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SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended March 31, 2001

or

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

Commission File Number: 0-21088

VICAL INCORPORATED

(Exact name of registrant as specified in its charter)

Delaware	**93-0948554**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
9373 Towne Centre Dr., Suite 100, San Diego, California	**92121**
(Address of principal executive offices)	(Zip code)

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

Not Applicable
(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 /x/ No / /

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

Class	Outstanding at March 31, 2001
Common Stock, $.01 par value	20,015,344

VICAL INCORPORATED

FORM 10-Q

TABLE OF CONTENTS

*
No information provided due to inapplicability of item.

Part I. Financial Information

Item 1. Financial Statements

VICAL INCORPORATED
BALANCE SHEETS

	March 31, 2001 (Unaudited)	December 31, 2000
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 44,454,527	$ 16,480,087
Marketable securities—available-for-sale	100,769,849	131,663,766
Receivables and other	5,100,926	4,413,077
Total current assets	150,325,302	152,556,930
Investment, at cost	5,000,000	5,000,000
Property and Equipment:		
Equipment	7,460,418	6,978,906
Leasehold improvements	3,882,528	3,062,779
	11,342,946	10,041,685
Less—accumulated depreciation and amortization	(6,805,079)	(6,504,640)
	4,537,867	3,537,045
Patent costs, net of accumulated amortization	1,700,309	1,638,935
Other assets	148,239	170,302
	$ 161,711,717	$ 162,903,212
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable and accrued expenses	$ 3,834,302	$ 3,895,531
Current portion of capital lease obligations	685,099	611,775
Current portion of notes payable	508,109	317,764
Current portion of deferred revenue	1,773,822	2,162,474
Total current liabilities	6,801,332	6,987,544

Long-Term Obligations:		
Long-term obligations under capital leases	1,596,873	1,413,602
Notes payable	1,245,544	707,869
Deferred revenue	2,727,274	3,000,001
Total long-term obligations	5,569,691	5,121,472
Stockholders' Equity:		
Preferred stock, $0.01 par value—5,000,000 shares authorized—none outstanding	—	—
Common stock, $0.01 par value—40,000,000 shares authorized—20,015,344 and 20,011,244 shares issued and outstanding at March 31, 2001 and December 31, 2000, respectively	200,153	200,112
Additional paid-in capital	203,157,798	203,106,680
Accumulated other comprehensive income	1,123,408	649,658
Accumulated deficit	(55,140,665)	(53,162,254)
Total stockholders' equity	149,340,694	150,794,196
	$ 161,711,717	$ 162,903,212

See accompanying notes.

VICAL INCORPORATED
STATEMENTS OF OPERATIONS
(Unaudited)

	Three months ended March 31,	
	2001	2000
Revenues:		
License/royalty revenue	$ 1,393,768	$ 799,057
Contract revenue	1,037,972	382,009
	2,431,740	1,181,066
Operating Expenses:		
Research and development	5,214,928	4,316,888
General and administrative	1,754,587	1,329,872
	6,969,515	5,646,760
Loss from operations	(4,537,775)	(4,465,694)
Investment income	2,625,134	1,777,108
Interest expense	(65,770)	(38,715)
Loss before cumulative effect of change in accounting principle	(1,978,411)	(2,727,301)
Cumulative effect of change in accounting principle	—	(1,510,036)
Net loss	$ (1,978,411)	$ (4,237,337)
Net loss per share (basic and diluted—Note 3):		
Loss per share before cumulative effect of change in accounting principle	$ (0.10)	$ (0.14)
Cumulative effect of change in accounting principle (Note 2)	—	(0.08)
Net loss per share	$ (0.10)	$ (0.22)
Weighted average shares used in computing net loss per share (Note 3)	20,014,118	19,021,921

See accompanying notes.

VICAL INCORPORATED
STATEMENTS OF CASH FLOWS
(Unaudited)

	Three months ended March 31,	
	2001	2000
OPERATING ACTIVITIES:		
Net loss	$ (1,978,411)	$ (4,237,337)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	362,991	258,892
Change in operating assets and liabilities:		
Receivables and other	(687,849)	777,764
Accounts payable and accrued expenses	(61,229)	(931,182)
Deferred revenue	(661,379)	1,054,578
Net cash used in operating activities	(3,025,877)	(3,077,285)
INVESTING ACTIVITIES:		
Sales of marketable securities	73,554,406	6,583,131
Purchases of marketable securities	(42,186,739)	(66,674,639)
Capital expenditures	(893,828)	(577,776)
Deposits and other	22,063	50,154
Patent expenditures	(93,037)	(72,016)
Net cash provided from (used in) investment activities	30,402,865	(60,691,146)
FINANCING ACTIVITIES:		
Issuance of common stock, net	51,159	119,058,750
Proceeds from notes payable	799,448	803,239
Payments on notes payable	(71,429)	(106,474)
Principal payments under capital lease obligations	(181,726)	(158,559)
Net cash provided from financing activities	597,452	119,596,956
Net increase in cash and cash equivalents	27,974,440	55,828,525
Cash and cash equivalents at beginning of period	16,480,087	11,149,587
Cash and cash equivalents at end of period	$ 44,454,527	$ 66,978,112
Supplemental Disclosure of Non-Cash Investing and Financing Activities:		
Investment in preferred stock of Vascular Genetics Inc. in exchange for grant of license	$ —	$ 5,000,000
Equipment acquired under capital lease financing	$ 438,321	$ 35,988

See accompanying notes.

