Gentium S.p.A.
Form 6-K
September 17, 2009

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 September, 2009.

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 a clinical update and its quarterly financial results for the period ended June 30, 2009 is attached hereto as Exhibit 1 and incorporated by reference herein in its entirety. This report and the exhibit attached hereto 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 September 17, 2009.

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: September 17, 2009

INDEX TO EXHIBITS

Exhibit	Description
1	Press release, dated September 17, 2009.

Exhibit 1

PRESS RELEASE

Gentium Reports Second Quarter Financial Results;
Provides Financial and Clinical Update

VILLA GUARDIA (Como), Italy, September 17, 2009 (BUSINESS WIRE) -- Gentium S.p.A. (NASDAQ: GENT) today reported financial results for the second quarter ended June 30, 2009.

Financial Highlights

Gentium S.p.A., or 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 June 30, 2009, €1.00 = $1.4134.

For the second quarter ended June 30, 2009 compared with the prior year's second quarter:

- Total revenues were €2.61 million, compared with €1.86 million. The increase was primarily attributable to the launch of the named-patient program for Defibrotide throughout the European and Asia-Pacific markets by IDIS Limited.
- Operating costs and expenses were €3.02 million, compared with €6.50 million.
- Research and development expenses, which are included in operating costs and expenses, were €0.36 million, compared with €1.76 million. Research and development expenses for second quarter 2009 and 2008 are net of €0.71 million and €1.14 million, respectively, of government grants in the form of a tax credit.
- Operating loss was €0.41 million, compared with €4.63 million.
- Net loss was €0.49 million, compared with €4.53 million.
- Basic and diluted net loss per share was €0.03 compared with €0.30 per share.

For the six months ended June 30, 2009 compared with the comparable prior-year period:

- Total revenues were €3.62 million, compared with €4.55 million.
- Operating costs and expenses were €7.17 million, compared with €14.03 million. Research and development expenses, which are included in operating costs and expenses, were €1.81 million, compared with €5.37 million. Research and development expenses for second quarter 2009 and 2008 are net of €0.71 million and €1.14 million, respectively, of government grants in the form of a tax credit.
- Operating loss was €3.55 million, compared with €9.48 million.
- Interest income (expense), net, was (€0.07) million, compared with €0.16 million.
- Net loss was €3.45 million, compared with €10.61 million.
- Basic and diluted net loss per share was €0.23 compared with €0.71 per share.

Cash and cash equivalents were €1.36 million compared with €11.49 million as of December 31, 2008. In March 2009, the Company made a final installment payment of €4.0 million to Crinos S.p.A related to the acquisition of marketing authorizations and trademarks for Prociclide and Noravid. Excluding the payment to Crinos, net cash used in operating activities for the six-month-period ended June 30, 2009, would have amounted to €5.31 compared to €8.65 million for the same period of 2008. The reduction in net cash used in operating activities between periods reflects a decrease in spending in R&D activities coupled with increased cash flows from the named-patient program. The Company also utilized Cassa Integrazione, a mechanism available to companies in Italy to temporarily lay off employees with the Italian government funding a portion of the costs of the employees during the layoff-period.

The Company anticipates that its current cash will meet its operating requirements through January of 2010. However, in order for the Company to continue as a going concern beyond this point, the Company will likely need to obtain capital from external sources.

Clinical Update

The Company has submitted abstracts for the American Society of Hematology Conference in New Orleans, LA, December 5-8, 2009. Data was submitted for the Phase III historically controlled trial for the treatment of severe VOD and for the Phase II/III European prevention of VOD trial in pediatric stem cell patients. The results from both studies are encouraging and demonstrate strong trends in favor of the Defibrotide-treated patients in both the treatment of severe VOD and the prevention of VOD. In the treatment study, 24% of patients in the Defibrotide arm compared to 9% of patients in the historical control arm achieved complete response at 100 days (p-value = 0.015) while 38% of patients in the Defibrotide arm compared to 25% of patients in the historical control arm demonstrated survival at 100 days (p-value = 0.051). In the prevention study, a 40% reduction in incidence of VOD within 30 days after stem cell transplantation (SCT) was observed in the prophylaxis arm (Intent to Treat p-value = 0.054, Per Protocol p-value = 0.037). The Company plans to announce further data from the pediatric prevention study in the upcoming weeks.

"Gentium continues to move forward with the development of Defibrotide to treat and prevent VOD, a disease for which there is currently no other viable treatment option," stated Gary Gemignani, Executive Vice President and Chief Financial Officer of Gentium S.p.A. "We believe that the results from our Phase II/III European pediatric prevention trial and the Phase III historically controlled treatment trial in the U.S. demonstrate the activity of Defibrotide that has consistently been seen in numerous investigator-sponsored studies. We have been able to extend our cash reserves through the margins generated from the named-patient program and our cost reduction measures. We look forward to working collaboratively with the Company’s incoming Board of Directors as we pursue strategic financing options to provide the capital necessary to further the development of Defibrotide."

