

Gentium S.p.A.  
Form 6-K  
April 13, 2006

**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, 2006.

Commission File Number 000-51341

Gentium S.p.A.

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(Translation of registrant's name into English)

Piazza XX Settembre 2, 22079 Villa Guardia (Como), Italy

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(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  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):

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Description of events affecting the Registrant are set forth in the Registrant's press release, dated April 13, 2006, attached hereto as Exhibit Number 1 and incorporated by reference herein in its entirety.

**Exhibit Description**

1 Press release, dated April 13, 2006.

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**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.**

Date: April 13, 2006

By: /s/ Cary Grossman

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Cary Grossman  
Title: Executive Vice President and Chief Financial  
Officer

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**INDEX TO EXHIBITS**

**Exhibit Description**

1 Press release, dated April 13, 2006.

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**PRESS RELEASE**

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**FOR IMMEDIATE RELEASE**

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**Gentium Reports 2005 Financial Results; Provides Financial and Clinical Update**

**Villa Guardia (Como), Italy (April 13, 2006) - Gentium S.p.A. (AMEX: GNT)** (the “Company”) today reported financial results for the quarter and year ended December 31, 2005. Highlights of the fourth quarter of 2005 and recent weeks as of the first week in April 2006 include:

- Phase III trial in U.S. for treatment of Venous Occlusive Disease (VOD) with Multiple Organ Failure (Severe VOD): The Institutional Review Board (IRB) of the Dana-Farber/Harvard Cancer Center of Boston, Mass., which is also the IRB for Dana-Farber Cancer Institute, Massachusetts General Hospital, Beth Israel Deaconess Medical Center and The Children’s Hospital, has given its approval to participate in the trial. All four of these institutions are expected to participate in the trial. Work to compile historical control data will begin immediately, and the first patients are expected to be treated by early May, 2006;
- Phase II/III clinical trials in Europe for the prevention of VOD in children: 30 centers have IRB approval, 11 centers are open for patient admission, 15 patients are enrolled;

- Independent Phase I/II study of Defibrotide to treat advanced and refractory Multiple Myeloma (MM) patients: 3 centers have IRB approval and are open for patient enrollment, 5 patients are enrolled;
- Phase II/III clinical trials in Europe for the prevention of VOD in adults: Investigators meeting scheduled for early Q2, trial expected to start Q2;
- The Company has recently engaged the first of several medical monitors, this one being based in the U.S., to act as a liaison with investigators, IRB's and CRO's; and,
- The Company has recently updated its investor presentation, which can found on its web site at [www.gentium.it](http://www.gentium.it), including updated estimates on the market size and pricing for VOD based on research by Medical Marketing Economics, LLC.

### **Clinical Highlights and Outlook**

Commenting on Gentium's clinical progress during the quarter, Laura Ferro, M.D., Chairman and Chief Executive Officer said, "We are excited to be beginning our Phase III trial for the treatment of Severe VOD with Defibrotide. We note that Defibrotide addresses a life threatening disease for which there are currently no treatment options."

### **Financial Highlights**

The Company reports its financial condition and operating results using U.S. Generally Accepted Accounting Principles (GAAP). The Company's manufacturing facility was closed from February through August 2004 for a major upgrade; therefore, comparison of 2005 operating results with 2004 results may not be meaningful. The Company's financial statements are prepared using the Euro (€), its functional currency. On December 31, 2005, €1.00 = \$1.18.

For the fourth quarter ended December 31, 2005 compared with the prior-year's fourth quarter:

- Total revenues were €1.44 million, compared to €1.23 million
  - Operating costs and expenses were €3.59 million, compared to €2.97 million
  - Operating loss was €2.15 million, compared to €1.73 million
  - Interest (income) expense, net, was (€0.05) million, compared to €2.16 million
  - Pre-tax loss was € 1.92 million, compared to €4.00 million
  - Net loss was €2.51 million, compared to €4.00 million
  - Basic and diluted net loss per share was €0.27, compared to €0.80
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For the year ended December 31, 2005 compared with the prior year:

- Total revenues were €3.64 million, compared to €3.70 million
- Operating costs and expenses were €11.02 million, compared to €8.45 million
- Operating loss was €7.38 million, compared to €4.75 million
- Interest expense, net, was €4.15 million, compared to €2.20 million
- Pre-tax loss was €11.78 million, compared to €7.0 million
- Net loss was €12.43 million, compared to €7.03 million
- Basic and diluted net loss per share was €1.79 compared to €1.41
- Cash used in operating activities was €8.7 million, compared to €4.1 million
- Cash and cash equivalents amounted to €12.8 million as of December 31, 2005.

The Company's Italian GAAP financial statements will be presented for shareholder approval at the Company's upcoming annual ordinary shareholders' meeting.

