

# VICAL INC

## FORM 8-K

(Current report filing)

Filed 09/13/10 for the Period Ending 09/13/10

Address	10390 PACIFIC CENTER COURT
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	SAN DIEGO, CA 92121-4340
Telephone	858-646-1100
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Industry	Biotechnology & Drugs
Sector	Healthcare
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# 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): **September 13, 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))
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#### Item 8.01. Other Events.

On September 13, 2010, Vical Incorporated issued a press release announcing the achievement of key efficacy, immunogenicity and safety results in a Phase 2 trial, establishing its TransVax cytomegalovirus vaccine as the first to provide evidence of protection in immunocompromised hematopoietic cell transplant recipients, and defining a potential pathway for further development. A copy of the press release is attached as Exhibit 99.1 to this Current Report.

The information in this Item 8.01, 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 September 13, 2010.

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## **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: September 13, 2010

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 September 13, 2010.

# Vical's TransVax(TM) CMV Vaccine Achieves Statistical Significance on Key Clinical Endpoints in Phase 2 Trial

## Conference Call and Webcast Concurrent With ICAAC Presentation at 11:15 a.m. EDT Tuesday

SAN DIEGO, Sept. 13, 2010 (GLOBE NEWSWIRE) -- Vical Incorporated (Nasdaq:VICL) announced today the achievement of key efficacy, immunogenicity and safety results in a Phase 2 trial, establishing its TransVax™ cytomegalovirus (CMV) vaccine as the first to provide evidence of protection in immunocompromised hematopoietic cell transplant (HCT) recipients, and defining a potential pathway for further development.

"The TransVax™ vaccine has demonstrated the ability to drive effective immune responses in the inherently difficult therapeutic setting of immunocompromised patients," said CMV and organ transplant expert Mark D. Pescovitz, M.D. "In addition to providing evidence of protective efficacy in HCT recipients, the TransVax™ Phase 2 results have identified clinically relevant endpoints that may be appropriate for further development."

"We look forward to finalizing our approach through discussions with CMV and transplant experts, and reviewing our resulting plans with the regulatory agencies," said Richard T. Kenney, M.D., Vical's Vice President of Clinical Development, who will present the data at 11:15 a.m. EDT Tuesday at the 50<sup>th</sup> Annual Interscience Conference on Antimicrobial Agents and Chemotherapy (Boston – September 12-15). Dr. Pescovitz, Professor of Surgery and Microbiology & Immunology, and Vice Chair of Research in Surgery at the Indiana University School of Medicine, will join Vical management on a concurrent conference call and webcast for the investment community.

### Efficacy Results

The TransVax™ Phase 2 trial was a 1:1 randomized, double-blind, placebo-controlled, multi-center study in 80 patients scheduled to receive HCTs for their underlying leukemias or lymphomas. Through 12 months post-transplant, significant reductions were achieved for key viral reactivation metrics:

- The incidence of CMV viremia (percentage of subjects with  $\geq 500$  copies of CMV virus per mL of blood by a central lab assay) was 32% in the TransVax™ group, and 62% in the placebo group ( $p=0.008$ );
- The median time to initial viremia was  $>365$  days (i.e., median not reached during the 12-month study period) for the TransVax™ group, and 109.5 days for the placebo group ( $p=0.003$ );
- The number of CMV viremia episodes (0-4 per subject) was significantly lower for the TransVax™ group than for the placebo group ( $p=0.017$ );
- The duration of viremia was lower for the TransVax™ group than for the placebo group (mean of 10.6 days vs. mean of 19.5 days, respectively;  $p=0.069$ ), and significantly lower as a percentage of the time subjects spent on study (mean of 4.9% vs. mean of 7.7%, respectively;  $p=0.042$ ); and
- The prevalence of CMV viremia episodes over the trial period was significantly lower for the TransVax™ group than for the placebo group ( $p=0.036$ ).

