

# VICAL INC

## FORM 8-K

(Current report filing)

Filed 11/07/12 for the Period Ending 11/07/12

Address	10390 PACIFIC CENTER COURT
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	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): **November 7, 2012**

### 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))
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#### Item 2.02. Results of Operations and Financial Condition.

On November 7, 2012, Vical Incorporated issued a press release announcing, among other things, its unaudited financial results for the three months and nine months ended September 30, 2012. 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: November 7, 2012

By: /s/ JILL M. BROADFOOT

Jill M. Broadfoot

*Senior Vice President, Chief Financial Officer and Secretary*

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## INDEX TO EXHIBITS

Exhibit No.	Description
99.1	Press release issued by Vical Incorporated on November 7, 2012.

## Vical Reports Third Quarter 2012 Financial Results and Progress in Key Development Programs

SAN DIEGO, Nov. 7, 2012 (GLOBE NEWSWIRE) -- Vical Incorporated (Nasdaq:VICL) today reported financial results for the three months and nine months ended September 30, 2012. Revenues were \$2.2 million for the third quarter of 2012 compared with \$26.6 million for the third quarter of 2011. The decrease in revenues was primarily a result of recognizing \$25.1 million of license revenue from Astellas Pharma Inc. in the third quarter of 2011 for TransVax™, Vical's therapeutic vaccine designed to control cytomegalovirus (CMV) reactivation in transplant recipients. Net loss was \$7.7 million for the third quarter of 2012, compared with net income of \$16.4 million for the third quarter of 2011.

Revenues were \$15.2 million for the first nine months of 2012 compared with \$28.1 million for the first nine months of 2011. The 2012 revenue includes the recognition of a \$10.0 million milestone payment from Astellas for progress with TransVax™. Net loss was \$15.4 million for the first nine months of 2012, compared with \$0.7 million for the first nine months of 2011.

Vical had cash and investments of approximately \$92 million at September 30, 2012. The company's net cash burn for the first nine months of 2012, excluding cash received from the sale of equity securities, was approximately \$13 million. The company has narrowed its net cash burn forecast range for the full year 2012 to between \$18 million and \$20 million.

The company also summarized recent developments:

### Allovectin®

- In September 2012, the company conducted a comprehensive sweep of all active clinical sites in its Phase 3 Allovectin® melanoma trial to eliminate any time lag in death event reporting. The sweep confirmed that the target number of events has not been reached. It also confirmed the steady progress towards that goal. Based on the moving average monthly event rate, the company has revised its projection for reaching the target number of death events to mid-2013. With immunotherapy like Allovectin®, the treatment impact may occur much later than with chemotherapy, in which case the greatest separation between the two survival curves could occur at later time points. Waiting to achieve the target number of death events will provide improved statistical power for the evaluation of the survival endpoint.
- The company also is extending the schedule for independent adjudication of data for the primary endpoint (response rate at 24 weeks or more after randomization) to allow as thorough a review as possible. The databases for both endpoints will remain blinded until the target number of death events is reached and results for both endpoints will be released simultaneously.
- An independent Safety Monitoring Board (SMB) for the company's Phase 3 Allovectin® trial completed its final review of comprehensive trial safety data in the third quarter and reported "no basis for any concern that there is undue risk" associated with Allovectin®.

### TransVax™ CMV Vaccine

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

### Other Events

- In September 2012, Vical entered into a worldwide, nonexclusive license with Bristol-Myers Squibb Company of Vical's patented platform DNA immunization technology and its Vaxfectin® adjuvant for use in the production of antibodies.
- In October 2012, George J. Morrow, former Executive Vice President of Global Commercial Operations at Amgen, Inc., was appointed to Vical's Board of Directors.
- In November 2012, Vical appointed Mammen P. "Anza" Mammen, Jr., M.D., as Vice President, Clinical Vaccines.

### Conference Call

Vical will conduct a conference call and webcast today, November 7, 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) 785-1765 (preferred), or (888) 455-2296 (toll-free), and reference confirmation code 2455055. 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 2455055. The call also will be available live and archived through the events page 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 [ir@vical.com](mailto: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. Additional information on Vical is available at [www.vical.com](http://www.vical.com).

The Vical Incorporated logo is available at <http://www.globenewswire.com/newsroom/prs/?pkgid=5768>

## 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. Risks and uncertainties include whether Vical or others will continue development of Allovectin<sup>®</sup>, TransVax<sup>™</sup>, or any other independent or collaborative programs; whether Vical will reach the target number of death events for the secondary endpoint (overall survival) and release data from the company's Phase 3 trial of Allovectin<sup>®</sup> in melanoma on the projected timetable, if at all; whether Astellas will initiate the planned HCT Phase 3 trial or the planned Phase 2 SOT trial of TransVax<sup>™</sup> in 2013, if at all; whether Bristol-Myers Squibb will continue development of any therapeutic antibodies using Vical's DNA immunization technology and/or Vaxfectin<sup>®</sup>; 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

(in thousands, except per share amounts)

##### Revenues:

Contract and grant revenue

\$ 1,682      \$ 1,360      \$ 4,267      \$ 2,607

License and royalty revenue

493      25,259      10,933      25,479

Total revenues

2,175      26,619      15,200      28,086

##### Operating expenses:

Research and development

3,682      5,505      13,901      14,004

Manufacturing and production

3,853      2,343      9,258      7,697

General and administrative

2,420      2,379      7,898      7,161

Total operating expenses

9,955      10,227      31,057      28,862

Income (loss) from operations

(7,780)      16,392      (15,857)      (776)

Net investment and other income (expense)

54      39      507      107

Net income (loss)

\$ (7,726)      \$ 16,431      \$ (15,350)      \$ (669)

Basic net income (loss) per share

\$ (0.09)      \$ 0.23      \$ (0.18)      \$ (0.01)

Diluted net income (loss) per share

\$ (0.09)      \$ 0.22      \$ (0.18)      \$ (0.01)

Weighted average shares used in basic net income (loss) calculation

86,408      72,075      85,762      71,987

Weighted average shares used in diluted net income (loss) calculation

86,408      73,739      85,762      71,987

##### Balance Sheets

(in thousands)

##### Assets:

September 30, December 31,

2012      2011

Cash, cash equivalents, and marketable securities, including restricted	\$ 89,952	\$ 50,427
Other current assets	<u>2,537</u>	<u>3,130</u>
Total current assets	92,489	53,557
Long-term investments	2,250	5,928
Property and equipment, net	5,572	6,226
Other assets	<u>3,014</u>	<u>3,062</u>
Total assets	<u><u>\$ 103,325</u></u>	<u><u>\$ 68,773</u></u>
Liabilities and stockholders' equity:		
Current liabilities	\$ 5,591	\$ 6,461
Long-term obligations	1,743	1,964
Stockholders' equity	<u>95,991</u>	<u>60,348</u>
Total liabilities and stockholders' equity	<u><u>\$ 103,325</u></u>	<u><u>\$ 68,773</u></u>

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Jill M. Broadfoot  
Senior Vice President and Chief Financial Officer

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