Gentium S.p.A.
Form 6-K
January 03, 2007

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 December, 2006.

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 o

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-_____.

A description of events affecting the Registrant set forth in the Registrant's press release, dated January 3, 2007, attached hereto as Exhibit Number 1, is incorporated by reference herein in its entirety. In addition, documents related to such event are attached hereto as Exhibits 2 through 8.

Exhibit	**Description**
1.	Press release, dated January 3, 2007.
2.	Master Agreement, dated December 28, 2006, among Gentium S.p.A., Crinos S.p.A., SFI Stada Financial Investments Ltd. and SFS Stada Financial Services International Ltd.
3.	AIC Transfer Agreement, dated December 28, 2006, between Gentium S.p.A. and Crinos S.p.A.
4.	Letter Agreement relating to AIC Transfer Agreement, dated December 28, 2006, between Gentium S.p.A. and Crinos S.p.A.
5.	Escrow Agreement, dated December 28, 2006, between Gentium S.p.A., Crinos S.p.A. and Deutsche Bank S.p.A.
6.	Distribution Agreement, dated December 28, 2006, between Gentium S.p.A. and Crinos S.p.A.
7.	License of Trademark Noravid, dated December 28, 2006, by and between SFI Stada Financial Investments Ltd., Crinos S.P.A. and Gentium S.P.A.
8.	License of Trademark Prociclide, dated December 28, 2006, by and between SFI Stada Financial Investments Ltd., SFS Stada Financial Services Ltd. and Gentium S.p.A.

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: January 3, 2007

INDEX TO EXHIBITS

Exhibit	Description
1.	Press release, dated January 3, 2007.
2.	Master Agreement, dated December 28, 2006, among Gentium S.p.A., Crinos S.p.A., SFI Stada Financial Investments Ltd. and SFS Stada Financial Services International Ltd.
3.	AIC Transfer Agreement, dated December 28, 2006, between Gentium S.p.A. and Crinos S.p.A.
4.	Letter Agreement relating to AIC Transfer Agreement, dated December 28, 2006, between Gentium S.p.A. and Crinos S.p.A.
5.	Escrow Agreement, dated December 28, 2006, between Gentium S.p.A., Crinos S.p.A. and Deutsche Bank S.p.A.
6.	Distribution Agreement, dated December 28, 2006, between Gentium S.p.A. and Crinos S.p.A.
7.	License of Trademark Noravid, dated December 28, 2006, by and between SFI Stada Financial Investments Ltd., Crinos S.P.A. and Gentium S.P.A.
8.	License of Trademark Prociclide, dated December 28, 2006, by and between SFI Stada Financial Investments Ltd., SFS Stada Financial Services Ltd. and Gentium S.p.A.

Exhibit 1

PRESS RELEASE

FOR IMMEDIATE RELEASE

Company Contact:
Gary Gemignani
Chief Financial Officer
212-332-1666
ggemignani@gentium.com

Investor Relations Contacts:
U.S.
Lippert/Heilshorn & Associates
Kim Sutton Golodetz
Kgolodetz@lhai.com
Anne Marie Fields
afields@lhai.com
212-838-3777
Italy:
Burson-Marsteller
Luca Ricci Maccarini
luca_maccarini@it.bm.com
+39 02.721431

GENTIUM ACQUIRES ITALIAN DEFIBROTIDE MARKETING RIGHTS FROM CRINOS

VILLA GUARDIA (Como), Italy (January 3, 2007) - Gentium S.p.A. (NASDAQ: GENT) today announced that on December 28, 2006 the Company agreed to acquire the Italian marketing authorizations for Defibrotide and related trademarks, as well as certain other related assets, from Crinos S.p.A. (Crinos) for €16 million in cash and other consideration, as described below. The purchase price will be paid in three installments, consisting of €8 million at closing, €4 million by December 31, 2007 and €4 million by December 31, 2008.

Gentium and Crinos also have agreed to enter into a distribution agreement whereby Crinos will be entitled to distribute only the oral formulation of Defibrotide in Italy until December 31, 2008. In addition Crinos has agreed to waive its right of first refusal to market future therapeutic indications for Defibrotide in the European market. In return, Gentium has agreed to pay Crinos a 1.5% royalty on net sales of Defibrotide for the treatment and/or prevention of hepatic veno-occlusive disease (VOD) in Europe for seven years.

