

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, 1999

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 JUNE 30, 1999
----	-----
Common Stock, \$.01 par value	16,190,913

VICAL INCORPORATED

FORM 10-Q

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PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

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VICAL INCORPORATED
BALANCE SHEETS

	June 30, 1999 (Unaudited)	December 31, 1998
<S>	<C>	<C>
ASSETS		
Current Assets:		
Cash and cash equivalents	\$ 11,107,132	\$ 13,567,817
Marketable securities - available-for-sale	30,405,667	26,615,939
Receivables and other	1,338,669	1,432,711
	-----	-----
Total current assets	42,851,468	41,616,467
	-----	-----
Property and Equipment:		
Equipment	5,426,830	5,139,944
Leasehold improvements	1,558,088	1,558,554
	-----	-----
	6,984,918	6,698,498
Less--accumulated depreciation and amortization	(5,248,136)	(4,992,121)
	-----	-----
	1,736,782	1,706,377
	-----	-----
Patent costs, net of accumulated amortization	1,487,137	1,387,936
Other assets	147,892	133,385
	-----	-----
	\$ 46,223,279	\$ 44,844,165
	=====	=====

LIABILITIES AND STOCKHOLDERS' EQUITY

Current Liabilities:

Accounts payable and accrued expenses	\$ 2,143,604	\$ 2,281,252
Current portion of capital lease obligations	554,166	473,466
Current portion of notes payable	160,330	213,773
Deferred revenue	935,276	250,000
	-----	-----

Total current liabilities	3,793,376	3,218,491
	-----	-----

Long-Term Obligations:

Long-term obligations under capital leases	800,280	747,807
Notes payable	-	53,443
	-----	-----
Total long-term obligations	800,280	801,250
	-----	-----

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-- 16,190,913 and 15,866,544 shares issued and outstanding at June 30, 1999 and December 31, 1998, respectively	161,909	158,665
Additional paid-in capital	83,173,596	78,332,483
Accumulated other comprehensive income (loss)	(92,482)	69,440
Accumulated deficit	(41,613,400)	(37,736,164)
	-----	-----
Total stockholders' equity	41,629,623	40,824,424
	-----	-----
Total Liabilities and Stockholders' Equity	\$ 46,223,279	\$ 44,844,165
	=====	=====

</TABLE>
See accompanying notes.

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VICAL INCORPORATED
STATEMENTS OF OPERATIONS
(Unaudited)

<TABLE>
<CAPTION>

months ended	Three months ended		Six	
	June 30,		June	
30,	-----		-----	
	1999	1998	1999	
-----	-----	-----	-----	
1998				
-----	-----	-----	-----	
<S>	<C>	<C>	<C>	
<C>				
Revenues:				
License/royalty revenue	\$ 610,371	\$ 548,170	\$ 3,275,706	\$
3,080,145				
Contract revenue	643,095	11,500	1,257,934	
211,860				
-----	-----	-----	-----	
	1,253,466	559,670	4,533,640	
-----	-----	-----	-----	
3,292,005				
-----	-----	-----	-----	
Expenses:				
Research and development	3,737,835	3,058,086	7,352,063	
6,152,924				
General and administrative	1,121,793	1,014,332	2,134,735	
1,981,398				
-----	-----	-----	-----	
	4,859,628	4,072,418	9,486,798	
-----	-----	-----	-----	
8,134,322				
-----	-----	-----	-----	
Loss from operations	(3,606,162)	(3,512,748)	(4,953,158)	
(4,842,317)				
Interest income	568,086	619,770	1,139,260	
1,271,495				
Interest expense	30,115	41,770	63,338	
84,994				
-----	-----	-----	-----	
Net loss	\$ (3,068,191)	\$ (2,934,748)	\$ (3,877,236)	
\$ (3,655,816)	=====	=====	=====	
=====	=====	=====	=====	
Net loss per share (basic and diluted--Note 2)	\$ (.19)	\$ (.19)	\$ (.24)	\$
(.23)	=====	=====	=====	
=====	=====	=====	=====	
Weighted average shares used in computing net loss per share	16,190,840	15,789,206	16,072,318	
15,771,298	=====	=====	=====	
(Note 2)	=====	=====	=====	
=====	=====	=====	=====	

</TABLE>
See accompanying notes.

