Gentium S.p.A. Form 424B3 August 15, 2006

# GENTIUM S.p.A.

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### **GENTIUM S.P.A.**

### PROSPECTUS SUPPLEMENT NO. 5 DATED AUGUST 15, 2006

### TO PROSPECTUS DATED JANUARY 30, 2006

This Prospectus Supplement No. 5 supplements information contained in our prospectus dated January 30, 2006, as amended and supplemented from time to time (the "Gentium Prospectus"). The information in this Supplement No. 5 supplements, modifies and supersedes some of the information contained in the Gentium Prospectus.

The primary purpose of this Prospectus Supplement No. 5 is to update certain financial information of Gentium S.p.A. to June 30, 2006.

You should read this Prospectus Supplement No. 5 in conjunction with the Gentium Prospectus. This Prospectus Supplement No. 5 is not complete without, and may not be delivered or utilized except in connection with, the Gentium Prospectus including any amendments or supplements thereto.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.

## GENTIUM S.p.A. Financial Statements For the Second Quarter of 2006

-1-

GENTIUM S.p.A. Financial Statements For the Second Quarter of 2006

## Index to Financial Statements

	<u>Page</u>
Balance Sheets As of December 31, 2005 and June 30, 2006	3
Statements of Operations For the Six Month Periods Ended June 30, 2005 and 2006	4
Statements of Cash Flows For the Six Months Ended June 30, 2005 and 2006	5
Operating Highlights	6
Financial Highlights	7
Operating Results and Trends	7
-2-	

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

(in thousands, except share data)

	As of December 3 2005	1,	As of June 30, 2006 (Unaudited)	
ASSETS				
Cash and cash equivalents	€ 12	,785	€ 24,819	
Receivables		8	178	
Receivables from related parties	1	,867	1,972	
Inventories	1	,628	1,867	
Prepaid expenses and other current assets		918	1,180	
Total Current Assets	17	,206	30,016	
Property, manufacturing facility and equipment, at cost		,456	18,552	
Less: Accumulated depreciation		,825	9,203	
Property, manufacturing facility and equipment, net	8	,631	9,349	
Intensible exects not of executivestics		267	536	
Intangible assets, net of amortization  Marketable securities		207	519	
Other non-current assets		9	12	
Total Assets	€ 26		€ 40,432	
Total Assets	₹ 20	,113	₹ 40,432	
LIABILITIES AND SHAREHOLDERS' EQUITY				
Accounts payable	2	,644	4,096	
Payables to related parties	_	542	378	
Accrued expenses and other current liabilities	1	,063	954	
Current maturities of long-term debt		916	261	
Current portion of capital lease		_	50	
Deferred income		283	213	
Total Current Liabilities	5	,448	5,952	
Long-term debt, net of current maturities	2	,485	5,321	
Capital lease obligation		-	100	
Termination indemnities		706	723	
Total Liabilities	8	,639	12,096	
Share capital (par value: €1.00; 12,690,321 and 15, 100, 292 shares				
authorized at December 31, 2005 and June 30, 2006, respectively;				
9,610,630 and 11,666,013 shares issued at December 31, 2005 and June 30,				
2006, respectively)				
,,				
	9	,611	11,666	
Additional paid in capital		,090	48,247	
Other comprehensive loss		-	(11)	

Accumulated deficit		(25,227)	(31,566)
Total Shareholders' Equity		17,474	28,336
Total Liabilities and Shareholders' Equity	€	26,113 €	40,432