VICAL INCORPORATED

NOTES TO FINANCIAL STATEMENTS

March 31, 2001

(unaudited)

1. ORGANIZATION AND BASIS OF PRESENTATION

Organization

Vical was incorporated in April 1987 and has devoted substantially all of its resources since that time to its research and development programs. We are currently focusing our resources on the development of our naked DNA and related technologies.

Basis of Presentation

The information contained herein has been prepared in accordance with instructions for Form 10-Q. The information at March 31, 2001, and for the three-month periods ended March 31, 2001 and 2000, is unaudited. In the opinion of management, the information reflects all adjustments necessary to present fairly the financial position and results of operations for the interim periods. 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. For a presentation including all disclosures required by accounting principles generally accepted in the United States, these financial statements should be read in conjunction with the audited financial statements for the year ended December 31, 2000, included in the Vical Incorporated Form 10-K filed with the Securities and Exchange Commission.

Recent Accounting Pronouncements

In June 1998, the FASB issued SFAS No. 133, "Accounting for Derivative Instruments and Hedging Activities." This statement changes the previous accounting definition of derivative, expanding it to include embedded derivatives and many commodity contracts. Under the Statement, every derivative is recorded in the balance sheet at its fair value, and any changes in the derivative's fair value are recognized currently in earnings, unless specific hedge accounting criteria are met. As amended by SFAS No. 137, "Accounting for Derivative Instruments and Hedging Activities—Deferral of the Effective Date of FASB Statement No. 133," SFAS No. 133 is effective for all fiscal quarters of all fiscal years beginning after June 15, 2000.

The Financial Accounting Standards Board has issued SFAS No. 138, "Accounting for Certain Derivative Instruments and Certain Hedging Activities—an Amendment of FASB Statement No. 133." This statement amends certain provisions of SFAS No. 133. SFAS No. 138 is effective concurrently with SFAS No. 133, if SFAS No. 133 is not adopted prior to June 15, 2000. The adoption of SFAS No. 133, as amended, and SFAS No. 138 did not have a material effect on our financial statements.

Reclassifications

Certain amounts in the prior period financial statements have been reclassified to conform with current period presentation.

2. CHANGE IN ACCOUNTING PRINCIPLE

In December 1999, the Securities and Exchange Commission (SEC) issued Staff Accounting Bulletin No. 101—"Revenue Recognition in Financial Statements," or SAB 101. SAB 101 reflects the SEC's views on revenue recognition. Vical implemented SAB 101 in the fourth quarter of 2000 by restating the first three quarters of 2000 financial statements to apply SAB 101 effective January 1, 2000. The statement of operations for the three-month period ended March 31, 2000, reflects a one-time charge to earnings for the cumulative effect of the change in accounting principle as of January 1, 2000, of $1.5 million. Accordingly, revenue for the quarter ended March 31, 2000 was increased by $0.2 million to reflect the recognition of the deferred license revenue arising from the SAB 101 adjustment.

3. NET LOSS PER SHARE

Net loss per share (basic and diluted) for the three-month periods ended March 31, 2001 and 2000, has been computed using the weighted average number of common shares outstanding during the respective periods. Diluted loss per share does not include any assumed exercise of stock options, as the effect would be antidilutive.

4. COMPREHENSIVE LOSS

Accumulated other comprehensive income represents net unrealized gains on marketable securities. Marketable securities consist of investments in debt instruments of financial institutions and corporations with strong credit ratings, and in U.S. government obligations. For the three-month periods ended March 31, 2001 and 2000, other comprehensive income (loss) was $473,750 and $(93,130), respectively, and total comprehensive loss was $1,504,661 and $4,330,467, respectively.

5. COMMITMENTS

The Company has a line of credit and loan agreement with a bank to provide financing of up to $2.3 million for certain leasehold improvements. At May 1, 2000, $1.0 million of this total had been used and converted to a term loan. At March 31, 2001, approximately $1.0 million of additional borrowings were made under the line, leaving $0.3 million available under the line until May 1, 2001. Any outstanding borrowings made under the additional $1.3 million credit line at June 1, 2001, convert to a term loan payable over 42 months at the bank's prime rate.

