Gentium S.p.A.
Form 6-K
December 06, 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 November, 2006.

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 set forth in the Registrant's press release, dated November 30, 2006, attached hereto as Exhibit Number 1, and the Registrant's quarterly report for the quarterly period ended September 30, 2006, attached hereto as Exhibit 2, are each incorporated by reference herein in its entirety.

Exhibit	**Description**
1	Press release, dated November 30, 2006.
2	Quarterly report for the quarterly period ended September 30, 2006.

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: December 5, 2006

INDEX TO EXHIBITS

Exhibit	Description
1	Press release, dated November 30, 2006.
2	Quarterly report for the quarterly period ended September 30, 2006.

PRESS RELEASE

FOR IMMEDIATE RELEASE

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Gentium Reports Third Quarter Financial Results and Clinical Update

Villa Guardia (Como), Italy (November 30, 2006) - Gentium S.p.A. (NASDAQ: GENT) (the "Company") today reported financial results for the three and nine months ended September 30, 2006. Highlights of the third quarter of 2006 and recent weeks include:

- Publication of an independent study showing Defibrotide could prevent Veno-Occlusive Disease (VOD) associated with Infantile Osteopetrosis;
- Publication of two independent studies of Defibrotide to treat VOD in children;
- Presentation of data at the 16th European Congress of Immunology demonstrating that Defibrotide modulates immune functions of endothelial cells and its impact for transplantation and cancer therapy;
- Progress with the Phase III clinical trial in the U.S. with Defibrotide for the treatment of severe Veno-Occlusive Disease with Multiple Organ Failure (Severe VOD): this study is expected to be conducted at approximately 32 clinical centers; 18 centers are open for enrollment and nine patients have been enrolled;
- Progress with the Phase II/III clinical trial in Europe with Defibrotide for the prevention of VOD in children: 30 centers have IRB approval and 25 centers are open for patient enrollment; 56 patients have been enrolled;

- Progress with an investigator-sponsored Phase I/II study with Defibrotide for the treatment of advanced and refractory Multiple Myeloma: four centers are open; 24 patients have been enrolled, which completes enrollment for the Phase I segment of the study;
- Acceptance of 10 abstracts on Defibrotide for presentation at the Annual Meeting of the American Society of Hematology (ASH) in Orlando, Fla., December 9-12;
- Scheduling of two presentations on Defibrotide for the EuroTIDES, 7th Annual Conference on Oligonucleotides in Hamburg, Germany, December 4-5.

Clinical Highlights and Outlook

Commenting on Gentium's clinical progress, Laura Ferro, M.D., Chairman and Chief Executive Officer, said, "During the third quarter we continued to make substantial progress in advancing our clinical programs and in building our infrastructure to support these efforts. To date, our U.S. Phase III trial with Defibrotide for the treatment of VOD has 18 sites opened for enrollment, an increase of 12 sites, and nine patients are being treated. We continue to add centers and expect to have nearly all 32 clinical sites open for patient enrollment by year end. As each center needs to treat only 2-3 patients to reach accrual, we are confident that this trial will remain on track to reach full enrollment by third quarter 2007. In order to ensure the necessary support and expertise in managing this trial, we have engaged a leading contract research organization (CRO) to oversee implementation and to provide data management services.

"Our European Phase II/III trial for the prevention of VOD in pediatric patients is progressing, and we are in the process of determining our regulatory strategy for developing a combined U.S. and European Phase II/III trial for the prevention of VOD in adults," she added. "We believe a combined trial offers a better registration strategy for this indication that could save the Company time and money in bringing this potentially life-saving drug to market."

Dr. Ferro continued, "We were extremely pleased that the independent study of Defibrotide to treat multiple myeloma completed its Phase I trial, and is moving forward into the Phase II segment of the study. Data from this Phase I study will be among 10 presentations on Defibrotide at the annual ASH conference next month. These presentations, along with the two Defibrotide presentations at the EuroTides conference in December, underscore the potential therapeutic value of Defibrotide and testify to the hard work and dedication of our collaborating clinicians and Gentium's medical and scientific team," noted Dr. Ferro.