Dr. Ferro commented, "We are pleased to report that the €8.7 million of cash used in operations and our capital expenditures for the year of €1.3 million are in-line with expectations we set at the time of our IPO. In 2006 we will have a full year of public company related expenses as well as a full year of our increased staffing. In addition, the number of clinical trials we are running will result in a substantial increase in research and development spending in 2006. These increased expenses will be partially offset by the significant decrease in interest expense since our Series A notes were all converted or redeemed in 2005. However, we still expect a significantly larger loss in 2006 than in 2005. Currently, we expect to use approximately €15 million of cash in operating activities and approximately € 1.7 million for capital expenditures."

### **Operating Results and Trends**

As noted above, the Company's manufacturing facility was closed from February through August 2004 for a major upgrade; therefore, comparisons of 2005 operating results with 2004 results may not be meaningful.

The fluctuation in product sales revenue for the three- and twelve-month periods compared with the prior year is primarily the result of changes in demand by our principal customer, Sirton, who experienced a slight increase in demand from its principal customer, Crinos, and for the twelve-month period due to a decrease in sales in 2005 compared to 2004 from a customer in Korea. Total revenues for the year ended December 31, 2005 were less than in 2004, in spite of an increase in product sales during the twelve-month period, because of milestone payments earned in 2004.

Cost of goods sold increased during the three and twelve month periods compared with the prior year period. The increase is mainly due to a revision of estimated lives on the Company's manufacturing facilities and equipment which resulted in lower depreciation expense in the fourth quarter offset by a inventory write-off and an increase in quality control costs. Additionally, in the fourth quarter of 2004 the Company expensed some batch costs associated with the start-up of the revamped manufacturing plant.

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Research and development spending increased during the three and twelve-month periods in 2005 compared to 2004 primarily due to the costs for the Company's Phase II trial in the U.S. for the treatment of Severe VOD and preparations for the Company's Phase III trial. Additionally during the fourth quarter of 2005 the Company incurred expenses in connection with the preparation of its Phase II/III trial for prevention of VOD in children.

The Company increased its employee headcount from 35 at the end of 2004 to 55 at December 31, 2005. Other general and administrative expense increases were primarily the result of building corporate infrastructure, public company expenses and an increase in internally provided administrative services to replace administrative services previously provided by affiliates, which began to occur in the second quarter. These factors also account for the decrease in charges from affiliates during the periods.

In the fourth quarter of 2004 and the first quarter of 2005, the Company issued approximately \$8.0 million of convertible notes. As a result, interest expense increased substantially in 2005. In conjunction with the Company's initial public offering, \$2.9 million of these notes were converted into common equity and the balance was repaid in June and July of 2005. The Company incurred interest expense of €4.3 million, which included non-cash interest expense of €3.8 million from amortization of the issue discount and issue costs on these notes during the year ended December 31, 2005.

In conclusion, Dr. Ferro said, "the coming year promises to be an important one for Gentium as we continue to move our product candidates forward toward future potential commercial use."

#### **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.

#### **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 Prospectus filed with the Securities and Exchange Commission under Rule 424(b)(5) under the caption "Risk Factors."*

(Tables to follow)

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**GENTIUM S.p.A.****Balance Sheets**

(in thousands, except share data)

	<b>As of December 31, 2004</b>	<b>As of December 31, 2005</b>
<b>ASSETS</b>		
Cash and cash equivalents	€ 2,461	€ 12,785
Receivables	9	8
Receivables from related parties	1,490	1,867
Inventories	886	1,628
Prepaid expenses and other current assets	1,617	918
<b>Total Current Assets</b>	<b>6,463</b>	<b>17,206</b>
Property, manufacturing facility and equipment, at cost	16,152	17,456
Less: Accumulated depreciation	(7,609)	(8,825)
Property, manufacturing facility and equipment, net	8,543	8,631
Intangible assets, net of amortization	243	267
Other non-current assets	660	9
<b>Total Assets.</b>	<b>€ 15,909</b>	<b>€ 26,113</b>
<b>LIABILITIES AND SHAREHOLDERS' EQUITY (DEFICIT)</b>		
Bank overdraft	€ 100	€ -
Accounts payable	3,927	2,644
Payables to related parties	1,498	542
Short-term bank borrowings	2,690	-
Accrued expenses and other current liabilities	432	1,063
Current maturities of long-term debt	2,781	916
Convertible notes payable, net of discount	2,082	-
Deferred income	564	283
<b>Total Current Liabilities</b>	<b>14,074</b>	<b>5,448</b>
Long-term debt, net of current maturities	3,361	2,485
Termination indemnities	548	706
<b>Total Liabilities</b>	<b>17,983</b>	<b>8,639</b>
Share capital (par value: €1.00; 13,300,100 and 12,690,321 shares authorized, 5,000,000 and 9,610,630 shares issued at December 31, 2004 and 2005, respectively)	5,000	9,611
Additional paid in capital	5,834	33,197
Accumulated deficit	(12,908)	(25,334)
<b>Total Shareholders' Equity (Deficit)</b>	<b>(2,074)</b>	<b>17,494</b>
<b>Total Liabilities and Shareholders' Equity</b>	<b>€ 15,909</b>	<b>€ 26,113</b>

