Gentium S.p.A.
Form 6-K
April 01, 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 April, 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-_____.

Description of events affecting the Registrant are set forth in the Registrant's press release, dated April 1, 2008, attached hereto as Exhibit Number 1 and incorporated by reference herein in its entirety.

Exhibit	**Description**
1	Press release, dated April 1, 2008.

INDEX TO EXHIBITS

Exhibit	Description
1	Press release, dated April 1, 2008.

Exhibit 1

PRESS RELEASE

FOR IMMEDIATE RELEASE

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Gentium Reports 2007 Financial Results; Provides Financial and Clinical Update

Villa Guardia (Como), Italy (April 1, 2008) - Gentium S.p.A. (NASDAQ: GENT) (the "Company") today reported financial results for the quarter and year ended December 31, 2007. Highlights of 2007, as well as developments since year end include:

· Continued progress was made in the ongoing Phase III clinical trial in the U.S., which is evaluating the Company's lead product, Defibrotide, as a potential treatment for patients with Veno-Occlusive Disease ("VOD") with multiple organ failure ("Severe VOD"). This trial has now enrolled 85 patients to date in its prospective arm and 86 patients in the historical control arm. The DSMB initiated its interim analysis in January 2008 and concluded that there are no safety concerns and that stratification between the prospective treatment and historical control arms appears to be balanced. The DSMB requested that certain trial data be clarified and supplemented. Once the DSMB has concluded its review, the Company plans to make a further announcement.

· In December 2007, the Company filed an amendment to the protocol for its Phase III clinical trial of Defibrotide to treat Severe VOD. The trial previously had a primary endpoint of survival at 100 days after stem cell transplantation, and a secondary endpoint of complete response. The amendment reversed those endpoints, making complete response the primary endpoint and survival a major secondary endpoint. The Company has already been collecting data on both endpoints, and therefore the change will not delay or require additional enrollment of patients. Complete response was the primary endpoint for the Phase II clinical trial of Defibrotide to treat Severe VOD that was completed in 2005. The Company made this change after discussions with the FDA and believes that complete response better demonstrates the efficacy of Defibrotide and therefore is a more appropriate endpoint for this trial.

- In Q4 2007, the Company instituted an expanded access program for Defibrotide to treat Severe VOD. Under an expanded access program, the FDA allows early access to investigational drugs that are being developed to treat serious diseases for which there is no satisfactory alternative therapy. The Company will collect additional safety data from the expanded access program patients to support its planned New Drug Application for the use of Defibrotide to treat Severe VOD.

- Progress has also been made with the Company's Phase II/III clinical trial in Europe, which is evaluating Defibrotide for the prevention of VOD in children. The trial has enrolled 251 of an expected 270 patients and the interim analysis is anticipated to begin during 2008.

- The Company has recently received a scientific advice letter from the European Medicine's Agency (EMEA) regarding the protocol of ongoing and future trials for Defibrotide in the prevention of VOD in adult and pediatric patients. The process of obtaining a scientific advice letter allows companies to establish a dialogue with the EMEA and receive advice regarding the trials and data necessary to demonstrate the quality, safety and efficacy of drugs in development. Scientific advice received from the EMEA is applicable across the European Union.

- In October 2007, in connection with its current License and Supply Agreement with Sigma-Tau Pharmaceuticals, Inc., the Company signed a letter agreement with Sigma-Tau whereby Sigma-Tau agreed to reimburse the Company for 50% of certain costs of the Company's Phase III clinical trial of Defibrotide to treat Severe VOD.

- In October 2007, the Company exercised a right to require the exercise of warrants issued in connection with its 2005 PIPE offering. The Company realized gross proceeds of approximately $5.384 million from these exercises, bringing cash and cash equivalents to €25.96 million at year end.

- Investigators from the European Phase I/II clinical trial of Defibrotide to treat advanced and refractory multiple myeloma patients presented the final results at the American Society of Hematology Annual Meeting in December 2007.

