

VICAL INC

FORM 8-K (Current report filing)

Filed 02/11/10 for the Period Ending 02/11/10

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): **February 11, 2010**

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 February 11, 2010, Vical Incorporated issued a press release announcing, among other things, its unaudited financial results for the three months and twelve months ended December 31, 2009. 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.

99.1 Press release issued by Vical Incorporated on February 11, 2010.

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 11, 2010

By: /s/ JILL M. BROADFOOT

Jill M. Broadfoot

Senior Vice President, Chief Financial Officer and Secretary

INDEX TO EXHIBITS

Exhibit No.	Description
--------------------	--------------------

99.1	Press release issued by Vical Incorporated on February 11, 2010.
------	--

Vical Reports 2009 Financial Results and Progress in Key Development Programs

SAN DIEGO, Feb. 11, 2010 (GLOBE NEWSWIRE) -- Vical Incorporated (Nasdaq:VICL) today reported financial results for the year ended December 31, 2009. Vical had cash and investments of approximately \$53 million at year-end 2009. The company raised approximately \$33 million of net proceeds from the sale of equity securities during 2009, and approximately \$3 million of additional net proceeds from the sale of equity securities to date in 2010.

Revenues for 2009 were \$12.7 million, compared with revenues of \$8.0 million for 2008. The net loss for 2009 was \$28.6 million, or \$0.61 per share, compared with a net loss of \$36.9 million, or \$0.93 per share, for 2008. The net cash burn for 2009, excluding financing activities, was approximately \$22 million, compared with approximately \$34 million for 2008. The decline in net cash burn was driven primarily by cost savings resulting from the company's November 2008 restructuring and staff reduction, as well as the increase in revenues. The company is projecting a net cash burn for 2010 of between \$20 million and \$24 million, including anticipated receipts from new or expanded partnerships not currently contracted.

Recent development highlights included:

Allovectin-7[®]

- Completion of enrollment of the planned 375 subjects in the company's pivotal Phase 3 AIMM trial of Allovectin-7[®] in patients with metastatic melanoma; and
- Completion of the AIMM trial's third scheduled safety analysis by an independent Safety Monitoring Board and the recommendation that the trial continue per the protocol.

CMV Vaccines

- Completion of the last scheduled follow-up visit for the final patient enrolled in a Phase 2 trial of the company's TransVax[™] cytomegalovirus (CMV) vaccine in hematopoietic stem cell transplant (HCT) recipients;
- Continued overall increase in cellular immune responses for the company's TransVax[™] CMV vaccine vs placebo at the seven-month immunogenicity data point in the ongoing Phase 2 HCT trial; and
- Allowance by the U.S. Food and Drug Administration (FDA) of the company's Investigational New Drug (IND) application for a Phase 1 trial of its CyMVectin[™] prophylactic vaccine to prevent CMV infection before and during pregnancy, the leading infectious disease cause of congenital birth defects.

H1N1 Influenza Vaccine

- A U.S. Navy contract to support large-scale cGMP vaccine manufacturing and related clinical and regulatory preparations for a Phase 1 clinical trial of the company's vaccine against H1N1 pandemic influenza; and
- Publication of data documenting the successful pilot lot production and initiation of animal immunogenicity testing of a Vaxfectin[®] -adjuvanted DNA vaccine for H1N1 influenza before conventional vaccine manufacturers even received the seed virus needed to start production.

Collaborations

- The launch by the company's licensee Merial Limited, the animal health subsidiary of sanofi-aventis, of its ONCEPT[™] canine melanoma vaccine, a therapeutic DNA vaccine designed to aid in extending survival of dogs with oral melanoma, at the North American Veterinary Conference in January, following full licensure by the U.S. Department of Agriculture (USDA); and
- Approval by the FDA of the Special Protocol Assessment (SPA) agreement for the company's licensee, AnGes MG, Inc., for a Phase 3 clinical trial of its Collatogene[™] angiogenesis product for patients with advanced peripheral arterial disease (PAD).

Anticipated program highlights for 2010 include:

- Periodic progress reports on the company's Phase 3 AIMM trial of Allovectin-7[®] in patients with metastatic melanoma;
- Final results in mid-2010 from the Phase 2 trial of the company's TransVax[™] CMV vaccine candidate for HCT patients;
- Initiation of a Phase 1 trial of the company's Vaxfectin[®] -adjuvanted DNA vaccine for H1N1 influenza in the first quarter of 2010 and immunogenicity data within two months of trial initiation; and
- Completion of an ongoing Phase 3 trial in the third quarter of 2010 and presentation of data in the fourth quarter of 2010 by the company's licensee, sanofi aventis Group, for Temusi[®], its DNA-based delivery of Fibroblast Growth Factor 1 (FGF-1), an angiogenic growth factor, intended to promote the growth of blood vessels in patients with reduced blood flow to the limbs to reduce the need for amputations.