Operating Results

Total Product sales, net for the six-month-period ended June 30, 2009 were €3.53 million compared to €2.91 million for the same period in 2008, an increase of €0.62 million. The increase was primarily due to the launch in April 2009 of Defibrotide via a named-patient program administered by IDIS Limited throughout the European and Asia-Pacific markets. Named-patient program gross sales for the period from April 21, 2009 through June 30, 2009 amounted to €1.21 million or €1.04 million net of service payments to IDIS. Through August 31, 2009, the Company has generated €2.3 million in gross revenue, or €2.0 million in net revenue, through the named-patient program.

Sales to a related party, Sirton, for the six-month-period ended June 30, 2009 and 2008 represented 6% and 12% of the total product sales, respectively. The decrease in sales to Sirton is primarily due to the fact that the Company entered into direct sales agreements with Sirton's customers in order to mitigate the risk associated with Sirton's poor financial condition.

Sales to third parties decreased to €2.30 million for the six-month-period ended June 30, 2009 compared to €2.36 million for the same period in 2008. The six-month-period ended June 30, 2009 did not include sales of Prociclide and Noravid (both forms of Defibrotide) due to the discontinuation of the sale of these products in the Italian market, which in the prior year period accounted for revenues of €1.13 million.

Other revenues, primarily cost-sharing revenues from Sigma-Tau, were €0.01 million for the six-month-period ended June 30, 2009, compared to €1.64 million for the same period in 2008. Fluctuation versus the prior period is primarily due to timing on the recognition of reimbursement of certain costs incurred for the Company's Phase III clinical trial of Defibrotide to treat Severe VOD.

Cost of goods sold was €2.00 million for the six-month-period ended June 30, 2009 compared to €2.95 million for the same period in 2008. Cost of goods sold as a percentage of product sales, net was 57% for the six-month-period ended June 30, 2009 compared to 102% for the same period in 2008. The percentage decrease is primarily due to (i) higher margin on Defibrotide sold through the named-patient program, (ii) price increases in the active pharmaceutical ingredient business, and (iii) discontinuation of negative margins associated with Prociclide and Noravid. The Company has fully expensed, during the prior six-month-period, costs associated with the production of Defibrotide; therefore, costs of goods sold do not reflect the full costs of production because a portion of the active pharmaceuticals ingredients, labor and overhead costs incurred to produce Defibrotide sold through the named-patient program were previously expensed. Additionally, the higher percentage for the six-month-period ended in 2008 was primarily due to the fact that product sales to Sirton were not recognized after March 2008, due to Sirton's poor financial condition and concerns over the collectability of such receivables.

The Company incurred research and development expenses of €1.81 million for the six-month-period ended June 30, 2009 compared to €5.37 million for the same period in 2008, which are net of €0.71 million and €1.14 million, respectively, of government grants in the form of a tax credit. Research and development expenses were primarily for the development of Defibrotide to treat and prevent VOD. The decrease from the comparable period in 2008 is primarily due to lower development costs related to the treatment trial as this trial has been completed.

General and administrative expenses were €2.76 million for the six-month-period ended June 30, 2009 compared to €4.80 million for the same period in 2008. General and administrative expenses from the prior six-month-period reflect the establishment of an allowance for doubtful accounts of €1.50 million which was partially released for €0.34 million in 2009. The decrease in general and administrative expense is also attributable to lower payroll costs due to the temporary layoffs under the Cassa Integrazione program during the six-month period ended June 30, 2009.

Foreign currency exchange gain (loss) is primarily due to re-measurement of U.S. dollar cash balances. The positive result between 2009 and 2008 is due to a more favorable exchange rate in 2009 and a lower cash balance in 2009 versus 2008.

Net loss was €3.45 million for the six-month-period ended June 30, 2009 compared to €10.61 million for the same period in 2008. The difference was primarily due to lower research and development expenses, offset by an increase in higher margin from product sales through the named-patient program.

In addition, the Company has moved forward on two key strategic initiatives. In August 2009, the Company received formal notification from the Italian Health Authority (AIFA) that the marketing authorizations for Prociclide and Noravid had been withdrawn. This move was important because it allows the Company to re-position and re-launch the VOD formulation of Defibrotide in Europe. Also, the Company has received approval from the U.S. FDA to move forward with Cost Recovery for the Treatment IND program. Under current regulations, companies are allowed to recover certain costs related to the implementation of a Treatment IND. The Company plans to launch the Cost Recovery program in the fourth quarter 2009.

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 chemo-radiation therapy 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 U.S. or the EU.

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,” “pred 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 financial projections, clinical trial results, and the Company’s ability to pursue a financing, 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.”

