

VICAL INC

FORM 8-K

(Current report filing)

Filed 02/12/14 for the Period Ending 02/12/14

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): **February 12, 2014**

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 12, 2014, Vical Incorporated issued a press release announcing, among other things, its unaudited financial results for the three months and twelve months ended December 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: February 12, 2014

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 February 12, 2014.

Vical Reports 2013 Financial Results and Progress in Key Development Programs

SAN DIEGO, Feb. 12, 2014 (GLOBE NEWSWIRE) -- Vical Incorporated (Nasdaq:VICL) today reported financial results for the year ended December 31, 2013. The net loss for 2013 was \$31.2 million, or \$0.36 per share, compared with a net loss of \$22.9 million, or \$0.27 per share, for 2012. Revenues for 2013 were \$7.7 million, compared with revenues of \$17.5 million for 2012, reflecting lower payments from Astellas Pharma Inc. under an exclusive worldwide license of ASP0113, Vical's therapeutic vaccine designed to control cytomegalovirus (CMV) reactivation in transplant recipients.

Vical had cash and investments of approximately \$55 million at December 31, 2013. The company's net cash burn for the second half of 2013 was \$14.1 million which was consistent with the company's prior guidance. The company is projecting net cash burn for 2014 of between \$13 million and \$16 million.

Program highlights include:

Herpes Simplex Vaccine

- In December 2013, the company initiated its Phase 1/2 trial of its Vaxfectin™-formulated therapeutic vaccine for herpes simplex virus type 2 (HSV-2), a cause of genital herpes, in 156 subjects. The randomized, double-blind, placebo-controlled trial will evaluate safety, tolerability and efficacy in otherwise healthy HSV-2- infected patients aged 18 to 50 years at six U.S. clinical sites.

ASP0113 CMV Vaccine

- Astellas is conducting a multinational Phase 3 registration trial of ASP0113 in approximately 500 hematopoietic stem cell transplant (HCT) recipients. The 1:1 randomized, double-blind, placebo-controlled trial will enroll CMV seropositive subjects undergoing HCT procedures. The trial will use an adaptive design composed of two parts. The first part will enroll approximately 100 subjects and the primary endpoint will be overall survival at one year. The second part will enroll approximately 400 subjects and the primary endpoint will be either survival or a composite endpoint including survival and other variables, depending on the statistical analysis of results from the first part. Treatment and follow-up for each subject will continue for one year following enrollment. The Phase 3 trial protocol was designed to support full approval of ASP0113 for the HCT indication.
- Astellas is conducting a Phase 2 trial of ASP0113 in approximately 140 solid organ transplant (SOT) recipients. The global, randomized, double-blind, placebo-controlled trial is designed to evaluate the efficacy of ASP0113 compared to placebo as measured by the incidence of CMV viremia in CMV-seronegative subjects receiving a kidney from a CMV-seropositive donor. The study will also evaluate the safety of ASP0113 in this patient population. Follow-up for each subject will continue for one year following enrollment.

Conference Call

Vical will conduct a conference call and webcast today, February 12, at noon Eastern Time, to discuss the company's financial results and program updates with invited participants. 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) 457-1035 (preferred), or (888) 510-1765 (toll-free), and reference confirmation code 7863802. 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 7863802. 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, in which the expressed protein is an immunogen; and cardiovascular therapies, in which the expressed protein is an angiogenic growth factor. The company is developing certain infectious disease vaccines 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.

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 of clinical trials. Risks and uncertainties include whether Vical or others will continue development of ASP0113, Vical's HSV-2 vaccine or any other independent or collaborative programs; whether the Phase 3 trial protocol for

ASP0113 will support full approval for the HCT indication; 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)	Three Months Ended Dec. 31,		Twelve Months Ended Dec. 31,	
	2013	2012	2013	2012
Revenues:				
Contract and grant revenue	\$ 2,230	\$ 1,909	\$ 5,846	\$ 6,176
License and royalty revenue	915	410	1,872	11,343
Total revenues	3,145	2,319	7,718	17,519
Operating expenses:				
Research and development	2,478	3,439	14,558	17,340
Manufacturing and production	1,194	3,797	12,698	13,055
General and administrative	1,695	2,659	11,814	10,557
Total operating expenses	5,367	9,895	39,070	40,952
Loss from operations	(2,222)	(7,576)	(31,352)	(23,433)
Net investment and other income (expense)	30	27	114	534
Net loss	<u>\$ (2,192)</u>	<u>\$ (7,549)</u>	<u>\$ (31,238)</u>	<u>\$ (22,899)</u>
Basic and diluted net loss per share	<u>\$ (0.03)</u>	<u>\$ (0.09)</u>	<u>\$ (0.36)</u>	<u>\$ (0.27)</u>
Weighted average shares used in computing basic and diluted net loss per share	<u>87,064</u>	<u>86,504</u>	<u>86,840</u>	<u>85,966</u>

Balance Sheets (in thousands)	December 31, 2013	December 31, 2012
Assets:		
Cash, cash equivalents, and marketable securities, including restricted	\$ 53,497	\$ 83,857
Other current assets	4,590	2,152
Total current assets	58,087	86,009
Long-term investments	1,980	2,225
Property and equipment, net	3,935	5,284
Other assets	2,351	3,004
Total assets	<u>\$ 66,353</u>	<u>\$ 96,522</u>
Liabilities and stockholders' equity:		
Current liabilities	\$ 3,653	\$ 5,779
Long-term liabilities	1,288	1,657
Stockholders' equity	61,412	89,086
Total liabilities and stockholders' equity	<u>\$ 66,353</u>	<u>\$ 96,522</u>

CONTACT: Andrew Hopkins
(858) 646-1127

Anthony Ramos

Vice President and Chief Accounting Officer

Website: www.vical.com