UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended June 30, 2004

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

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

(Former name, former address and former fiscal year, if changed since last report)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or 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 July 30, 2004: 23,477,604

VICAL INCORPORATED

FORM 10-Q

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Part I. Financial Information
Item 1. Financial Statements

VICAL INCORPORATED
BALANCE SHEETS
(Unaudited)

	June 30, 2004	December 31, 2003
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 14,235,494	$ 16,573,912
Cash equivalents—restricted	677,334	2,355,700
Marketable securities—available-for-sale	66,586,667	65,588,091
Marketable securities—restricted	3,989,659	—
Receivables and other	5,686,898	5,386,211
Total current assets	91,176,052	89,903,914
Property and Equipment:		
Equipment	16,506,248	17,922,355
Leasehold improvements	12,054,632	8,426,848
	28,560,880	26,349,203
Less—accumulated depreciation and amortization	(13,512,797)	(12,013,962)
	15,048,083	14,335,241
Intangible Assets, net	5,885,645	5,870,123
Other Assets	483,388	597,912
	$ 112,593,168	$ 110,707,190
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable and accrued expenses	$ 5,534,038	$ 5,626,914
Current portion of capital lease obligations	4,374,285	3,918,118
Current portion of notes payable	154,762	340,476
Current portion of deferred revenue	403,857	2,337,019
Total current liabilities	10,466,942	12,222,527
Long-Term Obligations:		
Long-term obligations under capital leases	6,645,220	7,196,376
Deferred revenue	—	131,130
Deferred lease credits	1,502,888	1,334,880
Other long-term obligations	1,000,000	—
Total long-term obligations	9,148,108	8,662,386
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—23,477,604 and 20,092,594 shares issued and outstanding at June 30, 2004, and December 31, 2003, respectively	234,776	200,926
Additional paid-in capital	221,132,366	203,607,418
Accumulated other comprehensive income	786,472	798,223
Accumulated deficit	(129,175,496)	(114,784,290)
Total stockholders' equity	92,978,118	89,822,277
	$ 112,593,168	$ 110,707,190

See accompanying notes to financial statements.

VICAL INCORPORATED
STATEMENTS OF OPERATIONS
(Unaudited)

	Three months ended June 30, 2004	Three months ended June 30, 2003	Six months ended June 30, 2004	Six months ended June 30, 2003
Revenues:				
License and royalty revenue	$ 1,926,846	$ 511,520	$ 2,548,966	$ 1,007,502
Contract revenue	3,814,708	89,672	4,101,771	502,024
	5,741,554	601,192	6,650,737	1,509,526
Operating expenses:				
Research and development	8,654,646	6,318,061	16,829,894	12,901,451
General and administrative	2,534,723	1,750,520	4,480,984	3,290,883
Write-down of investment	—	—	—	482,217
	11,189,369	8,068,581	21,310,878	16,674,551
Loss from operations	(5,447,815)	(7,467,389)	(14,660,141)	(15,165,025)
Other income (expense):				
Investment income	320,070	615,530	620,414	1,359,270
Interest expense	(188,888)	(70,267)	(351,479)	(141,268)
Net loss	$ (5,316,633)	$ (6,922,126)	$ (14,391,206)	$ (13,947,023)
Net loss per common share (basic and diluted—Note 5)	$ (0.23)	$ (0.34)	$ (0.66)	$ (0.69)
Weighted average shares used in computing net loss per common share (Note 5)	23,475,585	20,091,344	21,896,091	20,091,344

See accompanying notes to financial statements.

VICAL INCORPORATED
STATEMENTS OF CASH FLOWS
(Unaudited)

	Six months ended June 30, 2004	Six months ended June 30, 2003
OPERATING ACTIVITIES:		
Net loss	$ (14,391,206)	$ (13,947,023)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,881,603	1,774,166
Write-down of investment	—	482,217
Loss on sublease	—	78,402
Write-off of abandoned patents	34,749	—
Compensation expense related to stock options and awards	294,094	35,967
Deferred lease credits	168,008	235,943
Change in operating assets and liabilities:		
Receivables and other	(402,934)	407,885
Other assets	114,524	(60,842)
Accounts payable and accrued expenses	907,124	11,903
Deferred revenue	(2,064,292)	541,046
Net cash used in operating activities	(13,458,330)	(10,440,336)
INVESTING ACTIVITIES:		
Sales of marketable securities-including restricted	25,981,123	67,944,976
Purchases of marketable securities-including restricted	(30,981,109)	(73,664,445)
Capital expenditures	(151,029)	(1,377,934)
Licensed technology expenditures	—	(80,000)
Patent expenditures	(372,377)	(473,177)
Net cash used in investing activities	(5,523,392)	(7,650,580)
FINANCING ACTIVITIES:		
Issuance of common stock, net	17,264,704	—
Payments on notes payable	(185,714)	(328,570)
Principal payments under capital lease obligations	(2,114,052)	(803,366)
Sales of restricted cash equivalents	2,222,654	—
Purchases of restricted cash equivalents	(544,288)	—
Net cash provided from (used in) financing activities	16,643,304	(1,131,936)
Net decrease in cash and cash equivalents	(2,338,418)	(19,222,852)
Cash and cash equivalents at beginning of period	16,573,912	32,608,954

Cash and cash equivalents at end of period	$ 14,235,494	$ 13,386,102
Supplemental Disclosure of Cash Flow Information:		
Cash paid during the period for interest	$ 383,472	$ 156,575
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
Property and equipment acquired under capital lease financing	$ 2,121,309	$ 6,978,432

See accompanying notes to financial statements.

VICAL INCORPORATED

NOTES TO FINANCIAL STATEMENTS

June 30, 2004
(Unaudited)

1. ORGANIZATION AND BASIS OF PRESENTATION

Organization

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

Basis of Presentation

The information contained herein has been prepared in accordance with instructions for Form 10-Q. The information at June 30, 2004, and for the three-month and six-month periods ended June 30, 2004 and 2003, 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, 2003, included in its Form 10-K filed with the Securities and Exchange Commission.

2. REVENUE RECOGNITION

The Company earns revenue from licensing its proprietary technology and by performing services under research and development contracts and grants, and manufacturing contracts. In general, revenue is recognized when all of the following criteria are met: persuasive evidence of an arrangement exists, delivery has occurred or services have been rendered, the price is fixed or determined, and collection is reasonably assured. Any initial license or option payment received under an agreement under which the Company also provides research and development services is recognized as revenue over the term of the research and development period. Payments for options on a license to the Company's 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 agreed-upon events representing the achievement of substantive steps in the development process are achieved, or the passage of time, and where the amount of the milestone payment approximates the value of achieving the milestone, and collection of payment is reasonably assured. Royalty revenue is recognized as the cash is received from the licensee.

Revenue under research and development contracts and grants, and manufacturing and regulatory service contracts, except for fixed-price contracts, is recognized as the research and development expenses for services performed are incurred, provided that all of the revenue recognition criteria noted above have been met. The Company does not recognize revenue on contract change orders until the service is performed and it has 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 the Company will receive a signed modification, or if the Company has received a signed modification, increasing the funding under the contract which will allow it 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.

The Company also has entered into fixed-price manufacturing contracts under which the primary deliverables are investigational vaccines to be used for preclinical and clinical research. Under these contracts revenue is recognized when the product is shipped, provided all of the other revenue recognition criteria referred to above are met.

3. CASH EQUIVALENTS AND MARKETABLE SECURITIES

The Company invests its excess cash in debt instruments of financial institutions and of corporations with strong credit ratings, in U.S. government obligations, and in money market funds in financial institutions. The Company has established guidelines relative to investment ratings, diversification and maturities that maintain safety and liquidity. These guidelines are periodically reviewed and modified to take advantage of trends in yields and interest rates. Cash equivalents are short-term, highly-liquid

investments with original maturities at time of purchase of less than three months. Cash equivalents consist primarily of commercial paper, corporate asset backed securities, federal agency discount notes and money market funds.

The Company classifies its marketable securities as available-for-sale. Marketable securities and cash equivalents are classified as restricted when they are pledged as collateral for a standby letter of credit or borrowings outstanding under a lease line as more fully explained in Note 8. Unrealized gains or losses, net of related tax effect, are recorded as a component of accumulated other comprehensive income or loss. Realized gains or losses are calculated based on the specific identification method. A decline in the market value below cost that is deemed to be other than temporary would result in a charge to earnings in the period the decline occurs.

4. ACCOUNTING FOR STOCK OPTIONS AND AWARDS

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 because the exercise price of the option is equal to the fair market value of a share of common stock on the measurement date. 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 in the table below, based on the estimated fair value of each option grant on the grant date using the Black-Scholes option-pricing model with the weighted average risk-free interest rate and volatility assumptions shown. An expected option life of four years and a dividend rate of zero were assumed for the periods presented.

	Three months ended June 30,		Six months ended June 30,	
	2004	2003	2004	2003
Net loss, as reported	$ (5,316,633)	$ (6,922,126)	$ (14,391,206)	$ (13,947,023)
Add stock-based compensation expense included in reported net loss	216,692	47,100	294,094	35,967
Less stock-based compensation expense determined under fair value based method for all awards	(971,992)	(910,760)	(1,809,598)	(1,914,422)
Pro forma net loss	$ (6,071,933)	$ (7,785,786)	$ (15,906,710)	$ (15,825,478)
Net loss per common share (basic and diluted), as reported	$ (.23)	$ (.34)	$ (.66)	$ (.69)
Pro forma net loss per common share (basic and diluted)	$ (.26)	$ (.39)	$ (.73)	$ (.79)
Assumed risk-free interest rate	3.75%	1.9%	3.03%	2.51%
Assumed volatility	80%	82%	81%	81%

In February 2004, the Company granted 82,500 restricted stock units, or RSUs, to certain officers. These RSUs vest in equal quarterly installments over a two-year period and, once vested, allow the participants to acquire up to 82,500 shares of common stock at par value. In May 2004, the Company granted 8,000 RSUs to another officer. The participants are not entitled to vote, sell or transfer any unvested RSUs. Additionally, granted but unvested RSUs generally are forfeited at termination of employment. Compensation expense related to these grants for the three-month and six-month periods ended June 30, 2004, was approximately $107,000 and $151,000, respectively.

5. NET LOSS PER SHARE

Basic and diluted net loss per common share have been computed using the weighted average number of shares of common stock outstanding during each of the three-month and six-month periods ended June 30, 2004 and 2003. The weighted average number of shares used to compute diluted loss per share excludes any assumed exercise of stock options, and the assumed issuance of common stock under the RSUs, as the effect would be antidilutive. The number of shares so excluded was 4,054,314 and 3,486,984 at June 30, 2004 and 2003, respectively.

6. COMPREHENSIVE LOSS

Comprehensive loss consists of net loss and other comprehensive income or loss. Accumulated other comprehensive income represents net unrealized gains on marketable securities. For the three-month periods ended June 30, 2004 and 2003, other comprehensive (loss) and income were ($0.5) million and $0.1 million, respectively, and total comprehensive losses were $5.8 million and $6.8 million, respectively. For the six-month periods ended June 30, 2004 and 2003, other comprehensive losses were $12,000 and $0.2 million, respectively, and total comprehensive losses were $14.4 million and $14.1 million, respectively.

7. 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. In February 2003, VGI and GenStar Therapeutics Corporation merged, 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 American Stock Exchange, or AMEX. 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. The market value of the Company's investment in Corautus at June 30, 2004, was approximately $1.3 million.

8. LEASED FACILITY; LEASE LINE

In addition to its lease of the Pacific Center Court facility, or PCC, which terminates in 2017, the Company also holds leases, which terminate in late 2004, at three facilities for manufacturing, research and office space. Effective June 30, 2004, the Company renewed its lease for five years on approximately 10,000 square feet of research space. This lease will now expire in 2009, and cumulative payments under the extension will be approximately $1.9 million. In July 2004, the Company renewed its lease for one year on approximately 15,000 square feet of manufacturing space in one of these facilities. The lease on the office space in the third facility will not be renewed at termination.

