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):

September 21, 2004

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.

In a conference call today at approximately 8:30 a.m. (Pennsylvania time), members of Vicuron Pharmaceuticals Inc. s management presented an update of the status of its New Drug Application with the United States Food and Drug Administration for anidulafungin, its novel antifungal agent. Furnished below is a copy of the script of today s presentation.

Conference Call Script September 21, 2004, 8:30 a.m. EDT

Anidulafungin New Drug Application 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.

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.

In May of this year, Vicuron received an approvable letter from the FDA for anidulafungin. Since that time we have been in active discussions with the FDA to determine our next steps to gain approval for this product.

Based on Vicuron s discussions with the agency and the approvable letter, we plan to pursue the following two paths to approval:

For the first indication, the potential treatment of esophageal candidiasis, the initial NDA has been kept open.

We plan to file an amendment to that NDA for this indication. The amendment will provide supplemental clinical data for anidulafungin largely at the 100 mg dose from studies with enrollment already completed.

We anticipate making this amendment submission in the second quarter of 2005.

Under this timeline, the earliest anidulafungin could be approved for esophageal candidiasis would be in the fourth quarter of 2005.

For the second indication, the potential treatment of invasive candidiasis/candidemia, we need to file a new NDA.

We will file a new NDA for this indication using integrated clinical data, including data from the recently-completed Phase 3 pivotal trial.

Data from this trial are expected to be released in the first half of 2005.

The company plans to submit the NDA for this indication in the third quarter of 2005.

We expect a standard review period for this new NDA once it s been submitted.

We will continue to work closely with the agency on both of these programs and update you all as necessary.

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

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 the control of Vicuron Pharmaceuticals Inc. (Vicuron). 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 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: September 21, 2004

By: /s/ George F. Horner III

George F. Horner III
President and Chief Executive Officer