Gentium S.p.A.
Form 6-K
November 15, 2011

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, 2011.

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 x 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): o

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): o

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 x

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 financial results for the period ended September 30, 2011 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, File No. 333-141198, and File No. 333-174575, and on Forms S-8: File No. 333-137534 and File No. 333-146534.

Exhibit	Description
1	Press release dated November 15, 2011.

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/ Salvatore Calabrese	
	Name:	Salvatore Calabrese
	Title:	Chief Financial Officer and Senior VP, Finance

Date: November 15, 2011.

INDEX TO EXHIBITS

Exhibit	Description
1	Press release dated November 15, 2011.

Exhibit 1

PRESS RELEASE

Gentium Reports Third Quarter 2011 Financial Results

- Defibrotide product sales increased by 24%
- Product sales of EUR 16.02 million for the nine-months ended September 30, 2011
- Cash flow positive
- On target with revised projected product sales guidance of EUR 21-23 million for 2011

VILLA GUARDIA (COMO), Italy, November 15, 2011 (GlobeNewswire) — Gentium S.p.A. (NASDAQ: GENT) (the "Company") today reported financial results for the nine-month period and quarter ended September 30, 2011. 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 September 30, 2011, EUR 1.00 = $1.3503.

"We are pleased to report that Defibrotide product sales increased 24% to EUR 12.33 million when compared to EUR 9.97 million for the prior-year nine-month period and that we continue to be cash flow positive," stated Salvatore Calabrese, Senior Vice President and Chief Financial Officer of Gentium S.p.A. "The comparative quarterly results have been affected mainly by non-cash items such as the termination in revenue recognition for an up-front payment made by Sigma-Tau in 2010, as well as restructuring charges and sales and marketing expenses which were not present in the prior year's quarter. We expect to meet our revised product sales guidance of EUR 21-23 million for 2011."

"We continue to see an increase in the number of clinics using Defibrotide to treat and prevent veno-occlusive disease (VOD)," stated Dr. Khalid Islam, Chairman and Chief Executive Officer of Gentium S.p.A. "We credit this in part to the contribution of our specialized regional partners who distribute Defibrotide on a named-patient basis in local regions, simplifying access for clinics. We are exploring opportunities to expand into new territories, as well as increase our visibility in those geographic areas in which we are already present. On the regulatory front, we have engaged an independent clinical research organization who is reviewing and identifying issues related to the datasets previously submitted to the US Food and Drug Administration. In the meantime, we have received and reviewed the Day 120 List of Questions from the European Medicines Agency and anticipate that we will submit our responses by year end."

Financial Highlights

For the nine-month period ended September 30, 2011 compared to the same period in 2010:

- Defibrotide net-sales increased 24% to EUR 12.33 million, or 77% of total product sales, compared to EUR 9.97 million, or 67% of total product sales. Sales of the company's active pharmaceutical ingredients (API) amounted to EUR 3.69 million, or 23% of total product sales, compared to EUR 4.91 million or a 25% decrease. Total product

sales increased 8% to EUR 16.02 million compared to EUR 14.87 million.

- Total revenues were EUR 18.04 million compared to EUR 18.44 million.

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- Operating costs and expenses were EUR 14.99 million compared to EUR 14.83 million. 2011 and 2010 operating costs and expenses include restructuring charges of EUR 0.34 million and EUR 0.95 million, respectively.

- Research and development expenses, which are included in operating costs and expenses, were EUR 4.00 million compared to EUR 4.63 million.

- Sales and marketing expenses, which are included in operating costs and expenses, were EUR 1.34 million compared to none.

- Operating income was EUR 3.06 million compared to EUR 3.62 million.

- Income tax expenses were EUR 0.37 million compared to EUR 0.22.

- Net income was EUR 2.63 million compared to EUR 3.44 million.

- Basic and diluted net income per share was EUR 0.176 and EUR 0.167, respectively, compared to EUR 0.230 per share.