Financial Highlights

Gentium 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 September 30, 2006, €1.00 = $1.27.

For the third quarter ended September 30, 2006 compared with the prior-year's third quarter:

- Total revenues were €0.90 million, compared with €0.37 million
- Operating costs and expenses were €5.06 million, compared with €2.69 million
- Research and development expenses, which are included in operating costs and expenses, were €2.76 million, compared with €1.18 million
- Operating loss was €4.16 million, compared with €2.32 million
- Interest income (expense), net, was €0.2 million, compared with €0.05 million
- Pre-tax loss was €3.88 million, compared with €2.18 million
- Net loss was €3.88 million, compared with €2.20 million
- Net loss per share was €0.33, compared with €0.28

For the nine months ended September 30, 2006 compared with the comparable prior-year period:

- Total revenues were €3.00 million, compared with €2.21 million
- Operating costs and expenses were €13.42 million, compared with €7.44 million
- Research and development expenses, which are included in operating costs and expenses, were €6.36 million, compared with €3.12 million
- Operating loss was €10.41 million, compared with €5.23 million
- Interest income (expense), net, was €0.34 million, compared with (€4.20) million
- Pre-tax loss was €10.22 million, compared with €9.86 million
- Net loss was €10.22 million, compared with €9.91 million
- Net loss per share was €0.97, compared with €1.62
- Cash used in operating activities was €7.70 million, compared with €6.69 million
- Cash and cash equivalents were €21.55 million as of September 30, 2006

Dr. Ferro commented, "As we advance our clinical development programs, we expect proportionate increases in R&D and clinical and regulatory expenses to contribute to increasing losses for the balance of this year and next year. Our general and administrative expenses have increased substantially, with much of the higher expense a result of the costs of being a public company and the initiation of our Phase III VOD treatment clinical trial and Phase II/III VOD prevention trials. Our 2006 results also reflect a significant decline in interest expense due to the repayment and redemption of our Series A notes in June 2005 in conjunction with our initial public offering."

Operating Results and Trends

The fluctuation in total product sales for the three- and nine-month periods compared with the prior year is primarily the result of higher sales volume of the Company's active pharmaceutical ingredients defibrotide, urokinase and sulglicotide to our principal customer and affiliate, Sirton. Also contributing to the increase was an increase in sales and increases in third-party product sales, mainly due to the sales of sulglicotide to a Korean customer. Total product sales for the nine-month period ended September 30, 2006 increased by €0.81 million, or 41%, compared with the same period in 2005.

Cost of goods sold was €2.44 million for the nine-month period ended September 30, 2006, which included a €182 thousand inventory reserve attributable to slow-moving inventory, compared with cost of goods sold of €1.72 million for the comparable period in 2005. The increase in cost of goods sold was mainly due to increased sales volume in the nine-month period of 2006 compared to the same period in 2005.

Research and development spending increased during the three- and nine-month periods in 2006 compared with 2005, primarily due to the costs associated with the Company's Phase III trial in the U.S. for the treatment of Severe VOD, the Company's Phase II/III trial for prevention of VOD in children and preparations for the Phase II/III trial for the

prevention of VOD in adults. Growth in headcount and outside services to support increased activity in our clinical trials, including clinical product production costs, contract research organization expenses and stock-based compensation expense also contributed to increased research and development expenses.

The Company had 69 employees as of September 30, 2006, compared with 53 as of September 30, 2005. Other general and administrative expense increases were primarily the result of building corporate infrastructure, legal and public company expenses, an increase in internally provided administrative services to replace administrative services previously provided by affiliates and stock-based compensation expense. The increase in internally provided services accounted for the decrease in charges from affiliates between the periods. G&A expense includes a one-time charge of €104 thousand per the absorption of the fixed portion of our production costs, not otherwise included in cost of good sold, due to the partial shut-down of the manufacturing facility in July and August for the replacement of two reactors.