VICAL INCORPORATED
STATEMENTS OF CASH FLOWS
(UNAUDITED)

<TABLE>
<CAPTION>

	Six months ended June 30,	
	1999	1998
<S>	<C>	<C>
OPERATING ACTIVITIES:		
Net loss	\$ (3,877,236)	\$ (3,655,816)
Adjustments to reconcile net loss to net cash provided from (used in) operating activities:		
Depreciation and amortization	530,592	467,202
Write-off of abandoned patent costs	-	60,144
Change in operating assets and liabilities:		
Receivables and other	94,042	377,171
Accounts payable and accrued expenses	(137,648)	(32,167)
Deferred revenue	685,276	571,739
Net cash used in operating activities	(2,704,974)	(2,211,727)
INVESTING ACTIVITIES:		
Marketable securities	(3,951,650)	(145,810)
Capital expenditures	(159,985)	(16,253)
Deposits and other	14,493	(4,074)
Patent expenditures	(145,447)	(86,501)
Net cash used in investment activities	(4,242,589)	(252,638)
FINANCING ACTIVITIES:		
Principal payments under capital lease obligations	(250,593)	(249,970)
Payments on notes payable	(106,886)	(160,330)
Issuance of common stock, net	4,844,357	863,521
Net cash provided from financing activities	4,486,878	453,221
Net decrease in cash and cash equivalents	(2,460,685)	(2,011,144)
Cash and cash equivalents at beginning of period	13,567,817	12,157,149
Cash and cash equivalents at end of period	\$ 11,107,132	\$ 10,146,005
Supplemental Disclosure of Non-Cash Investing and Financing Activities: Equipment acquired under capital leases	\$ 383,766	\$ 179,135

</TABLE>

See accompanying notes.

VICAL INCORPORATED
NOTES TO FINANCIAL STATEMENTS

June 30, 1999
(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. The Company is currently focusing its resources on the development of its direct gene transfer and related technologies.

BASIS OF PRESENTATION

The information contained herein has been prepared in accordance with instructions for Form 10-Q. The information at June 30, 1999, and for the three-month and six-month periods ended June 30, 1999 and 1998, 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 generally accepted accounting principles 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 generally accepted accounting principles, these financial statements should be read in conjunction with the audited financial statements for the year ended December 31, 1998, included in the Vical Incorporated Form 10-K filed with the Securities and Exchange Commission.

2. NET LOSS PER SHARE

Net loss per share (basic and diluted) for the three-month and six-month periods ended June 30, 1999 and 1998, 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.

3. COMPREHENSIVE INCOME (LOSS)

Accumulated other comprehensive income (loss) represents unrealized gain or loss on marketable securities. For the three-month periods ended June 30, 1999 and 1998, other comprehensive loss was \$109,835 and \$19,031, respectively, and total comprehensive loss was \$3,178,026 and \$2,953,779, respectively. For the six-month periods ended June 30, 1999 and 1998, other comprehensive loss was \$161,922, and \$19,756, respectively, and total comprehensive loss was \$4,039,158 and \$3,675,572, respectively.