In March 2004, the Company signed an agreement with the leasing division of a bank to provide the Company with up to $8.5 million of financing for tenant improvements and equipment, with drawdowns available through December 15, 2004. The financial covenants of the agreement require the Company to maintain cash collateral to secure the outstanding borrowings. The bank also has a secured interest in the equipment financed under this agreement. Additionally, if unrestricted cash and marketable securities, as defined, fall below $45 million, the Company would be required to maintain a letter of credit issued by another financial institution equal to the amount of outstanding borrowings at that time. In the event this occurred, the Company expects that its restricted cash equivalents and marketable securities securing the lease would be returned, but the Company would have to make restricted cash deposits with another financial institution in order to obtain a letter of credit. At June 30, 2004, the Company had borrowed $2.1 million under the lease line. Outstanding amounts on the accompanying balance sheet at June 30, 2004 were classified as $0.6 and $1.4 million in current portion of capital lease obligations and long-term obligations under capital leases, respectively. Cash equivalents and marketable securities of $2.2 million were pledged as collateral for this lease line and are included as restricted in the accompanying balance sheet. At June 30, 2004, restricted cash equivalents and marketable securities also included $2.5 million of securities pledged as collateral for a standby letter of credit.

9. RECENT LICENSING AND CONTRACT ACTIVITIES

In May 2004, the Company granted an exclusive license to Merial Ltd., or Merial, a joint venture between Merck & Co., Inc. and Aventis, S.A., and a world leader in animal health products, for use of its patented DNA delivery technology in a vaccine to protect certain companion animals against a particular type of cancer. In the second quarter of 2004, the Company recognized revenue of $250,000 related to this agreement. Merial is responsible for research and development activities under this agreement. If Merial is successful in developing and marketing this product, milestone payments and royalties on sales of the resulting product would be due to the Company. A separate agreement with Merial, entered into in 1995, remains in place covering the use of the Company's patented DNA delivery technology in vaccines to prevent certain infectious diseases in livestock and companion animals.

In June 2004, the Company earned a $1.2 million milestone from Gencell SAS, or Gencell, a wholly-owned subsidiary of Aventis Pharma SA, under the companies' license agreement for certain cardiovascular applications of the Company's patented DNA delivery technology. Under the agreement, established in June 2000, Gencell is developing plasmid-based delivery of Fibroblast Growth Factor 1, or FGF-1, as a potential treatment for Peripheral Arterial Disease, or PAD, and other indications characterized by blood vessel blockage. Published interim results from an open-label Phase 1 clinical trial indicated that the FGF-1 plasmid-based therapeutic was well tolerated, with no serious adverse events considered related to the treatment. Interim results reported in this same publication demonstrated reduction in pain and evidence of newly visible blood vessels three months after treatment. Gencell is currently conducting double-blind, placebo-controlled Phase 2 trials in the United States and Europe.

The Company has an agreement to manufacture DNA vaccines for HIV, Ebola, West Nile Virus and severe acute respiratory syndrome, or SARS, for the Dale and Betty Bumpers Vaccine Research Center, or VRC, of the National Institutes of Health, or NIH. The Company manufactures these vaccines in its Eastgate manufacturing facility under a subcontract awarded in July 2002, which was amended most recently in June 2004 for additional production of one of these vaccines. Revenue recognized under this agreement was $3.8 million for the three-month and six-month periods ended June 30, 2004, and $29,000 for the same periods in the prior year.

In May 2003, the Company announced a separate subcontract to manufacture bulk DNA vaccines for the VRC, which will be produced in a 500-liter fermenter and related purification equipment being furnished as government equipment, or GFE, in the Company's PCC manufacturing facility.

In February 2004, the Company received orders under the two subcontracts totaling approximately $6 million. Production began in the first half of 2004 in the Company's Eastgate manufacturing facility, and expanded in July 2004 to the Company's PCC facility.

If the Company fails to satisfy its contractual obligations to deliver the vaccines ordered by the VRC in the manner required by the agreement, the applicable Federal Acquisition Regulations allow the VRC to cancel the agreement in whole or in part, and the Company may be required to perform corrective actions, including but not limited to delivering to the VRC any uncompleted or partially completed work, or government property in its possession, or paying a third-party supplier selected by the VRC to complete any uncompleted work. The performance of these corrective actions could have a material adverse impact on the Company's financial results in the period or periods affected. There are only a limited number of other contractors that could perform under this contract in the unlikely event that Vical was unable to perform. The price they might charge could be more than what Vical would charge based on their capacity, utilization, size of order and other factors. Accordingly, the Company is unable to estimate a range of potential cost it could be required to pay if the VRC were to engage a substitute contractor to meet any performance obligations that the Company was unable to meet.

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 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 is partially funding the development of the Company's DNA vaccine against anthrax. During the second quarter of 2004, the total amount of this grant increased to $5.9 million as a result of a negotiated change in allowable overhead rates.

In addition, the Company has received notification of funding of approximately $1 million for research and development related to its CMV vaccine program under two grants from the NIAID. A six-month Phase I SBIR grant of approximately $0.3 million is partially funding preclinical safety and toxicity evaluation of the CMV vaccine in support of the Company's planned Phase 1 human trial. An 18-month research grant of approximately $0.7 million is partially funding novel assays to measure and characterize immune responses in volunteers participating in the trial.

10. 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 Company 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 the first quarter of 2004, the Company accrued $1.5 million for settlement of this matter. In the second quarter of 2004, the Company and WARF entered into a settlement agreement and an amendment to the license agreement resolving all outstanding claims. Pursuant to the settlement agreement, the lawsuit was dismissed.

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. In April 2002, the Company filed an appeal, which is still pending, seeking to overturn this initial ruling.

The Company's core DNA delivery technology is also covered by a Canadian patent application 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 filed responses to the TFI requests in a timely manner and is awaiting further action by the JPO.

A European patent issued in 2003 covering a range of applications of the Company's core DNA delivery technology, including cationic lipid-formulated, gene-based immunotherapeutics such as its clinical-stage Allovectin-7® treatment for melanoma, cationic lipid-formulated DNA vaccines such as its investigational anthrax vaccine, and similar pharmaceutical products under development by others. This patent has been opposed by two companies. The Company intends to respond to the oppositions in a timely manner.

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

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, and opposed in December 2002. The Company has submitted a rebuttal response to the opposition. After careful analysis of the intellectual property, the Company maintained its rights to patents and applications in the United States and returned non-U.S. rights to the University of Michigan.

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

In addition, the Company has undertaken certain commitments under agreements with its collaborators, and its officers and directors. Under license agreements with its collaborators, the Company has agreed to continue to maintain and defend the patent rights licensed to the collaborators. In addition, the Company has entered into indemnification agreements with each officer and director of the Company which would indemnify those individuals for any expenses and liabilities in the event of a threatened, pending or actual investigation, lawsuit, or criminal or investigative proceeding. At June 30, 2004, the Company had commitments to pay salary continuation to four current officers under certain circumstances.

11. 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 VRC. For varying periods beginning from November 2000, the VRC has contracted with Vical for providing regulatory support, manufacturing services, and the production of research and clinical trial supplies. In May 2003, the Company announced a separate subcontract to manufacture bulk DNA vaccines for the VRC, which will be produced in a 500-liter fermenter and related purification equipment being furnished as GFE in the Company's new PCC manufacturing facility. Under this agreement, the Company is guaranteed minimum annual production orders beginning in 2004, subject to annual extension of the agreement. In February 2004, the Company received orders under the two subcontracts totaling approximately $6 million. Production began in the first half of 2004 in the Company's Eastgate manufacturing facility, and expanded in July 2004 to the Company's PCC facility.

Revenue recognized under these subcontracts was $3.8 million for both the three-month and six-month periods ended June 30, 2004. Revenue for both the three-month and six-month periods ended June 30, 2003, amounted to $0.1 million. Included in "receivables and other" at June 30, 2004, is a receivable from the VRC in the amount of $1.4 million, of which $0.6 million pertains to equipment reimbursements.

Dr. Douglas was on the board of directors of the International AIDS Vaccine Initiative, or IAVI, a not-for-profit entity, until June 30, 2003. 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. Revenue recognized under this agreement was $0.0 million for the three-month and six-month periods ended June 30, 2004, and $0.0 million and $0.2 million for the three-month and six-month periods ended June 30, 2003, respectively.

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

12. SHELF REGISTRATION STATEMENT

In December 2003, a shelf registration statement that the Company filed with the SEC was declared effective, which will allow the Company to issue from time to time an aggregate of up to $50 million, less amounts raised to date, 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.

In March 2004, the Company raised approximately $17.3 million in net proceeds from the sale of approximately 3.4 million shares of its common stock at $5.50 per share in a registered direct offering to a select group of institutional investors. All of the shares of common stock were offered by the Company pursuant to the effective shelf registration statement previously filed with the SEC.

13. STOCK INCENTIVE PLAN

The Company has a stock incentive plan under which 5,700,000 shares of common stock, subject to adjustment as provided in the plan, are reserved for issuance to employees, non-employee directors and consultants of the Company.

14. SEVERANCE OBLIGATIONS

In the second quarter of 2004, the Company entered into severance agreements with two former officers and accrued $0.4 million for cash payments due under these agreements, and an additional $0.1 million for compensation expense for certain stock options and restricted stock units. In June 2004, approximately $19,000 was paid under one agreement. Remaining payments are expected to be $0.2 million for the six months ended December 31, 2004, $0.1 million for 2005 and $0.1 million for 2006.

15. SUBSEQUENT EVENTS

In July 2004, the Company renewed its lease for one year on approximately 15,000 square feet of manufacturing space. The lease will now expire in late 2005, and cumulative payments under the extension will be approximately $0.5 million.

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, or Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or Exchange Act. 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 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,
- The attainment and defense of patent protection for any of these products,
- Market acceptance of and continuing demand for our products,
- The impact of competitive products, pricing and reimbursement policies,
- The continuation of our corporate collaborations and licenses,
- Our ability to enter into new corporate collaborations and licenses,
- Our ability to fulfill the terms of our contract services agreements,
- Our ability to obtain additional financing to support our operations,
- 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, 2003, 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(3)
INFECTIOUS DISEASES			
Infectious disease vaccines	*Plasmodium falciparum* (malaria)	Phase 1/2	Vical
	Cytomegalovirus	Phase 1	Vical
	Bacillus anthracis (anthrax)	Phase 1	Vical
	Ebola	Phase 1	Vical/NIH
	West Nile Virus	Preclinical	Vical/NIH
	HIV – preventive	Phase 1	Merck & Co., Inc.
	HIV – therapeutic	Phase 1	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 2	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 2	Corautus Genetics Inc.
FGF-1	Phase 2	Gencell SAS	

VETERINARY			
Preventive vaccines	Various undisclosed(2)	Research-Clinical	Merial Ltd.
Undisclosed fish disease(2)	Clinical	Aqua Health Ltd.	
Protective cancer vaccine	Companion animal cancer(2)	Clinical	Merial 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, or IND, application. "Phase 1" 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 2" 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 1/2" clinical trial. For veterinary products, "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.

(3) See "Management's Discussion and Analysis of Financial Condition and Results of Operations—Other Matters" for costs associated with Vical independent product development programs.

Business Summary

Allovectin-7®

Allovectin-7® is a DNA plasmid/lipid complex containing the DNA sequences encoding HLA-B7 and β2 microglobulin, which together form a Class I Major Histocompatibility Complex, or MHC-I antigen. Injection of Allovectin-7® directly into tumors, or intratumoral injection, may augment the immune response to both local and metastatic tumors by one or more mechanisms. In HLA-B7 negative recipients, a T-cell response may be initiated by the introduction of a foreign HLA, similar to that observed in tissue transplant rejections. In HLA-B7 positive recipients, enhanced HLA-B7 and b2 microglobulin surface expression by injected tumor cells could increase antigen presentation to tumor specific T-cells. In any recipient, a pro-inflammatory anti-tumor response may occur following intratumoral injection of the plasmid DNA/lipid complex, as demonstrated in preclinical animal tumor models.