For the third quarter ended September 30, 2011 compared to the third quarter of 2010:

- Defibrotide net sales increased 22% to EUR 4.10 million, or 78% of total product sales, compared to EUR 3.36 million, or 69% of the total product sales. Sales of the company's API amounted to EUR 1.13 million, or 22% of total product sales, compared to EUR 1.49 million or a 24% decrease. Total product sales increased 8% to EUR 5.23 million compared to EUR 4.85 million.

- Total revenues were EUR 5.27 million compared to EUR 5.91 million.

- Operating costs and expenses were EUR 5.30 million compared to EUR 4.36 million. 2011 operating costs and expenses include restructuring charges of EUR 0.34 million.

- Research and development expenses, which are included in operating costs and expenses, were EUR 1.34 million compared to EUR 1.17 million.

- Sales and marketing expenses, which are included in operating costs and expenses, were EUR 0.57 million compared to none.

- Operating income/(loss) was EUR (0.03) million compared to EUR 1.55 million.

- Net income/(loss) was EUR (0.04) million compared to EUR 1.12 million.

- Basic and diluted net income/(loss) per share was EUR (0.003) compared to EUR 0.075 per share.

Cash and cash equivalents were EUR 9.91 million as of September 30, 2011 compared to EUR 8.74 million as of December 31, 2010.

Operating Results

Product sales for the nine-month period ended September 30, 2011 were EUR 16.02 million compared to EUR 14.87 million for the same period in 2010, an increase of EUR 1.15 million or 8%. The increase was primarily due to the

increased distribution of Defibrotide through the named-patient and cost recovery programs.

For the nine-month periods ended September 30, 2011 and 2010, sales from the named-patient and cost recovery programs amounted to EUR 12.33 million and EUR 9.97 million, respectively, representing an increase of EUR 2.36 million or 24%. Sales from the named-patient and cost recovery programs are net of EUR 2.29 million and EUR 1.59 million, respectively, in service fees.

API revenues were EUR 3.69 million for the nine-month period ended September 30, 2011, compared to EUR 4.91 million for the same period in 2010, reflecting a decrease of EUR 1.22 million or 25%. The decrease was primarily due to lower sales and a reduction in the price and volume of sulglicotide to accommodate a commercial partner in South Korea that has experienced a 20% cut in reimbursement from its local government for its finished drug product that uses sulglicotide as the API.

Other revenues were EUR 2.02 million for the nine-month period ended September 30, 2011 compared to EUR 3.57 million for the same period in 2010. This fluctuation is primarily attributable to a decrease in pre-clinical and clinical trial activities that were eligible for reimbursement from Sigma-Tau under a cost sharing arrangement with the Company, which amounted to EUR 0.29 million and EUR 0.86 million for the nine months ended September 30, 2011 and 2010, respectively. In addition, the fluctuation is attributable to the ratable recognition of EUR 1.70 million ($2.23 million) and EUR 2.56 million ($3.50 million) for the nine months ended September 30, 2011 and 2010 of the EUR 5.11 million ($7.0 million) up-front payment made by Sigma-Tau in connection with the amendment of the existing license and supply agreement with the Company to include the prevention indication of Defibrotide in the Americas. The up-front payment was recognized ratably, commencing in January 2010 through the second quarter of 2011.

Cost of goods sold was EUR 4.15 million for the nine-month period ended September 30, 2011 compared to EUR 4.29 million for the same period in 2010. Cost of goods sold as a percentage of product sales was 26% for the nine-month period ended September 30, 2011 compared to 29% for the same period in 2010. The percentage decrease is primarily due to a different product mix with proportionately increased sales of Defibrotide, which has a higher margin compared to sales of the Company’s other active pharmaceutical ingredients.

The Company incurred research and development expenses of EUR 4.00 million for the nine-month period ended September 30, 2011 compared to EUR 4.63 million for the same period in 2010. Research and development expenses were primarily for the development of Defibrotide to treat and prevent VOD. The decrease from the comparable period in 2010 is attributed to the completion of certain pre-clinical and clinical trials, such as reproductive toxicity, hERG channel, QT/QTc and completion of a technology transfer to a third party, offset by an increase in scientific consultancy and regulatory activities.