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

OVERVIEW

Vical was incorporated in April 1987 and has devoted substantially all of its resources since that time to its research and development programs. The Company is focusing its resources on the development of its direct gene transfer and related technologies. The Company is developing its ALLOVECTIN-7, LEUVECTIN and VAXID cancer product candidates internally, while developing vaccine product candidates for infectious diseases primarily in collaboration with corporate partners Merck & Co., Inc. ("Merck") and Pasteur Merieux Connaught ("PMC"). Vical and Centocor, Inc. have a license agreement allowing Centocor, Inc. to use Vical's naked DNA technology to develop and market certain gene-based vaccines for the potential treatment of certain types of cancer. The Company has an agreement with Boston Scientific for the use of Vical's technology in catheter-based intravascular gene delivery. Vical has an agreement with Rhone-Poulenc Rorer to use its gene delivery technology to deliver certain neurological proteins for neurodegenerative diseases. Vical also has agreements with Pfizer Inc. for use of its technology for gene delivery of therapeutic proteins in certain animal health applications and with Merial for use of its technology for DNA vaccines in certain animal infectious disease targets.

To date, the Company has not received revenues from the sale of products. The Company expects to incur substantial operating losses for at least the next several years, due primarily to expansion of its research and development programs and the cost of preclinical studies and clinical trials. As of June 30, 1999, the Company's accumulated deficit was approximately \$41.6 million.

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, the Company believes 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.

In May 1998, the Company initiated registration-supportive expanded Phase II and Phase III multi-center clinical trials with ALLOVECTIN-7 in certain patients with metastatic melanoma. Either or both of the pivotal trials could support product registration if endpoints are achieved. Vical also has a multi-center Phase II study underway with ALLOVECTIN-7 in patients with head and neck cancer.

Vical is developing its 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 IL-2 and a lipid material to facilitate gene uptake. The Company expects 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, the Company believes that it may provide efficacy similar to systemic IL-2 therapy with fewer side effects.

In May 1998, the Company initiated a multicenter Phase II clinical trial using LEUVECTIN in patients with metastatic renal cell carcinoma. Preliminary results presented in May 1999 indicated that LEUVECTIN appears to be safe and well tolerated, appears to stimulate an intended immune response against tumors, and may inhibit progression of the disease in patients with metastatic kidney cancer. In May 1999, data were presented from a Phase I/II trial testing LEUVECTIN in patients with prostate cancer. Vical began Phase II clinical trials in prostate cancer during the second quarter of 1999.

In collaboration with Stanford University Medical Center, the Company is conducting a Phase I/II clinical trial of VAXID, a naked DNA vaccine against low-grade non-Hodgkin's B-cell lymphoma. VAXID contains a gene that encodes the patient-specific idiotype (characteristic feature) of cancerous B-cells. The Company believes that immunization of post-chemotherapy patients with VAXID could result in the

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elimination of residual disease and the prevention of the relapse of disease.

The National Cancer Institute (NCI) published data from a previous NCI clinical trial indicating a 42 percent response rate in end-stage melanoma patients after treatment with systemic IL-2 and a peptide-based vaccine using a modified gp100 protein developed at NCI. This Phase I/II study is being repeated at the National Cancer Institute with a naked DNA version of the gp100 vaccine provided by Vical.

Vical is collaborating with PMC and the U.S. Naval Medical Research Center (NMRC) to develop a DNA vaccine against malaria. In July 1997, Vical and PMC began a Phase I trial of an experimental vaccine against the parasite that causes malaria. NMRC conducted the clinical trial with approximately twenty volunteers. Trial results, reported in an October 1998 issue of SCIENCE, indicated that subjects immunized with a potential malaria DNA vaccine developed dose-related killer T-cell immune responses. As a result of these data, further clinical development is planned.

In January 1999, Vical and Pfizer Inc. entered into a license and option agreement granting Pfizer rights to use Vical's proprietary naked DNA technologies to deliver therapeutic proteins for animal health applications. The agreement resulted in a \$1,000,000 license payment to Vical, a \$6,000,000 investment in approximately 318,000 shares of Vical common stock at \$18.87 per share, and a commitment to fund Vical research for a total of \$1,500,000 over the next three years. In March 1999, Vical received \$1,100,000 from Merck for the extension to March 2000 of its option on vaccine targets.

