

VICAL INC

FORM 8-K

(Current report filing)

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Address	10390 PACIFIC CENTER COURT . SAN DIEGO, CA 92121-4340
Telephone	858-646-1100
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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 9, 2013**

Vical Incorporated

(Exact name of registrant as specified in its 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**

Not Applicable
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 2.02. Results of Operations and Financial Condition.

On May 9, 2013, Vical Incorporated issued a press release announcing, among other things, our unaudited financial results for the three months ended March 31, 2013. A copy of the press release is attached as Exhibit 99.1 to this Current Report.

The information in this Item 2.02, and Exhibit 99.1 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.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

SIGNATURES

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

Vical Incorporated

Date: May 9, 2013

By: /s/ VIJAY B. SAMANT
Vijay B. Samant
Chief Executive Officer

INDEX TO EXHIBITS

Exhibit No.	Description
99.1	Press release issued by Vical Incorporated on May 9, 2013

Vical Reports First Quarter 2013 Financial Results and Progress in Key Development Programs

SAN DIEGO, May 9, 2013 (GLOBE NEWSWIRE) -- Vical Incorporated (Nasdaq:VICAL) today reported financial results for the quarter ended March 31, 2013. Revenues decreased to \$1.6 million for the first quarter of 2013 compared with \$11.5 million for the first quarter of 2012, primarily as a result of the recognition in 2012 of a \$10 million milestone payment from Astellas Pharma Inc. for progress with TransVax™, Vical's therapeutic vaccine designed to control cytomegalovirus (CMV) in transplant recipients.

Net loss was \$9.3 million, or \$0.11 per share, for the first quarter of 2013, compared with net income of \$0.2 million, which rounds to \$0.00 per share, for the first quarter of 2012. Vical had cash and investments of approximately \$78 million at March 31, 2013. The company's first quarter 2013 net cash use was consistent with the company's prior guidance for the full year.

Program highlights include:

Allovectin®

The company is approaching completion of a Phase 3 registration trial of its investigational immunotherapy, Allovectin®, vs. chemotherapy in patients with metastatic melanoma.

- A survival data sweep conducted in March 2013 confirmed that the target number of death events for the secondary endpoint (overall survival) should be reached in mid-2013.
- The independent assessment and adjudication process for the primary endpoint (response rate at 24 weeks or more after randomization) is advancing through final audits and quality checks, and the company expects the adjudicated response data to be locked in July 2013.
- Data for both endpoints will remain blinded in separate third-party databases and be securely transferred to Vical and unblinded simultaneously. Top-line results for both endpoints are expected to be released during the third quarter of 2013.

TransVax™ CMV Vaccine

- Astellas is planning to initiate a Phase 3 trial of TransVax™ for hematopoietic cell transplant (HCT) recipients in the second quarter of 2013 and to initiate a Phase 2 trial of TransVax™ for solid organ transplant (SOT) recipients soon afterward.

Herpes Simplex Vaccine

- The company is planning to initiate a Phase 1/2 clinical trial of its Vaxfectin®-formulated therapeutic vaccine against herpes simplex virus type 2 (HSV-2) in the second half of 2013.

Vaxfectin®

- The company announced the online publication of Baxter's (Baxter International Inc.) preclinical evaluations of Vical's Vaxfectin® adjuvant in combination with Baxter's seasonal and pandemic influenza vaccines. Simple addition of Vaxfectin® to the influenza vaccines substantially increased both antibody and T-cell responses compared with nonadjuvanted vaccines in mice and guinea pigs.

Conference Call

Vical will conduct a conference call and webcast today, May 9, at noon Eastern Time, to discuss with invited analysts and institutional investors the company's financial results and program updates. The call and webcast are open on a listen-only basis to any interested parties. To listen to the conference call, dial in approximately ten minutes before the scheduled call to (719) 325-2469 (preferred), or (888) 523-1228 (toll-free), and reference confirmation code 5720239. A replay of the call will be available for 48 hours beginning about two hours after the call. To listen to the replay, dial (719) 457-0820 (preferred) or (888) 203-1112 (toll-free) and enter replay passcode 5720239. The call also will be available live and archived through the events page at www.vical.com. For further information, contact Vical's Investor Relations department by phone at (858) 646-1127 or by e-mail at ir@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. The company is developing certain infectious disease vaccines and cancer therapeutics internally. 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 address significant unmet medical needs.

Forward-Looking Statements

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 net cash use guidance, as well as anticipated developments in independent and collaborative programs, including the initiation and completion of clinical trials and the release of clinical trial results. Risks and uncertainties include whether Vical or others will continue development of Allovectin[®], TransVax[™], the HSV-2 vaccine, or any other independent or collaborative programs; whether the target number of death events for the secondary endpoint (overall survival) in the company's Phase 3 Allovectin[®] trial will be reached in mid-2013, if at all; whether the adjudicated response data in the company's Phase 3 Allovectin[®] trial will be locked in July 2013, if at all; whether the company will release top-line data from the company's Phase 3 Allovectin[®] trial during the third quarter of 2013, if at all; whether Astellas will initiate the planned HCT trial of TransVax[™] in the second quarter of 2013, if at all, and the planned SOT trial of TransVax[™] soon afterward, if at all; whether Vical or others will initiate a Phase 1/2 clinical trial of the HSV-2 vaccine in the second half of 2013, if at all; whether Vical, Baxter or others will develop any seasonal or pandemic influenza vaccines using Vical's Vaxfectin[®] adjuvant; whether Vical will achieve levels of revenues and control expenses to meet its financial projections; whether any product candidates will be shown to be safe and efficacious in clinical trials; the timing of clinical trials; whether Vical or its collaborative partners will seek or gain approval to market any product candidates; 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.

VICAL INCORPORATED

Selected Condensed Financial Information (Unaudited)

Statements of Operations	Three Months Ended	
	March 31,	
(in thousands, except per share amounts)	2013	2012
Revenues:		
Contract and grant revenue	\$ 1,136	\$ 1,221
License and royalty revenue	438	10,239
Total revenues	1,574	11,460
Operating expenses:		
Research and development	3,650	6,428
Manufacturing and production	3,713	2,472
General and administrative	3,518	2,700
Total operating expenses	10,881	11,600
Loss from operations	(9,307)	(140)
Net investment and other income	25	384
Net income (loss)	\$ (9,282)	\$ 244
Basic net income (loss) per share	\$ (0.11)	\$ 0.00
Diluted net income (loss) per share	\$ (0.11)	\$ 0.00
Weighted average shares used in basic net income (loss) calculation	86,638	84,519
Weighted average shares used in diluted net income (loss) calculation	86,638	86,124
Balance Sheets	March 31,	December 31,
(in thousands)	2013	2012
Assets:		
Cash, cash equivalents, and marketable securities, including restricted	\$ 75,437	\$ 83,857
Other current assets	2,390	2,152
Total current assets	77,827	86,009
Long-term investments	2,197	2,225
Property and equipment, net	5,042	5,284
Other assets	2,933	3,004
Total assets	\$ 87,999	\$ 96,522

Liabilities and stockholders' equity:

Current liabilities	\$ 5,276	\$ 5,779
Long-term liabilities	1,569	1,657
Stockholders' equity	<u>81,154</u>	<u>89,086</u>
Total liabilities and stockholders' equity	<u><u>\$ 87,999</u></u>	<u><u>\$ 96,522</u></u>

CONTACT: Alan R. Engbring
(858) 646-1127
Website: www.vical.com