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(Tables to follow)

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

	December 31, 2008	June 30, 2009 (unaudited)
ASSETS		
Cash and cash equivalents	€ 11,491	€ 1,359
Accounts receivable	625	2,545
Accounts receivable from related parties, net	320	10
Inventories, net	907	1,138
Prepaid expenses and other current assets	2,178	1,741
Total Current Assets	15,521	6,793
Property, manufacturing facility and equipment, at cost	21,019	21,267
Less: Accumulated depreciation	10,268	10,904
Property, manufacturing facility and equipment, net	10,751	10,363
Intangible assets, net of amortization	95	84
Available for sale securities	510	523
Other non-current assets	24	116
Total Assets	€ 26,901	€ 17,879
LIABILITIES AND SHAREHOLDERS' EQUITY		
Accounts payable	€ 5,823	€ 4,487
Accounts payable to Crinos	4,000	-
Accounts payable to related parties	325	114
Accrued expenses and other current liabilities	810	831
Current portion of capital lease obligations	65	66
Current maturities of long-term debt	1,346	1,240
Total Current Liabilities	12,369	6,738
Long-term debt, net of current maturities	3,268	2,656
Capital lease obligation	158	125
Termination indemnities	655	632
Total Liabilities	16,450	10,151
Share capital (€1;00 and no par value as of December 31, 2008 and June 30, 2009, respectively; 18,454,292 shares authorized; 14,956,317 and 14,956,317 shares issued at December 31, 2008 and June 30, 2009, respectively)	14,956	14,956
Additional paid in capital	90,619	91,396
Accumulated other comprehensive loss	(17)	(4)
Accumulated deficit	(95,107)	(98,560)
Total Shareholders' Equity	10,451	7,728
Total Liabilities and Shareholders' Equity	€ 26,901	€ 17,879

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

	Three months ended June 30,		Six months ended June 30,	
	2008	2009	2008	2009
Revenues:				
Product sales to related party	€ -	€ -	€ 555	€ 195
Product sales to third parties	1,156	1,520	2,355	2,297
Name Patient Program sales, net.	-	1,035	-	1,035
Total product sales, net	1,156	2,555	2,910	3,527
Other revenues	708	55	1,643	97
Total revenues	1,864	2,610	4,553	3,624
Operating costs and expenses:				
Cost of goods sold	1,525	1,244	2,954	2,000
Research and development	1,757	362	5,368	1,808
General and administrative	2,780	1,132	4,800	2,760
Charges from related parties	154	71	349	141
Depreciation and amortization	282	209	559	465
	6,498	3,018	14,030	7,174
Operating loss	(4,634)	(408)	(9,477)	(3,550)
Interest income (expense), net	34	(40)	158	(72)
Foreign currency exchange gain/(loss), net	74	(40)	(1,289)	169
Loss before income tax expense	(4,526)	(488)	(10,608)	(3,453)
Income tax expense	-	-	-	-
Net loss	€ (4,526)	€ (488)	€ (10,608)	€ (3,453)
Net loss per share:				
Basic and diluted net loss per share	(0.30)	(0.03)	(0.71)	(0.23)
Weighted average shares used to compute basic and diluted net loss per share	14,956,317	14,956,207	14,956,207	14,956,207

GENTIUM S.p.A.
Statements of Cash Flows
(Unaudited, amounts in thousands except share and share per data)

	Six Months Ended June 30,	
	2008	2009
Cash Flows From Operating Activities:		
Net loss	€ (10,608)	€ (3,453)
Adjustments to reconcile net loss to net cash used in operating activities:		
Unrealized foreign exchange loss (gain)	855	(200)
Depreciation and amortization	906	647
Stock based compensation	1,167	717
Loss on fixed asset disposal	7	-
Inventory allowance...	-	78
Allowance (release) for doubtful accounts.	1,504	(340)
Changes in operating assets and liabilities:		
Accounts receivable	(713)	(1,943)
Inventories	(550)	(309)
Prepaid expenses and other current and noncurrent assets	(1,368)	345
Accounts payable and accrued expenses	146	(849)
Accounts payable to Crinos.	-	(4,000)
Net cash used in operating activities	(8,654)	(9,307)
Cash Flows From Investing Activities:		
Capital expenditures	(325)	(248)
Intangible assets expenditures	(117)	-
Net cash used in investing activities	(442)	(248)
Cash Flows From Financing Activities:		
Proceeds from stock option exercises, net	38	-
Repayments of long-term debt	(578)	(718)
Proceeds from short term borrowings	222	-
Principal payment of capital lease obligations	(25)	(32)
Net cash used by financing activities	(343)	(750)
Decrease in cash and cash equivalents	(9,439)	(10,305)
Effect of exchange rate on cash and cash equivalents..	(872)	173
Cash and cash equivalents, beginning of period	25,964	11,491
Cash and cash equivalents, end of period	€ 15,653	€ 1,359