SANOFI-AVENTIS
Form 6-K
September 17, 2004

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 6-K

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

For the month of September 2004

Commission File Number: 001-31368

SANOFI-AVENTIS
(Translation of registrant's name into English)

174, avenue de France, 75013 Paris, FRANCE
(Address of principal executive offices)

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

Form 20-F [X] 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 [X]

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

This Report on Form 6-K shall be deemed to be incorporated by reference into Sanofi-Aventis' (formerly known as Sanofi-Synthelabo) Registration Statement on Form F-4 (Registration No. 333-112314), as post-effectively amended and declared effective on May 13, 2004 by the United States Securities Exchange Commission, and the related prospectus, dated April 9, 2004, and the prospectus supplement, dated May 27, 2004, each filed pursuant to Rule 424(b) under the United States Securities Act of 1933, as amended, and shall be part thereof from the date on which this Report is filed, to the extent not superseded by documents or reports subsequently filed or furnished.

On September 17, 2004, Sanofi-Aventis (formerly known as Sanofi-Synthelabo) issued the following press release.

[SANOFI-AVENTIS LOGO]

Paris September 17, 2004

ELOXATIN(R) TO RECEIVE EXPANDED INDICATION IN EUROPE FOR EARLY STAGE COLORECTAL CANCER TREATMENT

The sanofi-aventis Group (PARIS : SAN, NYSE : SNY) announced today that its anti-cancer agent Eloxatin(R) (oxaliplatin), which is currently marketed for the "treatment of Metastatic Colorectal Cancer in combination with 5-fluorouracil and folinic acid" has successfully completed a Mutual Recognition Procedure in Europe, which will result in an extended indication for the product in the adjuvant setting:

"ADJUVANT TREATMENT OF STAGE III (DUKE'S C) COLON CANCER AFTER COMPLETE RESECTION OF PRIMARY TUMOR'".

The European approval was based on the results of the landmark adjuvant clinical trial, MOSAIC, which was recently published in June 2004 in the New England Journal of Medicine.

MOSAIC is a large, international randomized Phase III trial involving 2,246 patients in 148 centres and 20 countries. The primary objective of the study was to evaluate the Disease Free Survival (time to relapse or death) in these patients, all of whom had a completely resected stage II/III colon cancer and received the current standard of adjuvant chemotherapy for colon cancer (5-fluorouracil/leucovorin known as 5-FU/LV) with or without the addition of Eloxatin(R).

The Mosaic trial demonstrated that the addition of Eloxatin(R) to 5-FU/LV increased Disease Free Survival at 3 years to 78.2% versus 72.9% for 5-FU/LV alone (p=0.002), with a 23% reduction in the risk of recurrence in the overall study population.
For patients with stage III colorectal cancer, 3-year Disease Free Survival was 72.2% with the addition of Eloxatin(R) and 65.3% for 5-FU/LV alone, with a 24% reduction in the risk of recurrence.(1)

These were the very first results to demonstrate a significant benefit over 5-FU/LV alone in this setting, and provide early-stage colon cancer patients with new hope for potential cure of their disease.

"The MOSAIC trial demonstrates that surgical removal of the primary tumour and treatment with Eloxatin(R)-based chemotherapy can increase the chances for patients with early-stage colon cancer to be cured," said Aimery de Gramont MD PhD, Professor of Medicine and Director of the Oncology Department, Saint-Antoine Hospital, Paris and principal investigator of the MOSAIC trial. "We are pleased to see that Eloxatin(R)-based adjuvant therapy will now be made available to these patients in the European Union."

The addition of Eloxatin(R) to 5-FU/LV is well tolerated. The most frequently reported side effect was neutropenia (decrease in the number of white blood

cells) but this was complicated by fever or infection in only 1.8 % of cases. Among patients experiencing peripheral sensory neuropathy ("pins and needles" in the fingers), partial or total recovery was observed in almost all cases within a period of six months following treatment.
On the basis of the MOSAIC trial findings, a supplemental New Drug Application (sNDA) was also submitted to the Food and Drug Administration (FDA) in the US in early 2004 to include the adjuvant treatment of patients with colon cancer in the labelling of Eloxatin(R). An extension of the approval to include the adjuvant treatment of patients with colon cancer has also been applied for in several other countries including Switzerland and Australia.

ABOUT ELOXATIN(R)
Eloxatin(R) received approval in France for the 2nd line treatment of metastatic colorectal cancer in April 1996, and as a 1st line treatment in April 1998. In July 1999, Eloxatin(R) was approved for the 1st line treatment indication in major European countries, through the Mutual Recognition Procedure, France being the Reference Member State.

Eloxatin(R) has successfully completed a Mutual Recognition Procedure in Europe in December 2003, which allowed the product to be indicated for the full indication: "Treatment of Metastatic Colorectal Cancer in combination with 5-fluorouracil and folinic acid" (i.e., 1st line and 2nd line treatment).

In the U.S., Eloxatin(R) received marketing approval on January 9, 2004, for the first line treatment of metastatic carcinoma of the colon or rectum. This approval recommends the use of Eloxatin(R), in combination with infusional 5-FU/LV, for the treatment of advanced carcinoma of the colon or rectum. Eloxatin(R) had previously (August 2002) received approval for second line treatment of these patients.

Eloxatin(R) is currently marketed by sanofi-aventis in more than 60 countries for the treatment of metastatic colorectal.

COLORECTAL CANCER LEADING CAUSE OF DEATH
Colorectal cancer is the third leading cause of cancer and the forth leading cause of mortality due to cancer in the world. About one million new cases of colorectal cancer are diagnosed worldwide every year.

FURTHER DEVELOPMENT IN OTHER TYPES OF CANCER
An extensive worldwide clinical development program is ongoing to explore the benefit of Eloxatin(R) in other types of cancer.

ABOUT SANOFI-AVENTIS
The sanofi-aventis Group is the world's 3rd largest pharmaceutical company, ranking number 1 in Europe. Backed by a world-class R&D organization, sanofi-aventis is developing leading positions in seven major therapeutic areas: cardiovascular disease, thrombosis, oncology, diabetes, central nervous system, internal medicine, vaccines.

(1)T. ANDRE, C. BONI, L. MOUNEDJI-BOUDIAF, M. NAVARRO, J. TABERNERO, T. HICKISH, C. TOPHAM, M. ZANINELLI, P. CLINGAN, J. BRIDGEWATER, I. TABAH-FISCH, A. DE GRAMONT. Oxaliplatin, Fluorouracil, and Leucovorin as Adjuvant Treatment for Colon Cancer. (MOSAIC). New Engl. J. Med., 2004; 350: 2343-2351".

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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.

Dated: September 17, 2004

SANOFI-AVENTIS

By: /s/ Jean-Claude Leroy
Name: Jean-Claude Leroy
Title: Senior Vice President & Chief Financial Officer