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SERONO S A
Form 6-K
September 08, 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 September, 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-)

ZYMOGENETICS

SERONO

Media Release

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FOR IMMEDIATE RELEASE

ZYMOGENETICS AND SERONO ESTABLISH BROAD STRATEGIC RESEARCH, DEVELOPMENT AND COMMERCIALIZATION ALLIANCE

SERONO AND ZYMOGENETICS TO COLLABORATE IN THE DEVELOPMENT OF NOVEL PROTEIN AND ANTIBODY THERAPEUTICS

SEATTLE (UNITED STATES) AND GENEVA (SWITZERLAND), SEPTEMBER 8, 2004 - ZymoGenetics, Inc. (Nasdaq: ZGEN) and Serono (virt-x: SEO and NYSE: SRA) today announced their intent to enter into a broad partnership to research, develop and commercialize novel protein and antibody therapeutics based on discoveries made by ZymoGenetics.

As part of this alliance:

- Serono will gain access to a large portfolio of ZymoGenetics' genes and proteins for in-house evaluation and screening, and rights to license such proteins over the next five years.
- Serono will also have rights over the next five years to license up to twelve products arising from ZymoGenetics' internal core research projects. ZymoGenetics will have an option to co-develop and co-commercialize in the U.S. any products selected by Serono. Until November 2006, Serono's rights to exclusively license proteins outside the U.S. will be subordinate to certain existing options of Novo Nordisk under a separate agreement.
- ZymoGenetics will license to Serono exclusive worldwide rights to develop and commercialize products based on Fibroblast Growth Factor 18 (FGF-18) and the Interleukin 22 Receptor (IL-22R). In addition, the companies will co-develop Interleukin 31 (IL-31).

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Expected payments to ZymoGenetics include:

- A payment of \$20 million in exchange for the rights to license proteins over the next five years.
- The purchase of \$50 million of ZymoGenetics' common stock.
- An equal share of profits from the co-commercialization of products in the U.S. for which ZymoGenetics has co-funded development.
- For every protein exclusively licensed or co-developed by Serono, up-front fees as well as potential milestone payments related to development progress, regulatory submissions and approvals.
- Royalty payments on product sales outside the U.S. and, to the extent ZymoGenetics elects not to co-develop products, on product sales in the U.S.

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The terms of this agreement are subject to review by the United States Federal Trade Commission and Department of Justice, under the provisions of Section 7A of the Clayton Act, 15 U.S.C. Sec. 18a, as added by the Hart-Scott-Rodino Antitrust Improvements Act of 1976.

"We are enthusiastic about building this alliance with Serono," said Bruce L.A. Carter, Ph.D., President and Chief Executive Officer of ZymoGenetics.

"Maximizing the value of our broad pipeline requires the effort of a proven research, development and commercial enterprise. Serono has not only demonstrated its strengths in these areas, but also has proven an effective partner in our collaborative development of TACI-Ig. The combination of our resources should work to create value for both companies over the years ahead."

"We are very pleased to expand our fruitful collaboration with ZymoGenetics", said Ernesto Bertarelli, Chief Executive Officer of Serono. "By combining ZymoGenetics' strong pipeline of therapeutic protein candidates with our research and development capabilities, we are well positioned to bring to the market further innovative treatments for medical conditions with significant unmet needs".

Three license agreements for FGF-18, IL-22R and IL-31 will be entered into as part of this alliance. Serono will have worldwide exclusive rights for FGF-18 and IL-22R, which may be useful for repairing cartilage damaged by osteoarthritis or physical injury, and psoriasis, respectively. ZymoGenetics will retain co-development and co-commercialization rights in the U.S. for IL-31, which could be useful in treating inflammatory conditions such as asthma, psoriasis and inflammatory bowel disease. In addition to the \$20 million payment mentioned above, ZymoGenetics will receive initial license fees totaling \$11.25 million related to these three projects. Total upfront and milestone payments under these licenses could exceed \$100 million.

Serono reiterates its guidance for 2004 with an increase in total revenues of at least 12% and an increase in net income of at least 20% in local currencies.

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ZymoGenetics will conduct a conference call/webcast in conjunction with today's release at 8:30 A.M. ET on Wednesday, September 8, 2004. The webcast will include a slide presentation. Members of the news media, investors and the general public are invited to access a live broadcast of the conference call via the ZymoGenetics website at [HTTP://WWW.ZYMOGENETICS.COM/IR/EVENTS.PHP](http://WWW.ZYMOGENETICS.COM/IR/EVENTS.PHP) or

through www.vcall.com. The event will be archived. The telephone replay will be

available until 11:59 PM Pacific Time on September 14, 2004. The webcast will be available for replay until 11:59 PM Pacific Time on October 7, 2004.

Phone numbers and access codes for the conference call are as follows:

Live Call- Domestic: 800-370-0740 International: 973-409-9259
An operator will answer calls for the live event.

