VICAL INC
Form 8-K
September 22, 2010

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 22, 2010

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 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.

Angiogenesis Out-License Update

On September 17, 2010 (Japanese time), our licensee AnGes MG, Inc., or AnGes, provided an update regarding the New Drug Application, or NDA, it previously submitted to the Japanese Ministry of Health, Labor and Welfare for Collategene , an angiogenic product candidate that uses our DNA delivery technology to deliver hepatocyte growth factor, or HGF, for indications related to critical limb ischemia.

AnGes announced that after a series of extensive consultations with the Japanese Pharmaceuticals and Medical Devices Agency, it had decided to conduct an additional clinical trial of Collategene and that in the interim, it would be withdrawing its NDA in Japan. AnGes also reported that it is currently preparing for a global Phase 3 clinical trial of Collategene in the United States, Europe, Japan and other countries and that it believes having Japanese sites participate in the Phase 3 trial represents the best potential pathway to approval in Japan. AnGes previously announced that it had reached agreement with the U.S. Food and Drug Administration, or FDA, regarding a Special Protocol Assessment for the Phase 3 trial.

AnGes also announced that the FDA has granted Fast Track designation of Collategene as a treatment for critical limb ischemia. Fast Track designation is intended to facilitate the development and expedite the review of drugs with demonstrated potential to address unmet medical needs for serious diseases. Fast Track designation also allows submission of a Biologics License Application on a rolling basis with ongoing FDA review during the submission process.

In addition to Collategene , our DNA delivery technology is utilized in NV1FGF (Temusl®), an investigational angiogenesis therapy under development by our licensee sanofi-aventis. On September 22, 2010, sanofi-aventis announced that NV1FGF did not meet the primary endpoint in a global Phase 3 clinical trial. The full study results will be presented at the American Heart Association Congress on November 16, 2010. Sanofi-aventis is evaluating all options with respect to NV1FGF development in light of the Phase 3 clinical trial results.

Allovectin-7® Update

On September 22, 2010, we announced that the FDA has also granted Fast Track designation of Allovectin-7®, a novel gene-based immunotherapeutic which we are developing as a treatment for metastatic melanoma.

Forward-Looking Statements

This Current Report on Form 8-K, or Report, contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, including statements regarding the research, development and regulatory approval of biopharmaceutical products based on our patented DNA delivery technologies. Such statements reflect current views and assumptions and are subject to risks and uncertainties, particularly those inherent in the process of developing and commercializing biopharmaceutical products based on our patented DNA delivery technologies. Actual results could differ materially from those projected herein. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in our Annual Report on Form 10-K for the year ended December 31, 2009, and in our other filings with the SEC. As a result, you are cautioned not to rely on these forward-looking statements. We disclaim any duty to update any forward-looking statement to reflect events or circumstances that occur after the date on which such statement is made.

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: September 22, 2010

By: /s/ JILL M. BROADFOOT
Jill M. Broadfoot
Senior Vice President, Chief Financial Officer
and Secretary