VICAL INC
Form 8-K
September 19, 2016

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 19, 2016

Vical Incorporated
(Exact Name of Registrant as Specified in Charter)

DELAWARE	**000-21088**	**93-0948554**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(I.R.S. Employer Identification Number)

10390 Pacific Center Court, San Diego, California
92121-4340
(Address of Principal Executive Offices) (Zip Code)

(858) 646-1100
(Registrant's telephone number, including area code)

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 September 19, 2016, Vical Incorporated and Astellas Pharma Inc. announced topline results from a randomized, double-blind, placebo-controlled Phase 2 study evaluating the safety and efficacy of cytomegalovirus (CMV) vaccine, ASP0113, versus placebo in kidney transplant patients receiving an organ from a CMV-seropositive donor. Results from the study demonstrated that the trial did not meet its primary endpoint, which was the proportion of patients having CMV viremia defined as a plasma viral load of ≥ 1000 IU/mL by central laboratory assay through one year after first injection of study drug. Additionally, the secondary endpoints of CMV-associated disease and CMV-specific antiviral therapy, which were evaluated by an independent, blinded Adjudication Committee, were similar in both treatment groups. The safety profiles were generally similar between treatment groups. However, local injection site reactions were more common in the ASP0113 treatment group.

The randomized, double-blind, placebo-controlled trial evaluated the safety and efficacy of ASP0113 in CMV-seronegative kidney transplant recipients receiving an organ from a CMV-seropositive donor (D+/R-). Enrollment included 150 kidney transplant recipients across approximately 80 centers in North America, Europe and Australia and randomized 1:1 to receive either ASP0113 or placebo, in addition to valganciclovir or ganciclovir prophylaxis for 100 days after kidney transplant.

The Phase 3 study of ASP0113 in hematopoietic cell transplant (HCT) recipients is on-going and has completed target enrollment.

Item 9.01. Financial Statements and Exhibits.

Exhibit 99.1. Press release dated September 19, 2016

SIGNATURE

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: September 19, 2016

By: /s/ Vijay B. Samant
Vijay B. Samant
Chief Executive Officer