During the second quarter of 1999, Vical was awarded a multi-year SBIR grant of up to \$553,000 from the National Cancer Institute (NCI) for cancer vaccine development work. Vical also was awarded multi-year contracts by the National Institute of Allergies and Infectious Diseases for infectious disease vaccine support work of at least \$250,000. In recent months, several Vical patents were issued including patents which cover: compositions and methods for naked DNA vaccination against Lyme disease; a class of cationic lipids useful in gene delivery; a method of inducing and repressing the activity of genes after IN VIVO delivery into cells; and specific plasmids and uses encompassing Vical's ALLOVECTIN-7 product candidate. In addition a European patent was issued which covers a class of cationic lipids including those used in Vical's ALLOVECTIN-7 and LEUVECTIN product candidates.

Merck is planning to initiate a clinical trial before year-end with a vaccine using Vical's patented naked DNA gene delivery technology to protect against infection by human immunodeficiency virus (HIV), the virus that causes acquired immunodeficiency syndrome. In May 1991, Vical entered into a research collaboration and license agreement with Merck to develop vaccines utilizing Vical's intramuscular delivery technology to prevent infection and/or disease in humans. In connection with the 1991 agreement, Vical granted Merck a worldwide exclusive license to preventive vaccines using Vical's technology against seven human infectious diseases: HIV, influenza, herpes simplex, hepatitis B, hepatitis C, human papillomavirus and tuberculosis. In exchange for the license granted under this agreement, Merck has paid Vical initial license and option fees, option exercise fees, research and development payments, and payments for the achievement of development milestones. Merck is obligated to pay additional fees if development milestones are achieved with respect to the products developed under the Merck agreement and royalties on net sales by Merck of products, if any products are developed and marketed. There can be no assurance that any products will be developed under the license agreement, that any products would be shown to be safe and efficacious in clinical trials, that any

products would receive the necessary regulatory approvals, or that any products would be marketed by Merck.

The Company's product candidates may not prove to be safe and effective in clinical trials and no commercially successful products may ultimately be developed by the Company.

This Form 10-Q contains, in addition to historical information, forward-looking statements. When used in this discussion, the words "expects," "anticipated" and similar expressions are intended to identify forward-looking statements. Such statements are subject to certain risks and uncertainties, including whether the

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Company's product candidates will be shown to be safe or efficacious in clinical trials, whether the Company's corporate collaborations will be successful, and whether the Company's product candidates will ultimately be successfully developed or receive necessary regulatory approvals and other matters discussed under the caption "Risk Factors" below, which could cause actual results to differ materially from those projected. These forward-looking statements speak only as of the date hereof. The Company undertakes no obligation to update these forward-looking statements to reflect events or circumstances after the date hereof or to reflect the occurrence of unanticipated events.

RESULTS OF OPERATIONS

Revenues of \$1,253,000 were recorded for the quarter ended June 30, 1999. License revenue primarily represented recognition of deferred license fees of \$275,000 from Merial and royalty revenue of \$281,000. Contract revenue recognized was \$643,000, and was primarily from a contract with the Office of Naval Research for the development work on a potential naked DNA vaccine to prevent malaria. This multi-year grant could provide up to \$2,700,000 of funding to the Company, of which \$1,758,000 was recognized as revenue through June 30, 1999.

The Company had revenues of \$560,000 for the quarter ended June 30, 1998. License revenue for the quarter ended June 30, 1998, included recognition of deferred license fees of \$350,000 under earlier agreements with PMC and Merial and royalty revenues of \$183,000.

Revenues for the six months ended June 30, 1999, were \$4,534,000. In addition to the revenue recognized in the second quarter of 1999, revenue for the six months ended June 30, 1999, also included \$1.0 million of license fee and \$1.2 million of equity premium pursuant to January 1999 agreements with Pfizer Inc., recognition of deferred license fees of \$250,000 from Merial, royalty revenue of \$215,000 and contract revenue of \$615,000 primarily from the Office of Naval Research.

