Gentium S.p.A.
Form 6-K
April 01, 2010

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, 2010.

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 release regarding its fourth quarter and 2009 financial results 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 and File No. 333-141198 and on Forms S-8: File No. 333-137534 and File No. 333-146534.

Exhibit	Description
1	Press release, dated March 31, 2010.

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/ Khalid Islam
Name: Khalid Islam
Title: Chief Executive Officer

Date: April 1, 2010

INDEX TO EXHIBITS

Exhibit	Description
1	Press release, dated March 31, 2010.

Exhibit 1

PRESS RELEASE

Gentium Announces Fourth Quarter And Year End 2009 Results

- Revenues increase by 78% compared with 2008
- 60% decrease in cash burn for operating activities
- Cash flow positive in Q4/2009 and expects to remain positive for 2010
- Expected revenue in 2010 to be in the range of $20 – $25 million

VILLA GUARDIA (COMO), Italy, March 31, 2010 (BUSINESS WIRE) -- Gentium S.p.A. (NASDAQ: GENT) today reported financial results for the quarter and year ended December 31, 2009. 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, 2009, EUR 1.00 = $1.4332.

“Total product sales rose 78 percent in 2009 resulting from the successful implementation of the named-patient program in Europe and cost recovery program in the U.S.,” stated Gary Gemignani, Executive Vice President and Chief Financial Officer of Gentium S.p.A. “For the fourth quarter 2009, we reported positive operating cash flow. We expect revenues in 2010 to be in the range of $20 – $25 million and cash flow to be positive in 2010.”

“We are pleased that Defibrotide was selected as one of the highlights at the American Society of Hematology (ASH) conference and more recently at European Bone Marrow Transplant (EBMT) conference stated Dr. Khalid Islam, Chief Executive Officer of Gentium S.p.A." “We are currently completing certain preclinical and clinical studies requested by regulatory authorities and we anticipate filing for regulatory approval in the U.S. and Europe by the end of second quarter 2011. With the $7 million upfront payment in connection with our recent expansion of the license and cost sharing agreements with Sigma-Tau and substantial revenues being generated by the named-patient program, we have significantly strengthened our balance sheet.”

Financial Highlights

For the fourth quarter ended December 31, 2009 compared to the prior year's fourth quarter:

- Total revenues were EUR 4.05 million, compared with EUR 1.04 million
- Operating costs and expenses were EUR 4.08 million, compared with EUR 4.88 million
- Research and development expenses, which are included in operating costs and expenses, were EUR 0.86 million, compared with EUR 1.70 million
- Operating loss was EUR 0.04 million, compared with EUR 3.84 million
- Interest income/(expense), net, was EUR (0.01) million, compared with EUR 0.08 million.
- Pre-tax loss was EUR 0.05 million, compared with EUR 3.45 million
- Net loss was EUR 0.05 million, compared with EUR 3.45 million
- Basic and diluted net loss per share was EUR 0.003, compared with EUR 0.23 per share

For the year ended December 31, 2009 compared with the prior year:

- Total revenues were EUR 10.17 million, compared with EUR 7.44 million
- Operating costs and expenses were EUR 14.75 million, compared with EUR 27.77 million, which included a write-down of assets of EUR 3.40 million
- Research and development expenses, which are included in operating costs and expenses, were EUR 3.51 million, compared with EUR 9.57 million
- Operating loss was EUR 4.58 million, compared with EUR 20.33 million, which included a write-down of EUR 3.4 million in assets
- Interest income/(expense), net, was EUR (0.11) million, compared with EUR 0.25 million
- Net loss was EUR 4.53 million, compared with EUR 19.90 million, which included a write-down of EUR 3.4 million in assets
- Basic and diluted net loss per share was EUR 0.30 compared with EUR 1.33 per share
- Cash used in operating activities was EUR 5.16 million, compared with EUR 12.78 million
- Cash and cash equivalents amounted to EUR 1.39 million as of December 31, 2009

Recent Company Highlights

Gentium announced that it amended its existing License and Supply and Cost Sharing Agreements with Sigma-Tau Pharmaceuticals, Inc., to include a license for the prevention indication of Defibrotide in the Americas. Gentium will continue to own exclusive rights to Defibrotide in Europe and the rest of the world.