In February 2001, we began a high-dose Phase 2 trial evaluating the Allovectin-7® gene-based immunotherapeutic for patients with Stage III or IV melanoma, who have few other treatment options. Our high-dose Phase 2 trial completed enrollment in July 2003. Efficacy data as of November 2003 were collected on the 127 patients receiving the full 2 milligram dose of Allovectin-7®, and safety data were collected for those plus 6 additional patients receiving lower doses in a dose-escalation stage. A summary of these data was reported in June 2004 at meetings of the American Society of Clinical Oncology and the American Society of Gene Therapy.

The overall response rate for the 127 patients receiving the high-dose treatment was 10.2 percent, with two complete responders and 11 partial responders. The raw median duration of response was at least 8.7 months, with a Kaplan-Meier estimated median duration of response of 12.1 months. The Kaplan-Meier estimated median survival was 18.0 months. Allovectin-7® was safe and well-tolerated in the high-dose trial. No patients withdrew from the trial because of toxicity or side effects, even with the 200-fold dose increase compared with earlier trials, and a median patient age of 60. Only one patient experienced a Grade 3 adverse event, classified as fatigue, possibly related to Allovectin-7®. One patient experienced a treatment-related Serious Adverse Event for non-specific arthritis.

We assembled a panel of leading melanoma experts with both clinical and regulatory expertise to provide guidance on the Allovectin-7® program. This panel reviewed the safety and efficacy data from our high-dose and low-dose trials. Based on this review, we decided to seek guidance from the U.S. Food and Drug Administration, or FDA, in two formal End-of-Phase 2, or EOP2, meetings on the potential for the results from our high-dose Phase 2 trial to support accelerated approval for marketing Allovectin-7® for use in certain patients with recurrent and/or otherwise treatment-intolerant metastatic melanoma.

We have completed our scheduled EOP2 meetings with the FDA for Allovectin-7®, and have received detailed guidance from those meetings. Based on those meetings, we believe that:

- although Allovectin-7® appears to be safe in patients who received different doses of the product, the safety database would need to be expanded to determine the safety profile required for licensure of the high dose product;
- a meaningful response rate with a reasonable duration of response could be acceptable as the surrogate endpoint for efficacy;
- for efficacy, approval would require at least 25 responders in the Allovectin-7® arm of a new registration trial; and
- no major issues were identified with our commercial lot release or product characterization plans.

As a result, we are designing a registration trial with high-dose Allovectin-7® for certain patients with metastatic melanoma. The trial design would include an interim analysis that could provide the basis for seeking approval before trial completion. We intend to review the design of the new registration trial with the FDA through a Special Protocol Assessment, or SPA, which we intend to complete in the second half of 2004.

Cytomegalovirus

In February 2003, we announced our first independent development program focused on infectious diseases, a DNA-based immunotherapeutic vaccine against cytomegalovirus, or CMV.

CMV infection is a life-long complication for transplant patients, who are tied to the clinic because of frequent testing for viral reactivation, and who must rely on expensive and toxic antiviral therapy. Currently, there is no approved vaccine for CMV.

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 groups such as immunocompromised individuals and women of reproductive age. Congenital CMV infection is the leading infectious cause of deafness, learning disabilities, and mental retardation in children.

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 HCT donors and recipients. We have established working relationships with some of the country's leading transplant centers, which have contributed to trial design and may participate in upcoming CMV vaccine trials. We also have secured intellectual property rights to the selected CMV gene sequences.

Our lead vaccine configuration consists of two plasmid constructs, one encoding the surface antigen, glycoprotein B, and the other a potent T-cell target, phosphoprotein 65, or pp65. These constructs have been tested individually and in combination in our own laboratories. We have verified in preclinical studies that these immunogens elicit potent immune responses, generating both antibodies and T-cell responses.

We announced the initiation of a Phase 1 clinical trial with this CMV immunotherapeutic vaccine in March 2004. Enrollment of the low-dose cohort has now been completed. The initial trial will test the vaccine for safety and immune responses in healthy volunteers, in preparation for planned Phase 2 trials in hematopoietic cell transplant, or HCT, patients.

The Phase 1 multi-center, randomized, open-label clinical trial is evaluating the safety and immunogenicity of Vical's CMV immunotherapeutic vaccine in up to 34 healthy subjects. Each subject receives three doses of the vaccine at either a 1 mg or 5 mg dose. All subjects are followed for six months after the last immunization. Subjects will be monitored primarily for safety. Secondary endpoints in this trial will include the immunogenicity of the vaccine in CMV seronegative and CMV seropositive healthy subjects. We expect to report initial safety and immunogenicity data from the trial at the Interscience Conference on Antimicrobial Agents and Chemotherapy, or ICAAC, beginning October 30, 2004.

Recently we identified a third viable immunogen that can be manufactured and that elicits a potent T-cell response. We are evaluating the benefit of incorporating this third plasmid into a trivalent vaccine to determine how this might further increase the likelihood of success of our CMV immunotherapeutic product, and are exploring the best way to integrate this discovery into our CMV immunotherapeutic program.

In addition, we have received notification of funding of approximately $1 million for research and development related to our CMV vaccine program under two grants from the NIAID. A six-month Phase I SBIR grant of approximately $0.3 million is partially funding preclinical safety and toxicity evaluation of the CMV vaccine in support of our planned Phase 1 human trial. An 18-month research grant of approximately $0.7 million is partially funding novel assays to measure and characterize immune responses in volunteers participating in the trial. The trial and immunological assays will be conducted in collaboration with the Fred Hutchinson Cancer Research Center in Seattle, Washington.

Anthrax

In March 2003, we announced our second independent infectious disease DNA vaccine development program, a next-generation vaccine designed to provide broader protection than any of the other anthrax vaccines either on the market or in development. Where the others target the single anthrax protein called Protective Antigen, or PA, our vaccine also targets the anthrax protein called Lethal Factor, or LF. This second-generation, bivalent, cationic-lipid formulated vaccine is designed to provide broader protection against weaponized forms of anthrax than the currently approved anthrax vaccine.

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, resulting in protective immune responses. Our technology allows us to readily produce detoxified forms of PA and LF that together may provide broader protection against weaponized forms of anthrax 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 can 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;

- DNA vaccines may 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.

Our anthrax vaccine team advanced this program from initial concept to evaluation of effectiveness in a stringent challenge model in less than ten months.

Encouraging results with multiple formulations of the vaccine in mouse and rabbit immunogenicity and challenge models were presented at an American Society for Microbiology, or ASM, meeting in March 2003. 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. Additional rabbit data presented at an ASM meeting in March 2004 suggested production of sterile immunity with our anthrax vaccine.

This research has been supported, in part, by a one-year Small Business Technology Transfer Research, or STTR, grant from the NIAID, as announced in July 2002. In July 2003, we were awarded a three-year, $5.7 million Phase II SBIR grant, subsequently increased to $5.9 million, from the NIAID. The grant is partially funding the development of our DNA vaccine against anthrax.

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

In the second quarter of 2004, the NIAID advised us that it will support a Phase 1 clinical trial of our anthrax vaccine at two NIAID-funded Vaccine and Treatment Evaluation Units. The trial began in July 2004, and will test the vaccine in up to 52 healthy adult volunteers for safety and immune responses. Successful completion of this trial could lead to potential larger trials to support marketing approval under the U.S. Food an Drug Administration's Animal Rule, and could encourage development of other vaccines using the same technology. The Animal Rule was published in 2002 by the FDA 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.

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

NIH Vaccine Research Center

We have an agreement to manufacture HIV, Ebola, West Nile Virus and severe acute respiratory syndrome, or SARS, DNA vaccines for the VRC in our Eastgate manufacturing facility under a subcontract awarded in July 2002 and amended most recently in June 2004 for additional production of one of these vaccines. In November 2003, the VRC began testing an investigational DNA vaccine against Ebola, using clinical supplies provided by us under this agreement, in healthy human volunteers.

In May 2003, we announced a separate subcontract to manufacture bulk DNA vaccines for the VRC, which will be produced in a 500-liter fermenter and related purification equipment being furnished as government equipment, or GFE, in our new Pacific Center Court, or PCC, manufacturing facility. Under this agreement, we are guaranteed minimum annual production orders beginning in 2004, subject to annual extension of the agreement.

In February 2004, we received orders under the two subcontracts totaling approximately $6 million. Production began in the first half of 2004 in our Eastgate manufacturing facility, and expanded in July 2004 to our PCC facility. Additional orders may be placed under both subcontracts. Revenue from these orders is expected to be recognized as product is shipped, providing our other general revenue recognition criteria are met, including no remaining significant performance obligations and collection being reasonably assured. This should substantially increase our contract revenues to more than $10 million in future years, subject to annual renewal. We have begun production as scheduled and we fully intend to meet the VRC's requirements, including vaccines for HIV, Ebola, West Nile Virus and SARS. Under Federal Acquisition Regulations, or FARs, the government has the right to terminate these agreements for convenience.

If we fail to satisfy our contractual obligations to deliver the vaccines ordered by the VRC in the manner required by the agreement, the applicable FARs allow the VRC to cancel the agreement in whole or in part, and we may be required to perform corrective actions, including but not limited to delivering to the VRC any uncompleted or partially completed work, or government

property in our possession, or paying a third-party supplier selected by the VRC to complete any uncompleted work. The performance of these corrective actions could have a material adverse impact on our financial results in the period or periods affected.

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, or CRADA. In January 2004, we secured a license from the CDC for technology used in a similar DNA vaccine, which was shown in independent tests at the CDC to protect horses from West Nile Virus after a single injection.

Recent Events

Shelf Registration. In December 2003, a shelf registration statement that we filed with the SEC was declared effective, which will allow us to issue from time to time an aggregate of up to $50 million, less amounts raised to date, 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. In March 2004, we raised approximately $17.3 million in net proceeds from the sale of approximately 3.4 million shares of our common stock at $5.50 per share in a registered direct offering to a select group of institutional investors pursuant to the shelf registration statement.

Management Changes. Effective June 1, 2004, Martha J. Demski resigned for personal reasons from her position as Vice President, Chief Financial Officer, Treasurer, and Secretary. Until a new Chief Financial Officer is named, Vijay B. Samant, our President and Chief Executive Officer, will serve as Acting Chief Financial Officer. In June 2004, Robin M. Jackman, Ph.D., joined us as Vice President, Business Development. Effective July 30, 2004, Alan E. Dow, J.D., Ph.D., formerly Vice President and General Counsel, resigned.

Additional Merial License. In May 2004, we granted an exclusive license to Merial Ltd., or Merial, a joint venture between Merck & Co., Inc. and Aventis, S.A., and a world leader in animal health products, for use of our patented DNA delivery technology in a vaccine to protect certain companion animals against a particular type of cancer. Under the new agreement, Merial is responsible for research and development activities. If Merial is successful in developingand marketing this product, milestone payments and royalties on sales of the resulting product would be due to us. In the second quarter of 2004, $250,000 of revenue was recognized relating to this agreement. A separate agreement entered into in 1995 with Merial remains in place covering the use of our patented DNA delivery technology in vaccines to prevent certain infectious diseases in livestock and companion animals.