Interest income (expense), net, changed primarily due to the repayment and conversion of the Company's Series A senior convertible notes in June 2005, and the higher level of invested funds compared with the prior year. For the nine months ended September 30, 2005, interest expense on the Series A notes was €4.2 million, including non-cash interest expense of €3.8 million from the amortization of the issue discount and debt issue cost. These notes were converted or redeemed in June 2005. Additionally, interest income increased by €416 thousand from €56 thousand in the period ended September 30, 2005 to €472 thousand in the comparable 2006 period, as the result of a higher level of invested funds.

The Company ended the third quarter of 2006 with €21.55 million in cash and cash equivalents, compared with cash and cash equivalents of €12.79 million as of December 31, 2005.

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, 2005 under the caption "Risk Factors."

Source: Gentium

(Tables to follow)

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2005	**2006**	**2005**	**2006**
Revenues:				
Sales to affiliates	€ 304	€ 799	€ 1,900	€ 2,652
Third party product sales	-	45	95	155
Total product sales	304	844	1,995	2,807
Royalties	-	7	-	14
Other income and revenues	70	51	210	183
Total Revenues	374	902	2,205	3,004
Operating costs and expenses:				
Cost of goods sold	426	828	1,721	2,444
Research and development	1,184	2,760	3,117	6,362
Charges from affiliates	200	251	781	632
General and administrative	844	1,138	1,738	3,787
Depreciation and amortization	35	87	78	190
	2,689	5,064	7,435	13,415
Operating loss	(2,315)	(4,162)	(5,230)	(10,411)
Foreign currency exchange gain (loss), net	85	86	(435)	(144)
Interest income (expense), net	48	198	(4,197)	338
Pre-tax loss	(2,182)	(3,878)	(9,862)	(10,217)
Income tax expense:				
Deferred	16	-	48	-
Net loss	€ (2,198)	€ (3,878)	€ (9,910)	€ (10,217)
Shares used in computing net loss per share, basic and diluted	7,977,983	11,666,013	6,104,650	10,510,315
Net loss per share:				
Basic and diluted net loss per share	€ (0.28)	€ (0.33)	€ (1.62)	€ (0.97)

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

	As of December 31, 2005	As of September 30, 2006 (Unaudited)
ASSETS		
Cash and cash equivalents	€ 12,785	€ 21,548
Receivables from third parties	8	75
Receivables from related parties	1,867	2,262
Inventories, net	1,628	1,443
Prepaid expenses and other current assets	918	1,142
Total Current Assets ……	17,206	26,470
Property, manufacturing facility and equipment, at cost	17,456	18,926
Less: Accumulated depreciation	8,825	9,440
Property, manufacturing facility and equipment, net	8,631	9,486
Intangible assets, net of amortization	267	566
Marketable securities	-	592
Other non-current assets	9	12
Total Assets	€ 26,113	€ 37,126
LIABILITIES AND SHAREHOLDERS' EQUITY		
Accounts payable	€ 2,644	€ 4,485
Payables to related parties	542	340
Accrued expenses and other current liabilities	1,063	953
Current maturities of long-term debt	916	261
Current portion of capital lease obligation	-	50
Deferred income	283	262
Total Current Liabilities	5,448	6,351
Long-term debt, net of current maturities	2,485	5,273
Capital lease obligation	-	80
Termination indemnities	706	648
Total Liabilities	8,639	12,352
Share capital (par value: €1.00; 12,690,321 and 15,100,292 shares authorized at December 31, 2005 and September 30, 2006, respectively; 9,610,630 and 11,666,013 shares issued at December 31, 2005 and September 30, 2006, respectively	9,611	11,666
Additional paid in capital	33,090	48,489
Other comprehensive income	-	63
Accumulated deficit	(25,227)	(35,444)
Total Shareholders' Equity	17,474	24,774
Total Liabilities and Shareholders' Equity	€ 26,113	€ 37,126