**GENTIUM S.p.A.**  
**Statements of Operations**  
**(Unaudited, in thousands, except per share data)**

	For the Three Months Ended		For the Year Ended December 31,	
	December 31,		2004	
	2004	2005	2004	2005
<b>Revenues:</b>				
Sales to affiliates	€ 1,151	€ 1,360	€ 2,870	€ 3,260
Third party product sales	-	6	243	101
Total product sales	1,151	1,366	3,113	3,361
Other income and revenues	82	70	583	280
Total Revenues	1,233	1,436	3,696	3,641
<b>Operating costs and expenses:</b>				
Cost of goods sold	1,126	1,199	2,579	2,920
Charges from affiliates	750	266	1,665	1,047
Research and development	461	1,512	2,922	4,629
General and administrative	592	571	1,194	2,309
Depreciation and amortization	37	40	89	118
	2,966	3,588	8,449	11,023
Operating loss	(1,733)	(2,152)	(4,753)	(7,382)
<b>Foreign currency exchange gain (loss), net</b>				
	(98)	186	(55)	(249)
Interest income (expense), net	(2,165)	49	(2,192)	(4,148)
Pre-tax loss	(3,996)	(1,917)	(7,000)	(11,779)
<b>Income tax expense (benefit):</b>				
Current	(113)	-	65	-
Deferred	65	(598)	(37)	(646)
	(48)	(598)	28	(646)
Net loss	€ (4,004)	€ (2,515)	€ (7,028)	€ (12,425)
<b>Net loss per share:</b>				
Basic and diluted net loss per share	€ (0.80)	€ (0.27)	€ (1.41)	€ (1.79)
Weighted average shares used to compute basic net loss per share	5,000,000	9,391,449	5,000,000	6,933,104
Weighted average shares used to compute diluted net loss per share	5,000,000	9,391,449	5,000,000	6,933,104

**GENTIUM S.p.A.**  
**Statements of Cash Flows**  
**(Unaudited, in thousands)**

**For the Three Months Ended**  
**December 31**

**For the Year Ended December 31**

**2004**                      **2005**                      **2004**                      **2005**

<b>Cash Flows From Operating Activities:</b>								
<b>Net loss</b>	€	(4,004)	€	(2,515)	€	(7,028)	€	(12,425)
Adjustments to reconcile net income to net cash provided by (used in) operating activities:								
Unrealized foreign exchange loss		313		-		313		575
Depreciation and amortization		386		208		743		1,315
Non cash interest expense		1,972		-		1,972		3,837
Deferred income taxes (benefit)		(9)		598		(37)		646
Write down of inventory to net realizable value		-		161		50		291
Stock based compensation		379		216		379		579
Changes in operating assets and liabilities:								
Accounts receivable		(1,098)		(966)		981		(376)
Inventories		423		(106)		534		(1,033)
Prepaid expenses and other current assets		(659)		(206)		(1,784)		(149)
Accounts payable and accrued expenses		102		696		359		(1,793)
Deferred income		(152)		(67)		(353)		(281)
Termination indemnities		24		13		19		158
Income taxes payable		(123)		-		(304)		-
<b>Net cash used in operating activities</b>		<b>(2,446)</b>		<b>(1,968)</b>		<b>(4,119)</b>		<b>(8,657)</b>
<b>Cash Flows From Investing Activities:</b>								
Capital expenditures		(823)		(239)		(5,178)		(1,263)
Intangible expenditures		(19)		(63)		(163)		(124)
<b>Net cash used in investing activities</b>		<b>(842)</b>		<b>(302)</b>		<b>(5,341)</b>		<b>(1,387)</b>
<b>Cash Flows From Financing Activities:</b>								
Capital contribution		-		-		-		3,900
Proceeds from long-term debt		2,350		-		5,205		-
Repayments of long-term debt		(67)		(111)		(374)		(581)
Proceeds from Series A convertible Notes		4,477		-		4,477		1,459
Repayment of Series A convertible Notes		-		-		-		(4,221)
Proceeds (repayment) of affiliate's loan		(800)		-		2,200		(2,200)
Proceeds (repayment) from bank overdrafts and short term borrowings		(779)		-		390		(2,790)
Proceeds from initial public offering and private placement, net of offering expenses		-		8,154		-		24,801

<b>Net cash provided by financing activities</b>	<b>5,181</b>	<b>8,043</b>	<b>11,898</b>	<b>20,368</b>
Increase in cash and cash equivalents	1,893	5,773	2,438	10,324
Cash and cash equivalents, beginning of period	568	7,012	23	2,461
<b>Cash and cash equivalents, end of period</b>	€ 2,461	€ 12,785	€ 2,461	€ 12,785

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