Commenting on the transaction, Laura Ferro, M.D., president and chief executive officer of Gentium, said, “Acquiring the Italian marketing rights for Defibrotide from Crinos is a major milestone for Gentium as it allows us to better manage this key asset in the European markets. It also gives us control over its distribution and the flexibility to market Defibrotide ourselves or alternatively seek marketing partners in the European market, both of which have long been strategic objectives. We specifically structured this transaction to spread the payments to Crinos out over a two year time period thereby minimizing the impact to our ongoing development activities.”

“We have made significant progress with our clinical development of Defibrotide and consider today’s announcement a strategic investment in its future potential. We are confident this investment will allow Gentium to maximize the value of its Defibrotide asset in a number of important clinical applications,” concluded Dr. Ferro.

About Gentium

Gentium S.p.A. is a biopharmaceutical company focused on the research, discovery and development of drugs derived from DNA extracted from natural sources, and drugs that are synthetic derivatives, to treat and prevent a variety of vascular diseases and conditions related to cancer and cancer treatments. Defibrotide, the Company's lead product candidate in the U.S., is an investigational drug that has been granted Orphan Drug status by the U.S. Food and Drug Administration to treat Severe VOD and Fast Track designation for the treatment of Severe VOD in recipients of stem cell transplants.

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 may differ, possibly 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 20F filed with the Securities and Exchange Commission under the caption "Risk Factors."

# # #

Exhibit 2

MASTER AGREEMENT

Dated as of 28 December 2006

among

GENTIUM S.p.A. (Fiscal Code and VAT Code no. 02098100130), with legal offices in Piazza XX Settembre, no. 2, 22079 Villa Guardia (Como), acting through its President, Chief Executive Officer and Chairperson, Ms. Laura Iris Ferro, who is domiciled for her office for the purposes of this Agreement at the offices of the company (hereinafter, "**GENTIUM**"),

and

CRINOS S.p.A. (Fiscal Code and VAT Code no. 03481280968), with legal offices in Milan, Via Pavia no. 6, acting through its Managing Director, Mr. Enrique Hausermann, who is domiciled for his office for the purposes of this Agreement at the offices of the company (hereinafter, "**CRINOS**").

and

Stada Financial Investments Ltd., a corporation organised and existing under the law of Ireland with its registered offices in Waterford Road, Clonmel, Ireland, acting through its attorney-in-fact, Mr. Enrique Hausermann, who is domiciled for his office for the purposes of this Agreement at the offices of the company (hereinafter, "**SFI**").

and

SFS Stada Financial Services International Ltd., a corporation organised and existing under the law of Ireland with its registered offices in Waterford Road, Clonmel, Ireland, acting through its attorney-in-fact, Mr. Enrique Hausermann, who is domiciled for his office for the purposes of this Agreement at the offices of the company (hereinafter, "**SFS**").

GENTIUM, CRINOS, SFI and SFS are also individually referred to as a "**Party**" and collectively as the "**Parties**").

DEFINITIONS

For purposes of this Agreement, all capitalized terms used herein, other than proper nouns, are defined as follows:

"**Agreement**" means this master agreement, including all its whereas clauses and Exhibits.

"**AICs**" means all of CRINOS's ownership, industrial, intellectual property and related rights to the marketing authorizations AIC no. 026111056 (Capsules) and of the AIC no. 026111029 (Ampoules) with respect to the Products marketed under Prociclide and AIC no. 026086052 (Capsules) and of the AIC no. 026086025 (Ampoules) with respect to the Products marketed under Noravid issued by the MOH.

"**AIC Transfer Agreement**" means the agreement between GENTIUM and CRINOS for the transfer of the AICs, in the form attached hereto as Exhibit 2.3(C).

"**AIFA**" means the *Agenzia Italiana del Farmaco*.

"**Ampoules**" means the pharmaceutical products for human use only, containing Defibrotide as the sole therapeutically active ingredient in ampoules of 200 mg each, and being marketed under Prociclide and Noravid.

"**Ampoule Inventory**" means the remaining inventory of the Ampoules for retail sale (not including sales pursuant to Exhibit 4.6) owned and unsold by CRINOS on the date of this Agreement as well as any shipments under way from SIRTON to CRINOS at the moment CRINOS has to stop sales of Ampoules according to Paragraph 2.3(A).

"**Business Day**" means any day other than a Saturday, Sunday or a day on which banking institutions in Milan (Italy) are authorized or obligated to close by law, executive order or any regulations specifically applicable to banking institutions.