-3-

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

	Three Months Ended June 30, 2005 2006		Six Months Ended 2005		d June 30, 2006		
Revenues:							
Sales to affiliates	€	1,096	€	941	€ 1,596	€	1,853
Third party product sales		2		107	95		110
Total product sales		1,098		1,048	1,691		1,963
Royalties		-		7	-		7
Other income and revenues		70		97	140	)	132
Total Revenues		1,168		1,152	1,831		2,102
Operating costs and expenses:							
Cost of goods sold		998		853	1,500		1,616
Research and development		1,084		1,979	1,728		3,602
Charges from affiliates		310		166	581		381
General and administrative		482		1,353	894		2,649
Depreciation and amortization		20		61	43		103
		2,894		4,412	4,746		8,351
Operating loss		(1,726)		(3,260)	(2,915)		(6,249)
Foreign currency exchange loss, net		(465)		(62)	(520)	1	(230)
Interest income (expense), net		(2,097)		88	(4,245)		140
Pre-tax loss		(4,288)		(3,234)	(7,680)	ı	(6,339)
Income tax expense:							
Current		-		-	-		-
Deferred		(16)		-	(32)		-
Net loss	€	(4,304)	€	(3,234)	€ (7,712)	€	(6,339)
Weighted average share:							
Basic		5,303,242		),244,414	5,152,459		9,929,273
Diluted		5,363,242	10	),625,886	5,212,459	1	10,330,788
Net loss per share:							
Basic net loss per share	€	(0.81)	€	(0.32)	€ (1.50)	€	(0.64)
Diluted net loss per share		(0.81)		(0.32)	(1.50)		(0.64)

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

	For the Six Months Ended June 30,		
	2005	2006	
Cash Flows From Operating Activities:			
Net loss	€ (7,712)	(6,339)	
Adjustments to reconcile net income to net cash provided by (used in)			
operating activities:			
Unrealized foreign exchange loss	569	224	
Depreciation and amortization	733	458	
Non cash interest expense	3,837	-	
Inventory write off	50	182	
Stock based compensation	106	423	
Gain on asset disposal	-	(23)	
Changes in operating assets and liabilities:			
Accounts receivable	(485)	(275)	
Inventories	(548)	(421)	
Prepaid expenses and other current assets	334	(228)	
Accounts payable and accrued expenses	(343)	1,180	
Deferred income	(143)	(70)	
Termination indemnities	79	17	
Net cash used in operating activities	(3,523)	(4,872)	
Cash Flows From Investing Activities:			
Capital expenditures	(478)	(922)	
Intangible expenditures	(52)	(352)	
Proceeds on sale of asset	-	11	
Investment in marketable securities	-	(530)	
Net cash used in investing activities	(530)	(1,793)	
Cash Flows From Financing Activities:			
Proceeds from warrants exercise	-	884	
Proceeds from long term debt, net	-	4,563	
Capital contribution	3,900	-	
Repayments of long-term debt	(307)	(551)	
Proceeds (repayment) from Series A convertible Notes	(1,929)	-	
Early extinguishment of long term debt	-	(1,868)	
Proceeds (repayment) of affiliate's loan	(1,200)	-	
Proceeds (repayment) from bank overdrafts and short term borrowings	(2,790)	-	
Proceeds from initial public offering and private placement, net of	14,584	15,896	
offering expenses			
Net cash provided by financing activities	12,258	18,924	
Effect of foreign exchange rate	-	(225)	
Increase in cash and cash equivalents	8,205	12,034	

Cash and cash equivalents, beginning of period		2,461	12,785
Cash and cash equivalents, end of period	€	10,666	24,819
-5-			

#### **Operating Highlights**

Operating highlights of the second quarter of 2006 and recent weeks include:

- · Raised \$22.1 million (gross proceeds) in a follow-on equity offering led by ThinkEquity Partners, LLC;
- ·Listed the Company's American Depository Shares (ADS) on the NASDAQ National Market System (now the NASDAQ Global Market);
- · Highlighted Defibrotide at a Symposium at the XXII World Congress of the International Union of Angiology;
  - · Publication of two independent pediatric studies of Defibrotide;
  - Strengthened U.S. presence with appointment of New York-based CFO, Gary Gemignani;
  - Phase III clinical trial in the U.S. for treatment of Veno-Occlusive Disease (VOD) with Multiple Organ Failure (Severe VOD): commenced enrollment; expected to be conducted at approximately 30 clinical centers; Institutional Review Board (IRB) approval has been received from 10 centers and four are open for patient enrollment;;
- •Phase II/III clinical trials in Europe for the prevention of VOD in children: 30 centers have IRB approval and 20 centers are open for patient enrollment; 30 patients have been enrolled;
- ·Independent Phase I/II study of Defibrotide to treat advanced and refractory Multiple Myeloma patients: 4 centers have IRB approval; 14 patients have been enrolled;
- •Phase II/III clinical trials in Europe for the prevention of VOD in adults: investigator's meeting was held in Hamburg (Germany) on March 22, 2006; anticipate initiation of these studies by the fourth quarter of 2006; and
- ·In August Axcan Pharmaceuticals Inc ("Axcan") announced it was not filing for regulatory approval for mesalazine in the U.S. and Canadian markets, the rights of which the Company sold to Axcan in 2002; under the terms of the agreement the Company would have been entitled to receive future milestone payments and a royalty stream; Axcan's decision had no impact on the Company's current period financial statements and the Company does not believe that this will have a material effect on its future operating results.

