VICAL INC

FORM 8-K
(Current report filing)

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Address	10390 PACIFIC CENTER COURT . SAN DIEGO, CA 92121-4340
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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): **June 22, 2015**

VICAL INCORPORATED
(Exact name of registrant as specified in its charter)

Delaware	**000-21088**	**93-0948554**
(State or other jurisdiction of incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

10390 Pacific Center Court **San Diego, California**	**92121-4340**
(Address of principal executive offices)	(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:

- ☐ 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 8.01. Other Events.

On June 22, 2015, Vical Incorporated issued a press release announcing results from an ongoing randomized, double-blind, placebo controlled Phase 1/2 clinical study of its therapeutic genital herpes vaccine, designed to reduce viral shedding and genital herpes lesions in herpes simplex virus type 2 (HSV-2) infected patients. The trial enrolled patients across seven U.S. sites and is evaluating two constructs: a monovalent (gD) vaccine and a bivalent (gD + UL46) vaccine, each formulated with Vical's proprietary Vaxfectin ® adjuvant. The top-line analysis compared pre-vaccination measurements for each arm with those taken during the swabbing period in months 2 and 3 following the last vaccine dose. Neither the monovalent nor bivalent vaccine met the primary endpoint. On prospectively defined secondary endpoints, the bivalent vaccine achieved statistically significant reductions in the rate of genital lesions (-51%, p = 0.0037) and viral load from positive swabs (-0.39 $\log_{10}$, p = 0.0008) versus baseline. The results are summarized in the table below:

	Monovalent (N=54)	**Bivalent (N=56)**	**Placebo (N=21)**
Primary Endpoint			
Change in shedding rate from baseline	-12% (p = 0.3862)	-19% (p = 0.1561)	-45% (p = 0.0144)
Secondary Endpoints			
Change in lesion rate from baseline	+3% (p = 0.8759)	-51% (p = 0.0037)	-46% (p = 0.0850)
Change in viral load in positive swabs from baseline (HSV copies, $\log_{10}$)	-0.38 (p = 0.0012)	-0.39 (p = 0.0008)	0.28 (p = 0.1268)

Both the monovalent and bivalent vaccines were generally well tolerated. Safety data have been reviewed throughout the trial by an independent safety monitoring board, and no grade 4 adverse events or serious adverse events related to vaccination have been observed.

The trial enrolled 165 symptomatic HSV-2 patients at seven investigational sites in the U.S. The trial consists of an initial dose escalation cohort with 14 patients and then an efficacy cohort with 151 patients at full dose. 131 evaluable patients are included in the top-line per protocol efficacy analysis.

All patients in the trial continue to be followed for safety for 12 months and efficacy for 9 months after their final vaccine dose, and during that 9-month period, additional clinical efficacy data such as recurrence rate and lesion rate will be evaluated.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

99.1 Press release issued by Vical Incorporated on June 22, 2015.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

VICAL INCORPORATED

Date: June 22, 2015

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 June 22, 2015.

Vical Reports Top-Line Results From Phase 1/2 Trial of Therapeutic Genital Herpes Vaccine

The Primary Endpoint of Shedding Rate was not Met

Conference Call and Webcast to be Held Today, June 22 at 5:00 pm ET

SAN DIEGO, June 22, 2015 (GLOBE NEWSWIRE) -- Vical Incorporated (Nasdaq:VICL) today announced top-line results from an ongoing randomized, double-blind, placebo controlled Phase 1/2 clinical study of its therapeutic genital herpes vaccine, designed to reduce viral shedding and genital herpes lesions in herpes simplex virus type 2 (HSV-2) infected patients. The trial enrolled patients across seven U.S. sites and is evaluating two constructs: a monovalent (gD) vaccine and a bivalent (gD + UL46) vaccine, each formulated with Vical's proprietary Vaxfectin ® adjuvant. The top-line analysis compared pre-vaccination measurements for each arm with those taken during the swabbing period in months 2 and 3 following the last vaccine dose. Neither the monovalent nor bivalent vaccine met the primary endpoint. On prospectively defined secondary endpoints, the bivalent vaccine achieved statistically significant reductions in the rate of genital lesions (-51%, p = 0.0037) and viral load from positive swabs (-0.39 $\log_{10}$, p = 0.0008) versus baseline. The results are summarized in the table below:

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Both the monovalent and bivalent vaccines were generally well tolerated. Safety data have been reviewed throughout the trial by an independent safety monitoring board, and no grade 4 adverse events or serious adverse events related to vaccination have been observed.