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. 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, assumptions or 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:

- "will likely result,"
- "are expected to,"
- "will continue,"
- "is anticipated,"
- "estimate,"
- "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 in:

- clinical trial results,
- obtaining and maintaining regulatory approval,
- market acceptance of and continuing demand for our products,
- the attainment of patent protection for any of these products,
- the impact of competitive products, pricing and reimbursement policies,
- our ability to obtain additional financing to support our operations,
- the continuation of our corporate collaborations, and
- changing market conditions and other risks detailed below.

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

- our Annual Report on Form 10-K,
- the risk factors contained in this report under the caption "Risk Factors," and
- our other filings with the Securities and Exchange Commission.

Any forward-looking statement speaks only as of the date on which that statement is made. We will not 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 April 1987 and have devoted substantially all of our resources since that time to our research and development programs. To date, we have not received revenues from the sale of products. We expect to incur substantial operating losses for at least the next few years, due primarily to the expansion of our research and development programs and the cost of preclinical studies and clinical trials. Losses may fluctuate from quarter to quarter as a result of differences in the timing of expenses incurred and the revenues received from collaborative agreements. Such fluctuations may be significant. As of March 31, 2001, our accumulated deficit was approximately $55.1 million.

We develop biopharmaceutical products based on our patented naked DNA gene transfer technologies for the prevention and treatment of life-threatening diseases. We currently focus our development on innovative cancer therapies to induce an immune response against cancer cells without causing serious side effects. We have retained all rights to our internally developed cancer product candidates.

We have entered into collaborations with major pharmaceutical companies to leverage our technologies primarily for non-cancer applications such as vaccines for infectious diseases and optimized delivery of therapeutic proteins. We have established relationships, through the license of our technology, with numerous corporate partners.

Vical has formulated Allovectin-7®, a complex containing the gene encoding a particular human histocompatibility antigen, HLA-B7, and a lipid material to facilitate gene uptake. After direct injection of Allovectin-7® into a tumor, we believe that the HLA-B7 gene will cause the tumor cells to produce the HLA-B7 antigen. This gene expression may then trigger a potent cellular immune response against the tumor cells. The treatment may also trigger an immune response against additional tumor cells, both locally and systemically, by exposing other features of the tumor cells to the immune system.

Allovectin-7® is in Phase III and Phase II registration trials for patients with advanced metastatic malignant melanoma, an aggressive form of skin cancer. At the May 2001 annual meeting of the American Society of Clinical Oncology, we presented interim safety and efficacy data from our Phase II Allovectin-7® registration trial for patients with late-stage metastatic melanoma.

We reported interim data for 73 patients who received at least one injection of Allovectin-7® (intent-to-treat patient population), including 54 patients who received at least one full treatment cycle (evaluable patient population). The conclusions based on these data were that the median duration of response and response rate to date confirm the activity of Allovectin-7®, and that the safety profile of Allovectin-7® remains excellent in comparison to approved treatments for metastatic melanoma. Several patients are still in treatment or followup under the Phase II trial, and final results are expected by year-end 2001. In addition, a concurrent Phase III Allovectin-7® registration trial is expected to complete enrollment of patients with newly diagnosed metastatic melanoma in the third quarter of 2001.

In the Phase II registration trial, treatment with Allovectin-7® resulted in a reduction in total tumor burden of 50 percent or more (systemic clinical responses) in 14.8 percent of the evaluable patients with a current median duration of response of approximately 5 months. Two of the patients, or 4 percent of the evaluable group, experienced complete responses in which all detectable tumors were eliminated. An additional 26 percent of the evaluable patients achieved stable disease, some with reductions in total tumor burden that are significant but did not reach 50 percent. On an intent-to-treat basis, 11 percent of the patients experienced systemic clinical responses, and an additional 19 percent achieved stable disease. The trial enrolled patients who had failed other treatments. All but 1 percent of the drug-related side effects were mild or moderate. Melanoma is

currently treated with

chemotherapy, biotherapy, or combinations of chemotherapy and biotherapy. Toxicity with such treatments is often significant, resulting in serious or life-threatening side effects in 50 percent or more of the patients treated.

The U.S. Food and Drug Administration, FDA, has reconfirmed that the company's Phase II and III trial designs could support registration of Allovectin-7® for melanoma. Written comments received from the FDA reconfirmed the acceptability of the company's registration program to support marketing approval if the data meet the study objectives, and if the company also meets product manufacturing and other typical regulatory requirements. In addition, the FDA reconfirmed that the Phase II registration trial could, on its own, be the basis for marketing approval, if the data meet the clinical endpoints. The FDA further confirmed that data from the Phase II trial and prior trials with Allovectin-7® would support a submission based on Phase III trial results, assuming that the Phase III data profile is consistent with prior experience.

In February 2001 we also started a multi-center Phase II Allovectin-7® trial in up to 80 patients with late-stage metastatic melanoma to identify if significantly higher doses of Allovectin-7® and/or the injection of multiple lesions further enhances efficacy. Previous trials have used very low, 10 mcg, doses of Allovectin-7® delivered to a single tumor lesion. Allovectin-7®'s current safety profile allowed us to design this new trial to test higher doses, up to 2 mg, a 200-fold increase, of Allovectin-7®, and delivery to multiple tumor lesions.

