VICURON PHARMACEUTICALS INC
Form 8-K
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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):

February 7, 2005

Vicuron Pharmaceuticals Inc.

(Exact Name of Registrant As Specified in its Charter)

Delaware	**000-31145**	**04-3278032**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(I.R.S. Employer Identification Number)**

455 South Gulph Road, Suite 305, King of Prussia, PA 19406

(Address of Principal Executive Offices) (Zip Code)

(610) 205-2300

(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 (see General Instruction A.2. below):

¨ 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 7.01. Regulation FD Disclosure.

On February 7, 2005, Vicuron Pharmaceuticals Inc. (Vicuron) issued a press release announcing the Phase 3 clinical trial results evaluating anidulafungin for the treatment of invasive candidiasis/candidemia, the most common hospital-acquired fungal infection. A copy of the February 7, 2005 press release is attached as Exhibit 99.1 to this Form 8-K. The exhibit listed on the Exhibit Index (following this Report s signature page) is furnished with this Report.

In a conference call today at approximately 10:30 a.m. (Pennsylvania time), members of Vicuron s management will discuss the matters addressed in the February 7, 2005 press release. Furnished below is a copy of the materials to be discussed in today s presentation.

Conference Call Script February 7, 2005, 10:30 a.m. EST

Anidulafungin Phase 3 Clinical Trial Update

Operator: *Introduces* Mr. George Horner, Vicuron Pharmaceuticals Inc. s Chief Executive Officer.

George Horner: Thank you for joining us this morning. Also on today s call with me is our Chief Financial Officer Dr. Dov Goldstein and Chief Medical Officer, Dr. David Krause.

Before I begin my formal remarks, first let me start with our safe harbor statement. During the course of this conference call, we will state our beliefs and make projections and other forward-looking statements regarding future events of Vicuron. We wish to caution you that such statements are predictions and expectations and actual events or results may differ materially. We refer you to Vicuron s publicly filed SEC disclosure documents for a detailed description of the risk factors affecting our business, especially the Forms 10-Q and 10-K. These documents identify important factors that could cause our actual results to differ materially from our predictions and other forward-looking statements.

Today we are pleased to announce phase 3 results demonstrating superiority of anidulafungin over fluconazole in invasive candidiasis/candidemia, the most common hospital-acquired fungal infection.

The study compared anidulafungin to fluconazole, a current standard of care, and was designed to show non-inferiority. Anidulafungin was superior to fluconazole in the primary endpoint which was global response at the end of intravenous therapy in the microbiological intent-to treat population.

Anidulafungin also demonstrated non-inferiority or superiority in all secondary endpoints, including response at the two-week and six-week follow-up visits after completion of therapy.

Anidulafungin was well tolerated in the study, with a comparable side effect profile to fluconazole.

Invasive candidiasis and candidemia are infections caused by Candida, which can invade various organs or the bloodstream. Candida is the fourth most common cause of bloodstream infections, and the most common fungal cause. Invasive Candida infections are more common in people who are immunocompromised, such as those with cancer, organ transplants or burns. Such infections are associated with high mortality in these critically ill patients.

Now I will turn to the clinical trial results.

This was a double-blind, multi-center, randomized Phase 3 trial examining anidulafungin compared to fluconazole, a standard of care agent.

We studied a 100 mg daily dose of anidulafungin preceded by an initial 200 mg loading dose of anidulafungin versus a 400 mg daily dose of fluconazole preceded by an initial 800 mg loading dose of fluconazole, in 256 patients with invasive candidiasis/candidemia.

Patients received daily IV infusion of either anidulafungin or fluconazole for 10 to 42 days. The primary endpoint was global assessment of composite clinical and microbiological response at the end of IV therapy in the microbiology intent-to-treat population.

Success in the global response at end of IV therapy in the microbiology intent to treat population was 75.6 percent (96/127) with anidulafungin and 60.2 percent (71/118) with fluconazole, a statistically superior difference in favor of anidulafungin. (95 percent confidence interval of the difference: 3.85, 26.99)

The secondary endpoint of success in the global response at two-week follow up visit in the microbiology intent to treat population was observed in 64.6 percent (82/127) of patients in the anidulafungin arm and 49.2 percent (58/118) of patients in the fluconazole arm. This also demonstrated statistical superiority. (95 percent confidence interval of the difference: 3.14, 27.68)

The secondary endpoint of success in the global response at six-week follow up visit in the microbiology intent to treat population was observed in 55.9 percent (71/127) of patients in the anidulafungin arm and 44.1 percent (52/118) of patients in the fluconazole arm demonstrating non-inferiority. (95 percent confidence interval of the difference: -0.6, 24.28)

Anidulafungin demonstrated comparable tolerability to fluconazole in the study.

We are very pleased with these trial results.

With these data Vicuron is on track to file a New Drug Application for invasive candidiasis/candidemia in the third quarter of this year and to complete submission of an amendment to the esophageal candidiasis NDA in the second quarter.

We will continue to work closely with the agency and update you all as necessary.

We believe that these exciting new results demonstrating the superiority of anidulafungin should enable us to competitively position anidulafungin, if approved by the FDA, as an important new option to battle invasive fungal infections due to Candida.

Thanks for your time this morning. I will now open up the call to questions.

Item 9.01. Financial Statements and Exhibits.

(c) Exhibits

99.1 Press Release of Vicuron Pharmaceuticals Inc. dated February 7, 2005.

Forward-Looking Statements

This report contains forward-looking statements that predict or describe future events or trends. The matters described in these forward-looking statements are subject to known and unknown risks, uncertainties and other unpredictable factors, many of which are beyond Vicuron s control. Vicuron faces many risks that could cause its actual performance to differ materially from the results predicted by its forward-looking statements, including the possibilities that clinical trials and the results thereof might be delayed or unsuccessful, that the timing of the filing of any new drug application or any amendment to a new drug application might be delayed, that clinical trials might indicate that a product candidate is unsafe or ineffective, that the FDA might require additional information to be submitted and additional actions to be taken before it will make any decision, that any filed new drug application may not be approved by the FDA, that ongoing proprietary and collaborative research might not occur or yield useful results, that the pipeline may not yield a new clinical candidate or a commercial product, that a third party may not be willing to license Vicuron s product candidates on terms acceptable to Vicuron or at all, that competitors might develop superior substitutes for Vicuron s products or market these competitive products more effectively, that a sales force may not be developed as contemplated and that one or more of Vicuron s product candidates may not be commercialized successfully. The reports that Vicuron files with the U.S. Securities and Exchange Commission contain a fuller description of these and many other risks to which Vicuron is subject. Because of those risks, Vicuron s actual results, performance or achievements may differ materially from the results, performance or achievements contemplated by its forward-looking statement. The information set forth in this report represents management s current expectations and intentions. Vicuron assumes no responsibility to issue updates to the forward-looking matters discussed in this report.

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.

VICURON PHARMACEUTICALS INC.

(Registrant)

Date: February 7, 2005

By: /s/ George F. Horner III
George F. Horner III
President and Chief Executive Officer

EXHIBIT INDEX

Pursuant to Item 601(a)(2) of Regulation S-K, this exhibit index immediately precedes the exhibit.

Exhibit No.	Description
99.1	Press release of Vicuron Pharmaceuticals Inc. dated February 7, 2005.