulk or finished AIDS VACCINE, or other vaccine for the prevention of human infectious disease if licensed hereunder, which utilizes the Technology or technology which is developed by VICAL during and as a result of the RESEARCH COLLABORATION PROGRAM; and (ii) upon the exercise of an Option for a CANCER VACCINE, such bulk or finished CANCER VACCINE for the prevention of CANCER INDICATIONS, provided, however, that if any vaccine under (i) or (ii) above is also capable of being used for treatment of the same human infectious disease or CANCER INDICATION, then such therapeutic use of such vaccine shall also be considered a LICENSED PRODUCT for purposes of the license being granted by VICAL to MERCK under this Agreement; and TREATMENT VACCINES.

1.14 TREATMENT VACCINES means a bulk or finished vaccine for the treatment of (i) Human Immunodeficiency Virus ("HIV-1") and/or diseases caused by infection with HIV-1 in humans; (ii) Hepatitis Virus ("HBV") and or diseases caused by infection with HBV in humans; and (iii) CANCER VACCINES for the treatment (but not prevention or prevention and treatment) of CANCER INDICATIONS.

9. Option to Obtain Exclusive License for CANCER TARGETS

(a) Option Grant. VICAL hereby grants MERCK an option (the "Option") to obtain a license under the VICAL PATENT RIGHTS and VICAL KNOW-HOW to make, have made, use, sell, offer to sell and import CANCER VACCINES in the TERRITORY for up to three (3) CANCER TARGETS ("CANCER TARGET LICENSE"). Such CANCER TARGET LICENSE shall be exclusive (even as to VICAL) for each CANCER TARGET so licensed, and shall be sublicenseable by MERCK pursuant to the terms applicable to LICENSED PRODUCTS in Section 3.1 of the Agreement.

(b) Option Period. The period of the Option shall commence on the Amendment Effective Date and shall expire on the**[…***…]** anniversary of the Amendment Effective Date (the "Option Period").

(c) Option Exercise. (1) MERCK shall notify VICAL in writing during the Option Period of its desire to obtain a CANCER VACCINE LICENSE for a particular CANCER TARGET, providing VICAL with a GenBank® accession number for such CANCER TARGET or similar information which uniquely

identifies such CANCER TARGET.

(2) VICAL shall notify MERCK in writing within thirty (30) days after receiving such written notice from MERCK whether VICAL shall grant such a CANCER TARGET LICENSE to MERCK, provided, however, that VICAL shall grant to MERCK such a CANCER TARGET LICENSE unless such CANCER TARGET has previously been licensed to an entity that is not an AFFILIATE of VICAL. In the event that an exclusive license for such CANCER TARGET is not available to MERCK, VICAL shall notify

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MERCK of the reasons why such an exclusive license is not available, consistent with VICAL's confidentiality obligations to third parties.

(3) The Option shall be deemed to have been exercised by MERCK upon written notice from VICAL pursuant to paragraph (c)(2) that VICAL shall grant a CANCER TARGET LICENSE for such CANCER TARGET, or upon written confirmation by MERCK to VICAL of the expiration of the thirty (30) day period set forth in paragraph (c)(2), whichever is earlier (the "Option Exercise"). Upon the Option Exercise, CANCER VACCINES for such CANCER TARGET shall be deemed to be LICENSED PRODUCTS under the Agreement.

(d) Payment upon Option Exercise. Within thirty (30) days after the Option Exercise for each CANCER TARGET, MERCK shall pay to VICAL a CANCER TARGET LICENSE fee of **[…***…]**.

(e) Milestones and Royalties for CANCER VACCINES. CANCER VACCINES that are not TREATMENT VACCINES shall be eligible for milestones set forth Schedule A of the Agreement and for royalties set forth in Section 8.4(a) of the Agreement. CANCER VACCINES that are TREATMENT VACCINES shall be eligible for milestones set forth in Schedule E of the Agreement and for royalties set forth in Section 8.4(b) of the Agreement, provided that for purposes of CANCER VACCINES, the "Effective Date" under Schedule E shall mean the date of Option Exercise for the CANCER TARGET for which such CANCER VACCINE facilitates an immune response.

(f) Diligence for CANCER VACCINES. Notwithstanding Section 13.1 of the Agreement, MERCK's diligence obligations regarding CANCER VACCINES shall be as set forth in this paragraph. MERCK shall use reasonable efforts, consistent with the usual practice followed by MERCK in pursuing the commercialization and marketing of its other vaccine products of a similar commercial value, at its own expense, to develop and commercialize a CANCER VACCINE for each CANCER TARGET for which it has received a CANCER TARGET LICENSE on a commercially reasonable basis in such countries in the Territory where in MERCK's opinion it is commercially viable to do so, provided, however, that such obligations of MERCK with respect to any CANCER TARGET are expressly conditioned upon the continuing absence of any adverse condition or event relating to the safety or efficacy of a CANCER VACCINE for such CANCER TARGET, and the obligation of MERCK to develop or market any CANCER VACCINE for such CANCER TARGET shall be delayed or suspended so long as in MERCK's opinion any such condition or event exists.

(g) Right of First Negotiation for CANCER VACCINES during Option Period. If VICAL desires during the Option Period to grant a license to an entity to any third party other than MERCK for any CANCER TARGET, and MERCK has not yet obtained a CANCER TARGET LICENSE for three (3) CANCER TARGETS, VICAL shall so notify MERCK in writing, identifying the CANCER TARGET with a GenBank® accession number or similar information which uniquely identifies such CANCER TARGET. MERCK shall have sixty (60) days in which to respond in writing to such notice indicating MERCK's desire to obtain a CANCER TARGET LICENSE for such CANCER TARGET. The Option for such CANCER TARGET LICENSE will be deemed to be exercised upon receipt by VICAL of such written notice by MERCK. If MERCK does not respond within such 60-day period, or if MERCK notifies VICAL in writing that MERCK is not interested in obtaining such a CANCER TARGET LICENSE, VICAL shall be free to proceed to pursue negotiation and grant of such license to a third party without further obligation to offer such license to MERCK.

