Gentium S.p.A.
Form 20-F
March 31, 2010
As filed with the Securities and Exchange Commission on March 31, 2010

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 20-F

o REGISTRATION STATEMENT PURSUANT TO SECTION 12(b) OR (g) OF THE SECURITIES EXCHANGE ACT OF 1934

OR

x ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the Fiscal Year Ended: December 31, 2009

OR

o TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

OR

o SHELL COMPANY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

000-51341
(Commission file number)

GENTIUM S.p.A.
(Exact Name of Registrant as Specified in its Charter)

NOT APPLICABLE
(Translation of Registrant's Name into English)

Italy
(Jurisdiction of incorporation or organization)

Piazza XX Settembre 2

22079 Villa Guardia (Como), Italy
+39 031 385111
(Address, including zip code, and telephone number,
including area code, of Registrant's principal executive offices)

Securities registered or to be registered pursuant to Section 12(b) of the Act.

Title of each class	Name of each exchange on which registered
American Depositary Shares	The Nasdaq Global Market
Ordinary shares, no par value*	The Nasdaq Global Market

(Title of Class)

Securities registered or to be registered pursuant to Section 12(g) of the Act: None

Securities for which there is a reporting obligation pursuant to Section 15(d) of the Act: None

Indicate the number of outstanding shares of each of the issuer's classes of capital or common stock as of the close of the period covered by the annual report.

14,956,317 ordinary shares

- Not for trading, but only in connection with the registration of the American Depositary Shares.

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.

Yes o No x

If this report is an annual or transition report, indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934.

Yes o No x

Note – Checking the box above will not relieve any registrant required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 from their obligations under those Sections.

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes x No o

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of "accelerated filer and large accelerated filer" in rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer o Accelerated filer o Non-accelerated filer x

Indicate by check mark which financial statement item the registrant has elected to follow.

Item 17 o Item 18 x

If this is an annual report, indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes o No x

Indicate by check mark whether the registrant has filed all documents and reports required to be filed by Sections 12, 13 or 15(d) of the Securities Exchange Act of 1934 subsequent to the distribution of securities under a plan confirmed by a court.

Not applicable.

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PART I

ITEM 1. IDENTITY OF DIRECTORS, SENIOR MANAGEMENT AND ADVISORS

Not applicable.

ITEM 2. OFFER STATISTICS AND EXPECTED TIMETABLE

Not applicable.

ITEM 3. KEY INFORMATION

GENTIUM S.P.A.

We are a biopharmaceutical company focused on the development and manufacture of our primary product candidate, defibrotide, an investigational drug based on single-stranded DNA extracted from pig intestines. Our development of defibrotide has been focused on the treatment and prevention of a disease called hepatic veno-occlusive disease, or VOD, a condition in which some of the veins in the liver are blocked as a result of cancer treatments, such as chemotherapy or radiation treatments, that are given prior to stem cell transplantation. Severe VOD is the most extreme form of VOD and is associated with multiple-organ failure and high rates of morbidity and mortality. We have completed two clinical trials, a Phase III trial of defibrotide for the treatment of severe VOD in the U.S., Canada and Israel and a Phase II/III pediatric trial in Europe for the prevention of VOD. Defibrotide has been given "orphan" status by the U.S. Food and Drug Agency, or FDA, and the European Medicines Agency, or EMEA, which means that we will have limited market exclusivity upon regulatory approval. Defibrotide has also been granted "fast-track product" designation by the FDA for the treatment of VOD. While we have not yet obtained regulatory approval to market defibrotide, we are authorized to distribute defibrotide on a pre-approved basis under a treatment IND protocol in the U.S. and through a named-patient program throughout the rest of the world. We do not know of any FDA or EMEA approved treatments for VOD.

We are currently completing certain preclinical and clinical studies requested by regulatory authorities. As part of our overall strategy, we anticipate filing for regulatory approval for defibrotide in the U.S. and Europe by the end of our second quarter in 2011. We are also working closely on our U.S. regulatory strategy with our commercial partner, Sigma-Tau Finanziaria S.p.A. and its affiliate Sigma-Tau Pharmaceuticals, Inc., to which we have licensed our commercial rights to defibrotide for both the treatment and prevention of VOD in the Americas.

We have a manufacturing plant in Italy where we produce active pharmaceutical ingredients, which are subsequently used to make the finished forms of various drugs. We believe that we are the sole worldwide producer of defibrotide. In addition to defibrotide, we manufacture urokinase and sulglicotide, both of which are sold to third parties. All of the Company's operating assets are located in Italy.

We have accumulated a deficit of approximately €100 million since our inception and expect to continue to incur net operating losses for the foreseeable future. However, absent the need to fund any additional clinical trials, we believe that our cash and cash equivalents, including the upfront payment received from Sigma-Tau Pharmaceuticals, Inc. in connection with the expansion of the license for defibrotide in the Americas, together with revenues generated from our named-patient and cost recovery programs, will be sufficient to meet our obligations for at least the next twelve months.

We are subject to a number of risks, including our ability to successfully obtain regulatory approval for defibrotide, the uncertainty that defibrotide will become a successful commercial product, our ability to generate projected revenue through our named-patient and cost recovery programs, our dependence on corporate partners, our ability to obtain

financing, if necessary, and potential changes in the health care industry.

SELECTED FINANCIAL DATA

The following selected financial data should be read in conjunction with "Operating and Financial Review and Prospects" and our financial statements and the related notes appearing elsewhere in this annual report. The selected financial data as of December 31, 2008 and December 31, 2009 and for the three years ended December 31, 2009 are derived from our audited financial statements, which are included in this annual report. The selected financial data as of December 31, 2005, December 31, 2006 and December 31, 2007 and for the years ended December 31, 2005 and December 31, 2006 have been derived from our audited financial statements, which are not included in this annual report. Our historical results are not necessarily indicative of results to be expected in any future period.

The convenience translation into U.S. dollars has been done solely for the benefit of the reader, and does not imply that our results would actually have been these amounts in U.S. dollars had the U.S. dollar been our functional currency.

Statement of Operations Data: (000s omitted except per share data)	For the Years Ended December 31,					
	2005	2006	2007	2008	2009	2009(1)
Revenues:						
Product sales to related party	€ 3,260	€ 3,754	€ 2,704	€ 651	€ 195	$ 279
Product sales to third parties	101	321	2,390	4,792	9,507	13,625
Total product sales	3,361	4,075	5,094	5,443	9,702	13,904
Other revenues	280	109	15	25	129	185
Other revenues from related party	-	140	2,500	1,970	337	483
Total revenues	3,641	4,324	7,609	7,438	10,168	14,572
Operating costs and expenses:						
Cost of goods sold	2,911	3,092	4,584	5,596	4,002	5,736
Charges from related parties	1,047	854	748	537	279	400
Research and development	4,557	8,927	14,497	9,569	3,512	5,033
General and administrative	2,284	5,421	6,279	7,668	6,036	8,651
Depreciation and amortization	118	261	725	998	916	1,313
Write-down of assets	-	-	13,740	3,403	-	-
	10,917	18,555	40,573	27, 771	14,745	21,133
Operating loss	(7,276)	(14,231)	(32,964)	(20,333)	(4,577)	(6,561)
Foreign currency exchange gain (loss), net	(249)	(627)	(4,001)	173	162	232
Interest income (expense), net	(4,148)	490	1,357	256	(110)	(158)
Pre-tax income loss	(11,673)	(14,368)	(35,608)	(19,904)	(4,525)	(6,487)
Income tax expense (benefit):						
Current	-	-	-	-	-	-
Deferred	646	-	-	-	-	