

# 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): **February 6, 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))

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**Item 2.02. Results of Operations and Financial Condition.**

On February 6, 2013, Vical Incorporated issued a press release announcing, among other things, its unaudited financial results for the three months and twelve months ended December 31, 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: February 6, 2013

By: /s/ JILL M. BROADFOOT

Jill M. Broadfoot

*Senior Vice President, Chief Financial Officer and Secretary*

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## INDEX TO EXHIBITS

<b>Exhibit No.</b>	<b>Description</b>
99.1	Press release issued by Vical Incorporated on February 6, 2013.

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

SAN DIEGO, Feb. 6, 2013 (GLOBE NEWSWIRE) -- Vical Incorporated (Nasdaq:VICAL) today reported financial results for the year ended December 31, 2012. Revenues for 2012 were \$17.5 million, compared with revenues of \$30.0 million for 2011, reflecting lower payments from Astellas Pharma Inc. under an exclusive worldwide license of TransVax™, Vical's therapeutic vaccine designed to control cytomegalovirus (CMV) reactivation in transplant recipients. In 2011, Vical received a \$25.0 million upfront license payment from Astellas. In 2012, Vical received a \$10.0 million milestone license payment and increased contract revenues from Astellas driven by delivery of clinical trial material for planned TransVax™ trials.

The net loss for 2012 was \$22.9 million, or \$0.27 per share, compared with a net loss of \$7.3 million, or \$0.10 per share, for 2011. The increase in net loss for 2012 was primarily a result of the lower license revenue partially offset by higher net contract revenue under the Astellas agreements.

Vical had cash and investments of approximately \$86 million at year-end 2012. The net cash burn of approximately \$19 million for 2012, excluding cash from financing activities, was within the projected range. The company is projecting net cash burn for the first half of 2013, excluding cash from financing activities, of between \$18 million and \$20 million.

The projected net cash burn includes spending for long-lead-time activities such as manufacturing, validation and others that the company believes will allow timely filing of a Biologics License Application (BLA) assuming success in its lead development program, Allovectin® immunotherapy for patients with metastatic melanoma. The company intends to provide net cash burn guidance for the remainder of the year after the release of Phase 3 results.

Program highlights include:

### Allovectin®

- In the company's Phase 3 registration trial of Allovectin® vs. chemotherapy in patients with metastatic melanoma, the company conducted a comprehensive sweep in September 2012 of all active clinical sites to eliminate any time lag in death event reporting. The sweep confirmed that the target number of events had not been reached. It also confirmed the steady progress towards that goal.
- An independent Safety Monitoring Board (SMB) for the Phase 3 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®.
- The company is tracking progress toward the Phase 3 secondary endpoint (overall survival) for both arms together in a blinded fashion. Independent assessment and adjudication of patient-by-patient data for the primary endpoint (response rate at 24 weeks or more after randomization) is approaching completion. Upon reaching the target number of death events, the databases for both endpoints will be unblinded simultaneously and top-line results for both endpoints are expected to be released in mid-2013.

### TransVax™ CMV Vaccine

- Astellas is planning to initiate a Phase 3 trial of TransVax™ for hematopoietic stem cell transplant (HSCT) recipients and to initiate a Phase 2 trial of TransVax™ for solid organ transplant (SOT) recipients in the first half of 2013.

### 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.
- At the 15th Annual Meeting of the American Society of Gene & Cell Therapy in May 2012, Vical presented results from multiple animal studies with the company's Vaxfectin®-formulated vaccines against HSV-2 demonstrating proof of concept.
- Results from the company's completed mouse studies with the HSV-2 vaccines were published in *The Journal of General Virology*.
- Results from the company's completed guinea pig studies with the HSV-2 vaccines were published in *Vaccine*.