Allovectin-7® is also in Phase II clinical testing for patients with cancer of the head and neck. Based on recently reported data, in February 2001 we announced the initiation of a multi-center Phase II trial with Allovectin-7® in up to 25 patients scheduled for surgical treatment of early-stage cancer of the oral cavity and oropharynx.

We are developing our second gene-based product candidate, Leuvectin™, also intended for direct injection into tumor lesions of cancer patients. Leuvectin™ contains a gene that encodes the potent immunostimulator interleukin-2, IL-2, and a lipid material to facilitate gene uptake. We expect that Leuvectin™, when injected into tumors, will cause the malignant cells to produce and secrete IL-2 in the vicinity of the tumor, stimulating the patient's immune system to attack and destroy tumor cells. Because Leuvectin™ is designed to deliver IL-2 only at the site of tumor lesions, we believe that it may provide efficacy similar to systemic IL-2 therapy with fewer side effects. Leuvectin™ is in Phase II clinical trials for high-risk patients with locally confined prostate cancer.

Leuvectin™ was also in Phase II clinical trials for patients with advanced metastatic kidney cancer. In April 2001, we announced that we were discontinuing the current Phase II clinical trial with Leuvectin™ for patients with metastatic kidney cancer and planning a new Phase II clinical trial using a new dose and dosing regimen. In the current Phase II kidney cancer trial with Leuvectin™, the study protocol required an interim analysis of data from the first 37 patients. Based on that analysis, we determined that efficacy failed to meet the level needed to continue the study. The efficacy also appears to be lower than that observed in prior kidney cancer trials with Leuvectin™. The Leuvectin™ used in the discontinued trial was formulated with a different process than the Leuvectin™ used in earlier trials. Comparative analysis suggested that expression of IL-2 for the product used in the discontinued trial may have been below historical levels. The new trial would use high-dose Leuvectin™ formulated with an optimized process.

Vaxid, a cancer vaccine intended to prevent recurrence of low-grade, non-Hodgkin's B-cell lymphoma, is in a Phase I/II clinical trial in a collaboration with Stanford University Medical Center. In March 2001, we announced positive safety and immunogenicity results in the Phase I/II trial of *Vaxid*, a patient-specific naked DNA vaccine for low-grade, non-Hodgkin's, B-cell lymphoma. *Vaxid* was not only well-tolerated in these patients, but also generated both cellular and humoral immune responses. We are supporting clinical testing of a cancer vaccine for the treatment of advanced metastatic melanoma in a collaboration with the National Cancer Institute, or NCI.

We are developing our cancer product candidates independently, while developing vaccine product candidates for infectious diseases primarily in collaboration with corporate partners Merck and Aventis Pasteur. We have a license agreement allowing Centocor to use our naked DNA technology to develop and market three specific gene-based vaccines for the potential treatment of certain types of cancer. We have agreements with Boston Scientific for the use of our technology in catheter-based intravascular gene delivery. We have agreements with Aventis Pharma to use our gene delivery technology to deliver neurological proteins for neurodegenerative diseases and to deliver a growth factor gene for which Aventis Pharma holds rights. We have agreements with Pfizer for use of our technology for DNA-based delivery of therapeutic proteins in animal health applications and with Merial for use of our technology for DNA vaccines in animal infectious disease targets.

We have a reciprocal royalty-bearing license agreement with Human Genome Sciences, HGS, under which we have the option to license exclusively up to three genes from HGS for gene-based product development. HGS has the option to license our patented naked DNA gene delivery technology for use in up to three gene-based products. In addition, we granted an exclusive, royalty-bearing license to Vascular Genetics Inc., VGI, a company in which HGS is a major shareholder, for naked DNA delivery of Vascular Endothelial Growth Factor-2, a protein with potential use for revascularization. The VGI trials were placed on clinical hold by the FDA in 2000 as a result of procedural irregularities in the conduct of the trials. VGI is preparing its response to the issues raised by the FDA.

We have licensed our naked DNA vaccination technology to Merck for a total of seven preventive vaccine targets:

- hepatitis B virus, HBV,
- hepatitis C virus, HCV,
- human immunodeficiency virus, HIV,
- human papilloma virus, HPV,
- herpes simplex virus, HSV,
- influenza virus, and
- tuberculosis, TB.

In addition, Merck also has a license covering three therapeutic vaccine targets, HBV, HIV and HPV.

In April 2001, we announced that Merck highlighted the success to date of its HIV vaccine development program, which includes a vaccine based on our patented naked DNA gene delivery technology. Merck presented preclinical data from its HIV vaccine program and reviewed the status of clinical trials at the Keystone Symposium, *AIDS Vaccines in the New Millennium,* in Keystone, Colorado. Merck is now developing vaccines based on our naked DNA vaccine technology to prevent and treat HIV infections. Merck is testing naked DNA vaccines for HIV in two human trials, one which began in December 1999 for uninfected volunteers and one which began in May 2000 for volunteers already infected with HIV and receiving highly active anti-retroviral therapy.