Archived Call- Domestic 877-519-4471 International: 973-341-3080

Replay Passcodes (required for playback):
Account #: 1628
Conference ID #: 5131574

About FGF-18

Fibroblast growth factor-18 (FGF-18) plays an important role during skeletal

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development and appears to be a trophic factor for chondrocytes, the cells that produce cartilage of the joint surfaces, in mammals. ZymoGenetics has previously shown that FGF-18 and the genes for two of its receptors are expressed by chondrocytes in adult human articular cartilage. Addition of FGF-18 to the culture medium of these cells increased both their proliferation and their production of extracellular matrix. Similar changes in chondrocyte proliferation and matrix deposition were observed at a number of sites following local or systemic delivery of FGF-18. These data suggest that FGF-18 may be useful for healing cartilage damaged by injury or disease.

About IL-22R

The IL-10 family cytokines IL-20 and IL-22 are pro-inflammatory and each can signal via the receptor subunit IL-22R alpha. Considerable evidence supports the inflammatory roles of IL-20 and IL-22 in psoriasis including their elevated expression in psoriatic lesions, transgenic mice phenotypes, genetic association data and animal pharmacology. Expression of the receptor subunit IL-22R alpha is also elevated in psoriatic lesions. Current work is directed towards choosing the most suitable antagonist for evaluation in the treatment of psoriasis. Such antagonists may also have use in other instances of impaired epithelial barrier function, such as in inflammatory bowel disease.

About IL-31

ZymoGenetics researchers discovered Interleukin 31 (IL-31) using the Company's genomics-based discovery platform. Current in vitro and in vivo data suggest that IL-31 may affect cellular infiltration and inflammation. Analysis of IL-31 and IL-31 receptor levels in human and murine disease tissues suggests that expression of IL-31, and/or its receptor, is significantly increased in the settings of inflammatory bowel disease, asthma and psoriasis. Further evidence suggests a potential role of IL-31 in the development of atopic dermatitis. A paper by ZymoGenetics scientists published in the July 2004 issue of the journal Nature Immunology characterizes IL-31, illustrates the hypothesized role of IL-31 in atopic dermatitis and respiratory disease, and suggests directions for future investigation of this cytokine and its role in human diseases.

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ABOUT ZYMOGENETICS

ZymoGenetics is a biopharmaceutical company focused on the discovery, development and commercialization of therapeutic proteins for the prevention or treatment of human diseases. The Company is developing a diverse pipeline of potential proprietary product candidates that are moving into and through clinical development. These span a wide array of clinical opportunities that include bleeding, autoimmune diseases and cancer. ZymoGenetics intends to commercialize these product candidates through internal development, collaborations with partners, and out-licensing of patents from its extensive patent portfolio. For further information, visit www.zymogenetics.com.

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), Zorbtive(TM) and Raptiva(R) (Luveris(R) is not approved in the USA). In addition to being the world leader in reproductive health, Serono has strong market positions in neurology, metabolism and growth and has

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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).

BACKGROUND MATERIAL

For free B-roll, video and other content about Serono, please visit the Serono Media Center www.thenewsmarket.com/Serono. You can download print-quality images

and receive broadcast-standard video digitally or by tape from this site. Registration and video is free to the media.

ZymoGenetics forward-looking statements

This press release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. These forward-looking statements are based on the current intent and expectations of the management of ZymoGenetics. These statements are not guarantees of future performance and involve risks and uncertainties that are difficult to predict. ZymoGenetics' actual results and the timing and outcome of events may differ materially from those expressed in or implied by the forward-looking statements because of risks associated with our unproven discovery strategy, preclinical and clinical development, regulatory oversight, intellectual property claims and litigation and other risks detailed in ZymoGenetics' public filings with the Securities and Exchange Commission, including ZymoGenetics' Annual Report on Form 10-K for the year ended December 31, 2003. Except as required by law, ZymoGenetics undertakes no obligation to update any forward-looking or other statements in this press release, whether as a result of new information, future events or otherwise.

Serono forward-looking statements

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.

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FOR MORE INFORMATION, PLEASE CONTACT:

ZYMOGENETICS

Investor Relations

Media Relations

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John Calhoun, MD, MBA
Director, Corporate Communications
& Investor Relations
(206) 442-6744

Susan W. Specht, MBA
Corporate Communications Manager
(206) 442-6592

SERONO

CORPORATE MEDIA RELATIONS:
Tel: +41 22 739 36 00
Fax: +41 22 739 30 85
<http://www.serono.com>

CORPORATE INVESTOR RELATIONS:
Tel: +41 22 739 36 01
Fax: +41 22 739 30 22
Reuters: SEO.VX / SRA.N
Bloomberg: SEO VX / SRA US

MEDIA RELATIONS, USA:
Tel: +1 781 681 2486
Fax: +1 781 681 2935
<http://www.seronousa.com>

INVESTOR RELATIONS, USA:
Tel: +1 781 681 2552
Fax: +1 781 681 2912

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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)

September 8, 2004

By: /s/ Francois Naef

Name: Francois Naef
Title: Secretary