### Vaxfectin® Adjuvant

- During the first quarter of 2012, the Naval Medical Research Center (NMRC) initiated a Phase 1 clinical trial of a tetravalent dengue DNA vaccine formulated with Vaxfectin®. Vical manufactured the vaccine and the adjuvant for both the preclinical and clinical studies, and is providing regulatory and clinical expertise to NMRC for the dengue program.
- Researchers at Ehime University in Japan and their collaborators developed a Vaxfectin®-formulated DNA vaccine candidate with the potential to prevent transmission of malaria and published encouraging initial results in *Vaccine*. Vical provided the DNA vaccine plasmid backbone and the adjuvant used in the research.
- 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 December 2012, Vical entered into a worldwide, nonexclusive license of the Vaxfectin<sup>®</sup> adjuvant to Cyvax, Inc., a privately held vaccine development company, for use in malaria vaccines.

## Conference Call

Vical will conduct a conference call and webcast today, February 6, 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 (913) 312-0696 (preferred), or (888) 282-4056 (toll-free), and reference confirmation code 4549145. 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 4549145. 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 burn guidance as well as statements about anticipated developments and timelines in the Allovectin<sup>®</sup>, TransVax<sup>™</sup> and HSV-2 vaccine programs, the Vaxfectin<sup>®</sup> adjuvant, and other independent and collaborative programs. Risks and uncertainties include whether Vical will achieve levels of revenues and control expenses to meet its financial projections; whether Vical or others will continue development of Allovectin<sup>®</sup>, TransVax<sup>™</sup>, HSV-2 vaccines, Vaxfectin<sup>®</sup> adjuvant, or any other independent or collaborative programs; whether Vical will release top-line data from the company's Phase 3 trial of Allovectin<sup>®</sup> in mid-2013, if at all; whether spending for long-lead-time activities will allow timely filing of a BLA for Allovectin<sup>®</sup>; whether the trial will achieve all, if any, of the defined endpoints; whether Astellas will initiate a Phase 3 trial of TransVax<sup>™</sup> for HSCT patients and/or a Phase 2 trial of TransVax<sup>™</sup> for SOT recipients in the first half of 2013, if at all; whether Vical will initiate a Phase 1/2 clinical trial of its therapeutic HSV-2 vaccine in the second half of 2013, if at all; 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)	Three Months Ended Dec. 31,		Twelve Months Ended Dec. 31,	
	2012	2011	2012	2011
Revenues:				
Contract and grant revenue	\$ 1,909	\$ 1,616	\$ 6,176	\$ 4,223
License and royalty revenue	410	316	11,343	25,795
Total revenues	2,319	1,932	17,519	30,018
Operating expenses:				
Research and development	3,439	3,971	17,340	17,975
Manufacturing and production	3,797	2,570	13,055	10,267
General and administrative	2,659	2,437	10,557	9,598
Total operating expenses	9,895	8,978	40,952	37,840
Loss from operations	(7,576)	(7,046)	(23,433)	(7,822)
Net investment and other income	27	432	534	539
Net loss	<u>\$ (7,549)</u>	<u>\$ (6,614)</u>	<u>\$ (22,899)</u>	<u>\$ (7,283)</u>

Basic and diluted net loss per share	<u>\$ (0.09)</u>	<u>\$ (0.09)</u>	<u>\$ (0.27)</u>	<u>\$ (0.10)</u>
Shares used to calculate basic and diluted net loss per share	<u>86,504</u>	<u>72,126</u>	<u>85,966</u>	<u>72,031</u>

	December 31,	
	2012	2011
<b>Balance Sheets</b>		
(in thousands)		
Assets:		
Cash, cash equivalents, and marketable securities, including restricted	\$ 83,857	\$ 50,427
Other current assets	<u>2,152</u>	<u>3,130</u>
Total current assets	86,009	53,557
Long-term investments	2,225	5,928
Property and equipment, net	5,284	6,226
Other assets	<u>3,004</u>	<u>3,062</u>
Total assets	<u>\$ 96,522</u>	<u>\$ 68,773</u>
Liabilities and stockholders' equity:		
Current liabilities	\$ 5,779	\$ 6,461
Long-term liabilities	1,657	1,964
Stockholders' equity	<u>89,086</u>	<u>60,348</u>
Total liabilities and stockholders' equity	<u>\$ 96,522</u>	<u>\$ 68,773</u>

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Senior Vice President and Chief Financial Officer

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