

VICAL INC

FORM 8-K

(Current report filing)

Filed 10/30/14 for the Period Ending 10/30/14

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): **October 30, 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))
-

Item 2.02. Results of Operations and Financial Condition.

On October 30, 2014, Vical Incorporated issued a press release announcing, among other things, its unaudited financial results for the three and nine months ended September 30, 2014. 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: October 30, 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 October 30, 2014.

Vical Reports Third Quarter 2014 Financial Results and Progress in Key Development Programs

SAN DIEGO, Oct. 30, 2014 (GLOBE NEWSWIRE) -- Vical Incorporated (Nasdaq:VICL) today reported financial results for the three months and nine months ended September 30, 2014. The net loss for the third quarter of 2014 was \$4.4 million, or \$0.05 per share, compared with a net loss of \$9.9 million, or \$0.11 per share, for the third quarter of 2013. Revenues for the third quarter of 2014 were \$3.4 million, compared with revenues of \$1.5 million for the third quarter of 2013, reflecting higher revenues from Astellas Pharma Inc. for development and manufacturing services performed under our ASP0113 collaborative agreements. ASP0113 is Vical's therapeutic vaccine designed to control cytomegalovirus (CMV) reactivation in transplant recipients.

Vical had cash and investments of \$51.6 million at September 30, 2014. The company's net cash use for the third quarter of 2014 was \$2.6 million which reflects the advancement of the Company's clinical programs and its ongoing efforts to manage its operating expenses. The company's net cash use for the first nine months of 2014 was \$7.6 million. The company is updating its 2014 full year cash use guidance to a range of between \$10 million and \$12 million down from its previous forecast of between \$13 million and \$16 million.

Program highlights include:

HSV-2 Vaccine

- The Company's Phase 1/2 trial of its therapeutic vaccine designed to reduce the frequency and magnitude of viral shedding and reduce genital lesion recurrences in herpes simplex virus type 2 (HSV-2) positive subjects is progressing according to plan. The dose escalation cohorts are fully enrolled and dosed. Enrollment and dosing of patients in the final cohort is ongoing. We currently expect the trial to be fully enrolled in the fourth quarter of 2014. The 156 subject 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 seven U.S. clinical sites.
- The Company recently announced the issuance of six U.S. patents that provide broad coverage of DNA vaccines for HSV-2, containing specific gene sequences and formulated with Vical's Vaxfectin[®] adjuvant. These patents resulted from collaboration with the laboratories of leading HSV experts Drs. David Koelle and Lawrence Corey at the University of Washington under a multi-year NIH grant. The intellectual property is jointly owned by the University of Washington and Vical.

ASP0113 CMV Vaccine

- Astellas continues to make good progress in our partnered ASP0113 clinical programs. ASP0113 is a therapeutic vaccine to prevent CMV reactivation in hematopoietic stem cell transplant (HCT) recipients and solid organ transplant subjects. Astellas is actively recruiting for three clinical trials of ASP0113: a multinational Phase 3 registration trial in approximately 500 HCT recipients, a multinational Phase 2 trial in approximately 140 kidney transplant recipients, and a Phase 1 pharmacokinetics and immunogenicity trial in dialysis patients in the U.S.

Conference Call

Vical will conduct a conference call and webcast today, October 30, 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) 325-2308 (preferred), or (888) 312-3048 (toll-free), and reference confirmation code 7288360. 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 7288360. 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 recruitment for 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 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 the Phase 1/2 trial of our HSV-2 vaccine will be fully enrolled by the fourth quarter of 2014; 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		Nine Months Ended	
	September 30,		September 30,	
	2014	2013	2014	2013
Revenues:				
Contract and grant revenue	\$ 3,004	\$ 1,311	\$ 9,073	\$ 3,617
License and royalty revenue	<u>438</u>	<u>232</u>	<u>1,321</u>	<u>956</u>
Total revenues	3,442	1,543	10,394	4,573
Operating expenses:				
Research and development	3,180	4,500	7,705	12,080
Manufacturing and production	2,292	3,900	7,457	11,504
General and administrative	<u>2,366</u>	<u>3,123</u>	<u>7,176</u>	<u>10,119</u>
Total operating expenses	<u>7,838</u>	<u>11,523</u>	<u>22,338</u>	<u>33,703</u>
Loss from operations	(4,396)	(9,980)	(11,944)	(29,130)
Net investment and other income	<u>32</u>	<u>97</u>	<u>85</u>	<u>84</u>
Net loss	<u>\$ (4,364)</u>	<u>\$ (9,883)</u>	<u>\$ (11,859)</u>	<u>\$ (29,046)</u>
Basic and diluted net loss per share	<u>\$ (0.05)</u>	<u>\$ (0.11)</u>	<u>\$ (0.13)</u>	<u>\$ (0.33)</u>
Weighted average shares used in computing basic and diluted net loss per share	<u>89,976</u>	<u>86,998</u>	<u>88,154</u>	<u>86,755</u>

Balance Sheets

(in thousands)

	September 30, 2014	December 31, 2013
Assets:		
Cash, cash equivalents, and marketable securities, including restricted	\$ 49,711	\$ 53,497
Other current assets	<u>4,689</u>	<u>4,590</u>
Total current assets	54,400	58,087
Long-term investments	1,937	1,980
Property and equipment, net	2,857	3,935
Other assets	<u>2,081</u>	<u>2,351</u>
Total assets	<u>\$ 61,275</u>	<u>\$ 66,353</u>
Liabilities and stockholders' equity:		
Current liabilities	\$ 4,638	\$ 3,653
Long-term liabilities	974	1,288
Stockholders' equity	<u>55,663</u>	<u>61,412</u>
Total liabilities and stockholders' equity	<u>\$ 61,275</u>	<u>\$ 66,353</u>

CONTACT: Andrew Hopkins
(858) 646-1127
Website: www.vical.com

Anthony Ramos
Vice President and Chief Accounting Officer