VICAL INC
Form 8-K
June 22, 2015
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:

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
o 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 log10, 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, log10)	-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.