Gentium S.p.A.
Form 6-K
June 05, 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 June, 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 releases are attached hereto as Exhibits 1 and 2 and incorporated by reference herein in their entirety. This report and the exhibits 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 June 5, 2008.
2	Press release, dated June 5, 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: Chief Financial Officer

Date: June 5, 2008

INDEX TO EXHIBITS

Exhibit	Description
1	Press release, dated June 5, 2008.
2	Press release, dated June 5, 2008.

Exhibit 1

PRESS RELEASE

FOR IMMEDIATE RELEASE

Company Contact:
Gary G. Gemignani
Chief Financial Officer
212-332-1666
ggemignani@gentium.com

Investor Relations Contacts:
U.S.
The Trout Group
Laura Okpala, 617-583-1306
lokpala@troutgroup.com

Marcy Strickler, 646-378-2927
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Gentium Announces Update from Data Safety Monitoring Board Review of the Phase III Treatment Trial of Defibrotide for Severe Veno-Occlusive Disease

VILLA GUARDIA (Como), Italy, June 5, 2008 (BUSINESS WIRE) -- Gentium S.p.A (NASDAQ: GENT) announced today that an independent Data Safety Monitoring Board (DSMB) has provided an update on the planned interim analysis for the Company's Phase III, historically controlled, multi-center study of Defibrotide for the treatment of severe veno-occlusive disease in hematopoietic stem cell transplant patients. The DSMB meeting was conducted after data relating to the primary and secondary efficacy endpoints (achievement of complete response and survival by day 100, respectively) had been collected on 46 patients in the Defibrotide treatment arm and 86 patients in the historical control group.

In January, the Company previously announced the initiation of the DSMB’s interim analysis. At that stage, the DSMB concluded that there were no safety concerns and that the prospective treatment and historical control arms appeared to be well-balanced as to the stratification factors in the protocol. In order to complete the interim analysis, the DSMB requested that the Company provide supplemental trial data. The Company has since provided the DSMB with additional information.

In its latest report, the DSMB reconfirmed its findings regarding safety and balance of the trial arms based on the data presented to date. However, the DSMB did have concerns and questions about the data assembled and, accordingly, the DSMB "did not regard it proper to make a recommendation concerning the further conduct of the study at this time." The DSMB did make one recommendation that the Company obtains confirmation of "the criteria used to select historical controls and the practical application of those criteria to guarantee that the historical patients match the patients in the prospective study arm." The Company is evaluating the comments made by the DSMB and will respond accordingly.

At present, the Company has already enrolled more patients than required under the protocol, with 86 patients in the historical control group and 101 patients in the treatment arm, and does not anticipate enrolling further patients in the trial.

"Due to the life threatening nature of severe VOD and the absence of any effective alternative therapy, it was necessary to use a historical control arm in the trial rather than a placebo control arm in order to meet ethical standards and attract the participation from key clinical transplant centers. Collecting high quality data from historical patient records is by its nature a challenging process," said Dr. Laura Ferro, Chairman and Chief Executive Officer of Gentium. "We will continue treatment and follow up of the last patients enrolled in our treatment arm and expect to have top-line data from this trial during Q4 2008."

Gentium will host a conference call today, June 5, 2008 at 5:00 p.m. (ET) to discuss this press release and the other press release issued today by the Company regarding clinical trial matters for Defibrotide.

Dial-in Information:
US/Canada Toll-Free callers: 877-407-8031
US/Canada Toll or International Toll callers: 201-689-8031

Live audio of the conference call will be simultaneously broadcast over the internet via a webcast. To access the live webcast, log on to the Gentium's corporate website at http://www.gentium.com.

A replay of the call also will be available until 11:59 PM US Eastern Time on June 12, 2008. To access the replay, dial 1-877-660-6853 from the US or Canada (toll-free) or 1-201-612-7415 from other locations, and enter account #286 and conference ID#287992. Additionally, an archived replay of the conference web cast will be available on the Gentium website for 30 days.

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.”

Source: Gentium

Exhibit 2

PRESS RELEASE

FOR IMMEDIATE RELEASE

Company Contact:
Gary G. Gemignani
Chief Financial Officer
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Gentium Announces Completion of Data Safety Monitoring Board Review and Continuation of the Phase II/III European Pediatric Prevention Trial of Defibrotide

VILLA GUARDIA (Como), Italy, June 5, 2008 (BUSINESS WIRE) -- Gentium S.p.A (NASDAQ: GENT) announced today that an independent Data Safety Monitoring Board (DSMB) has completed the planned interim analysis for the Company's Phase II/III multi-center, open label, randomized trial in Europe to evaluate prophylactic use of Defibrotide in pediatric patients undergoing stem cell transplantation at high risk for hepatic veno-occlusive disease (VOD). The interim analysis was performed subsequent to the enrollment of 240 patients.

The DSMB concluded that there are no significant safety concerns, the prophylactic treatment arm (Defibrotide) and the control arm (no drug) are well balanced, and there is no evidence of clinical futility in the trial. Further, the DSMB indicated that the results to date were satisfactory and recommended that the trial continue to accrue patients. The DSMB also recommended increasing total patient enrollment to 180 patients per arm from 135 patients per arm to achieve a more statistically significant benefit of Defibrotide over the control. There are no further planned interim analyses for this trial.

“The DSMB’s recommendation is very encouraging and we await the final outcome of this key trial with great interest,” said Dr. Dietger Niederwieser, Department of Hematology and Oncology, University of Leipzig and President of the European Group for Blood and Marrow Transplantation, the co-sponsor of the trial. “I am hopeful that the results will be consistent with the promising data from earlier published studies in prophylaxis and support the efficacy of Defibrotide in preventing VOD.”

“We are pleased with the DSMB’s review and are following their recommendation to accrue 180 patients in each arm of the study,” said Dr. Laura Ferro, Chairman and Chief Executive Officer of Gentium. “There are currently 276 patients enrolled in the trial and we plan to complete enrollment around year-end and report top-line results during the first half of 2009. We have also been advised recently by EMEA that our planned filing in this indication could be eligible for an accelerated review, which could reduce the review cycle from seven months to five.”

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Source: Gentium