

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 September 30, 2000

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.

<TABLE>
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Class	Outstanding At September 30, 2000
<S> Common Stock, \$.01 par value	<C> 20,004,818

</TABLE>

VICAL INCORPORATED

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* No information provided due to inapplicability of item.

PART I. FINANCIAL INFORMATION
ITEM 1. FINANCIAL STATEMENTS

VICAL INCORPORATED
BALANCE SHEETS

<TABLE>
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December 31,	September 30,	
	2000	1999
-----	-----	-----
	(Unaudited)	
	<C>	<C>
<S>		
ASSETS		
Current Assets:		
Cash and cash equivalents	\$ 19,786,374	\$
11,149,587		
Marketable securities - available-for-sale	130,619,852	
26,525,181		
Receivables and other	3,366,632	
3,971,621		
-----	-----	-----
Total current assets	153,772,858	
41,646,389		
-----	-----	-----
Investment, at cost	5,000,000	

-			
Property and Equipment:			
Equipment		6,677,662	
5,948,458			
Leasehold improvements		2,960,699	
1,646,023			

		9,638,361	
7,594,481			
Less--accumulated depreciation and amortization		(6,348,224)	
(5,708,349)			

		3,290,137	
1,886,132			

Patent costs, net of accumulated amortization		1,555,857	
1,380,245			
Other assets		139,892	
146,470			

		\$ 163,758,744	\$
45,059,236			
=====			
LIABILITIES AND STOCKHOLDERS' EQUITY			
Current Liabilities:			
Accounts payable and accrued expenses		\$ 3,082,464	\$
3,839,642			
Current portion of capital lease obligations		597,480	
627,957			
Current portion of notes payable		285,714	
106,887			
Current portion of deferred revenue		1,566,971	
1,076,166			

Total current liabilities		5,532,629	
5,650,652			

Long-Term Obligations:			
Long-term obligations under capital leases		1,266,371	
739,885			
Notes payable		619,047	
-			
Deferred revenue		3,272,728	
-			

Total long-term obligations		5,158,146	
739,885			

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--		200,048	
162,011			
20,004,818 and 16,201,136 shares issued and outstanding at September 30,			
2000 and December 31, 1999, respectively			
Additional paid-in capital		203,024,710	
83,292,870			
Accumulated other comprehensive income (loss)		88,737	
(140,801)			
Accumulated deficit		(50,245,526)	
(44,645,381)			

Total stockholders' equity		153,067,969	
38,668,699			

Total Liabilities and Stockholders' Equity		\$ 163,758,744	\$
45,059,236			
=====			

</TABLE>

See accompanying notes.

VICAL INCORPORATED
STATEMENTS OF OPERATIONS
(Unaudited)

<TABLE>
<CAPTION>

ended	Three months ended		Nine months	
	September 30,		September 30,	
	2000	1999	2000	
1999				
<S>	<C>	<C>	<C>	<C>
Revenues:				
License/royalty revenue	\$ 723,625	\$ 495,024	\$ 3,582,730	\$
3,770,731				
Contract revenue	705,985	733,817	1,608,919	
1,991,750				
	1,429,610	1,228,841	5,191,649	
5,762,481				
Operating Expenses:				
Research and development	4,524,155	3,514,247	13,551,454	
10,866,310				
General and administrative	1,263,224	1,066,402	3,902,986	
3,201,137				
	5,787,379	4,580,649	17,454,440	
14,067,447				
Loss from operations	(4,357,769)	(3,351,808)	(12,262,791)	
(8,304,966)				
Interest income	2,551,965	548,490	6,801,423	
1,687,750				
Interest expense	65,265	33,489	138,777	
96,827				
Net loss	\$ (1,871,069)	\$ (2,836,807)	\$ (5,600,145)	\$
(6,714,043)				
Net loss per share (basic and diluted)	\$ (0.09)	\$ (0.18)	\$ (0.29)	\$
(0.42)				
Weighted average shares used in computing net loss per share	19,896,427	16,196,078	19,581,493	
16,144,024				

</TABLE>

See accompanying notes.