Revenues for the six months ended June 30, 1998, were \$3,292,000, and in addition to the revenue recognized in the second quarter of 1998, also included license payments of \$2,200,000 from Centocor under a license and option agreement and reimbursement of certain costs, recognition of deferred license fees from PMC and Merial and royalty revenue totaling \$332,000, and \$200,000 of contract revenues from PMC.

The Company's total operating expenses for the quarter ended June 30, 1999, were \$4,860,000 compared with \$4,072,000 for the second quarter of 1998. Total operating expenses for the six months ended June 30, 1999, were \$9,487,000 compared with \$8,134,000 for the same period in 1998.

Research and development expenses increased to \$3,738,000 for the three months ended June 30, 1999, from \$3,058,000 for the same period in 1998. For the six months ended June 30, 1999, research and development expenses were \$7,352,000 compared with \$6,153,000 in the same period of 1998. The increase in research and development expenses for the three-month and six-month periods was generally due to increased preclinical and clinical trial costs, and personnel-related costs. The increase for the six-month period ended June 30, 1999 was partially offset by lower license payments to third parties.

General and administrative expenses increased to \$1,122,000 for the three months ended June 30, 1999, from \$1,014,000 for the same period in 1998. General and administrative expenses for the six months ended June 30, 1999, increased to \$2,135,000 from \$1,981,000 for the same period in 1998. The increase primarily is attributable to increased personnel costs.

Investment income for the three-month and six-month periods ended June 30, 1999, was \$568,000 and \$1,139,000, respectively. Investment income for the three-month and six-month periods ended June 30, 1998, was \$620,000 and \$1,271,000, respectively. The decreases primarily are a result of lower investment balances and lower rates of return on investments.

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The net loss was \$.19 per share for both the three months ended June 30, 1999, and the three months ended June 30, 1998. For the six months ended June

30, 1999, the net loss was \$.24 per share compared with a net loss of \$.23 per share for the same period in the prior year. The Company expects to incur losses throughout the remainder of 1999 and to report a net loss per share for the year ended December 31, 1999.

LIQUIDITY AND CAPITAL RESOURCES

Since its inception, Vical has financed its operations primarily through private placements of preferred and common stock, three public offerings of common stock and revenues from collaborative agreements. As of June 30, 1999, the Company had working capital of approximately \$39.1 million compared with \$38.4 million at December 31, 1998. Cash and marketable securities totaled approximately \$41.5 million at June 30, 1999, compared with \$40.2 million at December 31, 1998.

The Company expects to incur substantial additional research and development expense and general and administrative expense, including continued increases in personnel costs, costs related to preclinical testing and clinical trials, outside services and facilities. The Company's future capital requirements will depend on many factors, including continued scientific progress in its 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 and scale-up, and commercialization activities and arrangements. The Company intends to seek additional funding through research and development relationships with suitable potential corporate collaborators or through public or private financing. Additional funding may not be available on favorable terms or at all.

If additional funding is not available, Vical anticipates that its available cash and existing sources of funding will be adequate to satisfy its operating needs through at least 2000.

YEAR 2000 ISSUES

The Year 2000 problem is due to many computer systems using only two digits rather than four to designate a specific year. As a result, many of these systems may fail to function properly if a date beyond 1999 is entered. We have completed our assessment of any potential Year 2000 issues for our internal computer applications, including embedded control systems in equipment, to determine whether they will function for the year 2000 and beyond and what modifications would be required to ensure their continuing functionality. We upgraded our existing business applications software to the latest Year 2000 compliant release of the software. We also plan to implement a new financial and accounting system and related hardware to meet our growing needs into the near future. This new system will be Year 2000 compliant and implemented prior to year-end. Given the relatively small size of our systems and the predominantly new hardware, software and operating systems, we do not anticipate any significant delays in becoming Year 2000 compliant. To date our costs for Year 2000 compliance have been immaterial and we expect our costs to finish becoming Year 2000 compliant to be immaterial.