10. The parties have agreed upon a press release relating to this Amendment, which is attached hereto as Attachment 1.

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11. Effect of Amendment. In no event shall this Fourth Amendment be interpreted as a termination of the Agreement. This Fourth Amendment shall not be interpreted as an amendment of any provisions of the Agreement except as specifically set forth in this Fourth Amendment, and all other terms and conditions of the Agreement shall remain unmodified and in full force and effect except specifically amended by this Fourth Amendment.

12. Defined Terms. Unless otherwise provided in this Fourth Amendment, all capitalized terms in this Fourth Amendment shall have the meaning provided for in the Agreement.

13. Survival. Items 4 and 5 of this Amendment No. 4, as well as Sections 12.4 and 12.5 of the Agreement, and Articles 1, 6, 14, and 21 of the Agreement, shall survive termination of the Agreement.

14. Counterparts. This Amendment No. 4 may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

IN WITNESS WHEREOF the parties have executed this Agreement the day and year first above written.

MERCK & CO., INC.		VICAL INCORPORATED	
/s/ DR. ANTHONY FORD-HUTCHINSON		/s/ VIJAY B. SAMANT	
BY:	Dr. Anthony Ford-Hutchinson	BY:	Vijay B. Samant
TITLE:	Executive Vice President Worldwide Basic Research	TITLE:	President and CEO
DATE:	August 8, 2003	DATE:	August 20, 2003

Attachment 1

News Release

FOR IMMEDIATE RELEASE

August 21, 2003

Contacts:

Investors:
Alan R. Engbring
Vical Incorporated
(858) 646-1127

Media:
Janeen Hicks
Atkins + Associates
(858) 527-3486

VICAL GRANTS OPTIONS TO MERCK FOR CANCER TARGETS

SAN DIEGO—August 21, 2003—Vical Incorporated (Nasdaq:VICL) announced today that Merck & Co., Inc. (NYSE:MRK) and Vical have amended their existing license agreement. Under the amended agreement, Merck has obtained an option license for rights to use Vical's patented non-viral gene delivery technology for three cancer targets. Exercise of the option license for each oncology target would result in an option license fee payment to Vical, and further development may lead to milestone and royalty payments to Vical. In addition, Vical has expanded its infectious disease portfolio by re-acquiring the rights to apply its core vaccine technology for influenza, herpes simplex virus (HSV), and human papilloma virus (HPV) previously licensed to Merck. Merck will retain rights to use the technology for Human Immunodeficiency Virus (HIV), hepatitis C virus (HCV) and hepatitis B virus (HBV).

"We are excited with Merck's potential application of our technology in the oncology field in addition to their ongoing efforts with infectious disease vaccines," said Vijay B. Samant, Vical's President and Chief Executive Officer. "Each of the reacquired targets offers us significant opportunities for commercial development of vaccines leveraging our core technology. We are particularly pleased to regain rights to develop a vaccine for influenza, especially for the elderly, for whom improved effectiveness of vaccines is needed."

About Vical

Vical researches and develops biopharmaceutical products based on our patented DNA delivery technologies for the prevention and treatment of serious or life-threatening diseases. Potential applications of our DNA delivery technology include DNA vaccines for infectious diseases or cancer, in which the expressed protein is an immunogen; cancer immunotherapeutics, in which the expressed protein is an immune system stimulant; and cardiovascular therapies, in which the expressed protein is an angiogenic growth factor. We have retained all rights to our internally developed product candidates. In addition, we collaborate with major pharmaceutical companies and biotechnology companies that give us access to complementary technologies or greater

resources. These strategic partnerships provide us with mutually beneficial opportunities to expand our product pipeline and serve significant unmet medical needs.

This press release contains forward-looking statements subject to risks and uncertainties that could cause actual results to differ materially from those projected. Forward-looking statements include statements about potential development of products using the company's technology in the oncology field and the possibility of payments to the company, the company's focus, collaborative partners, product candidates, and developmental status. Risks and uncertainties include whether Merck will exercise an option with respect to any of the cancer targets, if any option is exercised, whether the company will receive payments upon Merck's development of product candidates, whether the company will pursue opportunities, on its own or with collaborative partners, to develop product candidates for HSV, HPV or influenza, whether vaccines for cancer or infectious diseases will be developed and approved, whether any product candidates will be shown to be safe and efficacious in clinical trials, the timing of clinical trials, whether Vical or its collaborative partners will seek or gain approval to market any product candidates, the dependence of the company on its collaborative partners, and additional risks set forth in the company's filings with the Securities and Exchange Commission. These forward-looking statements represent the company's judgment as of the date of this release. The company disclaims, however, any intent or obligation to update these forward-looking statements.

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(s) 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: November 13, 2003

/s/ VIJAY B. SAMANT
Vijay B. Samant
President and Chief Executive Officer

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: November 13, 2003

/s/ MARTHA J. DEMSKI
Martha J. Demski
Vice President and Chief Financial Officer

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 September 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: November 13, 2003

/s/ VIJAY B. SAMANT
Vijay B. Samant
Chief Executive Officer

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

Exhibit 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 September 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: November 13, 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.