

Edgar Filing: SERONO S A - Form 6-K

SERONO S A  
Form 6-K  
December 16, 2004

SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549

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 December, 2004

Serono S.A.

-----

(Registrant's Name)

15 bis, Chemin des Mines  
Case Postale 54  
CH-1211 Geneva 20  
Switzerland

-----

(Address of Principal Executive Offices)

1-15096

-----

(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  Form 40-F   
-----

(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).) \_\_\_\_\_

(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).) \_\_\_\_\_

(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   
-----

(If "Yes" is marked, indicate below the file number assigned to the registrant in connection with Rule 12g3-2(b): 82-\_\_\_\_\_)

[GRAPHIC OMITTED]  
SERONO

[GRAPHIC OMITTED]  
CANCER VAX (TM)

FOR IMMEDIATE RELEASE  
-----

## Edgar Filing: SERONO S A - Form 6-K

### SERONO AND CANCERVAX ANNOUNCE GLOBAL DEVELOPMENT AND COMMERCIALIZATION COLLABORATION FOR CANVAXIN(TM)

#### CANVAXIN(TM) IN PHASE 3 CLINICAL TRIALS FOR ADVANCED-STAGE MELANOMA

GENEVA, SWITZERLAND AND CARLSBAD, CALIFORNIA - DECEMBER 16, 2004 - Serono (Virt-X: SEO and NYSE: SRA) and CancerVax Corporation (NASDAQ: CNVX) announced today a worldwide collaboration for the development and commercialization of Canvaxin(TM), an investigational specific active immunotherapy product being developed for the treatment of advanced-stage melanoma, a deadly form of skin cancer. Canvaxin(TM) is currently being evaluated in two international, multi-center Phase 3 clinical trials for the treatment of Stage III and Stage IV melanoma.

Under the Agreement, CancerVax and Serono will jointly develop Canvaxin(TM) for melanoma, as well as other indications. The companies will share equally the costs of developing Canvaxin(TM) and seeking regulatory approvals for Canvaxin(TM).

CancerVax and Serono will co-promote Canvaxin(TM) in the U.S. and share certain expenses and profits on a 50/50 basis. Outside the U.S., Serono will have the exclusive right to commercialize Canvaxin(TM) and will pay royalties to CancerVax based on its sales of the product. Initially, CancerVax will manufacture Canvaxin(TM) for supply throughout the world. Serono may eventually establish a second manufacturing site for Canvaxin(TM), to supply primarily markets outside the U.S.

CancerVax will receive an initial cash payment of \$37 million, comprised of \$25 million in upfront signing fees and \$12 million for the purchase of 1 million shares of CancerVax common stock. CancerVax could receive up to \$253 million in additional payments linked to the achievement of development, regulatory and commercial milestones. The element of these milestone payments relating to the receipt of regulatory approvals through to marketing Canvaxin(TM) solely in Stage III and Stage IV melanoma in the U.S. and the EU could amount to \$100 million.

"This collaboration with CancerVax is a major milestone in Serono's establishment of a significant presence in the field of oncology, and further demonstrates Serono's commitment to expanding our portfolio of innovative clinical-stage projects which address significant, unmet medical needs," Ernesto Bertarelli, CEO of Serono, said. "Dermatologists have a significant role in the diagnosis and treatment of melanoma in Europe and many other countries around the world. The dermatology presence which Serono has established through the recent launch of Raptiva for the treatment of moderate-to-severe psoriasis will provide us with a significant operational asset on which to build for the commercialization of Canvaxin(TM)."

1/4

"We are very enthusiastic about establishing this collaboration with Serono to potentially bring Canvaxin(TM) to patients with advanced-stage melanoma around the world," said David F. Hale, President & CEO of CancerVax Corporation. "By partnering with Serono, a leading biotechnology company with significant expertise in the development and commercialization of biological products, CancerVax has taken a major step forward in achieving its goal of becoming a world leader in new therapies for the treatment of cancer," said Hale.

Consistent with guidance given in its third quarter results release, Serono considers the signing of this collaboration with CancerVax to be a significant further business development deal, and accordingly, the impact on net income of \$27.1m is considered exceptional.

## Edgar Filing: SERONO S A - Form 6-K

### ABOUT MELANOMA

According to the American Cancer Society, melanoma is the deadliest type of skin cancer and is the sixth most commonly diagnosed cancer in the United States. As reported by the World Health Organization, the worldwide incidence, or number of newly diagnosed cases, of melanoma in 2000 was 132,600, with 37,000 people dying of the disease. Furthermore, according to the National Cancer Institute, since 1997 the incidence of new melanoma cases in the United States has increased at an average rate of more than 5% per year, one of the highest growth rates for any type of cancer. In 2000, over 510,000 patients in the United States were living with melanoma. "Melanoma is one of the fastest growing types of cancers. According to the American Cancer Society, an estimated 55,000 new cases will be diagnosed in the United States in 2004, double the number from 30 years ago and 7,900 will die as a result of the disease," said Mary Loh, Executive Director of the American Melanoma Foundation. "Prevention and early detection are the best defenses against early-stage melanoma, but we desperately need new treatment options for patients suffering with advanced stages of this disease."