We are unable to control whether our current and future strategic partners' systems are Year 2000 compliant. The failure of systems maintained by our strategic partners or suppliers could cause us to incur significant expenses to remedy any problems, or otherwise seriously damage our business. We have communicated with strategic partners to assess the risk of Year 2000 issues. Based on these results, at this time, we do not expect any material Year 2000 issues regarding our dealings with our strategic partners.

At this time, we have no reason to believe that Year 2000 changes will have a material impact on Vical's business, financial condition or results of operations. Since no significant issues have been identified, we do not have a comprehensive contingency plan to address any material Year 2000 issues. We plan to perform backups of the existing and upgraded versions of the computer system so that in the event

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our planned new financial and accounting system and related hardware do not function properly we can continue to operate under the old system. Vical has not identified what it believes would be a reasonably likely worst case scenario with respect to Year 2000 failures.

RISK FACTORS

You should carefully consider the following risk factors when evaluating Vical and its prospects as presented in this report or elsewhere by management.

UNCERTAINTY CONCERNING OUR POTENTIAL PRODUCTS AND TECHNOLOGY MAY ADVERSELY AFFECT US

Very little data exists regarding the safety and efficacy of gene

therapy. Moreover, existing studies do not necessarily predict that gene therapy will be safe or effective in humans. This is significant because all of our potential products are either in research or development. A failure to successfully develop and commercialize products will materially adversely affect us. 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. This research and development may indicate that our potential products are unsafe or ineffective, in which case, regulatory authorities may not approve them. Even if approved, our products may not be commercially successful.

OUR LOSSES

We have not sold any products and do not expect to sell any products for the next several years. We have incurred cumulative losses totaling approximately \$41.6 million through June 30, 1999. Moreover, we expect that our negative cash flow and losses from operations will continue and increase for the foreseeable future. Indeed, 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.

OUR ADDITIONAL FINANCING REQUIREMENTS AND LACK OF ACCESS TO CAPITAL COULD ADVERSELY AFFECT US

We will need to raise more money to continue the research and development necessary to bring products to market and to establish manufacturing and marketing capabilities. If we cannot obtain more money we will be materially and adversely affected. The amount of money we will 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
- competing technological and market developments
- the commercial arrangements we may establish
- other factors not within our control

We intend to seek additional funds through public and private stock offerings, arrangements with corporate collaborators or other sources. However, we may be unable to obtain the money we need on acceptable terms. If this happens, we may have to eliminate or scale back some or all of our research and development programs or license others to develop products and/or technologies that we otherwise would seek to develop ourselves.

THE REGULATORY APPROVAL PROCESS IS EXPENSIVE, TIME CONSUMING AND UNCERTAIN WHICH MAY ADVERSELY AFFECT US

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The regulations governing gene therapy products are evolving and uncertain; seeking to comply with them is expensive and time consuming. Failure to obtain FDA approval of our products will materially and adversely affect us. For example, the FDA has not established guidelines concerning the length of the clinical trial period required for gene therapy products. Nor has that agency indicated how many patients it will require to be enrolled in clinical trials to establish the safety, efficacy and potency of gene therapy products. Furthermore, existing regulations are subject to substantial review by various governmental agencies. Therefore, future U.S. or foreign regulations could prevent or delay regulatory approval of our products or affect adversely our ability to develop, test, manufacture and market our products.

We believe that the FDA and comparable foreign regulatory bodies will regulate the commercial use of any of our products as either biologics or drugs. These agencies are likely to regulate each product containing a particular gene as a separate biologic or drug depending on its intended use and evolving policy. Presently, to commercialize any product we must sponsor and file a regulatory application for each proposed product. We then must conduct clinical studies to demonstrate the safety, efficacy and potency of the product necessary to obtain FDA approval.