- Investigators are presenting abstracts and publications featuring Defibrotide at the European Group Bone and Marrow Transplantation (EBMT) Annual Congress, taking place in Florence, Italy from March 30 through April 2, 2008.

Clinical Highlights and Outlook

Commenting on Gentium's progress during the quarter, Laura Ferro, M.D., Chairman and Chief Executive Officer said, "We are very pleased with the progress of our Defibrotide development program during 2007 and look ahead into 2008 as a landmark year for the Company. During the coming quarters, we will remain focused on advancing Defibrotide in the VOD indications through the completion of the interim analysis of the Company's Phase III clinical trial of Defibrotide to treat Severe VOD and expect results for this trial later in the year. We also expect to progress enrollment in the Phase II/III clinical of Defibrotide to prevent VOD in children in Europe, and plan to initiate a second Phase II/III clinical trial of Defibrotide to prevent VOD in adults and children in the United States and adults in Europe. We are particularly encouraged by the Scientific Advice letter received recently from the EMEA, as this will provide us with valuable guidance as we advance our Defibrotide development program in Europe."

Financial Highlights

The Company reports its financial condition and operating results using U.S. Generally Accepted Accounting Principles (GAAP). The Company's financial statements are prepared using the Euro as its functional currency. On December 31, 2007, €1.00 = $ 1.4603.

For the fourth quarter ended December 31, 2007 compared with the prior-year's fourth quarter:

- Total revenues were €2.23 million, compared with €1.32 million
- Operating costs and expenses were €7.84 million, compared with €5.14 million
- Research and development expenses, which are included in operating costs and expenses, were €4.36 million, compared with €2.56 million
- Operating loss was €5.61 million, compared with €3.82 million
- Interest income, net, was €0.4 million, compared with €0.2 million
- Pre-tax loss was €6.25 million, compared with €4.15 million
- Net loss was €6.25 million, compared with €4.15 million
- Basic and diluted net loss per share was €0.42 compared with €0.35 per share

For the year ended December 31, 2007 compared with prior-year:

- Total revenues were €7.61 million, compared with €4.32 million
- Operating costs and expenses were €40.58 million, compared with €18.55 million. Operating costs and expenses include a €13.74 million write-down of the assets the Company acquired from Crinos in 2007. Excluding such write-down, operating costs and expenses would have been €26.84 million.
- Research and development expenses, which are included in operating costs and expenses, were €15.09 million, compared with €8.93 million
- Operating loss was €32.96 million, compared with €14.23 million. Excluding the write-down of the assets acquired from Crinos, operating loss would have been €19.22 million.
- Interest income, net, was €1.36 million, compared with €0.49 million
- Pre-tax loss was €35.60 million, compared with €14.37 million
- Net loss was €35.60 million, compared with €14.37 million. Excluding the write-down of the assets acquired from Crinos, net loss would have been €21.86 million.

- Basic and diluted net loss per share was €2.52 compared with €1.33 per share. Excluding the write-down of the assets acquired from Crinos, basic and diluted net loss per share would have been €1.55 per share.
- Cash used in operating activities was €10.17 million, compared with €12.15 million
- Cash and cash equivalents amounted to €25.96 million as of December 31, 2007

Operating Results and Trends

The fluctuation in product sales revenues for the three- and twelve- month periods compared with the prior-year periods is primarily due to varying demand for our products from our customers. Total product sales revenues for year ended December 31, 2007 increased by €1.02 million, or 25%, compared with the same period in 2006. Sales to affiliates represented 53% and 92% of the total product sales in the twelve months ended December 31, 2007 and 2006, respectively. Sales to third parties increased to €2.39 million mainly due to higher demand for our active pharmaceutical ingredient sulglicotide in the South Korean market and due to our acquisition of the Italian marketing authorization and trademarks regarding Defibrotide, which allowed the Company to sell Defibrotide directly to distributors instead of indirectly through Sirton.

Other revenues were €2.51 million for the twelve-month period ended December 31, 2007, compared to €0.25 million in 2006. The increase is mainly attributable to the reimbursement of certain costs incurred in the Company's Phase III clinical trial of Defibrotide to treat Severe VOD under a cost-sharing agreement with Sigma-Tau Inc. Reimbursement payments from Sigma-Tau are now being accounted for as revenue as opposed to a reduction of R&D expense as they were previously classified in the third quarter 2007.

