

Gentium S.p.A.  
Form 6-K  
March 30, 2006

**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 March, 2006.

Commission File Number 000-51341

Gentium S.p.A.

(Translation of registrant's name into English)

Piazza XX Settembre 2, 22079 Villa Guardia (Como), Italy

(Address of principal executive office)

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):

**Note:** Regulation S-T Rule 101(b)(1) only permits the submission in paper of a Form 6-K if submitted solely to provide an attached annual report to security holders.

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):

**Note:** Regulation S-T Rule 101(b)(7) only permits the submission in paper of a Form 6-K if submitted to furnish a report or other document that the registrant foreign private issuer must furnish and make public under the laws of the jurisdiction in which the registrant is incorporated, domiciled or legally organized (the registrant's "home country"), or under the rules of the home country exchange on which the registrant's securities are traded, as long as the report or other document is not a press release, is not required to be and has not been distributed to the registrant's security holders, and, if discussing a material event, has already been the subject of a Form 6-K submission or other Commission filing on EDGAR.

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-\_\_\_\_\_.



Description of events affecting the Registrant are set forth in the Registrant's press release, dated March 28, 2006, attached hereto as Exhibit Number 1 and incorporated by reference herein in its entirety.

**Exhibit** **Description**

1 Press release, dated March 28, 2006.

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**SIGNATURE**

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.

**GENTIUM S.P.A.**

By: /s/ Cary Grossman

Name: Cary Grossman

Title: Executive Vice President and Chief Financial Officer

Date: March 28, 2006

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**INDEX TO EXHIBITS**

**Exhibit   Description**

1 Press release, dated March 28, 2006.

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**PRESS RELEASE**

**FOR IMMEDIATE RELEASE**

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GENTIUM RECEIVES FIRST IRB APPROVAL TO BEGIN U.S. PHASE III  
TRIAL WITH DEFIBROTIDE TO TREAT VENO-OCCLUSIVE DISEASE  
WITH MULTIPLE-ORGAN FAILURE

*Dana-Farber/Harvard Cancer Center, Massachusetts General Hospital, Beth Israel  
Deaconess Medical Center and The Children's Hospital Receive IRB Approval to Commence Study*

**Villa Guardia (Como), Italy (March 28, 2006) - Gentium S.p.A. (AMEX: GNT)** (the Company) has received its first Institutional Review Board (IRB) approvals to initiate a U.S. Phase III clinical trial with Defibrotide for the treatment of Venous Occlusive Disease (VOD) with Multiple Organ Failure (Severe VOD) as a complication of stem cell transplantation (SCT). Data from this 80-patient, multi-center trial will be compared to an historical control group of 80 patients, with survival at day 100 as the primary endpoint. The Company believes that approximately 80% of patients with Severe VOD die within 100 days of SCT without treatment. The Company believes that there are no approved treatments for Severe VOD.

The IRB of the Dana-Farber/Harvard Cancer Center of Boston, Mass., which is also the IRB for Dana-Farber Cancer Institute, Massachusetts General Hospital, Beth Israel Deaconess Medical Center and The Children's Hospital, is the first to give its approval to commence the study. All four of these institutions are expected to participate in the trial. Work to compile historical control data will begin immediately, and the first patients are expected to be treated by early May, 2006.

The multi-center trial will be conducted at approximately 20 U.S. cancer centers pending the IRB approval at each institution. In addition to the institutions mentioned above, the Company expects the trial to include M.D. Anderson Cancer Center, Fred Hutchinson Cancer Research Center, Memorial Sloan-Kettering Cancer Center, Johns Hopkins Hospital and Health System, Duke University Hospital, City of Hope Cancer Center, The Children's Hospital of Philadelphia, University of Minnesota Medical Center and The St. Jude Children's Research Hospital, among others.

Paul Richardson, M.D., Clinical Director of Dana-Farber Cancer Institute's Jerome Lipper Multiple Myeloma Center and Assistant Professor of Medicine at Harvard Medical School, is the principal investigator of this Phase III trial. He recently presented Phase II data of Defibrotide as a treatment for Severe VOD at the 2005 American Society of Hematology (ASH) Annual Scientific Meeting. Commenting on the 140-patient, multi-center, randomized, dose-finding Phase II study, Dr. Richardson said, "Treatment of Severe VOD with Defibrotide resulted in a survival rate at 100 days post SCT of approximately 40%, which compares favorably with the 100-day survival rate of approximately 20% or less reported in published studies of Severe VOD. These results are encouraging, with response and long-term survival seen even in patients who either were on dialysis or were ventilator-dependent at the start of Defibrotide therapy. In addition, the side effect profile of Defibrotide was favorable in this extremely sick patient population."

"As we continue to advance the development of Defibrotide, we are increasingly impressed by the consistency of the clinical findings and I am optimistic that we will soon be able to offer an effective treatment option for patients suffering from this otherwise often fatal disease," commented Laura Ferro, M.D., president and chief executive officer of Gentium. "We are pleased to initiate this U.S. Phase III study and hope to see compelling clinical results."

The U.S. Food and Drug Administration (FDA) has granted Defibrotide Orphan Drug Status and Fast Track designation for the treatment of Severe VOD. In addition, previous clinical trials with Defibrotide for the treatment of Severe VOD have been supported by grants from FDA's Office of Orphan Products Development.

### **About VOD**

VOD is a potentially life-threatening condition. Certain high dose chemotherapy and radiation therapies and stem cell transplantation (SCT) can damage cells of the blood vessels and result in VOD, a blockage of the small veins of the liver that can lead to liver failure and the failure of other organs (Severe VOD). SCT is a frequently used treatment following high dose chemotherapy and radiation therapy. The International Bone Marrow Transplant Registry estimated that approximately 45,000 people received blood and bone marrow transplants, which are types of SCT, in 2002. Based on the Company's review of more than 200 published papers, it believes that approximately 20% of patients who undergo SCT develop VOD, approximately one-third of those who develop VOD progress to multiple organ failure (Severe VOD), and approximately 80% of Severe VOD patients die within 100 days of the SCT. The Company believes that there are no approved therapies to treat or prevent VOD in the U.S or the EU.

**About Gentium**

Gentium S.p.A. is a biopharmaceutical company located in Villa Guardia (Como), Italy that is focused on the research, discovery and development of drugs derived from DNA extracted from natural sources, and drugs that are synthetic derivatives, to treat and prevent a variety of vascular diseases and conditions related to cancer and cancer treatments. Defibrotide, the Company's lead product candidate in the U.S., is an investigational drug that has been granted Orphan Drug status by the U.S. FDA to treat Severe VOD and Fast Track designation for the treatment of Severe VOD in recipients of stem cell transplants.

**Cautionary Note Regarding Forward-Looking Statements**

*This press release contains "forward-looking statements." In some cases, you can identify these statements by forward-looking words such as "may," "might," "will," "should," "expect," "plan," "anticipate," "believe," "estimate," "predict," "potential" or "continue," the negative of these terms and other comparable terminology. These statements are not historical facts but instead represent the Company's belief regarding future results, many of which, by their nature, are inherently uncertain and outside the Company's control. It is possible that actual results may differ, possibly materially, from those anticipated in these forward-looking statements. For a discussion of some of the risks and important factors that could affect future results, see the discussion in our Prospectus filed with the Securities and Exchange Commission under Rule 424(b)(5) under the caption "Risk Factors."*

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