IMMUNOMEDICS INC
Form 8-K
September 26, 2006

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 26, 2006

Immunomedics, Inc.
(Exact Name of Registrant as Specified in Charter)

Delaware	000-12104	61-1009366
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)

300 American Road, Morris Plains, New Jersey	07950
(Address of Principal Executive Offices)	(Zip Code)

(973) 605-8200
(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 is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

[ ] 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 8.01. OTHER EVENT.

Immunomedics, Inc., a Delaware corporation, reported that licensing

partner, UCB, SA, has temporarily suspended the clinical trials of epratuzumab in patients with systemic lupus erythematosus. The companies advised their investigators that this is not being done because of any adverse reactions in patients, but because of end-stage manufacturing observations by UCB during a recent audit. These observations, related to the filling processes during final product manufacturing, in UCB's opinion might result in a lack of consistent assurance of sterility in the final dosage form. This is a precautionary measure, taken voluntarily and pro-actively by UCB. No reports of clinical safety issues that suggest an association with these observations have been identified. In response to the voluntary suspension, FDA and certain other regulatory authorities have instituted a clinical hold status on the trials. The companies are working together to expedite their efforts to remove the clinical hold status and minimize any delay in making epratuzumab available to patients. Immunomedics does not believe this suspension will have a material effect on the trials.

Importantly, Immunomedics has reported to UCB that it has not encountered any product sterility failures for any batches that have been released for clinical use nor has it encountered any media fill failures. Furthermore, to date there have been no clinical safety reports associated with these observations in the more than 600 patients who have received epratuzumab therapy. UCB and Immunomedics are diligently addressing the process issues and UCB will propose a strategy to FDA and other authorities to remove the clinical hold status and resume dosing patients in the near future. The companies are particularly concerned that patients who may have already benefited from epratuzumab in the lupus clinical trials are able to resume treatment as soon as possible.

UCB has informed Immunomedics they remain fully committed to the further development of epratuzumab in lupus and potentially other autoimmune disease indications, while applying the highest quality, safety and ethical standards in clinical development.

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.

IMMUNOMEDICS, INC.

By: /s/ Cynthia L. Sullivan

Name: Cynthia L. Sullivan
Title: President and
Chief Executive Officer

Date: September 26, 2006