

# VICAL INC

# **FORM 8-K**

(Current report filing)

Filed 08/03/04 for the Period Ending 07/28/04

Address 10390 PACIFIC CENTER COURT  
                SAN DIEGO, CA 92121-4340  
Telephone 858-646-1100  
CIK 0000819050  
Symbol VICL  
SIC Code 2836 - Biological Products, Except Diagnostic Substances  
Industry Biotechnology & Drugs  
Sector Healthcare  
Fiscal Year 12/31

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549**

**FORM 8-K**

**CURRENT REPORT**

Pursuant to Section 13 or 15(d) of the  
Securities Exchange Act of 1934

Date of report (Date of earliest event reported): July 28, 2004

**Vical Incorporated**

(Exact Name of Registrant as Specified in Charter)

Delaware (State or Other Jurisdiction of Incorporation)	000-21088 (Commission File Number)	93-0948554 (IRS Employer Identification No.)
---	--	--

10390 Pacific Center Court San Diego, California (Address of Principal Executive Offices)	92121-4340 (Zip Code)
---	--------------------------

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

#### **Item 4. Changes in Registrant's Certifying Accountant.**

On July 28, 2004, Vical Incorporated (the "Company") made the decision to dismiss KPMG LLP ("KPMG") as its independent auditor upon the completion of their review of the Company's financial statements for the period ended June 30, 2004. On the same date, the Company engaged Deloitte & Touche LLP ("Deloitte") to serve as its independent auditor for fiscal periods subsequent to the quarter ended June 30, 2004. The decision to dismiss KPMG and engage Deloitte was approved by the Company's Audit Committee.

The audit reports of KPMG on the financial statements of Vical Incorporated as of and for the years ended December 31, 2003 and 2002 did not contain any adverse opinion or disclaimer of opinion, nor were they qualified or modified as to uncertainty, audit scope or accounting principles; and there were no reportable events, as listed in Item 304(a)(1)(v) of Regulation S-K.

In connection with the audits of the two fiscal years ended December 31, 2003, and the subsequent interim period through July 28, 2004, there were no disagreements with KPMG on any matter of accounting principles or practices, financial statement disclosure or auditing scope or procedures, which disagreements, if not resolved to their satisfaction, would have caused them to make reference in connection with their opinion to the subject matter of the disagreement.

A letter from KPMG is attached as Exhibit 16.1 to this Form 8-K.

During the fiscal years ended December 31, 2003 and 2002, and the interim period between December 31, 2003 and July 28, 2004, neither the Company nor anyone acting on its behalf consulted with Deloitte regarding the application of accounting principles to a specified transaction, either completed or proposed, the type of audit opinion that might be rendered on the Company's financial statements, or any matters or reportable events listed in Item 304(a)(2)(ii) of Regulation S-K.

#### **Item 7. Financial Statements, Pro Forma Financial Information and Exhibits.**

(c)	<b>Exhibits.</b>
16.1	Letter from KPMG LLP to the Securities and Exchange Commission, dated August 3, 2004.
99.1(1)	Press Release issued by Vical Incorporated on August 3, 2004.
(1)	As set forth in Item 12 of this Current Report, Exhibit 99.1 is being furnished and shall not be deemed "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended (the "Securities Act"), regardless of any general incorporation language in such filing.

**Item 12. Results of Operations and Financial Condition.**

On August 3, 2004, the Company issued a press release announcing, among other things, its financial results for the quarter ended June 30, 2004. A copy of the press release is attached as Exhibit 99.1 to this Current Report.

The information in this Item 12, and Exhibit 99.1 attached hereto, is being furnished and shall not be deemed "filed" for the purposes of Section 18 of the Exchange Act, or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act, regardless of any general incorporation language in such filing.

