

CANCERVAX CORP
Form 8-K
April 06, 2005

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**UNITED STATES
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): **April 6, 2005**

CANCERVAX CORPORATION

(Exact Name of Registrant as Specified in its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

0-50440
(Commission
File Number)

52-2243564
(IRS Employer
Identification No.)

2110 Rutherford Road, Carlsbad, CA
(Address of Principal Executive Offices)

92008
(Zip Code)

Registrant's telephone number, including area code: **(760) 494-4200**

(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))
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Item 7.01. Regulation FD Disclosure.

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Item 7.01. Regulation FD Disclosure.

In connection with the conference call held earlier today regarding the independent Data and Safety Monitoring Board recommendation to discontinue the Canvaxin Phase 3 clinical trial for patients with Stage IV melanoma, David F. Hale made the following disclosures in response to questions asked by call participants:

In connection with the collaboration agreement entered into with Serono Technologies, S.A. in December 2004, CancerVax has previously disclosed that it may received up to \$253.0 million in milestone payments from Serono upon the achievement of certain development-, regulatory- and sales-based goals. As a result of the plans to discontinue the Phase 3 clinical trial of Canvaxin in patients with Stage IV melanoma, CancerVax will no longer have the potential to receive the entire \$253.0 million in milestone payments.

The Phase 3 clinical trial in patients with Stage III melanoma is designed to have 80% power to detect a 33% improvement in median overall survival at an alpha level of 0.05. The application of this formula to the Stage III study results in 392 events being required in order to conduct the final efficacy analysis. In order for the study to be positive, the final alpha level must be less than 0.044 as a result of the statistical impact of the three interim analyses. Alpha levels, which are also referred to as p-values, indicate the likelihood that the results were due to random statistical fluctuations rather than a true cause and effect relationship. The lower the p-value, the more likely there is a true cause and effect relationship. Therefore, p-values provide a sense of the reliability of the results of the study in question.

The information in this Current Report on Form 8-K shall not be deemed filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the Exchange Act), or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

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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.

CANCERVAX CORPORATION

Date: April 6, 2005

By: /s/ David F. Hale
Name: David F. Hale
Title: President and Chief Executive
Officer