In March 2010, Gentium announced management and corporate restructuring changes resulting from a strategic decision to consolidate the Company's resources and operations within Italy. Mr. Gary Gemignani, Executive Vice-President and Chief Financial Officer is leaving the Company, effective today, but will provide transitional services through a consulting agreement.

The Company presented an abstract containing the final results for the Phase II/III pediatric prevention trial of Defibrotide for the prevention of VOD at the annual meetings of ASH and EBMT. In the intent to treat analysis Defibrotide demonstrated a 40% reduction in the incidence of VOD within 30 days after SCT, the primary endpoint of the study. In addition, a pre-specified analysis showed that the incidence and severity of acute graft versus host disease by day 100 in allogeneic SCT recipients was significantly reduced from 63% for the control arm to 45% for the prophylaxis arm.

Operating Results

Product sales were EUR 9.70 million for 2009 compared to EUR 5.44 million for 2008, an increase of EUR 4.26 million or 78%. The increase was primarily due to the launch in April 2009 of the named-patient program and the launch in September 2009 of the cost recovery program in the U.S. Named-patient program and cost recovery program sales, net, for the year ended December 31, 2009 amounted to EUR 4.90 million, which are net of EUR 0.79 million of service fees.

The active pharmaceutical ingredient, or API, revenues slightly decreased from EUR 4.79 million in 2008 to EUR 4.6 million, reflecting the decrease in volume of suglicotide offset by a price increase and higher sales volume of urokinase.

Sales to a related party, Sirton, for the year ended December 31, 2009 and 2008 represented 2% and 12% of the total product sales, respectively. The decrease in sales to a related party was primarily due to the fact that in the second quarter of 2009 the Company terminated the supply agreement with Sirton and entered into direct sales agreements with Sirton’s customers in order to mitigate the risk associated with Sirton’s poor financial condition and terminated the supply agreement with Sirton.

Other revenues were EUR 0.47 million for 2009 compared to EUR 1.99 million for 2008. The decrease versus the prior year is primarily attributable to a decrease in activities that were reimbursed from Sigma Tau under our cost sharing agreement, offset by a milestone payment from Sigma-Tau of $0.35 million for completion of the phase III clinical trial.

Cost of goods sold was EUR 4.0 million for 2009 compared to EUR 5.60 million in 2008. Cost of goods sold as a percentage of product sales, net, was 41% in 2009 compared to 103% in 2008. The percentage decrease is primarily due to higher margins on Defibrotide sold through the named-patient program and price increases in the API business. The Company fully expensed the cost of inventory in the prior year. Additionally, the higher percentage of cost of goods sold in 2008 was primarily due to the fact that product sales to a related party, Sirton, were not recognized in the amount of EUR 1.08 million due to Sirton's poor financial condition and concerns over the ability to collect such receivables.

The Company incurred research and development expenses of EUR 3.51 million in 2009 compared to EUR 9.57 million for 2008. Research and development expenses in 2009 and 2008 are net of EUR 0.85 and EUR 0.79 million, respectively, of government grants in the form of a tax credit. The decrease from the prior year is mainly due to completion of clinical trials.

General and administrative expenses were EUR 6.04 million in 2009 compared to EUR 7.67 million in 2008. In 2008, we established a reserve for doubtful in accounts in the amount of EUR 1.78 million, of which EUR 0.68 was released in 2009. Additionally, the Company had lower payroll costs due to the temporary layoffs under a special public fund used in Italy under the "Cassa Integrazione Guadagni" program and decrease in stock based compensation expenses.

