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

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 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 preliminary results to the phase 2/3 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 March 29, 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.

Date: March 30, 2009	By:	/s/ Gary G. Gemignani
	Name:	Gary G. Gemignani
	Title:	Executive Vice President and Chief Financial Officer

INDEX TO EXHIBITS

Exhibit	Description
1	Press release, dated March 29, 2009.

Exhibit 1

PRESS RELEASE

Gentium Announces Preliminary Results from a Phase 2/3 European Pediatric Prevention Trial for Veno-Occlusive Disease at the European Group for Blood and Marrow Transplantation Annual Meeting

VILLA GUARDIA (Como), Italy, March 29, 2009 (BUSINESS WIRE) -- Gentium S.p.A. (Nasdaq: GENT) today presented preliminary unaudited top-line results from the Phase 2/3 European pediatric prevention clinical trial of Defibrotide. The results were presented by Selim Corbacioglu, Department of Pediatrics, University of Ulm, Germany, principal investigator of the clinical trial, at the Annual Meeting of the European Group for Blood and Marrow Transplantation (EBMT) in Göteborg, Sweden.

The Phase 2/3 European pediatric prevention trial is a multi-center, open label, randomized clinical 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 this two-armed trial, patients were randomly assigned to receive Defibrotide. Patients in the prophylaxis arm received 25 mg/kg/day of Defibrotide in four divided doses beginning at the time of conditioning. Patients in the control arm, however, did not receive Defibrotide for VOD prophylactic measures. The primary endpoint of the study was development of VOD within 30 days post stem cell transplantation (SCT) based on the modified Seattle criteria.

The results from this clinical trial demonstrated a 40% reduction in incidence of VOD within 30 days after SCT and achieved a statistical P-value of 0.0539, with a hazard ratio of 1.68 (95% confidence interval of 0.98-2.86), in the intent-to-treat analysis of 180 patients in the prophylaxis arm and 176 patients in the control arm. In addition, the analysis of data pursuant to the protocol (patients who completed 30 days in the study), which included 164 patients in the prophylaxis arm and 169 patients in the control arm, showed a 40% reduction rate of the incidence of VOD within 30 days and achieved a statistical P-value of 0.0366, with a hazard ratio of 1.78 (95% confidence interval of 1.03-3.08). The data also demonstrated the excellent safety profile of Defibrotide showing no difference in adverse events between the prophylaxis and control arms.

“We are encouraged by the preliminary results from the Phase 2/3 trial of Defibrotide to prevent VOD in children and anticipate announcing the final results in the second half of 2009,” commented Dr. Laura Ferro, CEO of Gentium S.p.A. “We look forward to sharing the final results with the European Medicines Agency in order to determine the necessary steps for potential approval. In addition, we are hopeful that the progress indicated by the preliminary data will provide us with potential opportunities to allow us to complete the clinical and regulatory process so that we can provide patients with Defibrotide for this critical and unmet need.”

“The results seen in this study provide a compelling case for a novel, safe, effective, therapeutic option for preventing VOD in pediatric patients undergoing SCT who have multiple unfavorable prognostic factors,” said Professor Dietger Niederwieser, Department of Hematology and Oncology, University of Leipzig and President of the European Group for Blood and Marrow Transplantation.

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 chemotherapy or radiation treatments 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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