-6-

### **Financial Highlights**

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, 2006, 1.00 = 1.27.

For the second quarter ended June 30, 2006 compared with the prior-year's second quarter:

- Total revenues were €1.15 million, compared with €1.17 million
   Operating costs and expenses were €4.41 million, compared with €2.89 million
- ·Research and development expenses, which are included in operating costs and expenses, were €1.98 million, compared with €1.08 million
  - Operating loss was €3.26 million, compared with €1.73 million
    Interest income (expense), net, was €0.09 million, compared with (€2.1) million
  - Pre-tax loss was €3.23 million, compared with €4.29 million
  - Net loss was €3.23 million, compared with €4.30 million
- Basic and diluted net loss per share was €0.32 compared with €0.81 per share

For the six months ended June 30, 2006 compared with the comparable prior-year period:

- Total revenues were €2.10 million, compared with €1.83 million

  Operating costs and expenses were €8.35 million, compared with €4.75 million
- ·Research and development expenses, which are included in operating costs and expenses, were €3.60 million, compared with €1.73 million
  - · Operating loss was €6.25 million, compared with €2.92 million
  - Interest income (expense), net, was €0.14 million, compared with (€4.25) million
    - · Pre-tax loss was €6.34 million, compared with €7.68 million
    - Net loss was €6.34 million, compared with €7.71 million
  - Basic and diluted net loss per share was €0.64 compared with €1.50 per share
  - · Cash used in operating activities was €4.87 million, compared with €3.52 million
  - · Cash and cash equivalents amounted to €24.82 million as of June 30, 2006

### **Operating Results and Trends**

The fluctuation in total product sales for the three- and six-month periods compared with the prior year is primarily the result of changes in demand by our principal customer, Sirton, and by increased demand for sulglicotide by our Korean customer. Total product sales for the six-month period ended June 30, 2006 increased by 0.27 million, or 16%, compared with the same period in 2005.

Cost of goods sold was €1.62 million for the six-month period ended June 30, 2006, which included a €152 thousand inventory reserve attributable to slow-moving inventory, compared with cost of goods sold of €1.50 million for the comparable period in 2005. Cost of goods sold as a percent of product sales decreased from 89% to 82%. The decrease is primarily due to a revision in the estimated useful life of certain manufacturing equipment resulting in a reduction in depreciation expense, offset to some extent by increased quality control costs.

-7-

Research and development spending increased during the three- and six- 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 and stock-based compensation expense also contributed to increased research and development expenses.

The Company had 69 employees as of June 30, 2006, compared with 52 as of June 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 accounts for the decrease in charges from affiliates between the periods.

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 six months ended June 30, 2005, interest expense on the Series A notes was  $\{4.1 \text{ million}, \text{ including non-cash interest}\}$  expense of  $\{3.8 \text{ million} \text{ from the amortization of the issue discount and debt issue cost.}$  These notes were converted or redeemed in June 2005. Additionally, interest income increased by  $\{200 \text{ thousand from } \{11 \text{ thousand in the period}\}$  ended June 30, 2005 to  $\{211 \text{ thousand in the comparable 2006 period, as the result of a higher level of invested funds.}$ 

The Company ended the second quarter of 2006 with €24.8 million in cash and cash equivalents, compared with cash and cash equivalents of €12.8 million as of December 31, 2005.

-8-