### ABOUT CANVAXIN(TM)

Canvaxin(TM), one of a new class of products being developed in the area of specific active immunotherapy (SAI) or therapeutic cancer vaccines, is based on a proprietary technology that may potentially be applied to treat a number of cancers. Canvaxin(TM) is currently being evaluated in two international, randomized, double-blind, placebo-controlled trials designed to evaluate the ability of Canvaxin(TM) to extend the survival of patients with Stage III and Stage IV melanoma following surgical resection of their tumors. In September 2004, CancerVax completed the planned enrollment of 1,118 patients into its Phase 3 clinical trial of Canvaxin(TM) for the treatment of patients with Stage III melanoma. CancerVax continues to make progress with the enrollment of patients in the Stage IV clinical trial and is evaluating the potential for Canvaxin(TM) in the treatment of other types of cancer.

2/4

### ABOUT CANCERVAX CORPORATION ([WWW.CANCERVAX.COM](http://WWW.CANCERVAX.COM))

-----

CancerVax Corporation is a biotechnology company focused on the research, development and commercialization of novel biological products for the treatment and control of cancer. The Company's lead product candidate, Canvaxin(TM), is one of a new class of products being developed in the area of specific active immunotherapy, also known as therapeutic cancer vaccines. Canvaxin(TM) is currently being studied in two international Phase 3 clinical trials for the treatment of patients with Stage III or Stage IV, or advanced-stage, melanoma. The Company is also finalizing the design of exploratory Phase 2 clinical trials for patients with other advanced-stage solid tumors. In addition to Canvaxin(TM), CancerVax has licensed three specific active immunotherapeutic product candidates targeting the epidermal growth factor receptor signaling pathway, including SAI-EGF, which has been studied in Phase 2 clinical trials. The Company plans to identify and develop new product candidates based on its proprietary specific active immunotherapy, anti-angiogenesis and T-oligo, or telomere homolog oligonucleotide, technology, as well as on its human monoclonal antibodies. CancerVax's corporate headquarters and research and development

## Edgar Filing: SERONO S A - Form 6-K

facility is located in Carlsbad, California, and its biologics manufacturing facility is located in the Los Angeles area.

### 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 Rapitva(R). In addition to being the world leader in reproductive health, Serono has strong market positions in 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. Currently, there are approximately 30 ongoing development projects.

In 2003, Serono achieved worldwide revenues of US\$2,018.6 million, and a net income of US\$390.0 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).

### FORWARD-LOOKING STATEMENTS

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 25, 2004. 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, 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.

3/4

CancerVax

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 future payments under the collaboration agreement, if any, the manufacture of Canvaxin(TM) 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, statements about: the progress and timing of the clinical trials of Canvaxin(TM); the potential that results of Phase 1 and 2 clinical trials of Canvaxin(TM), which were evaluated using retrospective survival analyses that may be subject to potential selection biases, may not be predictive of future results of the ongoing Phase 3 clinical trials; difficulties or delays in researching, developing, testing, obtaining

## Edgar Filing: SERONO S A - Form 6-K

regulatory approval, producing and marketing Canvaxin(TM); unexpected adverse side effects or inadequate therapeutic efficacy of Canvaxin(TM) that could delay or prevent product development or commercialization, or that could result in recalls or product liability claims; CancerVax's inability to protect its intellectual property and proprietary technology and to maintain and enforce its licensing arrangements with respect to Canvaxin(TM); the scope and validity of patent protection for Canvaxin(TM); 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 Canvaxin(TM), as well as lost revenue; the risk that the collaboration agreement may be terminated by Serono in certain instances; 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, 2003 and its Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2004, and Serono's Form 20-F for the fiscal year ended December 31, 2003. 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.

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

FOR MORE INFORMATION, PLEASE CONTACT:

SERONO IN GENEVA, SWITZERLAND:

CORPORATE MEDIA RELATIONS:	CORPORATE INVESTOR RELATIONS:
Tel: +41 22 739 36 00	Tel: +41 22 739 36 01
Fax: +41 22 739 30 85	Fax: +41 22 739 30 22
<a href="http://www.serono.com">http://www.serono.com</a>	Reuters: SEO.VX / SRA.N
-----	Bloomberg: SEO VX / SRA US

CANCERVAX CONTACT:

VINCE REARDON  
CANCERVAX CORPORATION  
SENIOR DIRECTOR, INVESTOR RELATIONS  
760-494-4850

4/4

### 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)

Edgar Filing: SERONO S A - Form 6-K

December 16, 2004

By: /s/ Francois Naef

-----  
Name: Francois Naef

Title: Secretary