

# VICAL INC

## FORM 8-K (Current report filing)

Filed 11/05/03 for the Period Ending 11/05/03

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

# VICAL INC

## FORM 8-K (Unscheduled Material Events)

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

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**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): November 5, 2003

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**VICAL INCORPORATED**

(Exact Name of Registrant as Specified in Charter)

Delaware  
(State or Jurisdiction  
of Incorporation)

000-21088  
(Commission File Number)

93-0948554  
(I.R.S. Employer  
Identification No.)

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

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

**ITEM 12. RESULTS OF OPERATIONS AND FINANCIAL CONDITION.**

On November 5, 2003, Vical Incorporated issued a press release announcing its financial results for the quarter ended September 30, 2003. A copy of the press release is attached as Exhibit 99.1 to this Current Report.

The information in this Current Report, and the exhibit attached hereto, is being furnished and shall not be deemed "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended, 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, 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: November 5, 2003*

*By: /s/ MARTHA J. DEMSKI*

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*Martha J. Demski  
Vice President, Chief Financial Officer,  
Treasurer and Secretary*

Exhibit Index

Exhibit  
Number

Description

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99.1

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Press Release issued by Vical Incorporated on November 5, 2003

## Vical Announces Third-Quarter 2003 Financial Results

SAN DIEGO, Nov. 5 /PRNewswire-FirstCall/ -- Vical Incorporated (Nasdaq: VICL) today reported a net loss for the third quarter ended September 30, 2003, of \$3.6 million or \$0.18 per share, compared with \$10.2 million or \$0.51 per share for the third quarter of 2002. For the nine months ended September 30, 2003, the net loss was \$17.5 million or \$0.87 per share, compared with \$20.5 million or \$1.02 per share for the first nine months of 2002.

The net loss for the third quarter and first nine months of 2003 included a \$4.2 million write-down of the company's investment in Vascular Genetics Inc. (VGI), and the net loss for the first nine months of 2003 included an additional \$0.5 million write-down for VGI, now Corautus Genetics Inc., a publicly traded company. The decreases in net losses between the 2003 and 2002 periods also reflected the timing of revenue recognition for license payments and contract services, partially offset by the timing of related expense recognition and lower net investment income.

Revenues for the third quarter and first nine months of 2003 were \$4.9 million and \$6.4 million, respectively, compared with revenues of \$2.5 million and \$6.5 million for the same periods in the prior year. Approximately \$2.4 million of revenue recognized in the third quarter of 2003 was for shipment of product manufactured in the first half of 2003. Approximately \$1.9 million of revenue was recognized in the third quarter of 2003 from a three-year, \$5.7 million grant from the National Institute of Allergy and Infectious Diseases, which is partially funding development of Vical's anthrax vaccine.

The reported net losses for the third quarter and first nine months of 2003 were consistent with the company's projected net loss for the full year 2003 of between \$24 million and \$28 million. The company had cash, cash equivalents and marketable securities of \$93 million at September 30, 2003, compared with \$112 million at December 31, 2002.

Vijay B. Samant, Vical's President and Chief Executive Officer, said, "Financial results for the third quarter were consistent with our expectations and we remain on track to meet our forecast for the full year. We also are pleased with the progress made over the past few months in our independent development programs and have expanded our collaboration with the vaccine researchers at the National Institutes of Health (NIH), who are applying our technology in the development of vaccines for emerging and potentially threatening diseases such as West Nile Virus, Ebola and SARS."

Recent progress in the company's independent development programs includes:

\* The company's high-dose Phase II trial evaluating the Allovectin-7(R) gene-based immunotherapeutic completed enrollment in July 2003 with a total of 133 patients, including 6 in an initial dose-escalation cohort and 127 in the high-dose cohort. In May 2003, the company presented unaudited data from interim analyses performed in early March 2003 for the first 91 patients in the high-dose cohort, indicating an objective response rate of 13 percent with continued excellent safety and tolerability. An update in July 2003 yielded an estimated median duration of response of at least 6.4 months. The company intends to review data from the full 127-patient high-dose cohort with the U.S. Food and Drug Administration (FDA) and evaluate the potential for the high-dose trial to support accelerated marketing approval of Allovectin-7(R) for patients with Stage III or IV melanoma, who have few other treatment options. The company expects key clinical data on the full high-dose cohort in the first half of 2004.

\* Preclinical testing of the company's DNA-based immunotherapeutic vaccine against cytomegalovirus (CMV) is making good progress. The next goal is to initiate Phase I clinical testing of the vaccine in human subjects by year-end 2003 at three of the country's leading transplant centers.

\* With funding support from the \$5.7 million Small Business Innovation Research (SBIR) grant in July 2003, the company's anthrax vaccine development program is approaching completion of preclinical testing. During the third quarter of 2003, the company presented preclinical data from its anthrax vaccine program at several scientific conferences, demonstrating protection of rabbits at 7.5 months post- vaccination against an aerosolized spore inhalation challenge. The company recently secured an exclusive license from the Ohio State University to allow use of proprietary technology in the vaccine. The company expects to begin clinical testing within the next few months.