## SIGNATURES

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

### VICAL INCORPORATED

Date: August 3, 2004

By: /s/ VIJAY B. SAMANT

-----  
Vijay B. Samant  
President and Chief Executive Officer

## **INDEX TO EXHIBITS**

Exhibit Number	Description
16.1	Letter from KPMG LLP to the Securities and Exchange Commission, dated August 3, 2004.
99.1	Press Release issued by Vical Incorporated on August 3, 2004.

**EXHIBIT 16.1**

Office of the Chief Accountant  
Securities and Exchange Commission  
450 Fifth Street, N.W.  
Washington, D.C. 20549

August 3, 2004

Ladies and Gentlemen:

We are currently principal accountants for Vical Incorporated and, under the date of February 6, 2004, except as to the third paragraph of Note 13, which is as of March 4, 2004, we reported on the financial statements of Vical Incorporated as of and for the years ended December 31, 2003 and 2002. On July 28, 2004, we were notified that the auditor-client relationship with KPMG LLP will cease upon the completion of our review of the Company's financial statements for the period ended June 30, 2004. We have read Vical Incorporated's statements included under Item 4 of its Form 8-K dated July 28, 2004, and we agree with such statements, except we are not in a position to agree or disagree with the Company's statements made in the second and third sentences in the first paragraph, nor the fifth paragraph under Item 4.

Very truly yours,

*/s/ KPMG LLP*  
-----

Copy to: Vijay B. Samant, President and Chief Executive Officer, Vical Incorporated

## **EXHIBIT 99.1**

### **Vical Announces Second-Quarter 2004 Financial Results**

SAN DIEGO, Aug. 3 /PRNewswire-FirstCall/ -- Vical Incorporated (Nasdaq: VICL) today reported a net loss for the second quarter ended

June 30, 2004, of \$5.3 million or \$0.23 per share, compared with \$6.9 million or \$0.34 per share for the second quarter of 2003. The decrease in net loss reflected increased license and contract revenues partially offset by increases in spending on independent development programs. Investment income declined as a result of reductions in interest rates and lower average investment balances. For the six months ended June 30, 2004, the net loss was \$14.4 million or \$0.66 per share, compared with \$13.9 million or \$0.69 per share for the first six months of 2003. Per share amounts for the second quarter and first six months of 2004 reflect the increased weighted average numbers of shares outstanding for those periods as a result of the registered direct placement of approximately 3.4 million shares of stock during the first quarter of 2004, which generated net proceeds of approximately \$17.3 million.

Revenues for the second quarter of 2004 were \$5.7 million compared with revenues of \$0.6 million for the second quarter of the prior year. Revenues were \$6.7 million for the six months ended June 30, 2004, compared with revenues of \$1.5 million for the first six months of 2003. Revenues for the second quarter and first six months of 2004 reflected increased contract manufacturing shipments; accomplishment of a milestone under the company's agreement with Gencell SAS, a wholly-owned subsidiary of Aventis Pharma SA; and a new license agreement with Merial Ltd., a joint venture between Merck & Co., Inc. and Aventis, S.A.

The reported net losses for the second quarter and first six months of 2004 were consistent with the company's projected net loss for the full year 2004 of between \$26 million and \$29 million. The company had cash, cash equivalents and marketable securities of \$85 million at June 30, 2004.

Vijay B. Samant, Vical's President and Chief Executive Officer, said, "We are pleased with the progress of our independent and collaborative product development programs and will provide additional details in our conference call today. Financial results were consistent with our projections, and we remain on track to meet our forecast for the full year."

### **Allovecin-7(R)**

In February 2001, the company began a high-dose Phase 2 trial evaluating the Allovecin-7(R) gene-based immunotherapeutic for patients with Stage III or IV melanoma, who have few other treatment options. The high-dose Phase 2 trial completed enrollment in July 2003. A summary of efficacy and safety data as of November 2003 was reported in June 2004 at meetings of the American Society of Clinical Oncology and the American Society of Gene Therapy.