"**Capsules**" means the pharmaceutical products for human use only, containing Defibrotide as the sole therapeutically active ingredient in capsules of 400 mg each, and being marketed under Prociclide and Noravid.

"**Claim Notices**" as defined in Paragraph 8.5(A) hereof.

"**Clinical Data**" means all of CRINOS' ownership, industrial, intellectual property and related rights to all clinical data resulting from any clinical trials performed by CRINOS, including know-how, dossiers, studies, reports and relevant rights related to the Products, a list of which is attached hereto as Exhibit 2.3(B).

"**Collateral Agreements**" means the Distribution and Promotion Agreement, the Noravid Assignment of Trademarks, the Prociclide Assignment of Trademarks, the AIC Transfer Agreement, the Noravid License of Trademarks, the Prociclide License of Trademarks, the Future License Agreement and the Escrow Agreement.

"**CRINOS Amount**" as defined in Paragraph 3.3(A)(i) hereof.

"**CRINOS Assets**" means the AICs and the Clinical Data.

"**CRINOS Assets Price**" as defined in Paragraph 3.1 hereof.

"**CRINOS's Bank Account**" means the bank account no. 035022, held in the name of CRINOS with Deutsche Bank, branch of Milan, ABI 3104, CAB 01600, Swift CODE DEUT IT MM MIL, IBAN CODE IT 28V 0310401900000000035022.

"**CRINOS Indemnified Party**" as defined in Paragraph 8.3 hereof.

"**Defibrotide**" means a poli-desoxi-ribonucleotide extracted from swine mucose.

"**Distribution and Promotion Agreement**" means the distribution and promotion agreement as identified in Italy under the term *Concessione di Vendita* to be entered into between GENTIUM and CRINOS in the form attached hereto as Exhibit 2.3(D).

"**Escrow Account**" means the bank account no. [ ], held in the interests of the Parties with Deutsche Bank S.p.A. branch of Milan, ABI [ ], CAB [ ].

"**Escrow Agent**" means Deutsche Bank S.p.A.

"**Escrow Agreement**" means the escrow agreement to be entered into among GENTIUM, CRINOS and the Escrow Agent in the form attached hereto as Exhibit 2.3(E).

"**Escrow Amount**" as defined in Paragraph 3.3(A)(i) hereof.

"**Europe**" means all the member countries of the European Union on the date hereof and Switzerland.

2

"**First Closing**" means the closing of the transactions contemplated by Paragraph 2.3 hereof.

"**First Installment**" as defined in Paragraph 3.3(A)(i) hereof.

"Future License Agreements" means the agreements providing for the license of Know-how regarding the Products and the Patent by GENTIUM to CRINOS in the form attached hereto as Exhibit 2.3(I), one of which is with respect to the Products commercialized under Prociclide and the second of which is with respect to the Products commercialized under Noravid.

"**GENTIUM Indemnified Party**" as defined in Paragraph 8.1 hereof.

"**Gross Sales**" shall mean, with respect to any given Product during any given fiscal period, the total amount invoiced to third parties during such period by GENTIUM in connection with the sale of such Product.

"**Know-how**" means the whole of technical and scientific information, including data relating to tests or other confidential data the elaboration of which involves a significant effort and the submission of which is a precondition for the authorisation to introduce chemical and/or pharmaceutical products.

"**License Agreements**" means (i) the License Agreement dated May 17, 2002 between GENTIUM and CRINOS, through which GENTIUM granted the right to use certain Know-How and the Patent to market the Products under Prociclide to CRINOS in the Territory and (ii) the License Agreement dated July 15, 2004 between GENTIUM and CRINOS, through which GENTIUM granted the right to use certain Know-How and the Patent to market the Products under Noravid to CRINOS in the Territory.

"**Liens**" means liens, mortgages, charges, security interests, pledges and other such encumbrances.

"**Loss**" as defined in Paragraph 8.1 hereof.

"**Manufacturing and Supply Agreement**" means the Manufacturing and Supply Agreement executed on May 17, 2002 between SIRTON and CRINOS.

"**Material Breach**" means a material breach by one of the Parties of its representations and warranties or obligations under this Agreement or any of the Collateral Agreements, subject to a 45-day cure period (in the case of obligations).

"**MOH**" means the Italian Ministry of Health.

