VICAL INC
Form 8-K
October 02, 2017

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): October 2, 2017

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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2). Emerging growth company [ ]

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. [ ]

Item 8.01. Other Events.

On October 2, 2017, Vical Incorporated issued a press release announcing that the U.S. Food and Drug Administration (FDA) has advised that Vical's investigational antifungal VL 2397 would be eligible for a Limited Use Indication (LUI) approval assuming a successful outcome of a single Phase 2 trial carried out in accordance with a protocol and statistical analysis plan consistent with the Agency's advice. The final determination whether the drug is approvable will be made by FDA after review of all relevant data.

Vical plans to initiate a single Phase 2 trial for the treatment of invasive aspergillosis (IA) in acute leukemia patients and allogeneic hematopoietic cell transplant (HCT) recipients for whom alternative treatment regimens are not available in the fourth quarter of 2017. The global Phase 2 trial will be a non-inferiority study comparing VL-2397 to standard of care treatment for IA. Approximately 200 acute leukemia patients and recipients of allogeneic HCT will be enrolled and randomized 2:1. The primary endpoint will be all-cause mortality (ACM) at 4 weeks with a key secondary endpoint of ACM at 6 weeks. Achieving LUI approval is contingent upon successfully meeting both endpoints.

On October 2, 2017, Vical issued a press release regarding the eligibility of VL-2397 for LUI approval. A copy of the press release is attached at exhibit 99.1.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

99.1 Press release issued by Vical Incorporated on October 2, 2017.

Forward-Looking Statements.

This report contains forward-looking statements subject to risks and uncertainties that could cause actual results to differ materially from those projected. Forward-looking statements include anticipated developments in clinical programs, including the plans, timing of initiation, and enrollment for clinical trials. Risks and uncertainties include whether Vical or others will continue development of VL-2397; the risk that the FDA does not grant LUI approval of VL-2397 following the results of Vical's planned Phase 2 clinical trial; whether Vical will be able to obtain regulatory allowances or guidance necessary to proceed with proposed clinical trials or implement anticipated clinical trial designs; whether on-going or planned clinical trials will be initiated or completed on the timelines Vical currently expects; whether any product candidates will be shown to be safe and efficacious in clinical trials; the fact that results from the planned Phase 2 clinical trial of VL-2397 may be inconsistent with the results from prior preclinical studies and clinical trials; whether Vical will have access to sufficient capital to fund its planned development activities; whether Vical 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 Vical's judgment as of the date of this report. Vical disclaims, however, any intent or obligation to update these forward-looking statements.

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: October 2, 2017

By: /s/ ANTHONY A. RAMOS
Anthony A. Ramos
Chief Financial Officer

INDEX TO EXHIBITS

Exhibit No.	Description
99.1	Press release issued by Vical Incorporated on October 2, 2017.