

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.

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(Translation of registrant's name into English)

Piazza XX Settembre 2, 22079 Villa Guardia (Como), Italy

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(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  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):

**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

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.

| <b><u>Exhibit</u></b> | <b><u>Description</u></b>  |
|-----------------------|--|
| 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.      |

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**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

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**INDEX TO EXHIBITS**

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**PRESS RELEASE**

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**FOR IMMEDIATE RELEASE**

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**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.

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**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,” “predict” 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.”

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**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 Procyclide and Noravid.

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“**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.



“**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).



“**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 Procyclide, having acquired it from SFS, although SFS remains the registered owner of Procyclide.

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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 Procyclide 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 Procyclide 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, Procyclide 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* and issuance of a decree from AIFA approving the Distribution and Promotion Agreement, the Parties will (i) terminate the License Agreements and (ii) GENTIUM shall use its best efforts to cause SIRTON to amend the Manufacturing and Supply Agreement with regard to the supply of the Products.
- (C) GENTIUM Purchase of Ampoule Inventory. GENTIUM purchases the Ampoule Inventory from CRINOS at a price of € 6.94 per container of 10 Ampoules and € 1.56 per sample container of 2 Ampoules, plus VAT (which GENTIUM shall pay). CRINOS delivers the Ampoule Inventory within 10 (ten) Business Days of the date hereof and issues GENTIUM an invoice for the Ampoule Inventory at such time, which GENTIUM shall pay within 60 (sixty) days of receipt of the invoice.
- (D) GENTIUM Purchase of Ampoules Returned from Market. GENTIUM hereby further agrees to purchase any Ampoules returned to CRINOS from the market for retail sale (not including sales pursuant to Exhibit 4.6) after the date hereof at the prices set forth in Paragraph 2.4(C) above. CRINOS shall issue GENTIUM invoices for such Ampoules. GENTIUM shall make payments under this Paragraph 2.4(D) within sixty (60) days of receipt of the relevant invoice.



(E) Cessation of Sales of Capsules. CRINOS agrees to halt all sales of Capsules beginning on the earlier of 31 December 2008 and the termination of the Distribution and Promotion Agreement pursuant to its terms, including any shipments received from GENTIUM after such date, except for sales of Capsules pursuant to the legal or contractual obligations of CRINOS set forth on Exhibit 4.6. GENTIUM agrees and guarantees to supply the quantities of Capsules 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.

(F) GENTIUM Purchase of Capsules. GENTIUM hereby agrees to purchase (i) the remaining stock of Capsules owned and unsold by CRINOS at the end of the term of the Distribution and Promotion Agreement (being understood that shipments under way from GENTIUM to CRINOS at such moment are included in such remaining stock) and (ii) the Capsules returned to CRINOS from the market after the end of the term of the Distribution and Promotion Agreement, in each case at the same price CRINOS paid to GENTIUM, plus VAT (which GENTIUM shall pay), provided that, prior to end of the term of the Distribution and Promotion Agreement, CRINOS does not purchase more capsules than it reasonably expects to sell by the end of the term of the Distribution and Promotion Agreement. GENTIUM shall make payments under this Paragraph 2.4(F) within sixty (60) days of receipt of the relevant invoice.

2.5 Second Closing. GENTIUM shall give CRINOS, SFI and SFS thirty (30) Business Days notice of the date it proposes to pay the Third Installment (if such payment date is earlier than 31 December 2008). The Second Closing shall occur on the date upon which GENTIUM pays the Third Installment, subject to the provisions of Paragraph 3 below, at which time the following activities shall be carried out:

(A) Sale of Noravid. SFI shall sell Noravid to GENTIUM by executing and delivering to GENTIUM the Noravid Assignment of Trademarks in the form attached hereto as Exhibit 2.5(A); and

(B) Sale of Prociclide. SFI and SFS shall sell Prociclide to GENTIUM by executing and delivering to GENTIUM the Prociclide Assignment of Trademarks in the form attached hereto as Exhibit 2.5(B).