The company has completed two End of Phase 2 meetings with the U.S. Food and Drug Administration (FDA) for Allovecin-7(R), and has received detailed guidance from those meetings. As a result, the company is designing a registration trial with high-dose Allovecin-7(R) for certain patients with metastatic melanoma. The trial design would include an interim analysis that could provide the basis for seeking approval before trial completion. The company intends to review the design of the new registration trial with the FDA through a Special Protocol Assessment, which it intends to complete in the second half of 2004.

### **CMV**

In early March, the company announced the notification of funding of two grants from the U.S. National Institutes of Health (NIH) of approximately \$1 million for research and development related to the company's vaccine for cytomegalovirus (CMV). In late March, the company announced the initiation of a Phase 1 clinical trial of its bivalent CMV vaccine. This initial Phase 1 trial tests the vaccine for safety and immunogenicity in preparation for future clinical trials in hematopoietic cell transplant (HCT) patients. Enrollment of healthy volunteers in the trial is ongoing, and the company expects to report initial safety and immunogenicity data from the trial at the Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC) beginning October 30, 2004.

### **Anthrax**

The company's second-generation, bivalent, cationic-lipid formulated anthrax vaccine is designed to provide broader protection against anthrax than the currently approved anthrax vaccine. Preclinical data from the anthrax vaccine program demonstrated complete protection of rabbits at 7.5 months post-vaccination against a lethal aerosolized spore inhalation challenge. Non-clinical development of the anthrax vaccine is being supported by a three-year, \$5.9 million NIH grant awarded in July 2003. In June 2004, the National Institute of Allergy and Infectious Diseases (NIAID) of the NIH advised the company that it will support a Phase 1 clinical trial of the company's anthrax vaccine at two NIAID-funded Vaccine and Treatment Evaluation Units. The trial began in July 2004, and will test the vaccine in up to 52 healthy adult volunteers for safety and immune responses. Successful completion of this trial could lead to potential larger trials to support marketing approval under the FDA's Animal Rule, and could encourage development of other vaccines using the same technology.

### **Collaborations**

In May 2004, the company granted an exclusive license to Merial, a world leader in animal health products, for use of its patented DNA delivery technology in a vaccine to protect certain companion animals against a particular type of cancer.

A DNA vaccine for Ebola, based on Vical's patented gene delivery technology, is being developed by the Vaccine Research Center, NIAID, NIH. Human safety testing of the investigational Ebola vaccine began in November 2003, and enrollment is now complete. The company believes this is the only Ebola vaccine program that has advanced to human testing. Data from this study is expected to be available in the next several months, and could provide human proof-of-concept for the company's vaccine technology. This vaccine would likely be approved under the FDA's Animal Rule.

### **Change in Independent Public Accountants**

The company also announced that it has engaged Deloitte & Touche LLP as its independent public accountants for fiscal periods subsequent to the second quarter, replacing KPMG LLP, its current accounting firm.

### **Conference Call**

Vical will conduct a conference call and webcast to discuss the financial results with invited analysts and institutional investors today, August 3, at noon Eastern Time. The call is open on a listen-only basis to any interested parties. The company will provide additional details on independent and partnered development programs in the conference call and webcast.

To listen to the conference call, dial (800) 888-5452, or (719) 867-0660 for international participants. A replay of the call will be available for 48 hours beginning about two hours after the call. To listen to the replay, dial (888) 203-1112, or (719) 457-0820 for international participants, and enter conference identification number 172823. The call also will be available live and archived through the webcast center at [www.vical.com](http://www.vical.com). For further information, contact Vical's Investor Relations department by phone at (858) 646-1127 or by e-mail at [info@vical.com](mailto:info@vical.com).