We also have licensed to Aventis Pasteur a total of four preventive vaccine targets:

- cytomegalovirus, CMV,
- *Helicobacter pylori*,
- malaria, and
- respiratory syncytial virus, RSV.

We currently are in discussions with Aventis Pasteur concerning a possible renegotiation of the terms of this agreement.

We are collaborating with Aventis Pasteur and the U.S. Naval Medical Research Center, or NMRC, to develop a DNA vaccine against malaria. We and the Office of Naval Research have an agreement for the development of a potential naked DNA vaccine to prevent malaria. The agreement could provide up to approximately $5.5 million of funding to the company through June 30, 2001. We intend to request an extension of the funding period from June 30, 2001 to December 31, 2001. Through March 31, 2001, we had recognized revenue of $3.9 million of the total contract amount. In August 2000, we initiated a Phase II clinical trial to test the safety and efficacy of a naked DNA vaccine to prevent infection by the malaria parasite.

In April 2001, we were issued U.S. Patent No. 6,214,804, which expands our broad ownership of naked DNA gene delivery technologies by including administration of naked DNA into any tissue for the purpose of inducing an immune response. This patent effectively renews and reinforces our previously issued patent covering naked DNA injection into muscle or skin to stimulate an immune response systemically. Moreover, it generically covers both systemic and local administration of naked DNA vaccines. Local administration may alter the characteristics of the body's immune response, providing potentially improved immunity against certain diseases. For example, naked DNA vaccination via pulmonary or intranasal delivery may prove beneficial for certain diseases which have so far proven unresponsive to conventional vaccination. In May 2001, we were issued U.S. Patent No. 6,228,844, which covers naked DNA delivery of Vascular Endothelial Growth Factor (VEGF) to the heart to promote the growth of blood vessels.

Our product candidates or those of our collaborators may not prove to be safe and effective in clinical trials and no commercially successful products may ultimately be developed by us or our collaborators.

Results of Operations

Revenues of $2.4 million were recorded for the quarter ended March 31, 2001. License revenue of $1.4 million primarily represented recognition of a milestone payment of $0.5 million from Centocor and recognition of deferred license fees of $0.7 million from Merial, Pfizer and Vascular Genetics Inc., and royalty and other revenue of $0.2 million. Contract and grant revenue of $1.0 million included revenues from a contract with the Office of Naval Research for the development work on a potential naked DNA vaccine to prevent malaria, revenue from contracts and grants with National Institutes of Health, NIH, and revenue from Pfizer. The total contract amount under the agreement between Vical and the Office of Naval Research is $5.5 million through June 30, 2001. We intend to request an extension of the funding period from June 30, 2001 to December 31, 2001. Through March 31, 2001, we had recognized revenue of $3.9 million of the total contract amount.

Revenues of $1.2 million were recorded for the quarter ended March 31, 2000. License revenue of $0.8 million primarily represented recognition of deferred license fees of $0.6 million from Merial, Pfizer, HGS and royalty and other revenue of $0.2 million. Contract revenue recognized was $0.4 million, and included revenues from the contract with the Office of Naval Research, revenue from grants with NIH, and revenue from Pfizer and other agreements.

Our total operating expenses for the quarter ended March 31, 2001, were $7.0 million compared with $5.6 million for the first quarter of 2000. Research and development expenses increased to $5.2 million for the three months ended March 31, 2001, from $4.3 million for the same period in 2000. The increase in research and development expenses generally was due to increased preclinical costs, and increased facilities and personnel-related costs.

General and administrative expenses increased to $1.8 million for the three months ended March 31, 2001, from $1.3 million for the same period in 2000. The increase for the first quarter of 2001 is attributable primarily to increased professional fees related to corporate communications, recruiting and business development activities, and due to increased facilities and personnel-related costs in support of the expanded research and development activities.

In December 1999, the Securities and Exchange Commission (SEC) issued Staff Accounting Bulletin No. 101—"Revenue Recognition in Financial Statements," or SAB 101. SAB 101 reflects the SEC's views on revenue recognition. We implemented SAB 101 in the fourth quarter of 2000 by restating the first three quarters of 2000 financial statements to apply SAB 101 effective January 1, 2000. The statement of operations for the three-month period ended March 31, 2000, reflects a one-time charge to earnings for the cumulative effect of the change in accounting principle as of January 1, 2000, of $1.5 million, or approximately $0.08 per share. Accordingly, revenue for the quarter ended March 31, 2000 was increased by $0.2 million to reflect the recognition of the deferred license revenue arising from the SAB 101 adjustment.