### **Article 3 Price**

3.1 Price. The Parties agree that the aggregate purchase price (hereinafter, the “**Price**”) to be paid by GENTIUM in consideration for the transactions contemplated hereby, including the acquisition of all of the CRINOS Assets, Noravid and Prociclide, shall be equal to €16,000,000.00 (Euro: sixteen million), plus VAT (which will be paid as set forth in Paragraph 3.3(E)). In particular, the Price shall be allocated among the CRINOS Assets, Noravid and Prociclide as follows:

- AIC number 026111056 and number 026111029 (products commercialized under Prociclide): €7,850,000.00 (Euro: seven million eight hundred fifty thousand/00)
- AIC number 026086052 and number 026086025 (products commercialized under Noravid) €2,650,000.00 (Euro: two million six hundred fifty thousand/00)
- Trade Mark Noravid: €1,500,000.00 (Euro: one million five hundred thousand/00)
- Trade Mark Prociclide: €4,000,000.00 (Euro: four million/00).

CRINOS, SFI and SFS agree that the portion of the Price for the CRINOS Assets shall be € 10,500,000.00 (Euro: ten million five hundred thousand/00) (the “**CRINOS Assets Price**”). SFI, SFS and CRINOS agree that, for convenience’s

sake, GENTIUM shall pay the entire Price to CRINOS, and that GENTIUM, by paying the Price to CRINOS, is and will be fully released, discharged and indemnified from any obligation to CRINOS, SFI and SFS, except as otherwise provided herein.

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3.2 Royalty Payment. GENTIUM hereby agrees to pay CRINOS a royalty payment equal to 1.5% of GENTIUM's Net Sales realized for the treatment and prevention of VOD in Europe for a period of seven years starting from the official launch date of the first approved VOD indication (treatment or prevention) of the Product in any of Germany, France, Italy, United Kingdom or Spain (whichever country such indication is first launched). GENTIUM shall pay such royalties within sixty (60) days of the end of each quarterly period (ending March 31, June 30, September 30 and December 31) with respect to Net Sales made in that quarter. GENTIUM agrees to issue quarterly reports to CRINOS stating its applicable accrued Net Sales at the time it pays such royalties. CRINOS shall have the right, one time per calendar year during the whole period in which the royalty payment is due and for a period of two (2) years following such period, to examine or have its consultants examine the relevant books and records of GENTIUM (after at least 20 Business Days prior written notice) during business hours to determine whether appropriate accounting and royalty payment has been made by GENTIUM. GENTIUM shall retain any such books and records for the period of time subject to CRINOS's right of inspection. Once CRINOS has examined the books and records of GENTIUM for a particular period, it may not re-examine such books and records absent evident fraud on the part of GENTIUM. CRINOS agrees that this royalty is consideration for CRINOS permanently and irrevocably terminating and waiving its right of first refusal addressed in Article 5 of the License Agreement dated 17 May 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.

3.3 Terms of Payment. GENTIUM shall pay the Price to the CRINOS's Bank Account or to the Escrow Account, as the case may be, as follows. The Parties hereby agree that any withdrawal of the relevant AIC by the MOH after the date of this Agreement shall not affect GENTIUM's obligation to pay the Price.

(A) First Installment.