Additional progress in recent months includes:

\* Merck & Co., Inc. expanded its long-standing infectious disease vaccine license from Vical to include options for three cancer vaccine targets, while retaining rights to vaccines for Human Immunodeficiency Virus, hepatitis C virus, and hepatitis B virus. Vical expanded its infectious disease portfolio by re-acquiring the rights to other targets previously licensed to Merck.

\* The Vaccine Research Center (VRC) of the NIH placed orders for manufacturing of clinical-grade supplies of investigational DNA vaccines against both the West Nile Virus and the severe acute respiratory syndrome (SARS) virus. In October 2003, the VRC also formally notified the Company of its intention to place production orders under the bulk DNA vaccine manufacturing agreement, using the equipment being financed by the VRC, beginning in mid-2004.

\* In addition, Vical obtained an option to secure exclusive commercialization rights for a West Nile Virus vaccine being developed in collaboration with the VRC under a Cooperative Research and Development Agreement.

### Conference Call

Vical will conduct a conference call to discuss the financial results with invited analysts and institutional investors today, November 5, at noon Eastern Time. The call is open on a listen-only basis to any interested parties.

To listen to the conference call, dial (888) 224-3260, or (973) 317-5317 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 (800) 428-6051, or (973) 709-2089 for international participants, and enter conference identification number 308951. 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 its patented DNA delivery technologies for the prevention and treatment of serious or life-threatening diseases. Potential applications of the company's 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. Vical has retained all rights to its internally developed product candidates. In addition, the company collaborates with major pharmaceutical companies and biotechnology companies that give it access to complementary technologies or greater resources. These strategic partnerships provide Vical with mutually beneficial opportunities to expand its 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 expected recognition of revenues in future quarters, 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) Phase II trial and results of that trial, the company's infectious disease vaccine development efforts and plans for commencing 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 net loss in the first nine months of 2003 is indicative of the expected net loss for the remainder of 2003, whether results of the company's high-dose Allovectin-7(R) Phase II trial will demonstrate sufficient efficacy to support accelerated marketing approval or further development of that product candidate, whether preliminary, unaudited data on the full high-dose cohort from this trial will be available in the first half of 2004, whether the company's research and development activities will result in the advancement of anthrax and CMV vaccine candidates into clinical testing on schedule, 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, or Martha J. Demski, Vice President and Chief Financial Officer, both of Vical Incorporated, +1-858-646-1127.

### VICAL INCORPORATED STATEMENTS OF OPERATIONS

(in thousands, except share and per share amounts)

(Unaudited)

	Three Months Ended Sept. 30,		Nine Months Ended Sept. 30,	
	2003	2002	2003	2002
Revenues:				
License/royalty revenue	\$526	\$512	\$1,534	\$3,624
Contract revenue	4,347	2,008	4,849	2,855
Total revenues	4,873	2,520	6,383	6,479
Expenses:				
Research and development	6,923	7,516	19,825	19,884
General and administrative	1,738	1,975	5,029	5,747
Write-down of investment	--	4,200	482	4,200
Total expenses	8,661	13,691	25,336	29,831
Loss from operations	(3,788)	(11,171)	(18,953)	(23,352)
Net investment income	231	955	1,449	2,893
Net loss	\$(3,557)	\$(10,216)	\$(17,504)	\$(20,459)
Net loss per share (basic and diluted)	\$(0.18)	\$(0.51)	\$(0.87)	\$(1.02)
Shares used in per share calculation	20,091,344	20,082,648	20,091,344	20,074,293

### VICAL INCORPORATED CONDENSED BALANCE SHEETS

(in thousands)

(Unaudited)

	September 30, 2003	December 31, 2002
Assets:		
Cash and cash equivalents	\$20,718	\$32,609
Marketable securities	71,806	78,904
Other current assets	5,313	5,894
Total current assets	97,837	117,407
Investment	-	800
Property and equipment, net	13,982	4,943
Other assets	6,533	6,276
	\$118,352	\$129,426
Liabilities and Stockholders' Equity:		
Current liabilities	\$11,691	\$10,800
Long-term obligations	9,499	4,319
Stockholders' equity	97,162	114,307
	\$118,352	\$129,426

SOURCE Vical Incorporated

-0- 11/05/2003 /CONTACT: Alan R. Engbring, Director, Investor Relations, or Martha J. Demski, Vice President and Chief Financial Officer, both of Vical Incorporated, +1-858-646-1127/

/Web site: <http://www.vical.com/>

(VICL)

CO: Vical Incorporated; Vascular Genetics Inc.; Corautus Genetics Inc. ST: California

IN: BIO HEA MTC

SU: ERN CCA

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**End of Filing**

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