Investment income for the three-month periods ended March 31, 2001 and 2000, was $2.6 million and $1.8 million, respectively. The increase is a result of higher investment balances due to the January 2000 sale of 3,450,000 shares of our common stock in a public offering which raised net proceeds of approximately $117.5 million, and due to gain on sale of investments of $.3 million.

The net loss was $0.10 per share for the three months ended March 31, 2001. For the three months ended March 31, 2000, the net loss was $0.22, including an $0.08 per share loss for the effect of a change in accounting principle. We expect to incur losses throughout the remainder of 2001 and for our net burn rate to fall between $10 million and $13 million for the year ending December 31, 2001.

Liquidity and Capital Resources

Since its inception, we have financed our operations primarily through private placements of preferred and common stock, four public offerings of common stock and revenues from collaborative agreements. As of March 31, 2001, we had working capital of approximately $143.5 million compared with $145.6 million at December 31, 2000. Cash and marketable securities totaled approximately $145.2 million at March 31, 2001, compared with $148.1 million at December 31, 2000. We have an unsecured line of credit agreement with a bank to provide financing for leasehold improvements of up to $2.3 million. Outstanding borrowings under the agreement were $2.0 million and available credit was $0.3 million at March 31, 2001.

We expect to incur substantial additional research and development expenses and general and administrative expenses, including continued increases in personnel costs, costs related to preclinical testing and clinical trials, outside services and facilities. 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 commercialization activities and arrangements. We intend to seek additional funding through research and development relationships with suitable potential corporate collaborators. We may also seek additional funding through public or private financings. We cannot assure that additional financing will be available on favorable terms or at all.

If additional funding is not available, we anticipate that our available cash and existing sources of funding will be adequate to satisfy our operating needs through at least 2002.

Recent Accounting Pronouncements

In June 1998, the FASB issued SFAS No. 133, "Accounting for Derivative Instruments and Hedging Activities." This statement changes the previous accounting definition of derivative, expanding it to include embedded derivatives and many commodity contracts. Under the Statement, every derivative is recorded in the balance sheet at its fair value, and any changes in the derivative's fair value are recognized currently in earnings, unless specific hedge accounting criteria are met. As amended by SFAS No. 137 "Accounting for Derivative Instruments and Hedging Activities—Deferral of the Effective Date of FASB Statement No. 133," SFAS No. 133 is effective for all fiscal quarters of all fiscal years beginning after June 15, 2000.

The Financial Accounting Standards Board has issued SFAS No. 138, "Accounting for Certain Derivative Instruments and Certain Hedging Activities—an Amendment of FASB Statement No. 133." This statement amends SFAS No. 133. SFAS No. 138 is effective concurrently with SFAS No. 133, if SFAS No. 133 is not adopted prior to June 15, 2000. The adoption of SFAS No. 133, as amended, and SFAS No. 138 did not have a material effect on our financial statements.

Risk Factors

You should carefully consider the risks described below, together with all of the other information included in this report, before deciding whether to invest in our common stock. If any of the following risks actually occurs, our business, financial condition or results of operations could be harmed. In this case, the trading price of our common stock could decline, and you may lose all or part of your investment.

None of Our Products Have Been Approved for Sale. If We Do Not Develop Commercially Successful Products, We May Be Forced to Curtail or Cease Operations.

Very little data exists regarding the safety and efficacy of DNA therapeutics. 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. 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. Even if approved, our products may not be commercially successful. If we fail to develop and commercialize our products, we will not be successful.

We Have a History of Net Losses. We Expect to Continue to Incur Net Losses and We May Not Achieve or Maintain Profitability.

We have not sold any products and do not expect to sell any products for the next few years. For the period from our inception to March 31, 2001, we have incurred cumulative net losses totaling approximately $55.1 million. Moreover, our negative cash flow and losses from operations will continue and increase for the foreseeable future. We may never generate sufficient product revenue to become profitable. We also expect to have quarter-to-quarter fluctuations in revenues, expenses and losses, some of which could be significant.

We May Need Additional Capital in The Future. If Additional Capital Is Not Available, We May Have to Curtail or Cease Operations.

We may need to raise more money to continue the research and development necessary to bring our products to market and to establish manufacturing and marketing capabilities. We may seek additional funds through public and private stock offerings, arrangements with corporate partners, borrowings under lease lines of credit or other sources. In the event that we need more money, but are unable to raise more money we may have to reduce our capital expenditures, scale back our

development of new products, reduce our workforce and 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,
- the time and costs involved in:
  - obtaining necessary regulatory approvals,
  - filing, prosecuting and enforcing patent claims,
  - scaling up our manufacturing capabilities, and
-

the commercial arrangements we may establish.

The Regulatory Approval Process Is Expensive, Time Consuming and Uncertain, Which May Prevent Us From Obtaining Required Approvals for The Commercialization of Our Products.