"**Net Sales**" means, with respect to any given Product during a given fiscal period, Gross Sales with respect to such Products for such period, less (to the extent relating to such Products during such period): (a) credits granted for returns; (b) trade, quantity, cash and other discounts similar in the industry; (c) rebates under government programs to the extent customary in European practice; and (d) taxes /other than income taxes), duties or other governmental charged levied on, absorbed or otherwise imposed on sale of the Products, including without limitation valued-added taxes, or other governmental charges otherwise mentioned by the billing, as adjusted for rebates and refund.

"**Noravid**" means all ownership, industrial, intellectual property and related rights, including any goodwill associated therewith, to the International trademark "Noravid," including but not limited to the trademark registration class 5, application date 7 May 1962, application number 255910 (France), original registration date 21 May 1962, registration number 0255910, expiring on 21 May 2012.

"**Noravid Assignment of Trademarks**" means the private deed of transfer with respect to Noravid in the form attached hereto as Exhibit 2.5(A).

3

"**Noravid License of Trademarks**" means the license agreement with respect to Noravid in the form attached hereto as Exhibit 2.3(F).

"**Patent**" means Italian Patent no. IP 11903131, named "Process to obtain clinically defined and reproducible *poli-deoxyribonucleotide* and its pharmacologically active product" (application date 17 April 1986) and the Supplementary Protection Certificate granted to Defibrotide under number IT920405M and expiring on 13 March 2009.

"**Permits**" means the licences, authorizations and permits that are required by any authority for the Parties to carry out their business as currently conducted with respect to the Products.

"**Prociclide**" means all ownership, industrial, intellectual property and related rights, including any goodwill associated therewith, to the Italian trademark "Prociclide," including but not limited to the trademark registration class 5, application date 5 October 2004, application number MI2004C009818, previous registration number 709684, expiring on 29 January 2015.

"**Prociclide Assignment of Trademarks**" means the private deed of transfer with respect to Prociclide in the form attached hereto as Exhibit 2.5(B).

"**Prociclide License of Trademarks**" means the license agreement with respect to Prociclide in the form attached hereto as Exhibit 2.3(G).

"**Price**" as defined in Paragraph 3.1 hereof.

"**Products**" means the Ampoules and the Capsules.

"**Second Closing**" shall mean the consummation of the transactions contemplated pursuant to Paragraph 2.5 hereof.

"**Second Installment**" as defined in Paragraph 3.3(B) hereof.

"**SIRTON**" means Sirton Pharmaceuticals S.p.A., with a registered office at Piazza XX Settembre 2, Villa Guardia (Como), Italy, Inland Revenue code 01192270138.

"**Territory**" means Italy, San Marino and Vatican City.

"**Third Installment**" as defined in Paragraph 3.3(C) hereof.

"**Third Party Claim Notice**" as defined in Paragraph 8.6(A) hereof.

"**VAT**" means Italian value added tax.

"**VAT Credit**" as defined in Paragraph 3.3(E)(iii)(a) hereof.

"**VAT Year**" as defined in Paragraph 3.3(E)(iii) hereof.

"**VOD**" means hepatic veno-occlusive disease as a result of toxic cancer treatments such as high doses of chemotherapy, or as a result of stem cell transplants.

WHEREAS

A. GENTIUM is the sole owner of certain Know-How concerning the Products and the Patent.

B. SFI is the current, sole and exclusive owner of Prociclide, having acquired it from SFS, although SFS remains the registered owner of Prociclide.

C. SFI will be, on the Second Closing Date, the sole and exclusive owner of Noravid.

D. CRINOS is the current, sole and exclusive owner of the CRINOS Assets and the Ampoule Inventory.

E. Following the execution of the License Agreements, CRINOS has obtained from GENTIUM the rights to use GENTIUM's Know-How regarding the Products and the Patent to market the Products under Prociclide and Noravid within the Territory.

F. CRINOS, SFI and SFS form part of the same international pharmaceutical company group. CRINOS conducts a business in selling certain pharmaceutical products, including the Products. For internal company reasons, SFI and SFS hold certain intellectual property rights related to the Products, including Prociclide and Noravid.

NOW, **THEREFORE**, the Parties agree as follows:

Article 1
Definitions, whereas clauses and Exhibits

1.1 The definitions, whereas clauses and the Exhibits shall be considered as an integral part of this Agreement.

Article 2
Scope of this Agreement

2.1 Sale by CRINOS. Upon the terms and subject to the conditions of this Agreement, CRINOS hereby agrees to sell to GENTIUM, and GENTIUM hereby agrees to purchase from CRINOS, all of the CRINOS Assets and the Ampoule Inventory, as provided below.