VICAL INCORPORATED
STATEMENTS OF CASH FLOWS
(Unaudited)

<TABLE>
<CAPTION>

	Nine months ended September 30,	
-----	-----	
1999	2000	
-----	-----	
<S>	<C>	<C>
OPERATING ACTIVITIES:		
Net loss	\$	(5,600,145)
(6,714,043)		\$
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization		877,330
795,742		
Change in operating assets and liabilities:		
Receivables and other		604,989
(365,192)		
Accounts payable and accrued expenses		(757,178)
599,827		
Deferred revenue		(1,236,467)
460,637		
-----		-----
Net cash used in operating activities		(6,111,471)
(5,223,029)		
-----		-----
INVESTING ACTIVITIES:		
Marketable securities		(103,865,133)
(1,317,960)		
Capital expenditures		(1,133,214)
(182,509)		
Deposits and other		6,535
15,008		
Patent expenditures		(251,154)
(53,800)		
-----		-----
Net cash used in investment activities		(105,242,966)
(1,539,261)		
-----		-----
FINANCING ACTIVITIES:		
Issuance of common stock, net		119,769,877
4,930,347		
Payments on notes payable		(201,713)
(160,329)		
Proceeds from notes payable		999,587
-		
Principal payments under capital lease obligations		(576,527)
(388,707)		
-----		-----
Net cash provided from financing activities		119,991,224
4,381,311		
-----		-----
Net increase (decrease) in cash and cash equivalents		8,636,787
(2,380,979)		
Cash and cash equivalents at beginning of period		11,149,587
13,567,817		
-----		-----
Cash and cash equivalents at end of period	\$	19,786,374
11,186,838		\$
-----		-----
=====		
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 leases
493,254

\$ 1,072,536 \$

</TABLE>

See accompanying notes.

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VICAL INCORPORATED

NOTES TO FINANCIAL STATEMENTS

September 30, 2000
(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 September 30, 2000, and for the three-month and nine-month periods ended September 30, 2000 and 1999, 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, 1999, 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 nine-month periods ended September 30, 2000 and 1999, 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 (loss) 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 September 30, 2000 and 1999, other comprehensive income (loss) was \$294,000 and \$(24,000), respectively, and total comprehensive loss was \$1,577,000 and \$2,860,000, respectively. For the nine-month periods ended September 30, 2000 and 1999, other comprehensive income (loss) was \$230,000 and \$(186,000), respectively, and total comprehensive loss was \$5,371,000 and \$6,900,000, respectively.

4. PUBLIC STOCK OFFERING

In January 2000, Vical sold 3,450,000 shares of common stock in a public offering which raised net proceeds of approximately \$117.5 million.

5. LICENSE AGREEMENTS

On June 30, 2000, Vical and Aventis Pharma, the pharmaceutical company of Aventis S.A., entered into a license agreement granting Aventis Pharma rights to use Vical's naked DNA gene transfer technology to deliver a growth factor gene for which Aventis Pharma holds rights. The agreement resulted

in an initial payment to Vical of \$1.5 million in July 2000, and could generate milestone payments and royalties if products advance through commercialization.

On February 24, 2000, Vical and Human Genome Sciences, Inc., or HGS, signed a reciprocal royalty-bearing license. Under the agreement, Vical has the option to exclusively license up to three genes from HGS for gene-based product development. HGS has the option to license Vical's naked DNA gene delivery technology for use in up to three gene-based products. In addition, Vical granted an exclusive, royalty-bearing license to Vascular Genetics, Inc., or VGI, a company in which HGS is a major shareholder, for naked DNA delivery of a gene with potential use for revascularization. In exchange, Vical received shares of Preferred Stock Series B of VGI. This investment was recorded at estimated fair value of \$5.0 million on the date of investment and is reflected as Investment, at cost, in the accompanying balance sheet. The investment is being accounted for on the cost method. Vical also recorded a liability for deferred revenue of \$5.0 million. This deferred revenue is being recognized ratably each month through September 30, 2004.

6. COMMITMENTS

Vical expanded its leased space by approximately 5,100 square feet in one facility effective June 1, 2000, by amending an existing lease agreement. Total monthly rental on all facilities, including common area maintenance costs, is approximately \$125,000 effective June 1, 2000. This lease amendment increased our minimum lease commitments by approximately \$938,000 through the end of the lease in November 2004.

At September 30, 2000, Vical had borrowed \$1.0 million under the \$1.0 million line of credit with a bank to finance certain leasehold improvements. In November 2000, this line of credit was amended and increased to \$2.3 million. Under the terms of the amended agreement, Vical can use 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.

