

MEDAREX INC
Form 8-K
August 23, 2004

As filed with the Securities and Exchange Commission on August 23, 2004.

SECURITIES AND EXCHANGE COMMISSION

Washington, DC 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 23, 2004 (August 23, 2004)

MEDAREX, INC.

(Exact name of registrant as specified in its charter)

New Jersey
(State of other jurisdiction
of incorporation)

0-19312
(Commission
File Number)

22-2822175
(IRS Employer
Identification No.)

707 State Road, Princeton, N.J. 08540-1437

(Address of Principal Executive Offices)

Registrant's telephone number, including area code: **(609) 430-2880**

Not Applicable

(Former name or former address, if changed since last report)

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Signature

Item 8.01

Other Events

On August 23, 2004, Medarex announced that it had reached a Special Protocol Assessment (SPA) agreement with the U.S. Food and Drug Administration (FDA) for the initiation of a pivotal Phase III clinical trial for MDX-010 in combination with MDX-1379, a gp100 melanoma peptide vaccine, in patients with late stage unresectable metastatic melanoma who have failed or are intolerant to first line therapy. Medarex has in-licensed the MDX-1379 vaccine peptides from the National Cancer Institute (NCI). The SPA letter provides a written agreement between Medarex and the FDA concerning the trial design and outlines definitive clinical objectives and data analyses considered necessary to support regulatory approval. A copy of the Company's press release dated August 23, 2004, relating to the SPA is attached hereto as Exhibit 99.1.

Item 9.01

Financial Statements and Exhibits.

(c) Exhibits. The following material is filed as an exhibit to this Current Report on Form 8-K:

**Exhibit
Number**

99.1 Press Release issued August 23, 2004

SIGNATURE

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.

MEDAREX, INC.
Registrant

Date: August 23, 2004

By: /s/ W. Bradford Middlekauff
W. Bradford Middlekauff
Senior Vice President and General
Counsel

EXHIBIT INDEX

| Exhibit Number | Description |
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| 99.1 | Press Release issued August 23, 2004 |