- (i) On the date of this Agreement, GENTIUM shall pay an aggregate of Euro 8,000,000 (hereinafter, the "**First Installment**") by paying Euro 4,000,000 (the "**CRINOS Amount**") by wire transfer of immediately available funds to CRINOS's Bank Account and Euro 4,000,000 (the "**Escrow Amount**") by wire transfer of immediately available funds to the Escrow Account. The Escrow Agent, pursuant to the Escrow Agreement, shall release the Escrow Amount to CRINOS upon publication of the transfer of the AICs to GENTIUM in the *Italian Official Gazette*.
- (ii) If the publication of the transfer of AICs to GENTIUM in the *Italian Official Gazette* does not occur by 31 December 2007, (a) the transfer of the AICs shall be terminated, (b) except in the circumstances described in Paragraph 3.3(A)(iii), the Escrow Agent shall return the Escrow Amount, plus accrued interest, to GENTIUM, (c) CRINOS shall retain the Crinos Amount, (d) GENTIUM shall have no obligation to pay the Second Installment or the Third Installment, (e) the Future License Agreements will become effective, enforceable and binding upon the Parties, (f) SFI and SFS shall not be obligated to transfer Prociclide to GENTIUM, (g) SFI shall not be obligated to transfer Noravid to GENTIUM, (h) CRINOS shall not continue to be bound by its obligation to not sell the Ampoules as set forth in Paragraph 2.3(A), (i) CRINOS shall not be bound by its obligation to not sell the Capsules after 31 December 2008 as set forth in Paragraph 2.4(D) and (j) the royalty set forth in Paragraph 3.2 shall remain in effect.
- (iii) If GENTIUM fails to take any action required on its part for the Parties to apply for all necessary approvals and authorizations for CRINOS to validly transfer the AICs to GENTIUM within 30 (thirty) calendar days after execution of this Agreement as provided in Paragraph 2.4(A), the Escrow Agent shall release the Escrow Amount to CRINOS at the end of such 30 (thirty) calendar day period, and GENTIUM shall not be entitled to any reimbursement of the Escrow Amount from CRINOS, regardless of whether the publication of the transfer of the AICs to GENTIUM in the *Italian Official Gazette* occurs by 31 December 2007.





(B) Second Installment. If the publication of the transfer of AICs to GENTIUM in the *Italian Official Gazette* occurs by 31 December 2007 and GENTIUM does not claim any Material Breach by CRINOS, SFI or SFS, then, no later than 31 December 2007, GENTIUM shall pay Euro 4,000,000 (hereinafter, the “**Second Installment**”) by wire transfer of immediately available funds to CRINOS’s Bank Account. If GENTIUM does claim damages due to an alleged Material Breach of CRINOS, SFI or SFS, it shall pay the Second Installment by wire transfer of immediately available funds to the Escrow Account. The Escrow Agent shall release the Second Installment to CRINOS or return it to GENTIUM once the Material Breach damages claim is settled in accordance with the provisions of this Agreement and the Escrow Agreement.

(C) Third Installment. If the publication of the transfer of AICs to GENTIUM in the *Italian Official Gazette* occurs by 31 December 2007 and GENTIUM does not claim any Material Breach by CRINOS, SFI or SFS, then, no later than 31 December 2008, GENTIUM shall pay further Euro 4,000,000 (hereinafter, the “**Third Installment**”) by wire transfer of immediately available funds to CRINOS’s Bank Account. If GENTIUM does claim damages due to an alleged Material Breach of CRINOS, SFI or SFS, it shall pay the Third Installment by wire transfer of immediately available funds to the Escrow Account. The Escrow Agent shall release the Third Installment to CRINOS or return it to GENTIUM once the Material Breach damages claim is settled in accordance with the provisions of this Agreement and the Escrow Agreement.

(D) Prepayment. Notwithstanding the above, GENTIUM shall have the right to pre-pay the Second Installment and the Third Installment before the dates indicated above.

(E) VAT.