Gencell Milestone. In June 2004, we earned a milestone under our contract with Gencell. This resulted in the recognition of $1.2 million in revenue under our license agreement for certain cardiovascular applications of our patented DNA delivery technology. Under the agreement, established in June 2000, Gencell is developing plasmid-based delivery of Fibroblast Growth Factor 1, or FGF-1, as a potential treatment for Peripheral Arterial Disease, or PAD, and other indications characterized by blood vessel blockage. Published interim results from an open-label Phase 1 clinical trial indicated that the FGF-1 plasmid-based therapeutic was well tolerated, with no serious adverse events considered related to the treatment. Interim results reported in this same publication demonstrated reduction in pain and evidence of newly visible blood vessels three months after treatment. Gencell is currently conducting double-blind, placebo-controlled Phase 2 trials in the United States and Europe.

Change in Independent Public Accountants. In July 2004, we engaged Deloitte & Touche LLP as our independent public accountants for fiscal periods subsequent to the second quarter of 2004, replacing KPMG LLP, our current accounting firm.

Patents. During the first quarter of 2004, we were issued U.S. Patent No. 6,670,332, covering a class of cationic lipids useful in gene delivery applications, U.S. Patent No. 6,673,776, covering novel methods of using DNA to deliver biologically active proteins, U.S. Patent No. 6,696,424 covering a class of cationic lipids useful in gene delivery applications, U.S. Patent No. 6,710,035, covering administration of plasmid DNA encoding pathogen-specific antigens to generate immune responses, with or without adjuvants, and U.S. Patent No. 6,706,694, covering delivery to the heart of DNA encoding biologically active proteins. In addition, in the first quarter of 2004, we were granted European Patent EP0795015 specifically claiming the composition, manufacture and application of gene-based cancer treatments delivering the cytokine interleukin-2, or IL-2. In August 2004, we were granted European Patent EP1165140 claiming compositions and methods for gene-based vaccination using immunogens or immunogen-encoding polynucleotides plus the Vaxfectin™ cationic lipid/co-lipid formulation.

Also during the first quarter of 2004, European Patent 0737750, issued in 2003, was opposed by two companies, and European Patent 1032428, also issued in 2003, was opposed by three companies. We intend to respond to the oppositions in a timely manner.

We are the assignee of 32 issued U.S. and foreign patents having remaining lives of 5 to 15 years, which are listed below:

Patent No.	Description
U.S. PATENTS	
6,710,035	Generation of an immune response to a pathogen
6,706,694	Expression of exogenous polynucleotide sequences in a vertebrate
6,696,424	Cytofectin dimers and methods of use thereof
6,673,776	Expression of exogenous polynucleotide sequences in a vertebrate, mammal, fish, bird or human
6,670,332	Complex cationic lipids having quaternary nitrogens therein
6,586,409	Adjuvant compositions and methods for enhancing immune responses to polynucleotide-based vaccines
6,413,942	Methods of delivering a physiologically active polypeptide to a mammal
6,399,588	Cancer treatment method utilizing plasmids suitable for IL-2 expression
6,228,844	Stimulating vascular growth by administration of DNA sequences encoding VEGF
6,214,804	Induction of a protective immune response in a mammal by injecting a DNA sequence
6,147,055	Cancer treatment method utilizing plasmids suitable for IL-2 expression
6,022,874	Piperazine based cytofectins
5,994,317	Quaternary cytofectins
5,910,488	Plasmids suitable for gene therapy
5,891,718	Tetracycline inducible/repressible systems
5,861,397	Piperazine based cytofectins
5,707,812	Purification of plasmid DNA during column chromatography
5,703,055	Generation of antibodies through lipid mediated DNA delivery
5,693,622	Expression of exogenous polynucleotide sequences cardiac muscle of a mammal
5,641,665	Plasmids suitable for IL-2 expression
5,589,466	Induction of a protective immune response in a mammal by injecting a DNA sequence
5,580,859	Delivery of exogenous DNA sequences in a mammal
5,576,196	Process for reducing RNA concentration in a mixture of biological material using diatomaceous earth
5,561,064	Production of pharmaceutical-grade plasmid DNA
5,459,127	Cationic lipids for intracellular delivery of biologically active molecules
5,264,618	Cationic lipids for intracellular delivery of biologically active molecules
FOREIGN PATENTS	
EP0523189	Cationic lipids for intracellular delivery of biologically active molecules
EP0742820	Production of pharmaceutical-grade plasmid DNA
EP0795015	Plasmids suitable for IL-2 expression
EP0802975	Process for reducing RNA concentration in a mixture of biological material using diatomaceous earth
EP0902780	Quaternary cytofectins
EP1165140	Adjuvant compositions for enhancing immune responses to polynucleotide-based vaccines
JP2538474	Cationic lipids for intracellular delivery of biologically active molecules

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 ten years. We also capitalize certain costs related to patent applications which have alternative future use in multiple research and development projects. 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. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to the future net cash flows expected to be generated by the asset. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the assets exceeds the fair value of the assets. If assets are to be disposed of, they are reported at the lower of the carrying amount or fair value less costs to sell. 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. Clinical trial expense was $0.2 million and $0.1 million for the three-month periods ended June 30, 2004 and 2003, respectively, and $0.3 million and $0.3 million for the six-month periods ended June 30, 2004 and 2003, respectively. No material revisions to the estimates were made in the periods presented.

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 of approximately $0.6 million at June 30, 2004, 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. No material adjustments were made to the accruals in the periods presented.

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, delivery has occurred or 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 agreed-upon events representing the achievement of substantive steps in the development process are achieved, or the passage of time, and where the amount of the milestone payment approximates the value of achieving the milestone, and collection of payment is reasonably assured. Royalty revenue is recognized as the cash is received from the licensee.

Revenue under research and development contracts and grants, and manufacturing and regulatory service contracts, except for fixed-price contracts, is recognized as the research and development expenses for services performed are incurred, 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. Under these contracts, revenue is recognized when the product is shipped, provided all of the other revenue recognition criteria referred to above are met. Any deferred manufacturing costs are recognized as expense at the time the revenue is recognized.

Recent Accounting Pronouncements

In March 2004, the Financial Accounting Standards Board's Emerging Issues Task Force ("EITF") reached a consensus on EITF 03-01, *The Meaning of Other-Than-Temporary Impairment and Its Application to Certain Investments*. EITF 03-01 provides guidance regarding disclosures about unrealized losses on available-for-sale debt and equity securities accounted for under Statement of Financial Accounting Standard No. 115, *Accounting for Certain Investments in Debt and Equity Securities*. The guidance for evaluating whether an investment is other-than-temporarily impaired should be applied in reporting periods beginning after June 15, 2004. This EITF did not have a material effect on our financial position or results of operations.

Results of Operations

Three months ended June 30, 2004 and 2003

We recorded revenues of $5.7 million for the three months ended June 30, 2004, compared with revenues of $0.6 million for the three months ended June 30, 2003. License and royalty revenue for the three months ended June 30, 2004, was $1.9 million compared with $0.5 million for the same period in the prior year. License and royalty revenue for both periods included recognition of deferred license fees from Corautus and royalty revenue from Invitrogen. License and royalty revenue for the three months ended June 30, 2004, was higher than for the corresponding period in the prior year due to revenue recognized from a new license with Merial for cancer in companion animals, and the recognition of a $1.2 million milestone from Gencell. Contract revenue was $3.8 million for the

three months ended June 30, 2004, compared with $0.1 million for the same period in the prior year. Contract revenue for the three months ended June 30, 2004, was higher than for the corresponding period in the prior year due to contract manufacturing shipments to VRC for HIV, Ebola, West Nile Virus and SARS, and revenue from CMV grants. Contract revenue of $0.1 million for the three months ended June 30, 2003, was from the NIH.

Our total operating expenses for the three months ended June 30, 2004, were $11.2 million compared with $8.1 million for the same period in the prior year. Research and development expenses increased to $8.7 million for the three months ended June 30, 2004, from $6.3 million for the same period in 2003. This increase in research and development expenses was due to expensing contract manufacturing costs which were deferred until the related revenue was recognized upon shipment of the product, and to increases in personnel-related costs and facilities costs. The increase in personnel-related costs is due to fluctuations in average headcount, salary increases, and higher insurance costs. The increased facilities costs included increased depreciation, utilities, and maintenance and repair costs as a result of the increased capital purchases and increased occupancy of the PCC facility. These increases were partially offset by lower intellectual property expenses.

General and administrative expenses were $2.5 million for the three months ended June 30, 2004, and $1.8 million for the same period in 2003. The increase in general and administrative expenses for the three months ended June 30, 2004, compared with the same period in the prior year, was due to higher personnel-related costs, including severance costs, salary increases, and higher insurance costs.

Investment income was $0.3 million for the three months ended June 30, 2004, compared with $0.6 million, including realized gains on sales of investments of $0.1 million, for the same period in the prior year. The decrease in investment income in 2004 compared with 2003 was due to lower rates of return and lower investment balances, and approximately $2,000 in realized net gains on sales of investments in 2004

Our net loss was $5.3 million, or $0.23 per common share, for the three months ended June 30, 2004, compared with a net loss of $6.9 million, or $0.34 per common share, for the same period in the prior year. Per share amounts for the three months ended June 30, 2004, reflected the increased weighted average numbers of shares outstanding for the period as a result of the registered direct offering of approximately 3.4 million shares of stock during March 2004.

Six months ended June 30, 2004 and 2003

We recorded revenues of $6.7 million for the six months ended June 30, 2004, compared with $1.5 million for the corresponding period in the prior year. License and royalty revenue for the six months ended June 30, 2004, was $2.5 million compared with $1.0 million for the corresponding period in the prior year. License and royalty revenue for both periods included recognition of deferred license fees from Corautus and royalty revenue from Invitrogen. License and royalty revenue for the six months ended June 30, 2004, was higher than for the corresponding period in the prior year due to revenue recognized from a new license with Merial for cancer in companion animals, and the recognition of a $1.2 million milestone from Gencell. Contract revenue was $4.1 million for the six months ended June 30, 2004, compared with $0.5 million for the corresponding period in the prior year. Contract revenue for the six months ended June 30, 2004, was higher than for the corresponding period in the prior year due to contract manufacturing shipments to VRC for HIV, Ebola, West Nile Virus and SARS, and revenue from CMV grants. Contract revenue of $0.5 million for the six months ended June 30, 2003, was from the NIH, the IAVI, and the Office of Naval Research, or ONR.

Our total operating expenses for the six months ended June 30, 2004, were $21.3 million compared with $16.7 million for the same period in the prior year. Operating expenses for the six months ended June 30, 2003, included a write-down of investment of $0.5 million, as more fully explained below.

Research and development expenses increased to $16.8 million for the six months ended June 30, 2004, from $12.9 million for the same period in 2003.This increase in research and development expenses was due to the expensing of contract manufacturing costs which were deferred until the related revenue was recognized upon shipment of the product, a $1.5 million accrual for settlement of the WARF litigation and to increases in personnel-related costs and facilities costs. The increase in personnel-related costs was due to fluctuations in average headcount, salary increases, and higher insurance costs. The increased facilities costs included increased depreciation, utilities, and maintenance and repair costs as a result of the increased capital purchases and increased occupancy of the PCC facility. These increases were partially offset by lower intellectual property expenses.

General and administrative expenses were $4.5 million for the six months ended June 30, 2004, and $3.3 million for the same period in 2003. The increase in general and administrative expenses for the six months ended June 30, 2004, compared with the same period in the prior year, was due to higher personnel-related costs and increased legal fees associated with the WARF litigation. The higher personnel-related costs included severance costs, salary increases, and higher insurance costs.

Operating expenses for the six months ended June 30, 2003, also included a write-down of investment of $0.5 million. In February 2003, GenStar Therapeutics Corporation, a public company listed on AMEX, and VGI, a private company in which we received shares of preferred stock when we licensed our technology to VGI, completed their previously announced merger and created a new entity, known as Corautus. Subsequent to the merger, the shares of VGI were exchanged for common stock of Corautus, which is listed on AMEX. The value of our shares as measured by the quoted price on AMEX on March 31, 2003, was $0.3 million compared with our recorded value of $0.8 million. Based on this market information, we wrote down our investment to $0.3 million as of that date.