### **About Vical**

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

This press release contains forward-looking statements subject to risks and uncertainties that could cause actual results to differ materially from those projected. Forward-looking statements include statements about the company's projected financial performance; advancement of the company's research and development activities; expectations regarding the company's high-dose Allovectin-7(R) program, including plans for, and the proposed design of, a high-dose Allovectin-7(R) registration trial; the company's infectious disease vaccine development programs including results from ongoing clinical trials for these vaccine candidates; the potential revenues and other benefits of contract services agreements and grants; as well as potential applications of the company's technology and arrangements with collaborative partners. Risks and uncertainties that could adversely affect actual results include risks and uncertainties related to whether the company will achieve the levels of revenues and be able to control expenses to meet projected financial performance; whether the company will establish with the FDA, by the second half of 2004, if at all, the design of a high-dose Allovectin-7(R) registration trial adequate to support clinical and regulatory requirements for approval; whether the company will have the resources to conduct such a registration trial independently, if at all; whether results of such a registration trial will demonstrate sufficient efficacy to support approval before trial completion, if at all; whether the ongoing Phase 1 CMV vaccine trial will be completed as scheduled to allow the company to report safety and immunogenicity data in the second half of 2004; whether the company will complete Phase 1 clinical testing of its anthrax vaccine candidate on schedule, if at all; whether additional government funding will be available to support further development of the company's anthrax vaccine candidate; whether the company's independent or partnered research and development efforts will lead to viable product candidates; the scope and enforceability of the company's intellectual property; whether any product candidates will be shown to be safe and efficacious in clinical trials; the timing of clinical trials; and additional risks set forth in the company's filings with the Securities and Exchange Commission. These forward-looking statements represent the company's judgment as of the date of this release. The company disclaims, however, any intent or obligation to update these forward-looking statements.

For further information, please contact: Alan R. Engbring, Director, Investor Relations of Vical Incorporated, +1- 858-646-1127.

### **VICAL INCORPORATED STATEMENTS OF OPERATIONS**

(in thousands, except share and per share amounts)

(Unaudited)

	Three Months Ended June 30, 2004	Six Months Ended June 30, 2004	Six Months Ended June 30, 2003
<b>Revenues:</b>			
License/royalty revenue	\$1,927	\$512	\$2,549
Contract revenue	3,815	90	4,102
Total revenues	5,742	602	6,651
<b>Expenses:</b>			
Research and development	8,654	6,318	16,830
General and administrative	2,535	1,751	4,481
Write-down of investment	--	--	482
Total expenses	11,189	8,069	21,311
Loss from operations	(5,447)	(7,467)	(14,660)
Net investment income	131	545	269
Net loss	\$(5,316)	\$(6,922)	\$(14,391)
Net loss per share (basic and diluted)	\$(0.23)	\$(0.34)	\$(0.66)
Shares used in per share calculation(1)	23,475,585	20,091,344	21,896,091
			20,091,344

(1) Shares used in per share calculations for the three months and six months ended June 30, 2004, reflect the increased weighted average numbers of shares outstanding for those periods as a result of the registered direct placement of approximately 3.4 million shares of stock during the first quarter of 2004.

**VICAL INCORPORATED  
CONDENSED BALANCE SHEETS  
(in thousands)**

(Unaudited)

	June 30, 2004	December 31, 2003
<b>Assets:</b>		
Cash and cash equivalents, including restricted	\$14,913	\$18,929
Marketable securities, including restricted	70,576	65,588
Other current assets	5,687	5,386
Total current assets	91,176	89,903
Property and equipment, net	15,048	14,336
Other assets	6,369	6,468
	\$112,593	\$110,707
<b>Liabilities and Stockholders' Equity:</b>		
Current liabilities	\$10,467	\$12,223
Long-term obligations	9,148	8,662
Stockholders' equity	92,978	89,822
	\$112,593	\$110,707

SOURCE Vical Incorporated

-0-08/03/2004 /CONTACT: Alan R. Engbring, Director, Investor Relations of Vical Incorporated, +1-858-646-1127 /First Call Analyst: /  
/FCMN Contact: /  
/Web site: <http://www.vical.com> /

(VICL)

CO: Vical Incorporated

ST: California

IN: MTC BIO HEA FIN

SU: ERN CCA