7. RECENT ACCOUNTING PRONOUNCEMENTS

In December 1999, the SEC issued Staff Accounting Bulletin No. 101 - "Revenue Recognition," or SAB 101. SAB 101 reflects the SEC's views on revenue recognition. Historically Vical has recognized revenue from initial technology option and license fees in the period in which the agreement was signed if there were no significant performance obligations remaining. Revenue from milestone payments is recognized as revenue when the milestones are achieved. SAB 101 would require that when there has not been the culmination of the earnings process, revenue from technology option and license fees and milestone payments be deferred and recognized over the period over which the revenue is deemed to be earned. There is a lack of guidance about applying SAB 101 in the Life Sciences Industry, including what constitutes the culmination of the earnings process where there are up-front, milestone and royalty payments. Further, there is significant uncertainty about the life over which to recognize this revenue, particularly where royalties continue to be payable until the last related patent expires. There is no written guidance to determine whether it would be acceptable to amortize the revenue over the estimated product development period, which is a shorter period than the estimated life of the patents. Due to the uncertainties noted above, we have not completed our evaluation of the impact of SAB 101 on our financial statements, however, the potential impact is expected to be material to the financial statements. Effective from 1991, when our first license fee revenues were recognized, to September 30, 2000, Vical has recognized cumulative license fee revenue representing nonrefundable up-front and milestone payments of approximately \$39 million which will have to be evaluated for deferral under SAB 101. The amount that will need to be deferred will depend principally on the estimated life over which we are allowed to recognize the revenue under SAB 101.

When Vical implements SAB 101 in the fourth quarter of 2000, it will do so by restating the first quarter 2000 statements. The statement of operations will reflect a one-time charge to earnings for the cumulative effect of the change in accounting principle as of January 1, 2000, and license revenues will be recognized based on SAB 101 effective as of that date. The financial statements for the second and third quarters of 2000 will also be restated to apply SAB 101 effective January 1, 2000.

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 September 30, 2000, our accumulated deficit was approximately \$50.2 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 enter 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-Registered Trademark-, 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-Registered Trademark- 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-Registered Trademark- is in Phase III and Phase II registration trials for patients with advanced metastatic malignant melanoma, an aggressive form of skin cancer. Recruitment of patients in the Phase III trial is progressing toward possible completion in the first half of 2001. Allovectin-7-Registered Trademark- is also in Phase II clinical testing for patients with cancer of the head and neck. Based on recently reported data, Vical is planning a new Phase II study in patients with earlier-stage head and neck cancer.

Vical is developing its second gene-based product candidate, Leuvectin-TM-, also intended for direct injection into tumor lesions of cancer patients. Leuvectin-TM- contains a gene that encodes the potent immunostimulator IL-2 and a lipid material to facilitate gene uptake. We expect that Leuvectin-TM-, 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-TM- 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-TM- is in Phase II clinical trials for patients with advanced metastatic kidney cancer and for high-risk patients with locally confined prostate cancer.

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. 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 an agreement with Boston Scientific for the use of our technology in catheter-based intravascular gene delivery. We have an agreement with Aventis Pharma to use our gene delivery technology to deliver neurological proteins for neurodegenerative diseases. We have agreements with Pfizer for use of our technology for DNA-based delivery of therapeutic proteins in animal health

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applications and with Merial for use of our technology for DNA vaccines in animal infectious disease targets.

In February 2000, Vical and HGS signed a reciprocal royalty-bearing license. Under the agreement, Vical has the option to license exclusively up to three genes from HGS for gene-based product development. HGS has the option to license Vical's 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 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.

Effective June 30, 2000, Alain B. Schreiber, M.D., President and CEO, and member of the Board of Directors, left the company to pursue a career in the investment community. The Board of Directors has commenced a search for a replacement. During the transition, R. Gordon Douglas, M.D., Chairman of the Board of Vical, is assuming a more active role in managing the strategic direction of the company. Deirdre Y. Gillespie, M.D., formerly Executive Vice President and Chief Business Officer, was elected Chief Operating Officer and assumed additional operating responsibilities.

In May 2000, an independent Drug Safety Review Board recommended that current Phase II and Phase III registration trials targeting metastatic melanoma should progress as planned, based on a review of safety and preliminary efficacy data collected to date.

On June 30, 2000, Vical and Aventis Pharma, the pharmaceutical company of Aventis S.A., entered into a license agreement granting Aventis Pharma rights to use Vical's naked DNA gene transfer technology to deliver a growth factor gene for which Aventis Pharma holds rights. The agreement resulted in an initial payment to Vical of \$1.5 million in July 2000, and could generate milestone payments plus royalties if products advance through commercialization.

In June 2000, Vical and the Office of Naval Research amended their existing agreement for the development of a potential naked DNA vaccine to prevent malaria. The amendment increased the total contract amount from

\$2,813,000 to \$5,465,000 through December 31, 2000.

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.

Researchers at Merck and Harvard University/Beth Israel Deaconess Medical Center reported in the October 20, 2000, issue of SCIENCE successful testing in monkeys of an HIV vaccine under Merck's license of Vical's patented DNA vaccine technology. The vaccine, given alone or in combination with a booster (interleukin-2), protected the monkeys against a virulent strain of SHIV, a combination of simian (monkey) and human immunodeficiency virus. Seven of the eight test monkeys receiving a placebo vaccine developed AIDS, and four died. All eight monkeys receiving the booster vaccine, and two of the four monkeys receiving the DNA vaccine alone, remained healthy. None of these 12 monkeys died during the 140-day observation period.