The NIH also has established guidelines for research involving recombinant DNA molecules which is conducted at or supported by the NIH. We must comply with these guidelines because we and some of our collaborators use recombinant DNA molecules in our research and we have received grants from the NIH. Under current guidelines, we must submit for review to the NIH and the Recombinant DNA Advisory Committee each of our proposals to conduct clinical research.

We may be unable to obtain the necessary approvals for clinical

trials or for the manufacturing or marketing of our products. Even if we do obtain regulatory clearance, marketed products remain subject to continual review by U.S. regulators. If regulators discover a previously unknown problem with one of our products, or if we fail to comply with applicable regulations, regulators may:

- restrict marketing of the product
- withdraw the product from the market
- impose civil or criminal sanctions

In addition, many other companies and academic institutions are conducting research in the gene therapy field using a variety of approaches and technologies. If any of these researchers were to obtain adverse results in preclinical or clinical studies this could adversely affect the regulatory environment for gene therapy products in general, possibly leading to delays in the approval process for our potential products.

UNCERTAINTY REGARDING OUR INTELLECTUAL PROPERTY RIGHTS MAY HARM US

Patents may not issue from any of our applications. Moreover, if patents do issue, governmental authorities may not allow claims in such patents 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 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 seek to protect our proprietary technology through confidentiality agreements with corporate collaborators, employees, consultants and contractors. Others may breach these agreements and we may not have a remedy that is adequate to protect our rights.

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Protecting intellectual property rights can also be very expensive. Litigation may be necessary to enforce a patent 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.

Our success also will depend in part on our ability to keep from infringing upon patents issued to competitors and breaching the technology licenses that might cover technology used in our products. We do not know whether any patents held by others will require us to alter our products or processes, obtain licenses, or stop activities. 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 may suffer if we cannot obtain licenses, or if we can obtain them only on terms that are commercially unfavorable.

OUR DEPENDENCE ON OTHERS MAY ADVERSELY AFFECT US

Our strategy for the research, development and commercialization of our products requires us to enter into contractual arrangements with corporate collaborators, licensors, licensees and others. Our success depends upon the performance by these persons of their responsibilities under these arrangements. We cannot control the timing of their performance or the amount of resources they will devote to these activities. Some persons 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.

THE EFFECT OF COMPETITION AND TECHNOLOGICAL CHANGE MAY HURT US

Gene therapy is a new and rapidly evolving field. We expect that the field will continue to undergo significant and rapid technological change. Such change could render our products or technologies obsolete.

We compete with companies in the field of gene therapy and with

companies pursuing other forms of treatment or prevention for the diseases we have targeted. Several development stage and established entities, including major pharmaceutical and biotechnology firms, are exploring the field of human gene therapy or are actively engaged in research and development in areas related to gene therapy. 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 in aspects of gene therapy which may materially and adversely affect our business.

Some of our competitors and potential competitors have substantially greater product development capabilities and financial, scientific, marketing and human resources than we do. 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 might 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.

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WE CANNOT MANUFACTURE OR MARKET PRODUCTS ON A COMMERCIAL SCALE WHICH MAY HURT US

We have neither the resources nor the capability to manufacture or market our proposed products on a commercial scale. We may be dependent initially on corporate partners, licensees or others to manufacture and market our products commercially. If we decide to establish a commercial-scale manufacturing facility, we will require substantial additional funds and personnel. We also will be required to comply with extensive regulations applicable to a manufacturing facility. We may be unable to enter into any arrangement for the manufacture or marketing of our products. We also may be unable to obtain additional capital to perform these activities ourselves.