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

	For the Nine Months Ended September 30,	
	2005	**2006**
Cash Flows From Operating Activities:		
Net loss	€ (9,910)	€ (10,217)
Adjustments to reconcile net income to net cash provided by (used in) operating activities:		
Unrealized foreign exchange loss	575	149
Depreciation and amortization	1,107	747
(Gains) Loss on fixed assets disposal	-	(23)
Non cash interest expense	3,837	-
Amortization of debt financing cost	-	3
Inventory write off	130	182
Stock based compensation	363	665
Deferred income tax benefit	48	-
Changes in operating assets and liabilities:		
Accounts receivable	590	(462)
Inventories	(927)	3
Prepaid expenses and other current assets	56	(192)
Accounts payable and accrued expenses	(2,489)	1,522
Deferred income	(214)	(21)
Termination indemnities	145	(58)
Net cash used in operating activities	**(6,689)**	**(7,702)**
Cash Flows From Investing Activities:		
Capital expenditures	(1,024)	(1,311)
Intangible expenditures	(61)	(431)
Proceeds from sale of asset	-	23
Investment in marketable securities	-	(530)
Net cash used in investing activities	**(1,085)**	**(2,249)**
Cash Flows From Financing Activities:		
Proceeds from warrant exercises	-	884
Proceeds from long term debt, net	-	4,563
Capital contribution	3,900	-
Repayments of long-term debt	(470)	(599)
Repayment of Series A convertible Notes	(2,762)	-
Early extinguishment of long term debt	-	(1,868)
Principal payment of capital lease obligations		(20)
Repayment of affiliate's loan	(2,200)	-
Repayment of bank overdrafts and short term borrowings	(2,790)	-
Proceeds from equity offering, net	16,647	15,896
Net cash provided by financing activities	**12,325**	**18,856**
Effect of foreign exchange rate		(142)

Increase in cash and cash equivalents		4,551		8,905
Cash and cash equivalents, beginning of period		2,461		12,785
Cash and cash equivalents, end of period	€	7,012	€	21,548

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Exhibit 2

GENTIUM S.p.A.

QUARTERLY REPORT

For the quarterly period ended September 30, 2006

GENTIUM S.p.A.
QUARTERLY REPORT, SEPTEMBER 30, 2006
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CAUTIONARY NOTICE REGARDING FORWARD-LOOKING STATEMENTS

Certain matters discussed in this report, including matters discussed under the caption "Operating and Financial Review and Prospects," may constitute forward-looking statements for purposes of the Securities Act of 1933, as amended, or the Securities Act, and the Securities Exchange Act of 1934, as amended, or the Exchange Act, and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from the future results, performance or achievements expressed or implied by such forward-looking statements. The words "expect," "anticipate," "intend," "plan," "believe," "seek," "estimate," and expressions are intended to identify such forward-looking statements. Our actual results may differ materially from the results anticipated in these forward-looking statements due to a variety of factors, including, without limitation, those discussed under the captions "Operating and Financial Review and Prospects," and elsewhere in this report, as well as factors which may be identified from time to time in our other filings with the Securities and Exchange Commission, or in the documents where such forward-looking statements appear. All written or oral forward-looking statements attributable to us are expressly qualified in their entirety by these cautionary statements. Such forward-looking statements include, but are not limited to, those relating to:

• our expectations for increases or decreases in expenses;
• our expectations for the development, manufacturing, and approval of defibrotide or any other products we may acquire or license;
• our expectations for incurring additional capital expenditures to expand our manufacturing and research and development capabilities;
• our expectations for becoming profitable on a sustained basis;
• our expectations or ability to enter into marketing and other partnership agreements;
• our expectations or ability to enter into product acquisition and licensing transactions;
• our estimates of the sufficiency of our existing cash and cash equivalents and investments to finance our operating and capital requirements;
• our expected losses; and
• our expectations for future capital requirements.

The forward-looking statements contained in this report reflect our views and assumptions only as of the date of this report. Except as required by law, we assume no responsibility for updating any forward-looking statements.

PART 1. FINANCIAL INFORMATION
GENTIUM S.p.A.
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(in thousands, except share data)

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