Gentium S.p.A.
Form 6-K
November 19, 2008

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 November, 2008.

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 which provides an update on the Phase 3 treatment trial of Defibrotide for Severe Veno-Occlusive Disease 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.

Exhibit	**Description**
1	Press release, dated November 19, 2008.

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: November 19, 2008

INDEX TO EXHIBITS

Exhibit	**Description**
1	Press release, dated November 19, 2008.

Exhibit 1

PRESS RELEASE

Gentium Provides an Update on the Phase 3 Treatment Trial of Defibrotide for Severe Veno-Occlusive Disease

Results from Data Safety Monitoring Board Review
Assessment of Historical Control Arm by Independent Medical Review Committee

VILLA GUARDIA (Como), Italy, November 19, 2008 (BUSINESS WIRE) -- Gentium S.p.A. (NASDAQ: GENT) announced today interim results from an independent Data Safety Monitoring Board (DSMB) review of the Company's Phase 3 treatment trial of Defibrotide for Severe Veno-Occlusive Disease (VOD). The DSMB reported that in order for the study to be 80% powered to detect a p-value of .01, the necessary statistical hurdle under the current protocol for FDA approval, the sample size should be increased to 160 patients in the treatment arm and 80 patients in the historical control arm. The DSMB also noted that a sample size of 102 patients in the treatment arm and 51 patients in the historical control arm would be needed to achieve a p-value of .05. Furthermore, the DSMB indicated that the data presented thus far do not raise any safety concerns and did not recommend that the trial be stopped for futility.

Gentium also announced today the preliminary results of an independent Medical Review Committee's (MRC) selection of historical control patients in the trial. Following the results of a prior DSMB meeting announced on June 5, 2008 in which the DSMB expressed concerns regarding the practical application of the criteria used to enroll historical control patients, the MRC met to re-review the criteria and eligibility of all historical control cases. After reviewing the available information, the MRC was only able to conclude that 32 out of the 86 patients initially included in the historical control arm definitively met the eligibility criteria and had a confirmed diagnosis of severe VOD. There are currently 102 patients enrolled in the treatment arm of the study.

"While we were hoping to be in a better position following the reviews of the DSMB and MRC concerning our Phase 3 trial, we remain committed to the development of Defibrotide," said Dr. Laura Ferro, CEO of Gentium. "We do not intend to enroll the additional number of patients required to achieve a p-value of .01; however, we are evaluating the possible enrollment of additional patients in the historical control arm, which would allow us greater potential to achieve a p-value that could be used as supportive data in favor of an approval of Defibrotide."

"We are currently in discussions with our corporate partner regarding the future development of Defibrotide and are also evaluating our strategic options for the Company," said Gary Gemignani, CFO of Gentium. "We continue to make progress in our European Pediatric Phase 2/3 prevention trial. To date, 345 out of 360 patients have been enrolled and we look forward to reporting results in 2009."

About VOD

Veno-occlusive disease (VOD) is a potentially life-threatening condition, which typically occurs as an important complication of stem cell transplantation (SCT). Certain high-dose chemo-radiation therapy regimens used as part of SCT can damage the cells lining the 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 with multiple organ failure). 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 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 Form 20-F filed with the Securities and Exchange Commission under the caption “Risk Factors.”

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