

VICAL INC

FORM 8-K (Current report filing)

Filed 05/06/04 for the Period Ending 05/06/04

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|-------------|---|
| 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): May 6, 2004

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.)

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 May 6, 2004, Vical Incorporated issued a press release announcing its financial results for the quarter ended March 31, 2004. 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: May 6, 2004

By: /s/ MARTHA J. DEMSKI

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

Exhibit Index

| Exhibit Number | Description |
|-------------------|---|
| 99.1 | Press Release issued by Vical Incorporated on May 6, 2004 |

Vical Announces First-Quarter 2004 Financial Results and Plans for High-Dose Allovectin-7(R) Program

SAN DIEGO, May 6 /PRNewswire-FirstCall/ -- Vical Incorporated (Nasdaq: VICL) today reported revenues of \$0.9 million for the first quarter which ended March 31, 2004, compared with revenues of \$0.9 million for the first quarter of the prior year. Grant revenues for the company's cytomegalovirus (CMV) vaccine program and increased royalty payments were offset by a decrease in contract revenues resulting from the timing of bulk DNA vaccine shipments.

The net loss for the first quarter of 2004 was \$9.1 million or \$0.45 per share, compared with a net loss of \$7.0 million or \$0.35 per share for the first quarter of 2003. The increase in net loss reflected spending for the company's infectious disease vaccine programs, lower investment income, and an accrual for settlement of the company's dispute with the Wisconsin Alumni Research Foundation (WARF). The net loss for the first quarter of 2003 included a \$0.5 million write-down of the company's investment in Corautus Genetics Inc. The first quarter 2004 net loss was 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 \$94 million at March 31, 2004, compared with \$85 million at December 31, 2003. The company completed a registered direct placement of approximately 3.4 million shares of stock during the first quarter of 2004, generating net proceeds of approximately \$17.3 million.

Vijay B. Samant, Vical's President and Chief Executive Officer, said, "We are pleased with our discussions with the FDA (U.S. Food and Drug Administration) regarding our high-dose Allovectin-7(R) program and the initiation of Phase 1 testing in our CMV vaccine program, and we look forward to additional progress for the remainder of the year."

Allovectin-7(R)

The company has completed its scheduled End-of-Phase 2 (EOP2) meetings with FDA for Allovectin-7(R), and has received detailed guidance from those meetings. Based on those meetings, the company believes that:

- * although Allovectin-7(R) appears to be safe in patients who received different doses of the product, the safety database would need to be expanded to determine the safety profile required for licensure of the high dose product;
- * a meaningful response rate with a reasonable duration of response could be acceptable as the surrogate endpoint for efficacy;
- * for efficacy, approval would require at least 25 responders in the Allovectin-7(R) arm of a new registration trial; and
- * no major issues were identified with the company's commercial lot release or product characterization plans.

As a result, the company is designing a registration trial with high-dose Allovectin-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 FDA through a Special Protocol Assessment (SPA), which it intends to complete in the second half of 2004.

Summary safety and efficacy data from the high-dose Phase 2 study, which provided the basis for the EOP2 meeting, will be reported in June 2004 at meetings of the American Society of Clinical Oncology and the American Society of Gene Therapy.

CMV

In the first quarter of 2004, the company achieved two major milestones with its immunotherapeutic CMV vaccine. 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 CMV vaccine. In late March, the company announced the initiation of a Phase 1 clinical trial of its bivalent CMV vaccine. Enrollment of eight healthy volunteers in the first dose-escalation stage of the trial has now been completed. This initial Phase 1 trial tests the vaccine for safety and immunogenicity in preparation for future clinical trials in hematopoietic cell transplant (HCT) patients.

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, \$5.7 million NIH grant awarded in July 2003. All preclinical testing has been completed, and the company plans to proceed with human clinical testing of the vaccine pending commitment of additional government funding.

Conference Call

Vical will conduct a conference call and webcast to discuss the financial results with invited analysts and institutional investors today, May 6, 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) 432-7890, or (973) 317-1168 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 348999. The call also will be available live and archived for seven days through the webcast center at www.vical.com. For further information, contact Vical's Investor Relations department by phone at (858) 646-1127 or by e-mail at

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. The company 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 the company with mutually beneficial opportunities to expand its product pipeline and serve significant unmet medical needs. Additional information on Vical is available at www.vical.com.

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) Phase 2 trial, including results of that trial; plans for, and the proposed design of, a high-dose Allovectin-7(R) registration trial; plans for the preparation and filing of an application for approval of Allovectin-7(R); the company's infectious disease vaccine development efforts and plans for 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 data on the full high-dose cohort from the company's high-dose Allovectin-7(R) Phase 2 trial will be available by June 2004; whether the company will establish with 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 additional CMV vaccine trials will be conducted, and whether leading transplant centers will participate in the company's CMV vaccine trials; whether the company's CMV vaccine will prove safe and effective in clinical trials; whether additional government funding for clinical testing of the anthrax vaccine will be available; whether the company will advance its anthrax vaccine candidate into clinical testing; 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 | March 31, |
|---|--------------------|------------|
| | 2004 | 2003 |
| Revenues: | | |
| License and royalty revenue | \$622 | \$496 |
| Contract revenue | 287 | 412 |
| Total revenues | 909 | 908 |
| Operating expenses: | | |
| Research and development | 8,176 | 6,584 |
| General and administrative | 1,946 | 1,540 |
| Write-down of investment | -- | 482 |
| Total expenses | 10,122 | 8,606 |
| Loss from operations | (9,213) | (7,698) |
| Net investment income | 138 | 673 |
| Net loss | \$(9,075) | \$(7,025) |
| Net loss per share (basic and diluted) | \$(0.45) | \$(0.35) |
| Shares used in per share calculation | 20,316,597 | 20,091,344 |

VICAL INCORPORATED CONDENSED BALANCE SHEETS

(in thousands)

(Unaudited)

| | March 31, 2004 | December 31, 2003 |
|--|-------------------|----------------------|
| Assets: | | |
| Cash and cash equivalents, including restricted | \$21,527 | \$18,929 |
| Marketable securities, including restricted | 72,547 | 65,588 |
| Other current assets | 5,269 | 5,386 |
| Total current assets | 99,343 | 89,903 |
| Property and equipment, net | 14,597 | 14,336 |
| Other assets | 6,392 | 6,468 |
| | \$120,332 | \$110,707 |
| Liabilities and Stockholders' Equity: | | |
| Current liabilities | \$12,060 | \$12,223 |
| Long-term obligations | 9,671 | 8,662 |
| Stockholders' equity | 98,601 | 89,822 |
| | \$120,332 | \$110,707 |

SOURCE Vical Incorporated

-0- 05/06/2004 /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

ST: California

IN: HEA MTC BIO

SU: ERN CCA