Investment income was $0.6 million for the six months ended June 30, 2004, compared with $1.4 million, including realized gains on sales of investments of $0.2 million, for the same period in the prior year. The decrease in investment income in 2004 compared with 2003 is due to lower rates of return, lower investment balances, and no realized net gains on sales of investments in 2004. Some of our investments currently are yielding higher returns than we could expect when reinvesting the proceeds upon sale or maturity. Thus, our interest yields are expected to be lower in the full year 2004 than in 2003.

Our net loss was $14.4 million, or $0.66 per common share, for the six months ended June 30, 2004, compared with a net loss of $13.9 million, or $0.69 per common share, for the same period in the prior year. Per share amounts for the six months ended June 30, 2004, reflected the increased weighted average numbers of shares outstanding for the period as a result of the registered direct offering of approximately 3.4 million shares of stock during March 2004. We expect to incur losses throughout the remainder of 2004 and we expect our net loss for the year ending December 31, 2004, to be between $26 million and $29 million.

Other Matters

Since inception, we estimate that we have spent approximately $199 million on research and development. From inception, we have spent about $57 million in our Allovectin-7® program, for which we elected not to proceed with a Biologics License Application, or BLA, filing for a low dose based on low-dose clinical trial results. Based on EOP2 meetings with the FDA for the current high-dose Phase 2 trial in melanoma, we have determined that an additional trial would be required before proceeding with a BLA filing for high-dose Allovectin-7®. Future trials would add to the time and cost of development. From inception, we have spent approximately $18 million in our Leuvectin® program, for which development was discontinued in September 2002 due to other priorities. From inception, we have spent approximately $4 million on our malaria vaccine program.

Additionally, we are in the early stages of clinical development of vaccine candidates for CMV and anthrax. These infectious disease candidates will require significant costs to advance through the development stages. From inception, we have spent approximately $18 million on our CMV program and approximately $12 million on our anthrax program. These expenses will be partially covered by revenues received under U.S. government grants of approximately $1 million for our CMV program and $6 million for our anthrax program. See "Business Summary—Allovectin-7®" for a more detailed explanation of the status of Allovectin-7®. See also "Business Summary—Cytomegalovirus" and "—Anthrax" for more detailed discussions of our CMV and anthrax vaccine programs.

Research and development costs incurred by major program, as well as other expenses for research and development and technology enhancements, for the three-month and six-month periods ended June 30, 2004 and 2003, were as follows (in millions):

	Three months ended June 30,		Six months ended June 30,	
	2004	2003	2004	2003
Allovectin-7®	$ 1.0	$ 1.1	$ 3.1	$ 2.8
CMV	$ 2.5	$ 1.7	$ 4.7	$ 3.1
Anthrax	$ 0.5	$ 2.0	$ 2.0	$ 3.5
Leuvectin®	$ 0.0	$ 0.1	$ 0.0	$ 0.2
Malaria	$ 0.0	$ 0.1	$ 0.0	$ 0.1
Other research and development, and technology enhancements	$ 4.7	$ 1.3	$ 7.0	$ 3.2
Total R&D spending	$ 8.7	$ 6.3	$ 16.8	$ 12.9

We have several other product candidates in the research stage. It can take many years from the initial decision to screen product candidates, perform preclinical and safety studies, and perform clinical trials leading up to possible FDA approval of a product. The outcome of the research is unknown until each stage of the testing is completed, up through and including the registration clinical trials. Accordingly, we are unable to predict which potential product candidates we may proceed with, the time and cost to complete development, and ultimately whether we will have a product approved by the FDA.

Liquidity and Capital Resources

Since our inception, we have financed our operations primarily through private placements of preferred and common stock, five public offerings of common stock, and revenues from collaborative agreements. Cash, cash equivalents and marketable securities totaled approximately $85.5 million at June 30, 2004, compared with $84.5 million at December 31, 2003. In December 2003, a shelf registration statement that we filed with the SEC was declared effective, which will allow us to issue from time to time an aggregate of up to $50 million, less amounts raised to date, 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.

In March 2004, we raised approximately $17.3 million in net proceeds from the sale of approximately 3.4 million shares of Vical common stock at $5.50 per share in a registered direct offering to a select group of institutional investors. All of the shares of common stock were offered by us pursuant to the effective shelf registration statement previously filed with the SEC.

Cash used in operating activities increased to $13.5 million for the six months ended June 30, 2004, compared with $10.4 million for the same period in 2003. The increase in cash used in operating activities for the six months ended June 30, 2004, compared with same period in the prior year, is due to the company receiving cash prepayments in the second half of 2003 for which product shipments were made in 2004, thus not contributing significantly to cashflow in 2004. Also, receivables increased due to accruing the license and milestone amounts due from Merial and Gencell, which were subsequently received in July 2004, plus increases in receivables from contract manufacturing shipments. These increases were partially offset by a decrease in deferred contract costs that were recognized as expense when the products shipped in 2004 but for which the cash expenditures were made in 2003. An increase in the outstanding balance of accounts payable in 2004 also contributed to partially offset the increased cash used in operating activities. Net loss for the six-month period ended June 30, 2003, also included a noncash write-down of our investment in Corautus, as more fully explained under "Results of Operations" above.

Cash used in investing activities was $5.5 million for the six months ended June 30, 2004, compared with $7.7 million for the same period in 2003. Capital expenditures for the six months ended June 30, 2004, decreased $1.2 million from the same period in the prior year, and are expected to be lower for the full year 2004 compared with 2003 as the purchases for, and improvements to, our new facility near completion. Additionally, spending for licensed technology and patents decreased from the same period in the prior year.

Cash provided from financing activities for the six months ended June 30, 2004, was $16.6 million compared with cash used in financing activities of $1.1 million for the same period in 2003. Net proceeds from the registered direct stock offering in the first quarter of 2004 provided $17.3 million of cash. Reimbursements under our capital lease line provided $2.1 million of cash for the six months ended June 30, 2004. Payments on capital lease obligations for the six months ended June 30, 2004, increased by $1.3 million, compared with the same period in 2003, due to greater capital lease obligations.

In March 2004, we entered into a new lease line with the leasing division of a bank to provide up to $8.5 million of financing for tenant improvements and equipment, with drawdowns available through December 15, 2004. At June 30, 2004, we had used $2.1 million of this lease line, and $2.2 million of cash equivalents and marketable securities were pledged as collateral for this lease line and are included as restricted in the balance sheet. At June 30, 2004, restricted cash equivalents and marketable securities also included $2.5 million of securities pledged as collateral for a standby letter of credit. We intend to pursue additional lease financing at the expiration of the drawdown period under this agreement. In the event we are unable to obtain additional financing, we will be required to use our existing cash resources to finance additional purchases.

In addition to our lease of PCC, which terminates in 2017, we also hold leases, which were scheduled to terminate in late 2004, at three facilities for manufacturing, research and office space. Effective June 30, 2004, we renewed our lease for five years on approximately 10,000 square feet of research space. In July 2004, we renewed our lease for one year on approximately 15,000 square feet of manufacturing space in one of these three facilities. Total cumulative payments under these renewals will be approximately $2.4 million.

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 7 of the Notes to Financial Statements included in our Annual Report on Form 10-K for the year ended December 31, 2003. We also have other contractual obligations as described in such Annual Report under the heading "Management's Discussion and Analysis of Financial Condition and Results of Operations—Contractual Obligations."

Additional Business Risks

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

None of our products has been approved for sale, and we have only three product candidates in clinical trials. If we do not develop commercially successful products, we may be forced to curtail or cease operations.

All of our 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, our only product candidates currently in clinical trials are high-dose Allovectin-7® for metastatic melanoma, which is currently in Phase 2 clinical testing, and our vaccines for CMV and anthrax, which are currently in Phase 1 clinical testing. We may not be able to establish with the FDA, by the second half of 2004, if at all, the design of a high-dose Allovectin-7® registration trial adequate to support clinical and regulatory requirements for approval of Allovectin-7®. We may not have the resources to conduct such a trial independently, if at all. Results of such a registration trial may not demonstrate sufficient efficacy to support approval before trial completion, if at all. We may not conduct additional CMV vaccine trials, leading transplant centers may not participate in our trials, and our CMV vaccine may not elicit sufficient immune responses in humans. In addition, our continued development of the anthrax program is dependent on additional government funding, which may not be available at adequate levels, if at all. Our anthrax vaccine may not elicit sufficient antibody responses in humans.

Additionally, we are in preclinical stages of research and development with product candidates including a solid tumor application of our in-licensed electroporation technology and others. These product candidates will require significant costs to advance through the development stages. If such product candidates are advanced through clinical trials, the results of such trials may not support 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.

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 futureFor example, we have entered into an agreement to manufacture bulk DNA vaccines for the VRC. In connection with this agreement, the VRC has provided a 500-liter fermenter and related purification equipment being furnished as GFE in our PCC manufacturing facility. Our business is partially dependent on the continued performance by these government agencies of their responsibilities under these agreements, including adequate continued funding of the agencies and their programs. We have no control over the resources and funding that government agencies may devote to these agreements, which may be subject to annual renewal and which generally may be terminated by the government agencies at any time. If we fail to satisfy our contractual obligations to deliver the vaccines ordered by the VRC in the manner required by the agreement, the applicable Federal Acquisition Regulations allow the VRC to cancel the agreement in whole or in part, and we may be required to perform corrective actions, including but not limited to delivering to the VRC any uncompleted or partially completed work, or GFE or other government property in our possession, or paying a third-party supplier selected by the VRC to complete any uncompleted work. The performance of these corrective actions could have a material adverse impact on our financial results in the period or periods affected. Government agencies may fail to perform their responsibilities under these agreements, which may cause them to be terminated by the government agencies.

In addition, we may fail to perform our responsibilities under these agreements.We may also be unsuccessful in entering into additional agreements with government agencies.

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

We apply for and have received funding from government agencies under SBIR grants. Eligibility of public companies to receive SBIR grants is under review by the Small Business Administration and may be changed in the future, and there can be no assurance that additional funding from this source will be available.

We have a history of net losses. We expect to continue to incur net losses and we may not achieve or maintain profitability.

To date, we have not sold or received approval to sell any products. We do not expect to sell any products for the next several years. Our net losses were approximately $24.4 million, $27.9 million and $9.2 million for 2003, 2002 and 2001, respectively. As of June 30, 2004, we have incurred cumulative net losses totaling approximately $129.0 million. Moreover, we expect that our net losses will continue and may increase for the foreseeable future. For 2004, we have forecast a net loss of between $26 million and $29 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, we currently have on file an effective shelf registration statement with the SEC seeking to register an aggregate of up to $50 million of common stock or preferred stock, less amounts raised to date. In March 2004, we raised approximately $17.3 million in net proceeds pursuant to this registration statement from the sale of approximately 3.4 million shares of Vical common stock at $5.50 per share in a registered direct offering to a select group of institutional investors. However, we may not be able to raise additional funds on favorable terms, or at all. In March 2004, we signed a leasing agreement with the leasing division of a bank to provide us with up to $8.5 million of financing for tenant improvements and equipment with drawdowns available through December 15, 2004. The financial covenants of the agreement require us to maintain cash collateral equal to the amount of outstanding borrowings. The bank has a secured interest in the equipment financed under this agreement. Additionally, if unrestricted cash and marketable securities, as defined, are less than $45 million, we would be required to maintain a letter of credit issued by another financial institution equal to the amount of outstanding borrowings at that time. In the event this occurred, we expect that our restricted cash deposits securing the lease would be returned to us, but we would have to make restricted cash deposits with another financial institution in order to obtain a letter of credit. 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.

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

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 therapeutic and vaccine products,

- The FDA has provided only limited guidance on how many subjects it will require to be enrolled in clinical trials to establish the safety and efficacy of gene-based products, and

- Current regulations and guidances are subject to substantial review by various governmental agencies.

