

Gentium S.p.A.  
Form 6-K  
January 31, 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 January, 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-\_\_\_\_\_.



Descriptions of events affecting the Registrant are set forth in the Registrant's press releases, dated January 20, 2006 and January 30, 2006, attached hereto as Exhibits Number 1 and Number 2, respectively, both of which are incorporated by reference herein in their entirety.

**Exhibit** **Description**

1 Press release, dated January 20, 2006.

2 Press release, dated January 30, 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.**

Date: January 30, 2006

By: /s/ Cary Grossman

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Cary Grossman  
Executive Vice President and Chief Financial Officer

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**INDEX TO EXHIBITS**

**Exhibit   Description**

1 Press release, dated January 20, 2006.

2 Press release, dated January 30, 2006.



## **PRESS RELEASE**

### **FOR IMMEDIATE RELEASE**

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GENTIUM INITIATES PHASE II/III PEDIATRIC TRIAL WITH  
DEFIBROTIDE TO PREVENT VENO-OCCLUSIVE DISEASE

**European Group for Blood and Marrow Transplantation to Co-Sponsor Study at  
30 European and Israeli Clinical Sites**

**Villa Guardia (Como), Italy (January 20, 2006) - Gentium S.p.A. (AMEX: GNT)** (the “Company”) today announced the initiation of a Phase II/III trial with Defibrotide to prevent Veno-Occlusive Disease (“VOD”), a complication of bone marrow and stem cell transplantation (SCT), in pediatric patients. The randomized study will include 270 pediatric patients undergoing SCT at 30 clinical sites in Europe and Israel and will evaluate the ability of Defibrotide to prevent VOD. Secondary endpoints are measuring the severity of VOD and the occurrence of transplant-associated microangiopathy in each group. The European Group for Blood and Marrow Transplantation (EBMT) is co-sponsoring the study with additional support from the Deutsche Krebshilfe (German Cancer Aid). The principal investigator is Selim Corbacioglu, M.D., Dept of Pediatrics - University of Ulm, Germany.

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Certain chemotherapy and radiation therapies such as those used in stem cell transplantation can damage cells of the blood vessels and produce VOD, a blockage of the small veins of the liver which leads to damage of the liver cells. Approximately 20% of patients who undergo SCT develop VOD and approximately one-third of these patients progress to multiple organ failure (Severe VOD). Nearly 80% of Severe VOD patients die within three months. There are currently no approved therapies to treat or prevention VOD.

Laura Ferro, M.D., president and chief executive officer of Gentium, said, “Preventing VOD in stem cell transplant patients is critically important, especially for pediatric patients who are particularly susceptible to developing VOD due to the nature of their treatment regimen. We look forward to also beginning our European trial for the prevention of VOD and transplant-associated microangiopathy in adults in the second quarter of this year.”

“Earlier clinical trials of Defibrotide to treat and prevent VOD have shown encouraging results. We are pleased to begin this prevention trial in children and hope it will provide evidence of Defibrotide’s potential efficacy to prevent VOD. “

“We are delighted that the EBMT and the Deutsche Krebshilfe have agreed to support our efforts to develop a preventative drug for patients at risk of developing VOD, a potentially fatal disease, for which there are no currently approved therapies,” concluded Dr. Ferro.

#### **About Defibrotide**

Defibrotide is a single-stranded DNA that protects the vascular endothelial cells, particularly those of small vessels, from damage and activation. After binding to endothelial cells, Defibrotide decreases cell adhesion and pro-coagulant activity of activated endothelial cells, and increases the fibrinolytic potential of endothelial cells. Defibrotide’s effects are predominately local within the vascular bed, and there is no significant effect on systemic coagulation. Its beneficial pharmacological effects are due to its anti-thrombotic, anti-inflammatory and anti-ischemic properties.

Defibrotide is expected to be the subject of a U.S. Phase III study as a treatment for Severe VOD in the coming weeks. The Company also intends to initiate studies of Defibrotide to prevent VOD in the U.S. by early 2007.

#### **About VOD**

VOD is a potentially life-threatening condition. The International Bone Marrow Transplant Registry estimated that approximately 45,000 people received blood and bone marrow transplants in 2002. Based on the Company’s review of more than 200 published papers it is estimated that up to 20% of patients who receive blood and bone marrow transplants contract VOD. When Severe VOD occurs, blood vessels in the liver become blocked, liver failure follows and kidneys cease to function as a result of the toxic effects of cancer treatments such as high dose chemotherapy and radiation, used during SCT. Approximately 80% of patients who contract Severe VOD die within 100 days of SCT without treatment. VOD is considered one of the most important and challenging complications of SCT. There currently are no approved therapies to treat or prevent VOD.

## **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)(4) under the caption "Risk Factors."*

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## **PRESS RELEASE**

### **FOR IMMEDIATE RELEASE**

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**GENTIUM'S DEFIBROTIDE SUBJECT OF INDEPENDENT  
STUDY IN JAPAN**

**First Japanese Study Reports That Defibrotide Shows Success Treating Severe  
Veno-Occlusive Disease**

**Villa Guardia (Como), Italy (January 30, 2006) - Gentium S.p.A. (AMEX: GNT)** (the "Company") today reported that an independent study of Defibrotide was the subject of a published paper entitled, "*Successful Treatment with Defibrotide for Sinusoidal Obstruction Syndrome* (also known as Veno-Occlusive Disease or "VOD") *after Hematopoietic Stem Cell Transplantation (SCT)*," which appeared in the December 2005 issue of *Kobe Journal of Medical Science*. The lead author of the paper was Kimikazu Yakushijin, Division of Endocrinology/Metabolism, Neurology and Hematology/Oncology, Department of Clinical Molecular Medicine, Kobe University Graduate School of Medicine, Japan.

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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 which can lead to liver failure and the failure of the kidneys and other organs. SCT is a frequently used treatment following high dose chemotherapy and radiation therapy. Based on the Company's review of more than 200 published papers, 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. There are currently no approved therapies to treat or prevent VOD in the U.S. or the E.U.

According to the published study, all patients showed evidence of multiple organ failure at the start of treatment, four patients were treated with Defibrotide for 14 to 27 days, three patients (75%) responded to the therapy, two patients survived at 100 days post SCT (50%), and none of the patients suffered from significant adverse effects.

The paper concluded that this is the first report dealing with the use of of Defibrotide to treat Japanese patients with VOD and because Defibrotide is considered to be promising for the treatment of VOD, it is important that further studies be initiated as soon as possible in Japan.

Commenting on the publication, Dr. Laura Ferro, chairman and chief executive officer of Gentium, stated, "We were pleased with Dr. Yakushijin's independent study as it builds on our body of clinical evidence that supports the use of Defibrotide to treat Severe VOD. Data from Harvard University's Dana Farber Cancer Institute's U.S. Phase II study showed an increase in survival rate at 100 days post SCT of approximately 39%, compared with the historical 100-day survival rate of approximately 20%."

#### **Defibrotide to Treat Severe VOD**

The Company is awaiting Institutional Review Board approval for its pivotal U.S. Phase III trial of Defibrotide to treat Severe VOD and expects to initiate that trial in the coming weeks.

#### **Defibrotide to Prevent VOD**

The Company recently initiated a Phase II/III trial with Defibrotide to prevent VOD in pediatric patients. The randomized study will include 270 pediatric patients undergoing SCT at 30 clinical sites in Europe and Israel and will evaluate the ability of Defibrotide to prevent VOD.

The Company plans to initiate a Phase II/III trial with Defibrotide to prevent VOD in adult patients in Europe during the second quarter of 2006 and in the U.S. by early 2007.

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