Gentium S.p.A.
Form 6-K
August 19, 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 August, 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): o

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): o

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 results from its Phase III treatment 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 August 19, 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: August 19, 2009

INDEX TO EXHIBITS

Exhibit	Description
1	Press release, dated August 19, 2009.

Exhibit 1

PRESS RELEASE

Gentium Reports Top Line Results from the Phase III Treatment Trial of
Defibrotide for Severe Veno-Occlusive Disease

VILLA GUARDIA (Como), Italy, August 19, 2009 (BUSINESS WIRE) -- Gentium S.p.A. (NASDAQ: GENT) today announced top-line results from a historically controlled, multicenter, open label, Phase III trial designed to evaluate the safety and efficacy of 25 mg/kg/day of Defibrotide for the treatment of severe veno-occlusive disease (sVOD) in hematopoietic stem cell transplant (SCT) patients. The results demonstrate strong trends in favor of the Defibrotide-treated patients for complete response and survival, but did not reach the protocol-specified levels of significance for the primary and secondary endpoints at 100 days. With regard to safety, adverse events were well balanced between the historical control and treatment arms. The Company plans to present full results from this trial at the American Society of Hematology Conference in New Orleans, LA, December 5-8, 2009.

The primary endpoint of the trial was complete response at 100 days following SCT and utilized historical controls (patients who in the past received the best therapy and supportive care available at the time, but not Defibrotide) as a comparator. Secondary endpoints included survival rate at 100 days and six months post SCT. The historical control database was generated through a sequential, retrospective medical chart review, with final selection of the control group performed by an independent medical review committee (MRC). The MRC remained blinded to patient outcome data throughout the duration of the trial. Per the study protocol, data in the primary efficacy analysis were adjusted by quintiles of propensity score based on four stratification variables (allogeneic/autologous SCT, adult/pediatric, one/two+ SCTs, and ventilator/dialysis dependence) to aid in obtaining balance between the treatment and historical control arms in a non-randomized trial. As a stand-alone trial utilizing a historical control arm, the study protocol specified a p-value of less than or equal to 0.01 for the primary endpoint to achieve statistical significance, while the secondary endpoints required a p-value of less than or equal to 0.05, the more common threshold for statistical significance.

123 patients with symptoms consistent with VOD were identified and then reviewed for eligibility in the historical control arm by the MRC, with 32 cases selected as having an unequivocal diagnosis of sVOD (graft versus host disease was ruled out) and met all protocol-required entry criteria. 102 patients were enrolled in the Defibrotide treatment group and baseline characteristics were balanced between the two arms.

For the primary efficacy analysis on an intent to treat basis, 24% of patients in the Defibrotide arm compared to 9% of patients in the historical control arm achieved complete response at 100 days (p-value = 0.015). For the secondary efficacy analysis on an intent to treat basis, 38% of patients in the Defibrotide arm compared to 25% of patients in the historical control arm demonstrated survival at 100 days (p-value = 0.051). Thus, while the primary endpoint achieved a p-value less than 0.05 and the secondary endpoint showed a strong trend towards statistical significance, neither reached the level of significance required in the protocol for proof of efficacy with a single study.

“I am encouraged by the results of this trial, especially given the extremely sick patient population that was enrolled,” said Dr. Paul Richardson, Clinical Director of the Dana-Farber Cancer Institute’s Jerome Lipper Multiple Myeloma Center and principal investigator of the trial. “The data generated from this trial confirms the activity of Defibrotide seen in earlier studies, and supports the benefit of Defibrotide for the treatment of sVOD in improving complete response rates and survival, as well as its potential in less advanced stages of the disease.”

“Given the outcome of the data safety monitoring board’s interim review announced in November of last year, we expected that reaching the required statistical threshold for a single trial would be difficult,” said Gary Gemignani, Executive Vice-President and Chief Financial Officer. “We are pleased that the data are compelling and believe the results place us in a strong position to continue discussions with the FDA and others regarding next steps toward a regulatory filing. Additionally, we plan on announcing final results from our randomized, pediatric prevention study in the upcoming weeks.”

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., located in Como, Italy, is a biopharmaceutical company focused on the research, discovery and development of drugs 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 and Fast Track Designation by the U.S. FDA to treat Severe VOD and Orphan Medicinal Product Designation by the European Commission both to treat and to prevent VOD.

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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