

IMMUNOMEDICS INC
Form 8-K
May 02, 2007

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): May 1, 2007

IMMUNOMEDICS, INC.

(Exact Name of Registrant as Specified in Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

000-12104
(Commission File Number)

61-1009366
(I.R.S. Employer
Identification No.)

300 American Road, Morris Plains, New Jersey
(Address of Principal Executive Offices)
(973) 605-8200

07950
(Zip Code)

(Registrant's telephone number, including area code)

(Former Name or Former Address, if Changed Since Last Report)

Edgar Filing: IMMUNOMEDICS INC - Form 8-K

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 1.01 Entry Into a Material Definitive Agreement.

On May 1, 2007, Immunomedics, Inc., a Delaware corporation (the Company), entered into definitive subscription agreements (the Subscription Agreements) with institutional investors pursuant to which the Company issued and sold an aggregate of 4,848,485 registered shares of its common stock at \$4.95 per share, through a registered direct offering, for aggregate gross proceeds of approximately \$24 million, before deducting estimated fees and expenses associated with the offering (the Offering). The closing is expected to take place on May 7, 2007, subject to the satisfaction of customary closing conditions. The shares of common stock offered by the Company in this transaction were registered under the Company's existing shelf registration statement (File No. 333-114810) on Form S-3, which was declared effective by the Securities and Exchange Commission on May 25, 2004.

Lazard Capital Markets LLC (Lazard) acted as the exclusive placement agent for the Offering. On May 1, 2007, the Company executed a placement agent agreement (the Placement Agent Agreement) by and between the Company and Lazard. The Company will pay the placement agent an aggregate fee equal to 5.6% of the gross proceeds of the Offering equal to approximately \$1,344,000, plus estimated expenses of the Offering equal to approximately \$348,000.

A copy of each of the form of Subscription Agreement, the form of Placement Agent Agreement and the related press release of the Company, dated May 2, 2007, are filed herewith as Exhibits 10.1, 10.2 and 99.1, respectively, and are incorporated herein by reference. The foregoing description of the Offering by the Company and the documents related thereto, is qualified in its entirety by reference to such Exhibits.

Item 8.01 Other Events.

As previously disclosed, on May 9, 2006 we entered into a Development, Collaboration and License Agreement, or the UCB Agreement, with UCB, providing UCB an exclusive worldwide license to develop, manufacture, market and sell epratuzumab for the treatment of all autoimmune disease indications. Under the terms of the UCB Agreement, we retain the rights to develop epratuzumab in the field of oncology, and UCB has an option to acquire development and commercialization rights to epratuzumab with respect to cancer indications at anytime prior to the first commercial sales thereof. If UCB exercises its buy-in right with respect to epratuzumab in the field of oncology, UCB will reimburse us for the development cost actually incurred, plus a buy-in fee. Under the terms of the UCB Agreement, we received initial cash payments totaling \$38 million from UCB, which includes a \$25 million upfront payment, plus a \$13 million reimbursement for development costs of epratuzumab related to our clinical development of epratuzumab in patients with certain autoimmune conditions prior to the date of the UCB Agreement.

We determined that all elements under the UCB Agreement should be accounted for as a single unit of accounting under EITF 00-21, Accounting for Revenue Arrangements with Multiple Deliverables. In accordance with SAB No. 104 (Topic 13, Revenue Recognition), deferral of revenue is appropriate regarding nonrefundable, upfront fees received in single unit of accounting arrangements. As we have continuing obligations under the UCB Agreement, we recorded the \$38 million payment as deferred revenue. We are recognizing this deferred revenue over our best estimate of the period of time required to fulfill our obligations under the UCB Agreement. Through December 31, 2006, the Company recognized the \$38 million payment amount over the period, which was the Company's best estimate of the period of time required for the parties to fulfill their obligations under the UCB Agreement (originally estimated at approximately three and one-half years). Accordingly, the Company recognized \$5,335,000 as license fee revenues through the six-month period ended December 31, 2006.

On September 26, 2006, UCB decided to temporarily suspend the clinical trials of epratuzumab for patients with SLE. This suspension was implemented due to UCB's concerns regarding the sterility assurance in the final product. This was a voluntary precautionary step. There had been no reports of clinical safety issues regarding this matter. As a result of this step, the FDA and certain other regulatory authorities instituted a clinical hold status of these trials. On November 14, 2006, the FDA notified UCB that the clinical hold on existing trials with epratuzumab in patients with lupus was lifted. The Company did not incur significant expenses regarding this temporary suspension.

In January 2007, UCB decided to stop further new patient enrollment into the SLE clinical trials designed and initiated by the Company. Investigators have been advised by UCB of this decision, and protocol amendments have been submitted to Institutional Review Boards to seek approval to treat patients with SLE who demonstrated clinical benefit in these trials. The Company has been advised by UCB that it remains committed to developing epratuzumab for the treatment of SLE. At that time, UCB and its experts in the field of SLE believed that the existing clinical trial protocols should be revised, including potential changes to patient enrollment criteria as such changes may result in more rapid patient enrollment. In early March 2007, UCB made a determination to stop the SLE clinical trials designed and initiated by Immunomedics. UCB and their experts in the field of SLE have decided to establish new protocols under which new clinical trials for the treatment of SLE would be conducted. The clinical trial data from the recently stopped trials collected to date are extremely valuable and will be analyzed as support for the new clinical trials. The protocols for the new SLE clinical trials will need to be reviewed and approved by the regulatory authorities. As a result of the UCB decision in March 2007, the Company is no longer able to determine when these clinical trials will take place nor can it determine how these decisions will impact its obligation period under the terms of the agreement with UCB. Accordingly, beginning in the third quarter of 2007, the Company will cease amortizing to revenue the deferred revenue recorded with the receipt of the up front payments from UCB at the inception of the license agreement until such time as the obligation period is reasonably determinable.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
10.1	Form of Subscription Agreement by and among the Company and the Purchasers dated May 1, 2007.
10.2	Form of Placement Agent Agreement by and between the Company and Lazard Capital Markets LLC dated May 1, 2007.
99.1	Press Release of the Company dated May 2, 2007.

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
Cynthia L. Sullivan
President and Chief Executive Officer

Dated: May 1, 2007