Conference Call

Vical will conduct a conference call and webcast today, February 11, 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 (877) 879-6203, or (719) 325-4823 for international participants, and reference confirmation code 4635156. A replay of the call will be available for 48 hours beginning about two hours after the call. To listen to the replay, dial (888) 203-1112, or (719) 457-0820 for international participants, and enter replay passcode 4635156. 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 info@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.

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 loss and net cash burn guidance, as well as statements about Vical's Allovectin-7[®], TransVax[™] and pandemic influenza vaccine programs, and other independent and collaborative programs, as well as anticipated developments in independent and collaborative programs, and statements about the scope of coverage of and potential applications for Vical's patents. Risks and uncertainties include whether Vical or others will continue development of Allovectin-7[®], TransVax[™], CyMVectin[™], a vaccine against H1N1 pandemic influenza, the sanofi aventis FGF-1 angiogenesis therapy, the AnGes Collatogene[™] angiogenesis therapy, or any other independent or collaborative programs; whether Vical will provide periodic progress reports on the company's Phase 3 AIMM trial; whether final results from the TransVax[™] CMV vaccine Phase 2 trial will be available in mid-2010, if at all; whether Vical or others will initiate a Phase 1 trial of the company's CyMVectin[™] prophylactic vaccine; whether Vical will initiate a Phase 1 trial of the company's Vaxfectin[®] - adjuvanted DNA vaccine for H1N1 influenza in the first quarter of 2010, if at all; whether immunogenicity data from such a trial will be available within two months of trial initiation, if at all; whether AnGes will initiate a Phase 3 clinical trial of its Collatogene[™] angiogenesis product in the United States; whether sanofi aventis will successfully complete its ongoing Phase 3 trial of Temusi[®] in the third quarter of 2010 and present data in the fourth quarter of 2010, if at all; whether Vical's issued patents will be challenged and whether such challenges will have an adverse effect on the scope of the patents; whether Vical will pursue enforcement of its issued patents or be successful in any such enforcement efforts; whether Vical will achieve levels of revenues and control expenses to meet its financial projections; whether Vical will enter into any new partnerships or expand any existing partnerships and receive all, if any, anticipated payments; 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		Twelve Months Ended	
	Dec. 31,		Dec. 31,	
(in thousands, except per share amounts)	2009	2008	2009	2008
Revenues:				
Contract and grant revenue	\$949	\$542	\$3,692	\$2,146
License and royalty revenue	1,606	2,083	8,994	5,810
Total revenues	<u>2,555</u>	<u>2,625</u>	<u>12,686</u>	<u>7,956</u>
Operating expenses:				

Research and development	6,168	6,248	23,449	25,532
Manufacturing and production	1,887	2,274	10,354	11,046
General and administrative	1,914	2,282	7,469	8,721
Total operating expenses	<u>9,969</u>	<u>10,804</u>	<u>41,272</u>	<u>45,299</u>
Loss from operations	(7,414)	(8,179)	(28,586)	(37,343)
Net investment and other income (expense)	105	(845)	28	447
Net loss	<u><u>\$(7,309)</u></u>	<u><u>\$(9,024)</u></u>	<u><u>\$(28,558)</u></u>	<u><u>\$(36,896)</u></u>
Basic and diluted net loss per share	<u><u>\$(0.14)</u></u>	<u><u>\$(0.22)</u></u>	<u><u>\$(0.61)</u></u>	<u><u>\$(0.93)</u></u>
Shares used to calculate basic and diluted net loss per share	<u><u>52,192</u></u>	<u><u>40,356</u></u>	<u><u>47,086</u></u>	<u><u>39,856</u></u>

Balance Sheets

(in thousands)

	December 31, 2009	December 31, 2008
Assets:		
Cash, cash equivalents, and marketable securities, including restricted	\$47,085	\$36,266
Other current assets	<u>1,349</u>	<u>1,852</u>
Total current assets	48,434	38,118
Long-term investments	5,477	5,410
Property and equipment, net	9,260	10,734
Other assets	<u>4,201</u>	<u>4,795</u>
Total assets	<u><u>\$67,372</u></u>	<u><u>\$59,057</u></u>
Liabilities and stockholders' equity:		
Current liabilities	\$10,010	\$7,974
Long-term obligations	2,380	2,469
Stockholders' equity	<u>54,982</u>	<u>48,614</u>
Total liabilities and stockholders' equity	<u><u>\$67,372</u></u>	<u><u>\$59,057</u></u>

CONTACT: Vical Incorporated
Alan R. Engbring, Executive Director, Investor Relations
(858) 646-1127
Jill M. Broadfoot, Senior Vice President and Chief Financial
Officer
www.vical.com