Gentium S.p.A.
Form 20-F
March 31, 2011
As filed with the Securities and Exchange Commission on March 31, 2011

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 20-F

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

OR

þANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the Fiscal Year Ended: December 31, 2010

OR

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

OR

¨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 ¨ No þ

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 ¨ No þ

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 þ No ¨

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).

Yes ¨ No þ

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 ¨ Accelerated filer ¨ Non-accelerated filer þ

Indicate by check mark which basis of accounting the registrant has used to prepare the financial statements included in this filing:

U.S. GAAP þ International Financial Reporting Standards as issued by the International Accounting Standards Board ¨ Other ¨

If "Other has been checked in response to the previous question, indicated by check mark which financial item the registrant has elected to follow.

Yes ¨ No ¨

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 ¨ No þ

TABLE OF CONTENTS

PART I

ITEM 1. IDENTITY OF DIRECTORS, SENIOR MANAGEMENT AND ADVISERS

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 a mixture of single-stranded and double-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 that occurs when veins in the liver are blocked as a result of cancer treatments, such as chemotherapy or radiation, that are administered prior to stem cell transplantation. Severe VOD is the most extreme form of VOD and is linked to 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 EMA, 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-approval basis under a treatment Investigational New Drug, or IND, protocol, which we call our cost recovery program, in the U.S. and through a named-patient program throughout the rest of the world. We do not know of any FDA or EMA approved treatments for VOD.

We have completed 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 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 use defibrotide for both the treatment and prevention of VOD in the Americas. We are currently establishing our European sales force, as we intend to commercialize defibrotide in the major European countries on our own.

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 €95.6 million since our inception. In 2010, we have been cash flow positive, primarily due to the upfront payment received from Sigma-Tau Pharmaceuticals, Inc. in connection with the expansion of the license for defibrotide in the Americas, together with revenue generated from the cost recovery and named-patient programs. However, if we are unable to obtain regulatory approval to commercialize defibrotide, unable to continue to generate sufficient revenue through our cost recovery and named-patient programs, or if we are

required to fund additional clinical trials, we may revert to operating losses.

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. The risks we face are described in more detail under "Risk Factors" in this annual report. The risks described are not the only risks we face. Additional risks not presently known to us or that we currently deem immaterial may also impair our business operations. Our business, financial condition and operations could be materially adversely affected by any of these risks. The trading price of our securities could decline as a result of any of these risks and you may lose all or part of your investment. The discussion of risks includes or refers to forward-looking statements; you should read the explanation of the qualifications and limitations on such forward-looking statements discussed elsewhere in this annual report.

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, 2009 and December 31, 2010 and for the three years ended December 31, 2010 are derived from our audited financial statements, which are included in this annual report. The selected financial data as of December 31, 2006, December 31, 2007 and December 31, 2008 and for the years ended December 31, 2006 and December 31, 2007 are 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 is 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,					
	2006	2007	2008	2009	2010	2010(1)
Revenues:						
Product sales to related party	€3,754	€2,704	€651	€195	€-	$-
Product sales to third parties	321	2,390	4,792	9,507	19,715	26,160
Total product sales	4,075	5,094	5,443	9,702	19,715	26,160
Other revenues	109	15	25	129	289	383
Other revenues from related party	140	2,500	1,970	337	4,547	6,033
Total revenues	4,324	7,609	7,438	10,168	24,551	32,576
Operating costs and expenses:						
Cost of goods sold	3,092	4,584	5,596	4,002	5,786	7,677
Charges from related parties	854	748	537	279	346	459
Research and development	8,927	14,497	9,569	3,512	6,104	8,099
General and administrative	5,421	6,279	7,668	6,036	5,835	7,742
Restructuring charges	-	-	-	-	1,101	1,461
Depreciation and amortization	261	725	998	916	908	1,205
Write-down of assets	-	13,740	3,403	-	-	-
	18,555	40,573	27, 771	14,745	20,080	26,643
Operating income/(loss)	(14,231)	(32,964)	(20,333)	(4,577)	4,471	5,933
Foreign currency exchange gain (loss), net	(627)	(4,001)	173	162	90	119
Interest income/(expense), net	490	1,357	256	(110)	(87)	(115)
Pre-tax income/(loss)	(14,368)	(35,608)	(19,904)	(4,525)	4,474	5,937
Income tax expense:						
Current	-	-	-	-	(397)	(527)
	-	-	-	-	(397)	(527)
Net income/(loss)	€(14,368)	€(35,608)	€(19,904)	€(4,525)	€4,077	$5,410
Net income/(loss) per share:						

Basic and Diluted	€(1.33)	€(2.52)	€(1.33)	€(0.30)	€0.27	$0.36

(1) Euro amounts are translated into U.S. dollars using the Noon Buying Rate for the Euro on December 30, 2010, of U.S. $1.3269 per Euro. No representation is made that the Euro amounts referred to in this annual report could have been or could be converted into U.S. dollars at any particular rate or at all.

The following table summarizes certain of our balance sheet data.

(000s omitted except per share d share data	2006	2007	2008	2009	2010	2010(1)
Balance Sheet Data:						
Cash and cash equivalent	€10,205	€25,964	€11,491	€1,392	€8,742	$11,600
Working capital	13,543	19,002	3,152	1,041		