VICURON PHARMACEUTICALS INC
Form 8-K
November 17, 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):

November 15, 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 meetings yesterday, Vicuron Pharmaceuticals Inc. (the Company) discussed the following information: (1) the U.S. Food and Drug Administration (the FDA) has granted Fast Track status for dalbavancin in complicated skin and soft tissue infections; (2) the Company s intention to file a new drug application (NDA) for dalbavancin only for complicated skin and soft tissue infections; and (3) the Company s belief that the need to address complicated infections may increase the possibility that the FDA may conduct an expedited review of the contemplated NDA filing.

The Company also expressed its belief that its lead antibacterial product could ultimately need a sales force of up to 125 people.

The Company is furnishing promptly this Current Report on Form 8-K solely to satisfy the requirements of Regulation FD.

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 the Company s control, which may cause actual results to differ materially and adversely from any future results, performance or achievement expressed or implied by such forward-looking statements. Such factors include, without limitation, the possibilities that clinical trials and the results thereof might be delayed, that the timing of the filing of any NDA might be delayed, that the Company s NDA for dalbavancin may not receive an expedited review, that subsequent clinical trials might indicate that a product candidate is unsafe or ineffective, that any filed NDA may not be approved, that a sales force may not be developed as contemplated, that the commercialization of the Company s product candidates may require a larger sales force than contemplated by the Company, and that one or more of the Company s product candidates may not be commercialized successfully. Some of the important risk factors that could cause the Company s actual results to differ significantly from the results expressed or implied by its forward-looking statements are listed in the Company 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 filings with the Securities and Exchange Commission under similar captions. Because of those risks, the Company 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. The Company 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: November 16, 2004

By: /s/ George F. Horner III

George F. Horner III
President and Chief Executive Officer