In 2008, the Company recorded an impairment of EUR 3.40 million. Write-down of assets include the write-down of acquired trademarks, marketing authorizations, inventory, and the Company's patents. The trademarks and marketing authorizations have been written-down due to the expiration and non-renewal by the Company of the distribution agreement with Crinos S.p.A., which raised concern about the ability to recover the cost of these assets.

Interest income/(expense), net amounted to EUR (0.11) million and EUR 0.26 million in 2009 and 2008, respectively. The decrease in interest income/(expense), net is a result of a lower amounts of invested funds in 2009 compared to the prior period as well as a decrease in interest rates.

Net loss was EUR 4.53 million in 2009 compared to EUR 19.90 million in 2008. The difference was primarily due to increased net sales and higher margins associated with the named-patient and cost recovery programs and a decrease in development activities related to the treatment and prevention studies.

The Company ended the fourth quarter of 2009 with EUR 1.39 million in cash and cash equivalents, compared with cash and cash equivalents of EUR 11.49 million as of December 31, 2008. Absent the need to fund any additional clinical trials, management believes that the Company's cash and cash equivalents, including the upfront payment received from Sigma-Tau Pharmaceuticals, Inc. in connection with the expansion of the license agreement for Defibrotide in the Americas, together with revenues generated from its named-patient and cost recovery programs, will be sufficient to meet the Company's obligations for at least the next twelve months.

About VOD

Veno-occlusive disease is a potentially life-threatening condition, which typically occurs as an important complication of stem cell transplantation. Certain high-dose conditioning regimens used as part of SCT can damage the lining cells of 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). 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 US or the EU.

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. FDA and Orphan Medicinal Product Designation by the European Commission both to treat and to prevent VOD and 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.
Salvatore Calabrese, +39 031-385-287
Senior Vice President, Finance
scalabrese@gentium.it

or

The Trout Group
Marcy Nanus, +1 646-378-2927
mnanus@troutgroup.com

(Tables to follow)

GENTIUM S.p.A.

Balance Sheets

(in thousands, except share data)

	As of December 31,			
	2008		2009	
ASSETS				
Cash and cash equivalents	EUR	11,491	EUR	1,392
Accounts receivable		625		3,213
Accounts receivable from related parties, net		816		501
Inventories, net		907		1,551
Prepaid expenses and other current assets		1,682		1,431
Total Current Assets		15,521		8,088
Property, manufacturing facility and equipment, at cost		21,019		21,262
Less: Accumulated depreciation		10,268		11,545
Property, manufacturing facility and equipment, net		10,751		9,717
Intangible assets, net of amortization		95		76
Available for sale securities		510		263
Other non-current assets		24		23
Total Assets	EUR	26,901	EUR	18,167
LIABILITIES AND SHAREHOLDERS' EQUITY				
Accounts payable	EUR	5,823	EUR	4,379
Accounts payable to Crinos		4,000		-
Accounts payables to related parties		325		286
Accrued expenses and other current liabilities		810		1,907
Current portion of capital lease obligations		65		67
Current maturities of long-term debt		1,346		408
Total Current Liabilities		12,369		7,047
Long-term debt, net of current maturities		3,268		3,098
Capital lease obligation		158		91
Termination indemnities		655		601
Total Liabilities		16,450		10,837
Share capital (EUR 1.00 and no par value as of December 31, 2008 and 2009, respectively; 18,454,292 and 18,302,617 shares authorized as of December 31, 2008 and 2009, respectively; 14,956,317 shares issued and outstanding at December 31, 2008 and 2009)		14,956		106,962
Additional paid in capital		90,619		-
Accumulated other comprehensive loss		(17)		-
Accumulated deficit		(95,107)		(99,632)
Total Shareholders' Equity		10,451		7,330
Total Liabilities and Shareholders’ Equity	EUR	26,901	EUR	18,167

GENTIUM S.p.A.

