VICURON PHARMACEUTICALS INC
Form 8-K
August 12, 2004

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):

August 12, 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.)

Item 9. Regulation FD Disclosure.

In a conference call today at approximately 10:00 a.m. (Pennsylvania time), members of our management presented selected Phase III clinical trial data regarding our product candidate, dalbavancin, for skin and soft tissue infections. Furnished below is a copy of the script of today s presentation.

Conference Call Script August 12, 2004, 10:00 a.m. EST

Phase III Trial Results for Dalbavancin for Skin and Soft Tissue Infections

- **Operator:** Introduces Mr. George Horner, Vircuron s chief executive officer.

- **George Horner:** Thank you for joining us this morning to discuss the positive Phase III results for dalbavancin in skin and soft tissue infections. Joining me today are Dr. Dov Goldstein, our Chief Financial Officer and Dr. Tim Henkel, Vicuron s Chief Medical Officer.

- 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 announced results from our pivotal Phase III clinical trials comprising more than 1,500 patients evaluating once-weekly dalbavancin in skin and soft tissue infections caused by Gram-positive bacteria. All three studies met the primary endpoint of non-inferiority in evaluable patients clinical response at two weeks following therapy when compared to linezolid, cefazolin or vancomycin, the three most widely administered standard-of-care agents for SSTIs.

- All studies also met the secondary endpoint of non-inferiority in clinical response for the intent-to-treat patient population.

- Dalbavancin was also shown to be well tolerated in all three studies.

- Based on this compelling data, we plan to file a New Drug Application with the U.S. Food and Drug Administration later this year and look forward to working through the agency to bring this important antibiotic toward the market.

- The data revealed that the vast majority of the patients treated in these studies had SSTIs caused by *Staphylococcus (Staph) aureus* bacteria. More than 400 of these patients were infected with methicillin-resistant Staphylococcus aureus, or MRSA, one of the most difficult-to-treat strains.

- I will now go through the results of each of the three studies individually.

- **The study conducted in complicated SSTIs** was a randomized, controlled double-blind study of 854 patients versus linezolid. The primary endpoint was clinical response at the follow-up visit in the evaluable patient population.

- Evaluable patients taking dalbavancin demonstrated an 88.9 percent response versus 91.2 percent for linezolid patients (95 percent confidence interval -7.3, 2.9).

- In the intent-to-treat group, dalbavancin patients showed a 76.5 percent response versus 82.7 for linezolid (95 percent confidence interval of -12.0, -0.3).

- **The second pivotal study was in uncomplicated SSTIs** and was a randomized, controlled, double-blind study of 565 patients versus intravenous cefazolin followed by oral cephalexin. The primary endpoint was clinical response at the follow-up visit in the evaluable patient population.

- Evaluable patients taking dalbavancin demonstrated an 89.1 percent response versus 89.1 percent for cefazolin (95 percent confidence interval -6.8, 6.8).

- In the intent to treat group, dalbavancin patients showed a 76.0 percent response versus a 75.8 percent response for cefazolin (95 percent confidence interval -7.7, 8.2).

- **The final study we ll discuss today offered some interesting results in SSTIs caused by MRSA**. As you know infectious disease caused by MRSA has proven difficult-to-treat in many cases. This was a randomized, controlled, open-label study of 156 patients versus vancomycin in SSTIs suspected or confirmed to be caused by MRSA. The primary endpoint was clinical response at the time of follow-up visit in the evaluable patient population.

- Evaluable patients taking dalbavancin demonstrated an 89.9 percent response versus 86.7 percent for vancomycin (95 percent confidence interval -13.0, 19.4).

- In the intent to treat group, dalbavancin patients showed an 86.0 percent response versus 65.3 percent for vancomycin (95 percent confidence interval 4.3, 37.0).

- This third study is not pivotal, but will be part of the NDA submission.

- Lastly, I just want to reiterate that dalbavancin was well tolerated in all three of these studies.

- We are encouraged by the response we observed with dalbavancin across all three studies. Patients receiving dalbavancin in these studies required only up to two doses to achieve a clinical response, while patients receiving the standard-of-care comparator agents required up to 28 doses or more. We believe it has the potential to become an important new agent in the physician s armamentarium to treat serious skin and soft tissue infections caused by a broad spectrum of Gram-positive bacteria.

- Thank you all for your time this morning. I will now open the call up to questions.

Cautionary Note Regarding Forward-Looking Statements

This report contains forward-looking statements that predict or describe future events or trends. Words such as believes, anticipates, plans, expects, will, intends and similar expressions are intended to identify forward-looking statements. 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, that the timing of the filing of any new drug application might be delayed, that subsequent clinical trials might indicate that a product candidate is unsafe or ineffective, that any filed new drug application may not be approved, that ongoing proprietary and collaborative research might not occur or yield useful results, that a third party may not be willing to license our product candidates on terms acceptable to us or at all, that competitors might develop superior substitutes for their products or market them more effectively, that a sales force may not be developed as contemplated and that one or more of its product candidates may not be commercialized successfully. Some of the important risk factors that could cause Vicuron s actual results to differ significantly from the results expressed or implied by its forward-looking statements are listed in Vicuron s Annual Report on Form 10-K for the year ended December 31, 2003 under the caption Risk Factors, as well as in its other SEC filings under similar captions. 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 statements. 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: August 12, 2004

By: /s/ GEORGE F. HORNER III

George F. Horner III
President and Chief Executive Officer