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

- Impose costly procedures on our activities,

- Diminish any competitive advantages that we attain, or

- Negatively affect our results of operations and cash flows.

We 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 confidential commercial information, if implemented, may result in loss of advantage of competitive secrets. In March 2004, the NIH Office of Biotechnology Activities and the FDA Center for Biologics Evaluation and Research launched the jointly developed Genetic Modification Clinical Research Information System, or GeMCRIS, an Internet-based database of human gene transfer trials. In its current form, GeMCRIS enables individuals to easily view information on particular characteristics of clinical gene transfer trials, and includes special security features to protect patient privacy and confidential commercial information.

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.

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

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

We are the assignee of 32 issued U.S. and foreign patents. We are also co-assignee, together with Pasteur Mérieux Sérums et Vaccins, subsequently Aventis Pasteur, and the University of Texas Health Science Center of two issued U.S. patents related to vaccines against Lyme disease. In addition, we have been granted a Japanese patent related to our core gene delivery technology that was maintained after an opposition proceeding but is subject to requests for four TFIs, a patent in Europe related to our core gene delivery technology that was revoked as a result of an opposition is currently under appeal, a patent granted in Europe covering a range of applications of our core DNA delivery technology using cationic lipid formulations has been opposed, and a patent granted in Europe covering gene-based, extra-tumoral delivery of any cytokine for the treatment of cancer has also been opposed.

We are also prosecuting 66 pending patent applications in the U.S. and in foreign countries that cover various aspects of our proprietary technology, not including patent applications for which we are a co-assignee and that are being prosecuted by our partners. Five of the pending foreign patent applications are international patent applications under the PCT, each of which preserves our right to pursue national-phase patent applications in a large number of foreign countries. In addition, we are co-assignee, together with Merck, of foreign patent applications related to DNA-based vaccines against influenza that are being prosecuted by Merck.

We may not receive any patents from our current patent applications. 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 European patent that has been issued and revoked as a result of an opposition in Europe, and a Japanese patent that was originally revoked but subsequently reinstated in Japan. Furthermore, two European patents issued in 2003, one covering a range of applications of our core DNA delivery technology, including cationic lipid-formulated, gene-based pharmaceuticals, and the second patent broadly claiming gene-based, extra-tumoral delivery of any cytokine for the treatment of cancer, have both been opposed. In addition, our core DNA delivery technology is covered by a patent application that was allowed and then withdrawn as a result of a protest procedure in Canada. We are currently appealing the European revocation, have responded to TFI requests in Japan, are preparing responses to the two new European oppositions, and are continuing prosecution of the patent application that was protested 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 involved 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 which resulted in the maintenance of the patent. Based on our arguments and supporting evidence in that response, the JPO decided to reinstate the patent in July 2003. We also received notice that four TFI requests against this patent were filed in the JPO by two companies. We filed responses to the TFI requests in a timely manner and are awaiting further action by the JPO.

A European patent issued in 2003, 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. This patent has been opposed by two companies. We intend to respond to the oppositions in a timely manner.

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

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, and opposed in December 2002. We filed a rebuttal response to the opposition in a timely manner. After careful analysis of the intellectual property, we maintained our rights to patents and applications in the United States and returned non-U.S. rights to the University of Michigan.

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. However, due to the reasons noted above, we may not be successful in hiring or retaining qualified personnel.

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

The commercial manufacturing of vaccines and other biological products is a time-consuming and complex process, which must be performed in compliance with the FDA's current Good Manufacturing Practices, or cGMP, regulations. We may not be able to comply with the cGMP regulations, and our manufacturing process may be subject to delays, disruptions or quality control problems. In addition, we 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 cGMP 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, have become effective and may complicate the process by which clinical trials may be initiated, however the specific nature and degree of impact are not yet known.

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

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

Our research and development processes involve the controlled storage, use and disposal of hazardous materials, biological hazardous materials and minor amounts of low-level radioactive compounds. Our hazardous materials include certain compressed gases, flammable liquids, acids and bases, and other toxic compounds. We are subject to federal, state and local regulations governing the use, manufacture, storage, handling and disposal of materials and waste products. Although we believe that our safety procedures for handling and disposing of these hazardous materials comply with the standards prescribed by law and regulation, the risk of accidental contamination or injury from hazardous materials cannot be completely eliminated. In the event of an accident, we could be held liable for any damages that result. We have insurance that covers our use of hazardous materials with the following coverage limits: up to $25,000 per occurrence for losses related to the release of bio-contaminants, $1 million per occurrence for losses from refrigerant contamination and $25,000 per occurrence for losses from radioactive contamination. Any liability could exceed the limits or fall outside the coverage of our insurance. We could 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 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 pay for them.

The market price of our common stock, like that of many other life sciences companies, has been and is likely to continue to be highly volatile. During the three-year period ended June 30, 2004, our stock price has ranged from $2.12 to $14.10. 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 be the target of this litigation. Securities litigation could result in substantial costs and divert our management's attention and resources, and could seriously harm our business.

The ability of our investors to seek remedies against Arthur Andersen LLP, who audited some of the financial statements included in our Annual Reports on Form 10-K for the years ended December 31, 2003, 2002 and 2001, may be significantly limited.

Our annual financial statements for the year ended December 31, 2001, which were included in our Annual Reports on Form 10-K for the years ended December 31, 2003, 2002 and 2001, 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 December 2003, a shelf registration statement that we filed with the SEC was declared effective, which will allow us to issue from time to time an aggregate of up to $50 million of common stock or preferred stock, of which to date we have issued approximately $18.6 million of common stock, which yielded approximately $17.3 million in net proceeds. 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 classified as available-for-sale securities.

Marketable securities also include 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 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.

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 $0.6 million lower than the reported fair value of our non-equity investments at June 30, 2004. At June 30, 2004, our unrealized gain on marketable securities was $0.8 million, including an unrealized gain of $0.9 million on our investment in Corautus. We expect lower investment income in the full year 2004 compared with 2003 due to lower investment balances.

The fair market value of floating interest rate debt is subject to interest rate risk. Generally, the fair market value of floating interest rate debt will vary as interest rates increase or decrease. Based on our market risk-sensitive instruments outstanding at June 30, 2004, and December 31, 2003, 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 principal executive officer and acting principal 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 principal executive officer and acting principal financial officer concluded that our disclosure controls and procedures were effective as of the end of the period covered by this report. There has been no change in our internal control over financial reporting during the three months ended June 30, 2004, that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

On July 29, 2003, the 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 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. In the first quarter of 2004, we accrued $1.5 million for settlement of this matter. In the second quarter of 2004, we entered into a settlement agreement with the WARF and made an amendment to the license agreement resolving all outstanding claims. Pursuant to the settlement agreement, the lawsuit was dismissed.

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 application 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 also received notice that four TFI requests against this patent were filed in the JPO by two companies. We filed responses to the TFI requests in a timely manner and are awaiting further action by the JPO.

A European patent issued in 2003 covering 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. This patent has been opposed by two companies. We intend to respond to the oppositions in a timely manner.

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

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, and opposed in December 2002. We filed a rebuttal response to the opposition in a timely manner. After careful analysis of the intellectual property, we maintained our rights to patents and applications in the United States and returned non-U.S. rights to the University of Michigan.

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 which, individually or in the aggregate, is deemed to be material to our financial condition.

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

On May 10, 2004, we held our Annual Meeting of Stockholders. As of March 15, 2004, the record date for the meeting, 20,095,244 shares of our common stock were outstanding and entitled to vote. The following actions were taken at the meeting:

(a) The following Class III directors were elected:

Robert H. Campbell—16,733,767 shares voted in favor of the nominee; 1,149,045 withheld their vote.

Gary A. Lyons—16,733,103 shares voted in favor of the nominee; 1,149,709 withheld their vote.

Our Class I directors, Vijay B. Samant and Robert C. Merton, continue in office until the 2005 Annual Meeting. Our Class II directors, R. Gordon Douglas and M. Blake Ingle, Ph.D., continue in office until the 2006 Annual Meeting.

(b) The amendment and restatement of the Stock Incentive Plan of Vical Incorporated was approved. The number of shares of common stock reserved for issuance under the plan was increased to 5,700,000 from 5,200,000, subject to adjustment as provided in the plan. Shares voted for the proposal were 6,592,232, with 2,922,937 shares voted against the proposal and 44,314 shares abstained.

(c) The selection of KPMG LLP as the Company's independent public accountants for the year ending December 31, 2004, was ratified. Shares voted in favor of the proposal were 17,620,782, with 214,786 shares voted against the proposal and 47,244 shares abstained. In July 2004, the Company engaged Deloitte & Touche LLP as its independent public accountants for fiscal periods subsequent to the second quarter of 2004, replacing KPMG LLP.

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.
10.19(a)	Amendment dated November 3, 1997, to Research Collaboration and License Agreement dated May 31, 1991, between the Company and Merck & Co., Inc.
10.36(a)	Amendment dated May 20, 2004, to License Agreement dated January 1, 1991, between the Company and the Wisconsin Alumni Research Foundation.
31.1	Certification of Vijay B. Samant, Chief Executive Officer and Acting Chief Financial Officer, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of Vijay B. Samant, Chief Executive Officer and Acting 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 Annual Report on Form 10-K for the fiscal year ended December 31, 1994.

(a) 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 May 6, 2004, we filed a Form 8-K to disclose our press release of financial results for the three months and ended March 31, 2004.

SIGNATURES

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

Vical Incorporated

Date: August 9, 2004	By:	/s/ VIJAY B. SAMANT
		President and Chief Executive Officer, and Acting Chief Financial Officer (on behalf of the registrant and as the registrant’s Principal Financial and Accounting Officer)

Exhibit 10.19

[ ] = Confidential Treatment Requested Under 17 C.F.R. §§ 200.80(b)(4) and 240.24b-2; Text Omitted and Filed Separately with the Securities and Exchange Commission

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

This Third Amendment dated this 3rd day of November, 1997 between Merck & Co., Inc. ("Merck") and Vical Incorporated ("Vical").

WHEREAS on May 31, 1991 Merck and Vical entered into a Research Collaboration and License Agreement, as amended on April 27, 1994 and December 13, 1995 (the "Agreement") under which 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 (all as defined therein) upon the terms and conditions set forth therein; and

WHEREAS the parties wish to further amend the Agreement to provide that Merck shall have rights to vaccine products for the treatment of patients infected with Human Immunodeficiency Virus and Hepatitis B Virus upon the terms and conditions of the Agreement as amended hereby;

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

1. This Third Amendment shall be effective as of the date set forth above.

2. Article 1.3 of the Agreement is amended by adding at the end thereof the following sentence:

"LICENSED PRODUCT shall also mean TREATMENT VACCINE(S)."

3. The Agreement is amended by adding to Article 1 a new section as follows:

1.14 TREATMENT VACCINE(S) shall mean 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 and (ii) Hepatitis B Virus ("HBV") and/or diseases caused by infection with HBV in humans, which utilizes the Technology or technology which is developed by VICAL during and as a result of the RESEARCH COLLABORATION PROGRAM.

4. The Agreement is amended by adding Article 8.3(g) as follows:

8.3(g) Merck shall make the non-refundable research milestone payments provided for in Schedule E to the Third Amendment for the first TREATMENT VACCINE for HIV-1 and/or diseases caused by infection with HIV-1 in humans and the first TREATMENT VACCINE for HBV and/or diseases caused by infection with HBV in humans.

5. Article 8.4 is hereby amended to be replaced in its entirely as follows:

8.4(a) Except as set forth in Article 8.4(b) with respect to royalties for TREATMENT VACCINE(S), in consideration of the license granted in Article 3, MERCK shall pay royalties to VICAL in each calendar year in the amount of **[…***…]** of NET SALES by MERCK, its AFFILIATES or permitted sublicensees of each LICENSED PRODUCT which is covered by VALID PATENT RIGHTS.