"We just received the top-line study data and we are disappointed that the vaccines did not meet the primary endpoint," said Vijay Samant, President and Chief Executive Officer. "The trial is ongoing and all patients are being followed for safety for 12 months and efficacy for 9 months after their final vaccine dose. During that 9-month period, we will collect additional clinical efficacy data including recurrence rate and lesion rate, which will enable us to determine the appropriate next steps for this program. We greatly appreciate the ongoing support of the patients and investigators who are taking part in this trial."

Mr. Samant continued, "In the meantime, we remain focused on advancing our CMV vaccine candidate partnered with Astellas. Enrollment is complete in the Phase 2 solid organ transplant trial, placing us on track for data during the second half of 2016, and the Phase 3 pivotal trial is underway in hematopoietic stem cell transplant recipients. We are also moving our in-licensed antifungal compound toward a Phase 1 trial initiation during the first half of 2016. Because Astellas funds the CMV program and given the other operational efficiencies we have put in place, we anticipate that our current cash position will fund us through these milestones and into 2017."

About the Phase 1/2 HSV-2 Clinical Trial

The Phase 1/2 trial is an ongoing randomized double-blind, placebo controlled study which enrolled 165 symptomatic HSV-2 patients at seven investigational sites in the U.S. The trial consists of an initial dose escalation cohort with 14 patients and then an efficacy cohort with 151 patients at full dose. 131 evaluable patients are included in the top-line per protocol efficacy analysis.

Enrolled patients are required to have a history of symptomatic genital herpes with 2 to 9 lesion recurrences per year. The dose escalation component of the trial assessed the safety of ¼ dose, ½ dose, and a full dose of vaccines in a small number of patients prior to dosing additional patients at the full dose. Two vaccine constructs are being evaluated: monovalent (gD) and bivalent (gD + UL46), each formulated with Vical's proprietary Vaxfectin ® adjuvant. Regardless of the vaccine construct and dose, all patients received a vaccine or a placebo on days 0, 28, and 56. The patients in the efficacy cohort who received the full dose of vaccine or placebo are assessed for vaccine effectiveness in reducing HSV-2 shedding from baseline as the primary endpoint, and for secondary endpoints including changes in lesion rate and viral load from baseline.

Each patient in the efficacy cohort performed once daily swabbing to measure HSV shedding before and after vaccination. Sampling periods of 60 days for daily swab collections and diaries were used to generate shedding and lesion data to compare the post-vaccination to the pre-

vaccination periods. In addition, the quantity of virus during each positive shedding day was compared for each patient pre- and post-vaccination. All patients in the trial continue to be followed for safety for 12 months and efficacy for 9 months after their final vaccine dose, and during that 9-month period, additional clinical efficacy data including recurrence rate and lesion rate will be evaluated. Additional study details are available at https://www.clinicaltrials.gov/ct2/show/NCT02030301.

Conference Call

Vical will conduct a conference call and webcast today, June 22, at 5:00 pm Eastern Time, to discuss the results of the trial. Listeners may access the accompanying slide presentation through the webcast at www.vical.com. 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) 325-2430 (preferred), or (888) 523-1232 (toll-free), and reference confirmation code 6526980. 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 6526980. 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 develops biopharmaceutical products for the prevention and treatment of chronic or life-threatening infectious diseases, based on its patented DNA delivery technologies and other therapeutic approaches. Additional information on Vical is available at www.vical.com.

Forward-Looking Statements

This press release contains forward-looking statements that are subject to risks and uncertainties that could cause actual results to differ materially from those projected. Forward-looking statements include Vical's projected cash runway, clinical plans and anticipated timelines, and expected announcement of data for clinical trials. Risks and uncertainties include whether Vical or others will continue development of Vical's HSV-2 vaccine or its other independent or partnered programs; unexpected expenses or cash requirements; 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.

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