Statements of Operations

(Unaudited, in thousands, except per share data)

	For the Three Months Ended December 31,		For the Year Ended December 31,	
	2008	2009	2008	2009
Revenues:				
Product sales to related party	EUR 96	EUR -	EUR 651	EUR 195
Product sales to third parties	944	3,714	4,792	9,507
Total product sales	1,040	3,714	5,443	9,702
Other revenues	-	61	25	129
Other revenues from related party	-	274	1,970	337
Total Revenues	1,040	4,049	7,438	10,168
Operating costs and expenses:				
Cost of goods sold	1,279	872	5,596	4,002
Research and development	1,696	855	9,569	3,512
General and administrative	1,308	2,078	7,668	6,036
Depreciation and amortization	153	210	998	916
Charges from related parties	93	69	537	279
Write-down of acquired assets	351	-	3,403	-
	4,880	4,084	27,771	14,745
Operating loss	(3,840)	(35)	(20,333)	(4,577)
Foreign currency exchange gain (loss), net	310	(1)	173	162
Interest income (expense), net	83	(12)	256	(110)
Loss before income tax expenses	(3,447)	(48)	(19,904)	(4,525)
Income tax expense	-	-	-	-
Net loss	EUR (3,447)	EUR (48)	EUR (19,904)	EUR (4,525)
Shares used in computing net loss per share, basic and diluted	14,956,317	EUR 14,956,317	EUR 14,956,263	EUR 14,956,317
Net loss per share:				
Basic and diluted net loss per share	EUR (0.23)	EUR (0.003)	EUR (1.33)	EUR (0.30)

GENTIUM S.p.A.
Statement of Cash Flows
(in thousands)

	For the Three Months Ended December 31,		For the Year Ended December 31,	
	2008	2009	2008	2009
Cash Flows From Operating Activities:				
Net loss	EUR (3,447)	EUR (48)	EUR (19,904)	EUR (4,525)
Adjustments to reconcile net income to net cash provided by (used in) operating activities:				
Write-down of intangible assets	(396)	-	2,175	-
Write-down of inventory	1,228	19	1,228	19
Unrealized foreign exchange loss/(gain)	(11)	25	(337)	(223)
Depreciation and amortization	335	330	1,699	1,300
Stock based compensation	379	329	1,973	1,386
Loss on fixed asset disposal	-	2	7	2
Allowance/(release) for doubtful accounts	16	(271)	1,783	(684)
Loss on marketable securities	-	2	-	2
Changes in operating assets and liabilities:				
Accounts receivable	(363)	(1,009)	(1,001)	(2,603)
Inventories	(105)	(651)	(625)	(663)
Prepaid expenses and other current and noncurrent assets	960	507	568	524
Accounts payable and accrued expenses	216	1,416	(310)	363
Termination indemnities	(3)	-	(31)	(54)
Net cash provided by (used in) operating activities	(1,191)	651	(12,775)	(5,156)
Cash Flows From Investing Activities				
Capital expenditures	(5)	-	(437)	(245)
Intangible assets expenditures	-	-	(154)	(3)
Sales of marketable securities	-	262	-	262
Acquisition of Crinos Assets	-	-	-	(4,000)
Net cash provided by (used in) investing activities	(5)	262	(591)	(3,986)
Cash Flows From Financing Activities:				
Proceeds from long-term debt	147	-	-	-
Proceeds from warrant and stock option exercises, net	-	-	38	-
Repayment of long-term debt	(485)	(205)	(1,216)	(1,108)
Repayment of short term borrowings	-	-	(279)	-
Principal payment of capital lease obligation	(21)	(17)	(107)	(65)
Proceeds from long term debt	-	-	147	-
Net cash used in financing activities	(359)	(222)	(1,417)	(1,173)
Increase/(Decrease) in cash and cash equivalents	(1,555)	691	(14,783)	(10,315)
Effect of exchange rate on cash and cash equivalents	(53)	(3)	310	216

Cash and cash equivalents, beginning of period		13,099		704		25,964		11,491
Cash and cash equivalents, end of period	EUR	11,491	EUR	1,392	EUR	11,491	EUR	1,392