8.4(b) In consideration of the license granted in Article 3 for TREATMENT VACCINE(S), royalties shall be payable to VICAL in each calendar year as follows:

8.4(b)(i) for sales outside the United States, its territories and possessions by MERCK, its AFFILIATES or permitted sublicensees for each TREATMENT VACCINE:

[ ] = Confidential Treatment Requested; Text Filed Separately with the Securities and Exchange Commission

(A) 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 NET SALES less than or equal to **[…***…]**	**[…***…]** of NET SALES
For annual NET SALES greater than **[…***…]**,	**[…***…]** of NET SALES for that portion of NET SALES greater than **[…***…]**

(B) the sale of which is not covered by VALID PATENT RIGHTS in the country of sale, in the amount of **[…***…]** of NET SALES for a period of five (5) years from the date of first commercial sale in such country. MERCK shall pay royalties to VICAL pursuant to this section 8.4(b)(i)(B) and such royalties shall be in lieu of patent royalties and shall not be additive where patents later issue in a country.

8.4(b)(ii) For sales in the United States, its territories and possessions, whether or not covered by a claim of VALID PATENT RIGHTS:

For annual NET SALES less than or equal to **[…***…]**	**[…***…]**
For annual NET SALES greater than **[…***…]** and less than or equal to **[…***…]**, for that portion of NET SALES greater than **[…***…]**	**[…***…]**
For annual NET SALES greater than **[…***…]** or equal to **[…***…]**, for that portion of NET SALES greater than **[…***…]**	**[…***…]**
For annual NET SALES greater than **[…***…]**,	**[…***…]**

for that portion of NET SALES greater than **[…***…]**

(A) In the event the sale of TREATMENT VACCINE is covered by VALID PATENT RIGHTS in the country of sale, the royalty set forth in 8.4(b)(ii) shall be payable for the life of such VALID PATENT RIGHTS.

[ ] = Confidential Treatment Requested; Text Filed Separately with the Securities and Exchange Commission

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(B) In the event the sale of TREATMENT VACCINE are not covered by VALID PATENT RIGHTS in the country of sale, royalties shall begin on the date of first commercial sale and shall be payable for a period of five (5) years from first commercial sale. The royalties payable under this section shall be in lieu of patent royalties and shall not be additive where patents later issue in a country.

8.4(c) For purposes of calculating royalties due to Vical under Articles 8.4(b)(i)(A) and 8.4(b)(ii), the sales level tiers set forth therein will be adjusted cumulatively, using the U.S. Pharmaceutical Price Index for sales in the U.S., its territories and possessions and the corresponding European index for sales outside the U.S. Said adjustments will be made based on the change in each such Index from the effective date of this Third Amendment as compared to the dates of the first commercial Ex-U.S. and U.S. sales, respectively, of each TREATMENT VACCINE. Thereafter, the sales level tiers will be adjusted as of each anniversary date of such first commercial sale, based on the change in the weighted average selling price of each TREATMENT VACCINE for, respectively, U.S. and Ex-U.S. sales, based on a comparison of the two prior years weighted average selling price. It is understood that for the first anniversary, the weighted average selling price at launch will be compared to the weighted average selling price over the first year, in each case.

6. Article 8.5 is amended by adding the following at the beginning thereof:

“Other than for TREATMENT VACCINE(S),. . .”

7. Article 8.8 is hereby amended to be replaced in its entirety as follows:

8.8(a) Except for royalties for TREATMENT VACCDE(S), which is addressed in Article 8.8(b), if MERCK is required to pay cumulative royalties in excess of **[…***…]** of Net Sales for additional licenses required to commercialize a particular LICENSED PRODUCT, the royalties payable to VICAL herewith with respect to such LICENSED PRODUCT shall be reduced by **[…***…]** of the additional royalties beyond such **[…***…]** figure; provided however, that in no event shall the royalties due VICAL hereunder, after taking into account the above reduction, be reduced below **[…***…]**.

8.8(b) If MERCK is required to pay cumulative royalties in excess of **[…***…]** for licenses required to commercialize a particular TREATMENT VACCINE (including the royalties set forth under this Agreement), the royalties payable to VICAL with respect to such TREATMENT VACCINE shall be reduced by **[…***…]** of the royalties beyond such **[…***…]** figure; provided, however, that in no event shall the royalties due VICAL with respect to any country, after taking into account the above reduction, be reduced by more than **[…***…]**. Unused royalty credits may be carried into subsequent royalty periods.

8. The Agreement is amended by adding Articles 8.10, 8.11 and 8.12 thereto as follows:

8.10 Within thirty (30) days of the date of this Third Amendment, Merck will purchase duly issued and validly authorized unregistered shares of VICAL common stock having an aggregate purchase price of $5,000,000 (five million dollars) on the terns and subject to the conditions of the Stock Purchase

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Agreement dated of even date herewith, between VICAL and MERCK, at a price per share equal to the greater of $16.00 per share or 125% of the average of VICAL’s per share closing price for the twenty (20) trading days prior to, but not including, the Effective Date of the Third Amendment.

8.11 VICAL is hereby granted an option (the “OPTION) to co-promote TREATMENT VACCINE(S) in the United States to a select target audience that will be agreed upon by the parties. With respect to each TREATMENT VACCINE, the OPTION will be exercisable by VICAL at any time prior to MERCK’s completion of Phase III clinical trials for such TREATMENT VACCINE. Prior to exercising its OPTION with respect to a TREATMENT VACCINE, VICAL will establish, to MERCK’s reasonable satisfaction, that at the estimated time of the first PLA filing in the United States for such TREATMENT VACCINE, VICAL will have a sales force of at least **[…***…]** professional representatives who will be available to make at least 6 detail calls per day on at least 200 days per year with respect to such TREATMENT VACCINE. The parties will enter into a co-promotion agreement for such co-promotion by VICAL within six (6) months of the exercise of the OPTION. The co-promotion agreement will contain reasonable terms and conditions, consistent with industry standards and the terms of this Agreement. The co-promotion agreement will contain the financial terms set forth on Schedule F of this Third Amendment.

8.12 In the event a TREATMENT VACCINE is also capable of being used for the prevention of the same human infectious disease, in its sole discretion VICAL

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may choose to have royalty payments made under Article 8.4(a) and Article 8.5 or, alternatively, under Articles 8.4(b) and 8.11 (co-promotion option).

9. The effectiveness of this Third Amendment is subject to the execution and delivery of the Stock Purchase Agreement dated as of even date herewith, between VICAL and MERCK and payment by MERCK of the $5,000,000 (five million dollars) thereunder.

10. Except as amended hereby, all other terms and conditions of the Agreement shall remain unchanged and shall continue in full force and effect. Capitalized terms in this Third Amendment shall have the meaning set forth in the Agreement.

IN WITNESS WHEREOF, the parties hereto have had this Third Amendment executed by their authorized representatives as set forth below.

MERCK & CO., INC.		VICAL INCORPORATED	
BY:	/s/ Raymond Gilmartin	BY:	/s/ Alain B. Schreiber, M.D.
TITLE:	Chairman, President and Chief Executive Officer	TITLE:	Alain B. Schreiber, M.D. President & C.E.O.
DATE:	November 3, 1997	DATE:	October 27, 1997

SCHEDULE E - MILESTONES FOR TREATMENT PRODUCTS

[…*…]***	$	1.0M
[…*…]***	$	1.5M
[…*…]**		**[…***…]**
[…*…]**		**[…***…]**

*If the milestone is paid on the identified date, it will be paid only once and credited against the milestone due when the event is achieved.

"Major Market Country" shall mean the United States, EC countries, Canada, or Japan.

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SCHEDULE F – CO-PROMOTION FINANCIAL TERMS

1. All sales made by VICAL under the Co-Promotion Agreement will be booked by Merck.

2. VICAL will, in addition to the royalties set forth in Article 8.4(b), receive the following amounts in consideration for its Co-Promotion efforts:

A. If VICAL provides between [**…***…**] and [**…***…**] sales representatives for the co-promotion VICAL will receive the following royalty increment on U.S. NET SALES:

For annual U.S. NET SALES less than **[…***…]**	**[…***…]**
For annual U.S. NET SALES equal to or greater than **[…***…]** and less than or equal to **[…***…]** for that portion of U.S. NET SALES equal to or greater than **[…***…]**	**[…***…]**
For annual U.S. NET SALES greater than **[…***…]** for that portion of U.S. NET SALES greater than **[…***…]**	**[…***…]**

B. If VICAL provides 50 or more sales representatives for the co-promotion, VICAL will receive the following royalty increment on U.S. NET SALES:

For annual U.S. NET SALES less than **[…***…]**	**[…***…]**
For annual U.S. NET SALES equal to or greater than **[…***…]** and less than or equal to **[…***…]** for that portion of U.S. NET SALES equal to or greater than **[…***…]**	**[…***…]**
For annual U.S. NET SALES greater than **[…***…]** for that portion of U.S. NET SALES greater than **[…***…]**	**[…***…]**

3. It is understood that with respect to each TREATMENT VACCINE, the size of VICAL's sales force for such TREATMENT VACCINE on the date that VICAL exercises its option will determine permanently the level of incremental royalty that VICAL will receive on U.S. sales of such TREATMENT VACCINE, notwithstanding that VICAL may subsequently increase the size of such sales force.

4. It is understood that all costs related to the VICAL sales force, including training, will be for the account of VICAL.

5. For purposes of calculating the royalty increment described in Paragraph 2, above, the Sales level tiers set forth therein will be adjusted cumulatively, using the U.S. Pharmaceutical Price Index. Said adjustments will be made based on the change in such Index from the effective date of this Third Amendment as compared to the date of the First Commercial sale of each TREATMENT VACCINE in the U.S. Thereafter, the

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sales level tiers will be adjusted as of each anniversary date of such first commercial sale based on the change in the weighted average selling price of each TREATMENT VACCINE, based on a comparison of the two prior years weighted average selling price. It is understood that for the first anniversary, the weighted average selling price at launch will be compared to the weighted average selling price over the first year in each case.

[ ] = Confidential Treatment Requested Under 17 C.F.R. §§ 200.80(b)(4) and 240.24b-2; Text Omitted and Filed Separately with the Securities and Exchange Commission

Agreement No. 91-1022A

AMENDMENT TO LICENSE AGREEMENT

This Amendment made effective the 20th day of May, 2004, is by and between the Wisconsin Alumni Research Foundation (hereinafter called "WARF"), having an address at 614 Walnut Street, Madison, Wisconsin 53726; and Vical Incorporated (hereinafter called "Vical"), having an address at 10390 Pacific Center Court, San Diego, CA 92121-4340.

WITNESSETH

WHEREAS, WARF and Vical entered into a License Agreement made effective January 1, 1991 (the "Agreement"); and

WHEREAS, WARF and Vical would each like to amend the Agreement to clarify their rights and obligations under the Agreement as it pertains to the sublicensing activities of Vical.

