Gentium S.p.A.
Form 6-K
May 04, 2012

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 May, 2012.

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 x 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 x

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 its receipt of the Day 180 List of Outstanding Issues from the European Medicines Agency's Committee for Medicinal Products for Human Use in connection with its Marketing Authorization Application for Defibrotide 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, File No. 333-141198, and File No. 333-174575, and on Forms S-8: File No. 333-137534 and File No. 333-146534.

Exhibit	Description
1	Press release dated May 4, 2012.

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/ Salvatore Calabrese
Name: Salvatore Calabrese
Title: Chief Financial Officer and Senior VP, Finance
Date: May 4, 2012.

INDEX TO EXHIBITS

Exhibit	Description
1	Press Release dated May 4, 2012.

Exhibit 1

PRESS RELEASE

Gentium Receives Day 180

List of Outstanding Issues from the CHMP for Defibrotide MAA

VILLA GUARDIA, Italy, May 4, 2012, (GlobeNewswire), Gentium S.p.A. (Nasdaq: GENT) (the "Company") announced today that it has received the Day 180 List of Outstanding Issues (the “LoOIs”) from the European Medicines Agency’s (“EMA”) Committee for Medicinal Products for Human Use (“CHMP”) in connection with the Company’s Marketing Authorization Application (MAA) for Defibrotide to treat and prevent hepatic veno-occlusive disease (VOD) in adults and children undergoing haematopoietic stem cell transplantation therapy.

The Company plans to submit its responses to the LoOIs within 60 days, in line with the regulatory timetable. If the written responses satisfy the issues raised in the LoOIs and the CHMP does not require further explanation or clarification, a recommendation on the approval of Defibrotide could be made as early as the third quarter of 2012. If oral explanations are required, a clock stop may be imposed. The CHMP is expected to reach its final opinion no later than Day 210, based on the EMA review process timeline.

“We believe we have made good progress in working with the E.U. Rapporteurs to address the issues raised in their Day 120 List of Questions” said Dr. Khalid Islam, Chairman & Chief Executive Officer of the Company. “We plan to continue working closely with the EMA towards the approval of Defibrotide and to resolve any remaining open issues.”

About the EMA Review Process:

EMA guidelines permit companies in receipt of LoOIs to respond within one month. More information can be obtained from the EMA website www.ema.europa.eu.

About VOD

Veno-occlusive disease (VOD) is a potentially life-threatening condition, which typically occurs as a significant complication of stem cell transplantation. Certain high-dose conditioning regimens used as part of stem cell transplantation can damage the lining cells of hepatic blood vessels and result in VOD, a blockage of the small veins in 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). Stem cell transplantation is a frequently used treatment modality following high-dose chemotherapy and radiation therapy for hematologic cancers and other conditions in both adults and children. At present there is no approved agent for the treatment or prevention of VOD in the United States or the European Union.

About Gentium

Gentium S.p.A., located in Como, Italy, is a biopharmaceutical company focused on the development and manufacture of drugs to treat and prevent a variety of diseases and conditions, including vascular diseases 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 (FDA) and Orphan Medicinal Product Designation by the European Medicines Agency, both to treat and to prevent VOD, as well as Fast Track Designation by the U.S. FDA to treat 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," "predict," "potential" 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 with *respect to the possibility of any future regulatory approval, 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 20-F filed with the Securities and Exchange Commission under the caption "Risk Factors."*

SOURCE: Gentium S.p.A.

Gentium S.p.A.

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