

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 1934

Date of Report: December 11, 2002

Titan Pharmaceuticals, Inc.

(Exact name of registrant as specified in charter)

Delaware
(State or other jurisdiction
of incorporation)

0-27436
(Commission
File Number)

94-3171940
(IRS Employer
Identification No.)

400 Oyster Point Blvd., Suite 505, South San Francisco, California 94080

(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code: **(650) 244-4990**

Item 5. Other Events

On December 11, 2002, the Registrant announced results of a Phase III, randomized, placebo-controlled study of its monoclonal antibody CeaVac® in patients with metastatic colorectal cancer receiving chemotherapy with 5- fluorouracil (5-FU) and leucovorin. Preliminary analysis from the study demonstrated a trend toward overall survival improvement of approximately 2 to 3 months in patients receiving at least 5 doses of CeaVac versus placebo (modified intent-to-treat population) but failed to demonstrate a statistically significant improvement in the primary endpoint of survival in the overall efficacy evaluable population or intent-to-treat population..

Reference is made to the related press release filed as Exhibit 20.1 hereto, which is incorporated by reference herein.

Item 7. Financial Statements, Pro Forma Financial Information and Exhibits

(c) Exhibits

20.1 Press Release dated December 11, 2002

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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.

TITAN PHARMACEUTICALS, INC.

By: _____ /s/ ROBERT E. FARRELL

Robert E. Farrell, Executive Vice President
and Chief Financial Officer

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[Titan Pharmaceuticals, Inc. Logo]

Exhibit 20.1

Company:
Alison Roselli Lehanski
Director, Corporate Communications
650-244-4993

Media:
Mark Padgett
GCI Group
212-537-8082

Investors:
Robert Ferris
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TITAN ANNOUNCES RESULTS OF CEAVAC® CLINICAL STUDY IN COLORECTAL CANCER

South San Francisco, CA—December 11, 2002—Titan Pharmaceuticals, Inc. (ASE:TTP) announced today results of a Phase III, randomized, placebo-controlled study of its monoclonal antibody CeaVac® in patients with metastatic colorectal cancer receiving chemotherapy with 5-fluorouracil (5-FU) and leucovorin. Preliminary analysis from the study demonstrated a trend toward overall survival improvement of approximately 2 to 3 months in patients receiving at least 5 doses of CeaVac versus placebo (modified intent-to-treat population) but failed to demonstrate a statistically significant improvement in the primary endpoint of survival in the overall efficacy evaluable population or intent-to-treat population.

CeaVac is a monoclonal antibody that stimulates an immune response to carcinoembryonic antigen (CEA), and is administered as a subcutaneous injection. Patients in the study received injections of study drug once every two weeks for 2 months and then once per month thereafter. The study randomized 631 patients with previously untreated metastatic colorectal cancer to receive either CeaVac or placebo in combination with standard chemotherapy of 5-FU and leucovorin.

Previous studies of CeaVac in advanced cancer patients had indicated that on average at least 5 injections of CeaVac were required to produce an immune response to CEA in such patients. For this reason, the study analysis included a modified intent-to-treat population of patients who had received at least 5 injections of study drug, which demonstrated a trend toward survival improvement for CeaVac versus placebo treated patients (19.1 versus 17.1 months, respectively). This trend was also present for patients receiving at least 8 doses of study drug (21.3 versus 18.5 months, respectively), as well as higher numbers of doses.

However, many patients in the study did not receive more than a few doses of study drug and the resulting overall primary endpoint survival of patients receiving CeaVac was not different from those receiving placebo in the efficacy evaluable population (16.0 versus 15.6 months).

"Although we are disappointed in the demonstrated preliminary results of this study analysis, we are continuing to evaluate the data to further determine any potential relationship between dose regimen and outcome," stated Dr. Louis R. Bucalo, Chairman, President and CEO of Titan. "Because this study was placebo controlled, we are in a good position to determine with further analysis if more extended dosing may be related to improved survival."

Treatment with CeaVac was generally very well tolerated, with the most common side effect being some local injection site irritation.

"We emphasized up front and throughout this study the need to continue treatment with CeaVac," stated Dr. Frank Valone, Executive Vice President of Clinical Development and Regulatory Affairs at Titan. "The safety profile to date is excellent, and with overall survival of approximately 15 months in the control population, we would have preferred to see average time on study drug in the range of 12 months. Because patients on average were on study drug for much less than this time period, our ability to demonstrate a treatment benefit may have been impacted," stated Dr. Valone. "We will continue to further analyze the study results, and believe these data in aggregate suggest biologic

activity and the potential to improve survival with minimal side effects. We can potentially learn more from this study about the appropriate patient population and length of dosing regimen to achieve this goal."

CeaVac is also being studied in combination with TriAb®, another Titan monoclonal antibody, in resected Dukes' D colorectal cancer, a less advanced stage of the disease. This Phase II study is supported by the National Cancer Institute and is being conducted by the Cancer and Leukemia Group B (CALGB). The Radiation Therapy Oncology Group (RTOG) is also conducting a Phase II study of CeaVac in combination with TriAb in non-small cell lung cancer.

About Titan

Titan Pharmaceuticals, Inc. (ASE: TTP) is a biopharmaceutical company focused on the development and commercialization of novel treatments for central nervous system (CNS) disorders, cancer and other serious and life-threatening diseases. Titan's numerous products in development utilize novel technologies that have the potential to significantly improve the treatment of these diseases. Titan also establishes partnerships with multinational pharmaceutical companies and government institutions for the development of its products.

The press release may contain "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933 and

Section 21E of the Securities Exchange Act of 1934. Such statements include, but are not limited to, any statements relating to the Company's development program and any other statements that are not historical facts. Such statements involve risks and uncertainties, including, but not limited to, those risks and uncertainties relating to difficulties or delays in development, testing, regulatory approval, production and marketing of the Company's drug candidates, unexpected adverse side effects or inadequate therapeutic efficacy of the Company's drug candidates that could slow or prevent product development or commercialization, the uncertainty of patent protection for the Company's intellectual property or trade secrets and the Company's ability to obtain additional financing if necessary. Such statements are based on management's current expectations, but actual results may differ materially due to various factors, including those risks and uncertainties mentioned or referred to in this press release.

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[Exhibit 20.1](#)

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