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SERONO S A  
Form 6-K  
October 04, 2005

SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549  
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FORM 6-K

REPORT OF FOREIGN PRIVATE ISSUER  
PURSUANT TO RULE 13a-16 OR 15d-16 OF  
THE SECURITIES EXCHANGE ACT OF 1934

For the month of October, 2005

Serono S.A.  
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(Registrant's Name)

15 bis, Chemin des Mines  
Case Postale 54  
CH-1211 Geneva 20  
Switzerland  
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(Address of Principal Executive Offices)

1-15096  
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(Commission File No.)

(Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F.)

Form 20-F    X    Form 40-F  
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(Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101 (b)(1).)  
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(Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101 (b)(7).)  
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(Indicate by check mark whether the registrant by furnishing the information contained in this form is also thereby furnishing the information to the Commission pursuant to Rule 12g3-2(b) under the Securities Exchange Act of 1934.)

Yes                      No    X  
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(If "Yes" is marked, indicate below the file number assigned to the registrant in connection with Rule 12g3-2(b): 82-                      )  
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CancerVax (TM)

Serono

Media Release

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FOR IMMEDIATE RELEASE  
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## DATA AND SAFETY MONITORING BOARD RECOMMENDS DISCONTINUATION OF CANVAXIN(TM) PHASE 3 CLINICAL TRIAL FOR PATIENTS WITH STAGE III MELANOMA

GENEVA, SWITZERLAND AND CARLSBAD, CALIFORNIA, USA - OCTOBER 3, 2005 - Serono (virt-x: SEO and NYSE: SRA) and CancerVax Corporation (NASDAQ:CNVX) announced today their decision to discontinue the Phase 3 clinical trial of Canvaxin(TM) in patients with Stage III melanoma based upon the recommendation of the independent Data and Safety Monitoring Board (DSMB), which recently completed its planned, third, interim analysis of the data from this study. The DSMB found that the data are unlikely to provide significant evidence of an overall survival benefit for patients with Stage III melanoma who were treated with Canvaxin(TM) versus those who received placebo.

"This news is particularly disappointing because we understand the devastating impact of this disease on patients with advanced-stage melanoma, as well as their families and friends. We are extremely grateful for the strong support we have received for this clinical trial from the clinicians, nurses, study coordinators and, especially, the patients who participated in this clinical trial," said David F. Hale, President and CEO of CancerVax Corporation. "We will discontinue all further development and manufacturing operations for Canvaxin(TM), but we currently plan to continue to further the development of the other product candidates in our product pipeline, which we believe hold promise for the treatment of patients with cancer."

"The Phase 2 results were promising, and we were thus hopeful that this highly innovative product would be successful in a Phase 3 clinical trial in patients with Stage III melanoma," said Franck Latrille, Senior Executive Vice President, Corporate Global Product Development of Serono. "We continue to have a strong pipeline with five Phase 3 programs and significant newsflow expected in the next year. Serono remains committed to oncology with Humax-CD4, adcatumumab and TACI-Ig with study results from all three programs expected in 2006."

There were no significant safety issues identified with either the Phase 3 clinical trial of Canvaxin(TM) in patients with Stage III melanoma, or with the Phase 3 clinical trial of Canvaxin(TM) in patients with Stage IV melanoma, which was discontinued earlier this year. The recommendations to close both of these clinical trials were not made because of any potential safety concerns. Once the data from these clinical trials are fully analyzed, they will be presented at appropriate scientific meetings.

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### ABOUT THE DSMB AND INTERIM ANALYSES

The DSMB consists of independent experts in medical and surgical oncology, statistics and medical ethics who are not participating in the clinical trials, whose primary responsibility is to monitor, on a periodic basis, the data emerging from a clinical trial and to provide recommendations to the sponsor on whether a study should be modified or discontinued.

### ABOUT SERONO

Serono is a global biotechnology leader. The Company has eight biotechnology products, Rebif(R), Gonal-f(R), Luveris(R), Ovidrel(R)/Ovitrelle(R), Serostim(R), Saizen(R), Zorbitive(TM) and Raptiva(R). In addition to being the world leader in reproductive health, Serono has strong market positions in

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neurology, metabolism and growth and has recently entered the psoriasis area. The Company's research programs are focused on growing these businesses and on establishing new therapeutic areas, including oncology. Currently, there are approximately 30 ongoing development projects.

In 2004, Serono achieved worldwide revenues of US\$2,458.1 million, and a net income of US\$494.2 million, making it the third largest biotech company in the world. Its products are sold in over 90 countries. Bearer shares of Serono S.A., the holding company, are traded on the virt-x (SEO) and its American Depositary Shares are traded on the New York Stock Exchange (SRA).