General and administrative expenses were EUR 4.34 million for the nine-month period ended September 30, 2011 compared to EUR 4.07 million for the same period in 2010. 2010 general and administrative expenses include a release of a reserve for doubtful accounts for EUR 0.27 million due to the deemed payment of accounts receivable through the elimination of the same amount of accounts payable due to the same counterparty. The slight increase in general and administrative expenses was primarily due to administrative expenses incurred with the incorporation of a subsidiary in Switzerland along with higher stock-based compensation expenses which amounted to EUR 1.07 million and EUR 0.85 million for the nine months ended September 30, 2011 and 2010, respectively, offset by a decrease in administrative and payroll expenses previously incurred by the Company’s New York office, which closed in 2010.

Sales and marketing expenses were EUR 1.34 million for the nine-month period ended September 30, 2011 compared to none for the same period in 2010. Sales and marketing expenses mainly refer to expenses relating to recruiting, payroll, marketing and health economics analysis, and stock-based compensation expenses.

Corporate restructuring charges were EUR 0.34 million and EUR 0.95 million for the nine-month periods ended September 30, 2011 and 2010 respectively.

Income tax expenses were EUR 0.37 million and EUR 0.22 million for the nine-month periods ended September 30, 2011 and 2010, respectively. Income tax expenses include a provision for the Italian Regional Tax on Productive Activities, or "IRAP," which has a statutory rate of 3.9%. The IRAP tax is not deductible for corporate purposes. The IRAP tax base is similar to the corporate tax base, but does not permit a deduction for labor and interest.

Net income was EUR 2.63 million for the nine-month period ended September 30, 2011 compared to EUR 3.44 million for the same period in 2010. The difference is mainly due to an increase in the volume of Defibrotide sold through the named-patient and cost recovery programs. The increase in Defibrotide sales has offset the decrease in the Company's active pharmaceutical ingredient sales, the decrease in activities that were eligible for reimbursement from Sigma-Tau under a cost sharing arrangement with the Company, costs associated with the establishment of our European sales infrastructure, which was not present in 2010. 2011 and 2010 financial results were also affected by restructuring charges of EUR 0.34 million and EUR 0.95 million, respectively.

About VOD

Veno-occlusive disease (VOD) is a potentially life-threatening condition, which typically occurs as a result of a significant complication of stem cell transplantation. Certain high-dose conditioning regimens used as part of stem cell transplants (SCT) can damage the lining cells of hepatic blood vessels and result in VOD, a blockage of the small veins of the liver that leads to liver failure and can result in significant dysfunction of 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 United States or the European Union.

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 any financial forecast or 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 the Company's Form 20-F filed with the Securities and Exchange Commission under the caption "Risk Factors."

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

	As of December 31, 2010	As of September 30, 2011 (unaudited)
ASSETS		
Cash and cash equivalents	€ 8,742	€ 9,907
Available for sale securities	263	-
Accounts receivable net of allowance of €27 as of December 31, 2010 and September 30, 2011	3,442	4,771
Accounts receivable from related parties, net of allowance of €850 as of December 31, 2010 and September 30, 2011	657	204
Inventories, net of allowance of €451 and €366 as of December 31, 2010 and September 30, 2011, respectively	2,364	3,173
Prepaid expenses and other current assets	541	572
Total Current Assets	16,009	18,627
Property, manufacturing facility and equipment, at cost	21,437	22,662
Less: Accumulated depreciation	12,839	13,806
Property, manufacturing facility and equipment, net	8,598	8,856
Intangible assets, net of amortization	54	47
Other non-current assets	13	24
Total Assets	€ 24,674	€ 27,554
LIABILITIES AND SHAREHOLDERS' EQUITY		
Accounts payable	€ 4,308	€ 5,095
Accounts payable to related parties	372	188
Accrued expenses and other current liabilities	1,902	2,189
Deferred Revenues	1,704	401
Current portion of capital lease obligations	70	39
Current maturities of long-term debt	1,098	524
Total Current Liabilities	9,454	8,436
Long-term debt, net of current maturities	1,759	1,722
Capital lease obligations	21	-
Termination indemnities	510	424
Total Liabilities	11,744	10,582
Share capital (no par value; 18,302,617 and 19,656,317 shares authorized as of December 31, 2010 and September 30, 2011; 14,956,317 and 14,969,150 shares issued and outstanding at December 31, 2010 and September 30, 2011, respectively)	108,485	109,895
Accumulated deficit	(95,555)	(92,923)
Total Shareholders' Equity	12,930	16,972
Total Liabilities and Shareholders' Equity	€ 24,674	€ 27,554