Antiviral therapy use was triggered by site-specific treatment practices based on local lab assays, which impeded comparability among the 16 enrolling U.S. sites. Overall, 48% of subjects in the TransVax™ group vs. 62% of subjects in the placebo group received antiviral drugs for CMV during the study. The median duration of antiviral treatment was approximately 30 days in the TransVax™ group vs. approximately 40 days in the placebo group. Because antiviral drugs are used preemptively to control CMV outbreaks, CMV-associated disease is rare and the study was not powered to detect a difference in this endpoint. Only three of 40 subjects (8%) in the TransVax™ group and four of 34 subjects (12%) in the placebo group developed CMV-associated disease. Antiviral drug usage and CMV-associated disease are not practical endpoints for future studies.

### Immunogenicity Results

Published data have shown that T-cell responses are critical for controlling CMV reactivation; antibody responses may provide additional protection. The HCT recipients in the study all had preexisting CMV infections and therefore would be expected to have baseline immune responses against CMV. They were also immunosuppressed as a result of treatments for their underlying leukemias or lymphomas. Despite these challenges:

- T-cell responses to phosphoprotein 65 (pp65) were significantly higher in the TransVax™ group than in the placebo group over the one-year trial ( $p=0.003$ ); and
- T-cell and antibody responses to glycoprotein B (gB) were higher in the TransVax™ group than in the placebo group and trending toward greater separation over the one-year trial.

### Safety Results

The TransVax™ vaccine was well tolerated in the Phase 2 trial in immunocompromised HCT recipients, and no safety concerns were raised during the trial. There was no significant difference in the number of serious adverse events (SAEs) between the TransVax™ and placebo groups. There also were fewer deaths in the TransVax™ group (18%) than in the placebo group (32%) during the trial.

## **Phase 2 Trial Design**

The Phase 2 trial evaluated the potential for TransVax™ to control CMV reactivation in immunosuppressed CMV-seropositive HCT recipients, which could reduce antiviral usage and CMV-associated disease. Subjects were randomized by site, transplant donor CMV-seropositive or -seronegative status, and donor/recipient genetic match (matching either 5 of 6 or 6 of 6 human leukocyte antigen alleles) and received either the TransVax™ vaccine or placebo shortly before the transplant and again at approximately 1, 3 and 6 months post-transplant. The study was conducted at 16 U.S. sites, and the endpoints evaluated for 12 months post-transplant included safety, immunogenicity, use of CMV antiviral therapy, and viral load.

## **About TransVax™**

TransVax™ is a bivalent DNA vaccine containing plasmids (closed loops of DNA) encoding CMV pp65 and gB antigens for induction of both cellular and humoral immune responses. TransVax™ is formulated with a proprietary poloxamer-based delivery system. TransVax™ has received orphan drug designation in the United States for HCT and solid organ transplant patients.

## **Conference Call/Webcast**

Vical will conduct an audio-only conference call and audio/slide webcast at 11:15 a.m. EDT Tuesday to discuss details of the results with invited analysts and institutional investors. The call is open on a listen-only basis to any interested parties. The webcast audio and slides also will be available live and archived through the Events page of the company's website at [www.vical.com](http://www.vical.com). To listen to the conference call, dial in approximately ten minutes before the scheduled call to (888) 205-6648, or (913) 981-5543 for international participants, and reference confirmation code 4384312. 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 4384312. For further information, contact Vical's Investor Relations department by phone at (858) 646-1127 or by e-mail at [info@vical.com](mailto: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](http://www.vical.com).

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

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 statements about Vical's technologies, the TransVax™ vaccine effectiveness in reducing key CMV reactivation metrics, as well as the company's focus, collaborative partners, and independent and partnered product candidates. Risks and uncertainties include whether Vical or others will continue development of TransVax™ or any other product candidates; whether endpoints identified in or as a result of the Phase 2 trial will be acceptable to the relevant regulatory agencies; whether Phase 2 results will be predictive of results in any future studies; whether Vical or others will advance TransVax™ to Phase 3 testing; whether such testing, if conducted, will be successful; whether Vical or its collaborative partners will seek or gain approval to market TransVax™ or any other DNA-based human vaccine or therapeutic product candidates; whether Vical or its collaborative partners will succeed in marketing 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.

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