2.2 Sale by SFI and SFS. Upon the terms and subject to the conditions of this Agreement, SFI and SFS hereby agree to sell to GENTIUM, and GENTIUM hereby agrees to purchase from SFI and SFS, Prociclide and Noravid, as provided below.

2.3 First Closing. The First Closing occurs on the date hereof, at which time, simultaneously with the payment of the First Installment as set forth in Paragraph 3.3(A), the execution of which by GENTIUM shall be adequately documented by GENTIUM, the following activities are carried out:

(A) Cessation of Sales of Ampoules. CRINOS halts all sales of Ampoules, including any shipments received from SIRTON after the First Closing, except for sales of Ampoules pursuant to the legal or contractual obligations of CRINOS set forth on Exhibit 4.6. GENTIUM agrees and guarantees to supply the quantities of Ampoules that CRINOS is obligated to sell and orders pursuant to such legal and contractual obligations, as provided in and subject to the more detailed provisions of the Distribution and Promotion Agreement. In this respect, subject to the foregoing agreement of GENTIUM, CRINOS agrees that any obligations and liabilities deriving from the aforesaid legal and contractual obligations will remain the sole and exclusive responsibility of CRINOS.

(B) Clinical Data. CRINOS sells to GENTIUM, and GENTIUM purchases from CRINOS, all of the Clinical Data. In this respect, CRINOS shall deliver to GENTIUM the Clinical Data listed under Exhibit 2.3(B).

(C) Sale of the AICs. CRINOS sells the AICs to GENTIUM, and GENTIUM purchases the AICs from CRINOS by duly executing, before Mr. Massimo Caspani, Notary Public, with the offices in Como, Via Pessina n.3, the AIC Transfer Agreement in the form attached hereto as Exhibit 2.3(C).

(D) Distribution and Promotion Agreement. GENTIUM and CRINOS execute the Distribution and Promotion Agreement in the form attached hereto as Exhibit 2.3(D). GENTIUM guarantees the supply of the Products throughout the duration of the Distribution and Promotion Agreement, as provided in and subject to the more detailed provisions of the Distribution and Promotion Agreement.

(E) Escrow Agreement. GENTIUM and CRINOS execute, and CRINOS causes the Escrow Agent to execute, the Escrow Agreement, in the form attached hereto as Exhibit 2.3(E).

(F) License of Noravid. SFI licenses Noravid to GENTIUM, effective upon the issuance of a decree from AIFA approving the Distribution and Promotion Agreement, by executing the Noravid License of Trademarks in the form attached hereto as Exhibit 2.3(F).

(G) License of Prociclide. SFI and SFS license Prociclide to GENTIUM, effective upon the issuance of a decree from AIFA approving the Distribution and Promotion Agreement, by executing the Prociclide License of Trademarks in the form attached hereto as Exhibit 2.3(G).

(H) Invoice. CRINOS delivers to GENTIUM an invoice for an amount equal to the CRINOS Assets Price.

(I) Future License Agreements. GENTIUM and CRINOS execute the Future License Agreements in the form attached hereto as Exhibit 2.3(I), which will become effective only in case of specific events enlisted in this Agreement and the Future License Agreements itself.

(J) Payment of the First Installment. GENTIUM shall pay to CRINOS the First Installment by wire transfer to the CRINOS Account and the Escrow Account, as set forth in Paragraph 3.3(A).

(K) Simultaneous Transactions. All of the different activities indicated under this Paragraph 2.3 shall be deemed to occur simultaneously and the First Closing will not be considered to have been successfully consummated until all of such activities are completed.

2.4 Activities to be carried out following the First Closing.

(A) Approvals for AIC Transfers and Distribution and Promotion Agreement. The Parties agree, no later than 30 (thirty) calendar days after the execution of this Agreement, to apply for all necessary approvals and authorizations, including filing the AIC Transfer Agreement with the MOH and the AIFA, for CRINOS to validly transfer the AICs to GENTIUM as set forth under Paragraph 2.3(C) above and with respect to the Distribution and Promotion Agreement.

(B) Termination of the License Agreements and Amendment of Manufacturing and Supply Agreement. Upon publication of the transfer of the AICs to GENTIUM in the *Italian Official Gazette*