THERE IS UNCERTAINTY CONCERNING INSURANCE COVERAGE AND REIMBURSEMENT FOR OUR POTENTIAL PRODUCTS WHICH MAY ADVERSELY AFFECT US

As with many health care products and services, the commercial viability of our gene therapy products and related treatments may depend in part on whether their costs are covered by health insurers. These insurers include:

- government health administration authorities
- private health coverage insurers
- managed care organizations
- other similar organizations

Whenever a new health care product is approved by the regulatory authorities it is always uncertain whether insurers will cover the product. We do not know whether or to what extent insurers will cover our potential products. If purchasers or users of our potential products are not entitled to adequate reimbursement for the cost of using our potential products, they may decide not to use them or to limit their use. This could harm our business.

OUR USE OF HAZARDOUS MATERIALS COULD ADVERSELY AFFECT US

Although we do not manufacture commercial quantities of our potential products we do produce limited quantities of our potential products for clinical trials. 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. There is a risk of accidental contamination or injury from these materials. In the event of an accident, we could be held liable for any damages that result, and any liability could exceed our resources. We could be required to incur significant costs to comply with current or future environmental laws and regulations. This could materially or adversely affect our operations, business or assets.

VOLATILITY OF STOCK PRICE AND ABSENCE OF DIVIDENDS

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 adverse impact on the market price of our common stock:

- the results of our preclinical studies and clinical trials or those of one of our collaborators or competitors
- other evidence of the safety or efficacy of our potential

products or the products of our competitors

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- the announcement by us or one of our competitors of technological innovations or new products
- governmental regulatory actions
- developments with our collaborators

- developments concerning our patent or other proprietary rights or those of one 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
- other factors not within our control

We have never paid cash dividends on our common stock and do not anticipate paying any cash dividends in the foreseeable future.

YEAR 2000 ISSUES

We are unable to control whether our current and future strategic partners' computer systems are Year 2000 compliant. Any of the following events could affect our operations:

- if a strategic partner were unable to purchase our clinical materials or services
- if a strategic partner were unable to manage its clinical trials or research and development activities
- if a strategic partner were unable to pay its invoices owed to us
- if a supplier were unable to manufacture and ship materials to us or provide requested contract services

Failure of systems maintained by our strategic partners or suppliers could cause us to incur significant expenses to remedy any problems, or otherwise seriously damage our business.

PART II. OTHER INFORMATION

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

On May 27, 1999, the Company held its Annual Meeting of Stockholders. The following actions were taken at the annual meeting.

1. The following Class I directors were elected:

a. Alain B. Schreiber, M.D.--13,594,355 shares voted in favor of the nominee, 84,287 withheld their vote.

b. Philip M. Young-- 13,593,015 shares voted in favor of the nominee, 85,627 withheld their vote.

The Company's Class II directors, Dr. M. Blake Ingle and R. Gordon Douglas, Jr., M.D continue in office until 2000.

The Company's Class III directors, Patrick F. Latterell, Gary A. Lyons and Dale A. Smith, continue in office until 2001.

2. The amendment and restatement of the Stock Incentive Plan of Vical Incorporated was approved. Shares voted for the proposal were 10,342,846, with 3,226,748 shares voted against the proposal and 109,048 shares abstained.

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3. The selection of the Company's independent auditors was ratified. Shares voted in favor of the proposal were 13,610,998, with 23,129 shares voted against the proposal and 44,515 shares abstained.

ITEM 6. EXHIBITS AND REPORTS ON FORM 8-K

1. Exhibits

EXHIBIT 27 Financial Data Schedule

2. Reports on Form 8-K

None

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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: August 12, 1999

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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EXHIBIT
NUMBER

DESCRIPTION OF DOCUMENT

1 EXHIBIT 27

Financial Data Schedule

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THIS SCHEDULE CONTAINS SUMMARY FINANCIAL INFORMATION EXTRACTED FROM THE BALANCE SHEETS AND STATEMENTS OF OPERATIONS OF THE COMPANY'S FORM 10-Q FOR THE SIX-MONTH PERIOD ENDED JUNE 30, 1999 AND IS QUALIFIED IN ITS ENTIRETY BY REFERENCE TO SUCH FINANCIAL STATEMENTS.

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