Testing of the potential drugs we develop is regulated 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 U.S. Food and Drug Administration, the FDA, has not established guidelines concerning the scope of clinical trials required for DNA therapeutics,
- the FDA has not indicated how many patients it will require to be enrolled in clinical trials to establish the safety and efficacy of DNA therapeutics, and
- current regulations are subject to substantial review by various governmental agencies.

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

- impose costly procedures on our activities,
- diminish any competitive advantages that we attain, and
- negatively affect our ability to receive royalties.

We believe that the FDA and comparable foreign regulatory bodies will regulate separately each product containing a particular gene depending on its intended use. Presently, to commercialize any product we must sponsor and file a regulatory application for each proposed use. We then must conduct clinical studies to demonstrate the safety and efficacy of the product necessary to obtain FDA approval. The results obtained so far in our clinical trials may not be replicated in our on-going or future trials. This may prevent any of our potential products from receiving FDA approval.

We use recombinant DNA molecules in our product candidates, and therefore we also must comply with guidelines instituted by the National Institutes of Health, the NIH, and its Recombinant DNA Advisory Committee. The NIH could restrict or delay the development of our products.

Adverse Events in the Field of Gene Therapy, or with Respect to Our Potential Products, May Negatively Impact Regulatory Approval or Public Perception of Our Products.

The death in 1999 of a patient undergoing a viral-based gene therapy at the University of Pennsylvania in an investigator-sponsored trial has been widely publicized. This death and other adverse events in the field of gene therapy could result in greater governmental regulation of gene therapies, including our non-viral naked DNA technology, and potential regulatory delays relating to the testing or approval of our potential products. In addition, the field of gene therapy is under increased scrutiny, which may affect our product development efforts or clinical trials.

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.

The commercial success of our potential products will depend in part on public acceptance of the use of gene therapies for the prevention or treatment of human diseases. Public attitudes may be influenced by claims that gene therapies are unsafe and our naked DNA therapeutics may not gain the acceptance of the public or the medical community. Negative public reaction to adverse events in our trials or gene therapy in general could result in greater government regulation and stricter labeling requirements of gene therapies, including our naked DNA therapeutics, and could cause a decrease in the demand for any products we may develop.

Our Patents and Proprietary Rights May Not Provide Us with Any Benefit and the Patents of Others May Prevent Us from Commercializing Our Products.

Patents may not issue from any of our current applications. Moreover, if patents do issue, governmental authorities may not allow claims sufficient to protect our technology. Finally, others may challenge or seek to circumvent or invalidate patents that are issued to us or to licensors of our technology. In that event, the rights granted under patents may be inadequate to protect our proprietary technology or to provide any commercial advantage.

Our core DNA delivery technology is covered by a patent issued in Europe which is being opposed by several companies under European patent procedures. If we are not successful in this opposition proceeding we may lose part or all of our proprietary protection on our potential products in Europe.

Others may have or may receive patents which contain claims applicable to our products. These patents may impede our ability to commercialize products.

The Legal Proceedings to Obtain 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 protecting our proprietary technology in part through confidentiality agreements with our corporate collaborators, employees, consultants and certain contractors. These agreements may be breached and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or independently discovered by our competitors.

Protecting intellectual property rights can be very expensive. Litigation may be necessary to enforce a patent 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 U.S. Patent and Trademark Office or in a foreign counterpart 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 so as 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 on, patents not owned or controlled by us. We do not know whether any patents held by others will 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. A number of genetic sequences or proteins encoded by genetic sequences that we are investigating are, or may become, patented by others. As a result, we may have to obtain licenses to test, use or market these products. Our business will suffer if we are not able to obtain licenses at all or on terms commercially reasonable to us and we may not be able to redesign our products or processes to avoid infringement.

Competition and Technological Change May Make Our Potential Products 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 the diseases 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 than we have. Other companies may succeed in developing products earlier than we do, obtaining FDA approval for products more rapidly than we do, or developing products that are more effective than those we propose to develop. 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 therapy developed by us. Additionally, consumers may not prefer therapies developed by us over existing or newly developed therapies.

The Method of Administration of Some of Our Potential Products Can Cause Adverse Events in Patients, Including Death.

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

Commercialization of Some of Our Potential Products Depends on Collaborations With Others. If Our Collaborators Are Not Successful or if We Are Unable to Find Collaborators in the Future, We May Not Be Able to Develop These Products.

Our strategy for the research, development and commercialization of some of our product candidates requires us to enter into contractual arrangements with corporate collaborators, licensors, licensees and others. Our success depends upon the performance by these collaborators of their responsibilities under these arrangements. Some collaborators may not perform their obligations as we expect or we may not derive any revenue from these arrangements.

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

If We Lose Our Key Personnel or Are Unable to Attract and Retain Additional Personnel, We May Not Be Able to Pursue Collaborations or Develop Our Own Products.

We are highly dependent on the principal scientific, manufacturing, marketing and management personnel, the loss of whose services might significantly delay or prevent the achievement of our objectives. We face competition from other companies, academic institutions, government entities and other organizations in attracting and retaining personnel.

