

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: July 24, 2001

TITAN PHARMACEUTICALS, INC.

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(Exact name of registrant as specified in charter)

DELAWARE

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(State or other jurisdiction of incorporation)

0-27436

94-3171940

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(Commission File Number)

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(IRS Employer Identification No.)

400 OYSTER POINT BLVD., SUITE 505, SOUTH SAN FRANCISCO, CALIFORNIA

94080

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(Address of principal executive offices)

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(Zip Code)

Registrant's telephone number, including area code: (650) 244-4990  
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Item 5. OTHER EVENTS

On July 24, 2001, the Registrant and Novartis Pharma AG announced their plan to conduct additional clinical trials to further strengthen the profile of iloperidone (Zomaril) for the treatment of schizophrenia. Data from these studies will be included in the initial regulatory submissions, the first of which is expected to be filed in the U.S. around the end of 2002.

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 July 24, 2001

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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

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

*Dated: July 24, 2001*

[Titan Pharmaceuticals Inc. Logo]

COMPANY:	MEDIA:	INVESTORS:
Louis R. Bucalo, M.D. Chairman, President & CEO Titan Pharmaceuticals, Inc. Tel: 650-244-4990	Alison Roselli Ogilvy Public Relations 212-880-5257	Amy Mumma Ogilvy Public Relations 212-884-4036

TITAN AND NOVARTIS PLAN ADDITIONAL CLINICAL TRIALS TO FURTHER  
STRENGTHEN PROFILE OF ILOPERIDONE FOR THE TREATMENT OF  
SCHIZOPHRENIA

STUDIES TO DATE SUPPORT SAFETY AND EFFICACY OF NOVEL DEVELOPMENT COMPOUND

South San Francisco, CA / Basel 24 July 2001 - Titan Pharmaceuticals Inc. and Novartis Pharma AG announced today that they will initiate dose-related trials, including once-a-day dosing, which will more fully profile iloperidone. The companies also said that clinical trials conducted to date support the favorable efficacy, safety and tolerability profile of iloperidone in the treatment of acute schizophrenia.

Additional studies will further investigate once-a-day-dosing, demonstrate a favorable safety profile when switching from other antipsychotic agents to iloperidone, and support the competitive profile of the compound. Data from these studies will be included in the initial regulatory submissions. The first submission is anticipated in the US around the end of 2002, followed by filings elsewhere. Studies in additional indications such as acute mania are also planned.

"We believe iloperidone represents an improvement in the treatment of schizophrenia," said Joerg Reinhardt, Global Head of Development for Novartis Pharma. "We recognize the need not only for an effective, well-tolerated medication but also for simplified dosing to enhance overall compliance in this often poorly compliant patient population. Therefore we have decided it is important to include additional once-daily dosing studies in our program. We believe the additional studies will strengthen the clinical profile of iloperidone and will facilitate iloperidone's successful regulatory review both in the United States and Europe", said Joerg Reinhardt.

The most recently completed placebo-controlled trial, Study 3005, investigated two dose ranges of iloperidone for six weeks. Results from the high dose arm (20-24 mg/day) showed a statistically significant improvement in symptoms measured by the 18-item Brief Psychiatric Rating Scale (BPRS) and the Positive and Negative Symptom Scale (PANSS). Results from the low dose arm (12-16 mg/day), showed statistically significant results for iloperidone compared

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with placebo at weeks three, four and five, as well as a numerical trend at week six. The favorable safety and tolerability profile of iloperidone was reconfirmed in this study, with overall low incidence of extra-pyramidal symptoms (EPS), and cardiovascular effects, little weight gain and low sedation, which frequently affect patient compliance with agents in this class.

Analysis of safety and efficacy data from Phase III clinical trials, with more than 3500 patients at some 300 sites around the world, shows that iloperidone is efficacious and possesses a favorable safety and tolerability profile. Overall, the development program has studied a range of doses from 4-24 milligrams per day.

Long-term data from three double blind safety studies in approximately 1200 patients shows that patients in the iloperidone arm experienced a mean weight gain of only 1.6-3.7 kg at 52 weeks and minimal EPS which remains stable or even improves over 52 weeks. There was no increase in serum prolactin, no seizures, and minimal effect on heart rate and blood pressure over 52 weeks.

Novartis acquired the rights to develop, manufacture and market iloperidone worldwide from Titan Pharmaceuticals, Inc. of South San Francisco, California in November 1997.

"More than 45 million people worldwide suffer from schizophrenia and many patients and physicians are unsatisfied with current therapeutic options," said Titan Chairman and CEO, Dr. Louis R. Bucalo. "We believe that iloperidone has clinical benefits that can help satisfy some of the unmet medical needs of these patients, and we are committed to making it available to them as soon as possible in a dose regimen that will be most advantageous to them."

Approximately 1% of the world's population, 45 million people in total, suffer from schizophrenia. Despite major gains in diagnosis and treatment of the disease during the 1990's, this large market remains unsatisfied by current antipsychotic therapies. One common problem is the fact that many patients discontinue therapy because of troubling or dangerous side effects such as weight gain, impaired motor function, and cognitive disorders.

The foregoing press release contains forward-looking statements that can be identified by terminology such as "will, believe, planned, show, can help, may, as soon as possible, will be", or similar expressions. Such forward looking statements involve known and unknown risks, uncertainties and other factors that may cause the actual results involving iloperidone to be materially different from any future results, performance, or achievements expressed or implied by such statements. In particular, management's expectations could be affected, by among other things, uncertainties relating to clinical trials, unexpected regulatory delays or restrictions or government regulation generally; the company's ability to obtain or maintain patent and other proprietary intellectual property protection; and competition in general. Any of these factors can cause the results to defer materiality.

Novartis (NYSE: NVS) is a world leader in healthcare with core businesses in pharmaceuticals, consumer health, generics, eye-care, and animal health. In 2000, the Group's ongoing businesses achieved sales of CHF 29.1 billion (USD 17.2 billion) and a net income of CHF 6.5 billion (USD 3.9 billion). The Group invested approximately CHF 4.0 billion (USD 2.4 billion) in R&D. Headquartered in Basel, Switzerland, Novartis employs about 69 000 people and operates

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in over 140 countries around the world. For further information please consult <http://www.novartis.com>.

Titan Pharmaceuticals, Inc. (ASE: TTP) is a biopharmaceutical company developing proprietary therapeutics for the treatment of central nervous system disorders, cancer and other serious and life-threatening diseases.

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