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.

EXHIBIT 99.1

Vical Announces that its Antifungal VL-2397 is Eligible for Limited Use Indication Approval by FDA Based on a Single Phase 2 Efficacy Trial

Vical plans to initiate Phase 2 trial of VL-2397 for the treatment of invasive aspergillosis in 4Q 2017

Management to host conference call on October 3rd at 12:00 pm ET to discuss the Phase 2 trial design

SAN DIEGO, Oct. 02, 2017 (GLOBE NEWSWIRE) -- Vical Incorporated (Nasdaq:VICL) today announced 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.

The LUI is a provision of the Limited Population Pathway (LPP) established under the 21st Century Cures Act of 2016. 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 in the fourth quarter of 2017.

"The LPP will allow Vical to develop and commercialize VL-2397 on a potentially accelerated basis for a limited use indication," said Vijay Samant, Vical's President and CEO. "New antifungals with novel mechanisms of action are needed to address the urgent need in IA, particularly in patients who are intolerant to existing drugs and in patients infected by azole-resistant strains."

Dr. Haran Schlamm, MD, Vical's infectious disease consultant and former Pfizer Senior Medical Director responsible for Pfizer's antifungal portfolio also commented, "The preclinical and clinical data to date for VL-2397 supports the profile of an ideal antifungal agent which must be fast acting, have minimal drug interactions, and a low risk for toxicity."

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.

In addition to interactions with the FDA, Vical has worked extensively with the Mycoses Study Group Education and Research Consortium (MSGERC) on the Phase 2 study design and preparations. MSGERC provides scientific and medical thought leadership for evidence-based medicine in the diagnoses, prevention, treatment and maintenance of patients at risk for or afflicted with invasive fungal infections.

Vical will conduct a conference call and webcast tomorrow, October 3, at noon Eastern Time, to discuss this announcement. 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 (913)312-1496 (preferred), or (888)417-2254 (toll-free), and reference confirmation code 9759530. 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 9759530. The webcast will also 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 the Limited Population Pathway
The LPP is designed to streamline development programs for certain antimicrobial agents intended to treat specific groups of patients who are not well addressed by available therapies for their serious or life-threatening infections. Under this pathway, the drug can be used to treat only the limited population for which it is approved while additional trials are conducted to establish safety and effectiveness for broader indications. Standards for a new drug application must be met for LUI approval. In the case of VL-2397, the limited population approval would be for patients for whom alternative regimens are not available to treat their invasive aspergillosis. A Phase 3 trial would be required to support full approval of VL-2397 for the treatment of IA in a broader population.

About VL-2397
VL-2397 is Vical's novel antifungal compound that was licensed from Astellas Pharma in 2015. VL-2397 was isolated from a leaf litter fungus collected in a Malaysian national park and represents the first agent in a potentially new class of antifungal drugs. The FDA has granted Vical Qualified Infectious Disease Product (QIDP), Orphan Drug and Fast Track designations for VL-2397 in the treatment of invasive aspergillosis.

About Invasive Aspergillosis
Invasive aspergillosis is a life-threatening infection that typically affects immunocompromised patients, including those with acute leukemia and recipients of allogeneic HCT or lung transplants. Infection typically starts in the lungs and rapidly disseminates to other tissues. More than 200,000 cases of IA are diagnosed annually worldwide.

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 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 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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