We May Not Be Able to Manufacture Products on a Commercial Scale.

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

The Company May Suffer Adverse Effects Due to the Impact of Electric Energy Blackouts and Higher Energy Costs.

Demand for electric power has exceeded supply in California periodically. To respond to this situation when it arises the California Independent System Operator, ISO, which is responsible for purchasing electricity from electricity generating companies, subjects areas to rolling blackouts by shutting off power to selected areas. We have incurred some blackouts and we may incur more in the future. We are unable to predict when these blackouts might occur or how long they will last. Our operations could be adversely impacted depending upon the frequency and duration of such blackouts. Further, energy prices continue to increase due to demand exceeding supply. We are subject to price escalation depending upon the price that the ISO has to pay to electricity providers.

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 cancer 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 cancer 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. Our inability to successfully employ qualified marketing and sales personnel and develop our sales and marketing capabilities will harm our business.

Health Care Reform and Restrictions on Reimbursement May Limit Our Returns on Potential Products.

Our ability to earn sufficient returns on our products will depend in part on the extent to which reimbursement for our products and related treatments will be available from:

- government health administration authorities,
- private health coverage insurers,
- managed care organizations, and

- other organizations.

If we fail to obtain appropriate reimbursement, it could prevent us from successfully commercializing our potential products.

There are efforts by governmental and third-party payors to contain or reduce the costs of health care 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.

Additionally, third-party payors 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 health care products, and whether adequate third-party coverage will be available.

We Use Hazardous Materials in Our Business. Any Claims Relating to Improper Handling, Storage or Disposal of These Materials Could Be Time Consuming and Costly.

Our research and development processes involve the controlled storage, use and disposal of hazardous materials, biological hazardous materials and radioactive compounds. We are subject to federal, state and local regulations governing the use, manufacture, storage, handling and disposal of materials and waste products. Although we believe that our safety procedures for handling and disposing of these hazardous materials comply with the standards prescribed by law and regulation, the risk of accidental contamination or injury from hazardous materials cannot be completely eliminated. In the event of an accident, we could be held liable for any damages that result, and any liability could exceed the limits or fall outside the coverage of our insurance. We may not be able to maintain insurance on acceptable terms, or at all. We could be required to incur significant costs to comply with current or future environmental laws and regulations.

We May Have Significant Product Liability Exposure.

We face an inherent business risk of exposure to product liability and other claims in the event that our technologies or products are alleged to have caused harm. These risks are inherent in the development of chemical and pharmaceutical products. Although we currently maintain product liability insurance, we may not have sufficient insurance coverage and we may not be able to obtain sufficient coverage at a reasonable cost. Our inability to obtain product liability insurance at an acceptable cost or to otherwise protect against potential product liability claims could prevent or inhibit the commercialization of any products developed by us or our collaborators. We also have liability for products manufactured by us on a contract basis for third parties. If we are sued for any injury caused by our technology or products, our liability could exceed our total assets.

Our Stock Price Could Continue to Be Highly Volatile and You May Not Be Able to Resell Your Shares at or Above the Price You Paid for Them.

The market price of our common stock, like that of many other life sciences companies, has been highly volatile and is likely to continue to be highly volatile. The following factors, among others, could have a significant impact on the market price of our common stock:

- the results of our preclinical studies and clinical trials or those of our collaborators or competitors or for DNA therapeutics in general,
- evidence of the safety or efficacy of our potential products or the products of our competitors,
- the announcement by us or our competitors of technological innovations or new products,

- governmental regulatory actions,
- changes or announcements in reimbursement policies,
- developments with our collaborators,
- developments concerning our patent or other proprietary rights or those of our competitors, including litigation,
- 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, and
- changes in estimates of our performance by securities analysts.

Our Anti-Takeover Provisions Could Discourage Potential Takeover Attempts and Make Attempts by Stockholders to Change Management More Difficult.

The approval of two-thirds of our voting stock is required to approve some transactions and to take some stockholder actions, including the calling of a special meeting of stockholders and the amendment of any of the anti-takeover provisions contained in our certificate of incorporation. Further, pursuant to the terms of our stockholder rights plan adopted in March 1995, we have distributed a dividend of one right for each outstanding share of common stock. These rights will cause substantial dilution to the ownership of a person or group that attempts to acquire us on terms not approved by our Board of Directors and may have the effect of deterring hostile takeover attempts.

Part II. Other Information

ITEM 6. EXHIBITS AND REPORTS ON FORM 8-K

(a) Reports on Form 8-K

None

VICAL INCORPORATED

SIGNATURES

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

		Vical Incorporated
Date: May 14, 2001	By:	/s/ MARTHA J. DEMSKI
		Martha J. Demski Vice President and Chief Financial Officer (on behalf of the registrant and as the registrant's Principal Financial and Accounting Officer)

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