Cost of goods sold was €4.0 million for the twelve-month period ended December 31, 2007, compared to €3.01 million in 2006. In 2007, we wrote down €206 thousand of inventory to adjust product cost to its net realizable value. Cost of goods sold as percentage of product sales was 78.2% in 2006 and 75.9% in 2006.

Research and development spending increased during the three- and twelve- month periods in 2007 compared with 2006, primarily due to the costs associated with the Company’s Phase III trial in the U.S. for the treatment of Severe VOD. Growth in headcount and outside services to support increased activity in our clinical trials, including clinical product production costs, contract research organization expenses, regulatory activities and stock-based compensation expense also contributed to increased research and development expenses.

The Company had 80 employees as of December 31, 2007, compared with 65 as of December 31, 2006. Other general and administrative expense increases were primarily the result of increased headcount and facilities related expenses, costs incurred on Sarbanes-Oxley implementation, general corporate expenses and stock-based compensation expense.

In 2007, the Company recorded an impairment charge of €13.74 million regarding the Italian marketing authorization and related trademarks for Defibrotide. The charge reflects the adjustment of the assets acquired to the net present value of the estimated future cash-flow from the sales of the oral formulation of Defibrotide in the indication currently approved in the Italian market.

Interest income, net, increased to €1.36 million in the twelve-month period ending December 31, 2007 over comparable period in 2006. Interest income amounted to €1.67 million and €0.71 million in the twelve months ended December 31, 2007 and 2006, respectively, an increase of €0.96 million. The increase is due to a higher amount of invested funds as a result of a private placement completed in February 2007. Interest expense totaled €0.31 million and €0.22 million in the twelve months ended December 31, 2007 and 2006, respectively.

The Company ended the fourth quarter of 2007 with €25.96 million in cash and cash equivalents, compared with cash and cash equivalents of €10.21 million as of December 31, 2006.

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," "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 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 for the year ended December 31, 2007 under the caption "Risk Factors."

Source: Gentium

(Tables to follow)

GENTIUM S.p.A.
Balance Sheets
(in thousands, except share data)

	As of December 31,	
	2006	**2007**
ASSETS		
Cash and cash equivalents	€ 10,205	€ 25,964
Restricted cash	4,000	-
Accounts receivables	227	805
Accounts receivables from related parties	3,478	4,149
Inventories, net	1,499	1,510
Prepaid expenses and other current assets	1,427	4,844
Total Current Assets	20,836	37,272
Property, manufacturing facility and equipment, at cost	18,974	20,590
Less: Accumulated depreciation	9,550	9,046
Property, manufacturing facility and equipment, net	9,424	11,544
Intangible assets, net of amortization	556	2,592
Marketable securities	560	525
Other non-current assets	4,017	26
Total Assets	**€ 35,393**	**€ 51,959**
LIABILITIES AND SHAREHOLDERS' EQUITY		
Accounts payable	€ 4,734	€ 9,583
Accounts payable to Crinos	-	4,000
Accounts payable to related parties	454	2,095
Accrued expenses and other current liabilities	1,198	1,223
Deferred revenue	140	-
Current portion of capital lease obligation	43	107
Current maturities of long-term debt	724	1,262
Total Current Liabilities	7,293	18,270
Long-term debt, net of current maturities	5,683	4,421
Capital lease obligation	48	223
Termination indemnities	682	686
Total Liabilities	13,706	23,600
Share capital (par value: €1.00; 15,111,292 and 18,454,292 shares authorized at December 31, 2006 and 2007, respectively; 11,773,613 and 14,946,317 shares issued at December 31, 2006 and 2007, respectively)	11,774	14,946
Additional paid in capital	49,476	88,618
Accumulated other comprehensive income (loss)	32	(2)
Accumulated deficit	(39,595)	(75,203)
Total Shareholde		