Merck is now developing vaccines based on Vical's naked DNA vaccine technology to prevent and treat HIV infections. Merck is testing naked DNA vaccines for HIV in two human trials, one for

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uninfected volunteers and one for volunteers already infected with HIV and receiving highly active anti-retroviral therapy. The human testing began in December 1999.

We also have a license and option agreement with Aventis Pasteur for a total of six preventive vaccine targets:

- cytomegalovirus, CMV,
- HELICOBACTER PYLORI,
- Lyme disease,
- malaria,
- respiratory syncytial virus, RSV, and
- varicella zoster virus, VZV.

Vical is collaborating with Aventis Pasteur and the U.S. Naval Medical Research Center, or NMRC, to develop a DNA vaccine against malaria. 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.

Vical's 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 Vical or our collaborators.

RESULTS OF OPERATIONS

Revenues of \$1,430,000 were recorded for the quarter ended September 30, 2000. License revenue of \$724,000 primarily represented recognition of deferred license fees of \$473,000 from Merial and Vascular Genetics Inc., and royalty and other revenue of \$251,000. Contract and grant revenue of \$706,000 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 NIH, and revenue from Pfizer. The total contract amount under the agreement between Vical and the Office of Naval Research is \$5,465,000 through December 31, 2000. Through September 30, 2000, Vical had recognized revenue of \$3,048,000 of the total contract amount.

Revenues of \$1,229,000 were recorded for the quarter ended September 30, 1999. License revenue of \$495,000 primarily represented recognition of deferred license fees of \$275,000 from Merial, and royalty and other revenue of \$220,000. Contract revenue recognized was \$734,000, and was primarily from the contract with the Office of Naval Research.

Revenues for the nine months ended September 30, 2000, were \$5,192,000. In addition to the revenue recognized in the third quarter of 2000, license revenue for the nine months ended September 30, 2000, included \$1,500,000 of license fees accrued for a June 2000 license agreement with Aventis Pharma, recognition of deferred license fees of \$839,000 from Merial and Vascular Genetics Inc., and royalty and other revenue of \$520,000. Contract and grant revenue recognized for the nine months ended September 30, 2000, in addition to the amounts recognized in the third quarter of 2000, included \$903,000 of

revenues from the contract with the Office of Naval Research, revenue from contracts and grants with NIH, and revenue from Pfizer and other agreements.

Revenues for the nine months ended September 30, 1999, were \$5,762,000. In addition to the revenue recognized in the third quarter of 1999, revenue for the nine months ended September 30, 1999, included \$1,000,000 of option and license fees, and \$1,200,000 of equity premium under January 1999 agreements with Pfizer Inc., recognition of deferred license fees of \$525,000 from Merial, royalty and other revenue of \$551,000 and contract revenue of \$1,258,000 primarily from the Office of Naval Research.

Our total operating expenses for the quarter ended September 30, 2000, were \$5,787,000 compared with \$4,581,000 for the third quarter of 1999. Total operating expenses for the nine months ended September 30, 2000 and 1999, were \$17,454,000 and \$14,067,000, respectively. Research and development expenses increased to \$4,524,000 for the three months ended September 30, 2000, from \$3,514,000 for the same period in 1999. For the nine months ended September 30, 2000, research and

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development expenses were \$13,551,000 compared with \$10,866,000 for the same period in 1999. The increase in research and development expenses generally was due to increased preclinical and clinical trial costs, and personnel-related costs.

General and administrative expenses increased to \$1,263,000 for the three months ended September 30, 2000, from \$1,066,000 for the same period in 1999. General and administrative expenses for the nine months ended September 30, 2000, were \$3,903,000 compared with \$3,201,000 for the same period in 1999. The increase for the third quarter of 2000 is attributable primarily to increased professional fees related to corporate communications, recruiting and other costs related to the vacant CEO position, and business development activities. The increase for the nine months ended September 30, 2000, is attributable primarily to the foregoing factors plus increased personnel-related costs in support of the expanded research and development activities.

Investment income for the three-month and nine-month periods ended September 30, 2000, was \$2,552,000 and \$6,801,000, respectively. Investment income for the three-month and nine-month periods ended September 30, 1999, was \$548,000 and \$1,688,000, respectively. The increase is a result of higher investment balances due to the January 2000 sale of 3,450,000 shares of Vical common stock in a public offering which raised net proceeds of approximately \$117,500,000.

