Gentium S.p.A.
Form 6-K
January 27, 2009

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, 2009.

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 S Form 40-F o

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 o No S

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

82-_____.

The Registrant's press release regarding completed enrollment of the Phase II/III European Pediatric Prevention Trial is attached hereto as Exhibit 1 and incorporated by reference herein in its entirety. This report and the exhibit attached thereto are incorporated by reference into the registration statements of Gentium S.p.A. on Forms F-3: File No. 333-135622, File No. 333-137551, File No. 333-138202, File No. 333-139422 and File No. 333-141198 and on Forms S-8: File No. 333-137534 and File No. 333-146534.

Exhibit	Description
1	Press release, dated January 22, 2009.

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/ Gary G. Gemignani	
	Name:	Gary G. Gemignani
	Title:	Executive Vice President and Chief Financial Officer

Date: January 27, 2009

INDEX TO EXHIBITS

Exhibit	Description
1	Press release, dated January 22, 2009.

Exhibit 1

PRESS RELEASE

Gentium Announces Completion of Enrollment for the Phase II/III European Pediatric Prevention Trial of Defibrotide

VILLA GUARDIA (Como), Italy, January 22, 2009 (BUSINESS WIRE) -- Gentium S.p.A. (Nasdaq: GENT) announced today the completion of patient enrollment in a Phase II/III European, multi-center, open label, randomized trial to evaluate the prophylactic use of Defibrotide in pediatric patients undergoing stem cell transplantation who are at high risk for hepatic veno-occlusive disease (VOD).

In the Phase II/III trial, patients are randomly assigned to one of two treatment arms. Those allocated to the Defibrotide prophylaxis arm receive 25mg/kg/day in four divided doses beginning at the time of conditioning and finishing 30 days after stem cell transplantation (SCT) or upon discharge from inpatient care. Patients allocated to the control arm do not receive VOD prophylactic measures. The primary efficacy endpoint for the trial is the incidence of VOD within 30 days after SCT. The secondary safety endpoints include the occurrence of multi-system organ failure and survival at 100 days after SCT. Additional information on this trial can be found at www.clinicaltrials.gov.

Gentium plans to release initial results of this trial at the Annual Meeting of the European Group for Blood and Marrow Transplantation, March 29 to April 1, 2009 in Göteborg, Sweden. As was previously announced, following discussions with the European Medicines Agency, Gentium has been notified of the potential for an accelerated review of Defibrotide in the pediatric prevention indication.

“We are excited to have completed enrollment in our European Phase II/III prophylaxis trial for Defibrotide in pediatric patients,” stated Dr. Laura Ferro, CEO of Gentium S.p.A. “Prior investigator sponsored trials for Defibrotide in the prevention setting have shown promising results, and we are hopeful that this trial will fall in line with what we have previously seen.”

About VOD

Veno-occlusive disease is a potentially life-threatening condition, which typically occurs as an important complication of stem cell transplantation. Certain high-dose chemo-radiation therapy regimens used as part of SCT can damage the lining cells of hepatic blood vessels and so result in VOD, a blockage of the small veins of the liver that leads to liver failure and can result in significant dysfunction in other organs such as the kidneys and lungs (so-called severe VOD). SCT is a frequently used treatment modality following high-dose chemotherapy and radiation therapy for hematologic cancers and other conditions in both adults and children. There is currently no approved agent for the treatment or prevention of VOD in the U.S. or the EU.

About Gentium

Gentium S.p.A. is a biopharmaceutical company 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, is an investigational drug that has been granted Orphan Drug status by the U.S. Food and Drug Administration and EMEA to prevent and to treat VOD and Fast Track designation by the U.S. FDA 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,” “pred 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, including clinical trial results and regulatory reviews, may differ 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 Form 20F filed with the Securities and Exchange Commission under the caption “Risk Factors.”

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