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

	Three months ended September 30		Nine months ended September 30,	
	2010	2011	2010	2011
Revenues:				
API product sales	€1,489	€1,128	€4,909	€3,692
NPP product sales	3,361	4,098	9,961	12,330
Total product sales	4,850	5,226	14,870	16,022
Other revenues	112	6	150	24
Other revenues from related party	946	41	3,422	1,997
Total revenues	5,908	5,273	18,442	18,043
Operating costs and expenses:				
Cost of goods sold	1,420	1,395	4,285	4,147
Research and development	1,174	1,337	4,625	3,996
General and administrative	1,468	1,369	4,074	4,341
Sales and Marketing	-	566	-	1,344
Charges from related parties	69	51	218	177
Restructuring charges	-	344	953	344
Depreciation and amortization	224	239	671	639
	4,355	5,301	14,826	14,988
Operating income/(loss)	1,553	(28)	3,616	3,055
Foreign currency exchange gain/(loss), net	(191)	53	104	(10)
Interest income/(expense), net	(23)	10	(64)	(48)
Income before income tax expense	1,339	35	3,656	2,997
Provision for income taxes:				
Income tax expense	(216)	(77)	(216)	(365)
Net income/(loss)	€1,123	€(42)	€3,440	€2,632
Shares used in calculation of earnings per share				
Basic	14,956,317	14,968,333	14,956,317	14,962,286
Diluted	14,956,317	14,968,333	14,956,317	15,793,186
Earnings per share:				
Basic	0.075	(0.003)	0.230	0.176
Diluted	0.075	(0.003)	0.230	0.167

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

	For the Nine Months Ended September 30,	
	2010	2011
Cash Flows From Operating Activities:		
Net income	€3,440	€2,632
Adjustments to reconcile net income to net cash provided by operating activities:	-	
Inventory allowance/(release of allowance)	143	(85)
Unrealized foreign exchange gain	(32)	(16)
Depreciation and amortization	983	978
Stock based compensation	1,179	1,334
Loss on fixed asset disposal	20	-
Release of allowance for doubtful accounts	(250)	-
Deferred revenues	2,556	(1,303)
Provision for income tax	216	509
Changes in operating assets and liabilities:		
Accounts receivable	(482)	(823)
Inventories	(358)	(724)
Prepaid expenses and other current and noncurrent assets	769	(42)
Accounts payable and accrued expenses	102	(344)
Termination indemnities	(94)	(86)
Net cash provided by operating activities	8,192	2,030
Cash Flows From Investing Activities		
Purchase of equipments and furniture	(84)	(512)
Proceeds from sales of marketable securities	-	263
Net cash used in investing activities	(84)	(249)
Cash Flows From Financing Activities:		
Repayment of long-term debt	(188)	(611)
Principal payment of capital lease obligations	(50)	(51)
Proceeds from stock option exercise	-	77
Net cash used in financing activities	(238)	(585)
Increase in cash and cash equivalents	7,870	1,196
Effect of exchange rate on cash and cash equivalents	28	(29)
Cash and cash equivalents, beginning of period	1,392	8,742
Cash and cash equivalents, end of period	€9,290	€9,909

SOURCE: Gentium S.p.A.

Gentium S.p.A.
Salvatore Calabrese, +39 031-385-287
SVP & CFO
scalabrese@gentium.it

or

The Trout Group
Christine Labaree, +1 646-378-2951
clabaree@troutgroup.com