The net loss was \$0.09 per share for the three months ended September 30, 2000, and \$0.18 for the three months ended September 30, 1999. For the nine months ended September 30, 2000, the net loss was \$0.29 per share compared with a net loss of \$0.42 per share for the same period in the prior year. We expect to incur losses throughout the remainder of 2000 and to report a net loss for the year ending December 31, 2000.

LIQUIDITY AND CAPITAL RESOURCES

Since its inception, Vical has financed its operations primarily through private placements of preferred and common stock, four public offerings of common stock and revenues from collaborative agreements. In January 2000, Vical sold 3,450,000 shares of common stock in a public offering which raised net proceeds of approximately \$117.5 million. The net proceeds were invested in marketable securities and cash equivalents during the first quarter of 2000. As of September 30, 2000, we had working capital of approximately \$148.2 million compared with \$36.0 million at December 31, 1999. Cash and marketable securities totaled approximately \$150.4 million at September 30, 2000, compared with \$37.7 million at December 31, 1999. We have an unsecured line of credit agreement with a bank to provide financing for leasehold improvements. Under the terms of the agreement, Vical had borrowed up to the credit limit of \$1.0 million at September 30, 2000. In November 2000, this line of credit was amended and increased to \$2.3 million. Under the terms of the amended agreement, Vical can use the credit 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.

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, Vical anticipates that its available cash and existing sources of funding will be adequate to satisfy its operating needs through at least 2002.

RECENT ACCOUNTING PRONOUNCEMENTS

In December 1999, the SEC issued Staff Accounting Bulletin No. 101 - "Revenue Recognition," or SAB 101. SAB 101 reflects the SEC's views on revenue recognition. Historically Vical has recognized

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revenue from initial technology option and license fees in the period in which the agreement was signed if there were no significant performance obligations remaining. Revenue from milestone payments is recognized as revenue when the milestones are achieved. SAB 101 would require that when there has not been the culmination of the earnings process, revenue from technology option and license fees and milestone payments be deferred and recognized over the period over which the revenue is deemed to be earned. There is a lack of guidance about applying SAB 101 in the Life Sciences Industry, including what constitutes the culmination of the earnings process where there are up-front, milestone and royalty payments. Further, there is significant uncertainty about the life over which to recognize this revenue, particularly where royalties continue to be payable until the last related patent expires. There is no written guidance to determine whether it would be acceptable to amortize the revenue over the estimated product development period, which is a shorter period than the estimated life of the patents. Due to the uncertainties noted above, we have not completed our evaluation of the impact of SAB 101 on our financial statements, however, the potential impact is expected to be material to the financial statements. Effective from 1991, when our first license fee revenues were recognized, to September 30, 2000, Vical has recognized cumulative license fee revenue representing nonrefundable up-front and milestone payments of approximately \$39 million which will have to be evaluated for deferral under SAB 101. The amount that will need to be deferred will depend principally on the estimated life over which we are allowed to recognize the revenue under SAB 101.

When the company implements SAB 101 in the fourth quarter of 2000, it will do so by restating the first quarter 2000 statements. The statement of operations will reflect a one-time charge to earnings for the cumulative effect of the change in accounting principle as of January 1, 2000, and license revenues will be recognized based on SAB 101 effective as of that date. The financial statements for the second and third quarters of 2000 will also be restated to apply SAB 101 effective January 1, 2000.

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 COMMERCIALY 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 September 30, 2000, we have incurred cumulative net losses totaling approximately \$50.2 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

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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 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.

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For example, one patient who had undergone treatment with Allovectin-7-Registered Trademark- 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-Registered Trademark- 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.

Effective June 30, 2000, Alain B. Schreiber, M.D., President and CEO, and member of the Board of Directors, left the company to pursue a career in the investment community. The Board of Directors has commenced a search for a replacement. During the transition, R. Gordon Douglas, M.D., Chairman of the Board of Vical, is assuming a more active role in managing the strategic direction of the company. Deirdre Y. Gillespie, M.D., formerly Executive Vice President and Chief Business Officer, was elected Chief Operating Officer and assumed additional operating responsibilities.

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.

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

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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.

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PART II. OTHER INFORMATION

ITEM 6. EXHIBITS AND REPORTS ON FORM 8-K

- (a) EXHIBIT 27 Financial Data Schedule
 - (b) 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: November 13, 2000 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

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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 NINE-MONTH PERIOD ENDED SEPTEMBER 30, 2000 AND IS QUALIFIED IN ITS ENTIRETY BY REFERENCE TO SUCH FINANCIAL STATEMENTS.

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