ABOUT CANCERVAX CORPORATION (WWW.CANCERVAX.COM)  
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CancerVax Corporation is a biotechnology company focused on the research, development and commercialization of novel biological products for the treatment and control of cancer. CancerVax has been evaluating Canvaxin(TM) in a Phase 3 clinical trial for the treatment of patients with Stage III melanoma in collaboration with Serono. CancerVax also has a pipeline of product candidates and technologies that are being developed for the potential treatment of cancer. These include SAI-EGF, a product candidate that targets the epidermal growth factor (EGF) receptor signaling pathway; and D93, CancerVax's lead anti-angiogenic humanized monoclonal antibody. CancerVax plans to file an Investigational New Drug (IND) application for clinical trials of D93 in early 2006, and to initiate a clinical trial with SAI-EGF in patients with advanced non-small-cell lung cancer in 2006.

CANCERVAX CORPORATION

CONFERENCE CALL AND WEBCAST TUESDAY, OCTOBER 4, AT 9:00 EASTERN TIME  
CancerVax management will host a conference call on Tuesday, October 4, at 9:00 a.m. Eastern Time to discuss the DSMB recommendation to discontinue the Canvaxin Phase 3 clinical trial for patients with Stage III melanoma. A live audio webcast of management's presentation will be available at <http://ir.cancervax.com>. Alternatively, callers may participate in the conference call by dialing (866) 831-6270 (domestic) or (617) 213-8858 (international). The passcode is 70660579. A replay of the conference call can be accessed by dialing (888) 286-8010 (domestic) or (617) 801-6888 (international). The passcode for the replay is 42654318. The webcast will also be archived on CancerVax's website.

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FORWARD-LOOKING STATEMENTS  
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SERONO

Some of the statements in this press release are forward looking. Such statements are inherently subject to known and unknown risks, uncertainties and other factors that may cause actual results, performance or achievements of Serono S.A. and affiliates to be materially different from those expected or anticipated in the forward-looking statements. Forward-looking statements are based on Serono's current expectations and assumptions, which may be affected by a number of factors, including those discussed in this press release and more fully described in Serono's Annual Report on Form 20-F filed with the U.S. Securities and Exchange Commission on March 16, 2005. These factors include any failure or delay in Serono's ability to develop new products, any failure to receive anticipated regulatory approvals, any problems in commercializing current products as a result of competition or other factors, our ability to obtain reimbursement coverage for our products, the outcome of government investigations and litigation and government regulations limiting our ability to sell our products. Serono has no responsibility to update the forward-looking statements contained in this press release to reflect events or circumstances occurring after the date of this press release.

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## CANCERVAX CORPORATION

CancerVax cautions you that statements included in this press release that are not a description of historical facts are forward-looking statements. For example, statements about the timing of the initiation of clinical trials with any of CancerVax's product candidates, and plans and objectives of management, are all forward-looking statements. The inclusion of forward-looking statements should not be regarded as a representation by CancerVax that any of its plans will be achieved. Actual results may differ materially from those set forth in this release due to the risks and uncertainties inherent in CancerVax's business including, without limitation: the progress, timing and outcome of its clinical trials; its ability to obtain additional financing to support its operations, which could adversely affect its ability to continue to operate as a going concern; the risk that the collaboration agreement for Canvaxin(TM) may be terminated by Serono in certain instances; the risk that CancerVax may be required to pre-pay the debt incurred to expand its manufacturing capacity prior to the termination of the loan because of a failure to comply with covenants included in the loan agreement; unexpected adverse side effects or inadequate therapeutic efficacy of its product candidates that could delay or prevent product development or commercialization, or that could result in recalls or product liability claims; competition from other pharmaceutical or biotechnology companies; CancerVax's limited experience in manufacturing and testing biological products, which may result in delayed development or commercialization of its product candidates, as well as lost revenue; and other risks detailed in CancerVax's Securities and Exchange Commission filings, including CancerVax's Annual Report on Form 10-K for the fiscal year ended December 31, 2004, and Quarterly Report for the fiscal quarter ended June 30, 2005. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. All forward-looking statements are qualified in their entirety by this cautionary statement and CancerVax undertakes no obligation to revise or update this news release to reflect events or circumstances after the date hereof. This caution is made under the safe harbor provisions of the Private Securities Litigation Reform Act of 1995.

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CancerVax(R) is a registered trademark of CancerVax Corporation.  
Canvaxin(TM) is a trademark of CancerVax Corporation.

FOR MORE INFORMATION, PLEASE CONTACT:

SERONO

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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, thereunto duly authorized.

SERONO S.A.  
a Swiss corporation  
(Registrant)

October 3, 2005

By: /s/ Stuart Grant  
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Name: Stuart Grant  
Title: Chief Financial Officer