NOW THEREFORE, in consideration of the mutual covenants and agreements set forth below and in the Agreement, the parties covenant and agree as follows:

1. Section 2C of the Agreement is hereby deleted and replaced with the following:

"(i) WARF hereby grants to Vical the exclusive right to grant sublicenses under this Agreement. Such sublicense agreements shall be in writing. Any such sublicense shall fully protect WARF's income stream, product liability and other rights consistent with the terms of this Agreement, including, without limitation, Section 10. Such sublicenses under this Agreement shall continue only for as long as this Agreement remains in force, and Vical shall state that fact prominently and unambiguously in any sublicense agreement. Notwithstanding the foregoing, Vical may grant exclusive sublicenses under this Agreement which extend beyond the termination of this Agreement with the prior written consent of WARF. Such consent shall not be unreasonably withheld. Such exclusive sublicenses shall contain terms obligating the sublicensee to WARF and to the terms of this Agreement (including royalty rates, product liability and other rights owing WARF hereunder) as if such sublicensee were Vical in the event of such termination. During the term of this Agreement, Vical shall have the same responsibility for the activities of a sublicensee as if the activities were directly those of Vical; provided, however, that WARF shall be paid by Vical with regard to the activities of its sublicensee as if those activities were Vical's at the royalty rate set forth in the chart below:

Royalty Rate to be Paid by Vical to WARF	Royalty Rate Received by Vical from its Sublicensees
[…*…]%**	**[…***…]%**
[…*…]%**	**[…***…]%**
[…*…]%**	**[…***…]%**

(ii) In addition to the royalties described in Section 2C(i) above, Vical agrees to pay to WARF**[…***…]** percent (**[…***…]**%) of all monetary fees and consideration received by Vical (including equity, which shall be held in trust to WARF's benefit pending liquidity and subject to compliance with applicable securities laws, and option exercise fees received upon the exercise of an option to obtain a sublicense under the Licensed Patent) in exchange for rights granted under the Licensed Patents, except for earned royalties as prescribed by Section 2C(i) and the following:

(1) Payments received solely for the achievement of clinical milestones;

(2) Payments received as a reimbursement or remittance for the actual documented cost of research and development activities performed by Vical (or its subcontractors) under an agreement with a sublicensee under which Vical (including its subcontractors) is obligated to undertake the research and development and Vical receives specified payment for said research and development activities or the specified payment is made to reimburse Vical for past research and development activities actually performed by Vical (or its subcontractors) specifically on behalf of the sublicense making such payment;

(3) Payments received as a reimbursement or remittance for the actual documented costs associated with preparing, prosecuting and maintaining the Licensed Patents; and

(4) Bona fide loans if Vical repays the loan in full.

Notwithstanding the foregoing, Vical shall be obligated to pay to WARF **[…***…]** percent (**[…***…]**%) of any payments received solely for the achievement of either time-based or combination time-based/clinical milestones (but excluding payments received solely for the achievement of clinical milestones) under (a) any sublicense of rights under the Licensed Patents granted under any new agreement that is entered into by Vical after **[…***…]**; or (b) any amendment of an agreement existing before **[…***…]** that is entered into by Vical after**[…***…]** (subject to the last sentence of paragraph 2 of this Amendment), which amends such agreement to include either time-based or combination time-based/clinical milestones. Vical shall not owe any payment to WARF with respect to any payments received by Vical solely for the achievement of either time-based or combination time-based/clinical milestones under any agreement existing before **[…***…]**, unless an amendment to that agreement as described in subsection (b) of the preceding sentence is entered into by Vical after **[…***…]**.

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(iii) Vical shall have the right to include in any sublicenses granted pursuant to this Agreement other technology licensed, developed and/or patented by Vical and not within the Licensed Patents. In the event of such sublicense, Vical shall make a good faith allocation regarding the percentage of consideration provided under said sublicense attributed to Licensed Patents and that attributed to such other technology. Within sixty (60) days of execution of said sublicense, or any amendment providing such a sublicense, Vical shall forward to WARF a summary of the technology included under said agreement, a summary of the financial consideration to be paid, and a description of Vical's proposed allocation. In the event that WARF desires to challenge any such allocation, Vical shall provide to WARF reasonably available documents in support of Vical's proposed allocation. If the parties disagree as to a fair allocation of such consideration, the parties agree that the Chief Executive Officer of Vical and the Managing Director of WARF shall meet and confer in good faith in an attempt to resolve the dispute. If a dispute remains after thirty (30) days following the initial meeting of such representatives of Vical and WARF, the parties agree to submit the issue to binding arbitration to be conducted in Chicago, Illinois under the auspices of Judicial Arbitration and Mediation Services, Inc. ("JAMS"). The parties agree that they shall mutually select a single JAMS representative to preside over the arbitration proceeding. If the parties are unable to agree to the appointment of such representative, then JAMS shall appoint one from its prevailing roster of Chicago based representatives. The parties agree that the determination of the issues of the dispute and the procedures for resolving the dispute shall be conclusively and finally resolved by the JAMS representative, with the express understanding that the parties desire a very efficient and expeditious resolution.

(iv) Vical agrees to provide to WARF within sixty (60) days of the execution of each agreement or amendment granting rights under the Licensed Patents a written summary of the financial terms of such agreement or amendment."

2. Vical and WARF agree that the foregoing revisions to Section 2C of the Agreement shall apply to (1) agreements and amendments entered into by Vical after **[…***…]**, granting new or additional rights under the Licensed Patents; (2) any amendments entered into by Vical after **[…***…]**, amending the financial terms associated with any rights granted under the Licensed Patents prior to **[…***…]**; and (3) monetary fees and consideration received by Vical after **[…***…]**, in exchange for rights granted under the Licensed Patents prior to **[…***…]**. The parties acknowledge and agree that any consideration received by Vical solely in exchange for its right to co-promote products under the 1991 Merck agreement, as amended, shall not be subject to the revised revenue sharing provisions of Section 2C above.

3. Section 2 of the Agreement is amended to include the following new Section 2D:

"Vical hereby grants to the University of Wisconsin, and hereby agrees to grant to other academic institutions and other non-profit research institutions upon request, without payment of any initial monetary consideration, a fully paid-up, royalty-free, nontransferable, nonexclusive license to use the inventions of the Licensed Patents for non-commercial research purposes. As used herein, "non-commercial research purposes" shall specifically exclude research sponsored by a for-profit entity in which such entity

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receives rights, direct or indirect, actual or contingent, to the results of the research. For clarification, under no circumstances will Vical be deemed to have granted, or agreed to grant, any license or rights to the Licensed Patents for any commercial purposes to the University of Wisconsin, any academic institution or other non-profit research institution or any other non-profit or for-profit person or entity under this Agreement."

4. Section 3A of the Agreement is hereby deleted and replaced with the following:

"Vical warrants that it or its sublicensees will diligently pursue commercialization of the inventions of the Licensed Patents. Within one (1) month following the end of each calendar year until the Date of First Commercial Sale of Products, Vical will provide to WARF a written Development Report summarizing Vical's product development activities since the last Development Report, and the known and non-confidential development activities of its sublicensees. Within one (1) month following the end of each calendar year, Vical will provide to WARF a written report summarizing Vical's sublicensing activities under this Agreement and the sublicensing payments received during the preceding year. All development activities, strategies and aspects of Product design and the like are entirely at the discretion of Vical and its sublicensees, and Vical and its sublicensees shall rely entirely on their own expertise with respect thereto. WARF's review of Vical's Development Reports and sublicensing reports is solely to verify Vical's compliance with its obligations under this Agreement. All Development Reports and sublicensing reports provided to WARF under this Section 3A shall be deemed confidential and maintained in confidence by WARF."

5. The first sentence of Section 3E of the Agreement is hereby amended by replacing "Section 3C" with "Sections 2C and 3C".

6. Section 8 of the Agreement is hereby deleted and replaced with the following:

"A. Patent Prosecution.

(i) WARF hereby grants to Vical the exclusive right to file, prosecute and maintain the Licensed Patents and will provide reasonable cooperation to Vical, at Vical's expense, in connection with Vical's exercise of such rights. Vical shall provide to WARF a copy all significant prosecution actions and correspondence received from and provided to the United States Patent and Trademark Office as part of the filing, prosecution and maintenance of the Licensed Patents. Vical shall provide such actions and correspondence to WARF within thirty (30) days of their receipt by Vical; provided that any such information shall be kept confidential and made available only to WARF's patent attorneys, patent agents and WARF employees who work with those patent attorneys and patent agents, in each case who have a need to know such information, unless otherwise agreed by the parties. WARF shall hold such actions and correspondences in confidence until made public, whether by Vical or through the issuance or publication of the corresponding patent or patent application.

(ii) WARF and Vical acknowledge that either party may pursue, or be pursuing, patent protection for technologies having some relation to the inventions of the Licensed

Patents, and that under certain patent laws, they may be required to disclose certain aspects of the prosecution history of the Licensed Patents as part of the patent prosecution for such other technologies. In such event, WARF and Vical shall be entitled to disclose its files pertaining to the Licensed Patents to their respective patent counsel, and the relevant aspects of the prosecution history to the relevant patent office.

B. Enforcement.

(i) It is the intent of WARF and Vical to protect the Licensed Patents under this Agreement from infringement and to prosecute infringers or otherwise to act to eliminate infringement when such action may be reasonably necessary, proper and justified. However, Vical shall retain the sole and final right to decide on the enforcement strategy for the Licensed Patents.

(ii) Vical shall have the right, in its sole discretion, to bring an action to enforce the Licensed Patents; provided that Vical shall indemnify and defend WARF for any claims, fees, judgments and any reasonable costs and expenses arising out of any action, counteraction or other activities resulting as a consequence of Vical bringing such action, unless WARF decides to join in such action as permitted below. WARF will provide reasonable cooperation to Vical, at Vical's expense, in connection with any such action. WARF shall have the right to join in any action in its sole discretion. In the event WARF joins an action, WARF and Vical agree to meet to discuss a fair and equitable sharing arrangement of the costs and revenues generated through such action. If the parties disagree as to a fair allocation, then WARF and Viral will each bear its own expenses in proceeding with such action throughout the course of such action and share any revenues generated through such action pro rata based upon the respective costs borne by each of them. In such case, after the conclusion of such action (or such earlier time as mutually agreed by WARF and Vical), the parties shall follow the same procedure as set forth in Section 2C(iii) above, starting with the meet and confer step between the Chief Executive Officer of Vical and the Managing Director of WARF, to determine whether a different allocation of costs and any revenues generated through such action is appropriate. In the event that WARF does not join in any such action, Viral shall be entitled to retain all revenues resulting from a judgment therein. Any agreement granting rights under the Licensed Patents and entered into as a result of enforcement activities pursuant to this Section 8B shall be deemed to be a sublicense granted pursuant to Section 2C above such that any revenues generated therefrom shall be distributed in accordance with Section 2C."

7. Except as otherwise provided in this Amendment, all terms and conditions previously set forth in the Agreement shall remain in effect as set forth therein. In the event that this Amendment and the Agreement are inconsistent, the terms and provisions of this Amendment shall supercede the terms and provisions of the Agreement, but only to the extent necessary to satisfy the purpose of this Amendment. Each party hereto represents to the other that it has the full authority to execute, deliver and perform this Amendment in accordance with its terms.

IN WITNESS WHEREOF, the parties hereto have duly executed this Amendment on the dates indicated below.

WISCONSIN ALUMNI RESEARCH FOUNDATION

By: /s/ Carl E. Gulbrandsen Date: May 20, 2004
Carl E. Gulbrandsen, Managing Director

VICAL INCORPORATED

By: /s/ Vijay B. Samant by David C. Kaslow, M.D. Date: May 24, 2004
Vijay B. Samant, President and CEO

By: /s/ David C. Kaslow
David C. Kaslow, Chief Scientific Officer

Reviewed by WARF's General Counsel:

/s/ Elizabeth L.R. Donley
Elizabeth L.R. Donley, Esq.

(WARF's attorney shall not be deemed a signatory to this Agreement.)

WARF Ref. No.: Felgner – P90042US

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. I am 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 my supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to me 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 my 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. I have disclosed, based on my most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

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

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

Date: August 9, 2004

/s/ VIJAY B. SAMANT

Vijay B. Samant
Chief Executive Officer and Acting 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 and Acting Chief Financial Officer of Vical Incorporated (the "Company"), hereby certifies that, to the best of his knowledge:

1. The Company's Quarterly Report on Form 10-Q for the period ended June 30, 2004, to which this Certification is attached as Exhibit 32.1 (the "Periodic Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934, as amended; and

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

Dated: August 9, 2004

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