- (i) The VAT to be applied on the CRINOS Assets Price invoiced by CRINOS amounts to €2,100,000.00 (Euro two million one hundred thousand/00).
- (ii) At the First Closing, CRINOS will issue an invoice to GENTIUM for the entire CRINOS Assets Price evidencing the VAT applicable and CRINOS will subsequently pay such applicable VAT, equal to Euro 2,100,000.00, to the tax authorities in accordance with the Italian Fiscal Law, giving adequate evidence of such payment to GENTIUM.
- (iii) The calendar year following the calendar year in which GENTIUM validly acquires ownership (*diritto di proprietà*) of the CRINOS Assets (as evidenced by publication in the *Italian Gazette*) shall be referred to as the “**VAT Year**.” As an example, if GENTIUM validly acquires ownership of the CRINOS Assets in 2007, the VAT Year would be 2008.
  - (a) To the extent that GENTIUM will have a VAT credit position, GENTIUM will submit a VAT credit reimbursement request to the applicable tax authorities up to Euro 2,100,000.00 (Euro two million one hundred thousand/00) (such VAT credit to be requested being the “**VAT Credit**”) within 60 (sixty) calendar days of when it is legally possible for GENTIUM to do so during the VAT Year. GENTIUM shall provide CRINOS with a draft of such VAT credit reimbursement request a reasonable time prior to submission for CRINOS’s review and reasonable comment.
  - (b) GENTIUM will execute a notarial deed assigning such VAT Credit to CRINOS no later than 31 December of the VAT Year, such assignment discharging any obligations of GENTIUM towards CRINOS regarding payment of VAT on the CRINOS Assets Price and CRINOS bearing any cost or tax connected to such assignment.
  - (c) If GENTIUM fails to execute the above mentioned notarial deed assigning the VAT Credit by 31 December of the VAT Year, the Parties agree that (a) the AICs will be retransferred by GENTIUM to

CRINOS according to the AIC Transfer Agreement (if the AICs have been transferred to GENTIUM by such date), (b) CRINOS will be entitled to retain any portion of the Price it has received by such date; (c) GENTIUM shall have no obligation to pay any portion of the Price to the extent unpaid prior to such date, (d) the Future License Agreements will become effective, enforceable and binding upon the Parties, (e) SFI and SFS shall not be obligated to transfer Procyclide to GENTIUM, (f) SFI shall not be obligated to transfer Noravid to GENTIUM, (g) CRINOS shall not continue to be bound by its obligation to not sell the Ampoules as set forth in Paragraph 2.3(A), (h) CRINOS shall not be bound by its obligation to not sell the Capsules after 31 December 2008 as set forth in Paragraph 2.4(D) and (i) the royalty set forth in Paragraph 3.2 shall remain in effect.

- (iv) If the tax reimbursement procedure requires a bank guarantee, GENTIUM will submit such bank guarantee, but CRINOS will bear any fees and expenses related to such bank guarantee.
- (v) If GENTIUM utilizes the VAT Credit (totally or partially) in any year, including prior to the VAT Year, by setting off the equivalent amount against any kind of taxes or social security due, GENTIUM will pay the equivalent of the offset amounts to CRINOS within 30 (thirty days) from such setting off. The same applies in case the tax authorities reimburse (totally or partially) the VAT Credit to GENTIUM, including before the VAT Credit is assigned to CRINOS.
- (vi) The Parties agree that, subject to the above, GENTIUM is not required to utilize any other tax credit available to GENTIUM at any time to ensure payment of the VAT Credit to CRINOS.
- (vii) In order to allow CRINOS to check and verify all relevant circumstances related to the VAT credit position of GENTIUM, pursuant to the provisions set forth in this paragraph 3.3 (E), GENTIUM shall provide to Crinos all relevant documents required to prepare the VAT annual return, there included the possibility to check VAT books, invoices, VAT payments and off-settings. GENTIUM will also deliver to CRINOS a printout of the list of tax payments (“versamenti F24”) as results in the internet site of the tax office (“cassetto fiscale Entratel”) at the end of each year, redacted to omit information not related to offsets against the VAT Credit. In addition, in order to verify the “non-operative” status, GENTIUM will deliver to CRINOS a copy of income tax returns of year 2004, 2005 and 2006.

#### 3.4 Default of Payment.

(A) Interest. Subject to any other remedy provided in this Agreement or under applicable law, on the amount of the Price that is from time to time outstanding after the date on which the relevant payment is to be made pursuant to this Agreement, interest at a rate of the 30 day LIBOR rate plus 1.5% per annum, shall accrue (without the need for any notice) from the day after the date such amount should have been paid until the date of full payment thereof. Should the aforesaid interest rate (as fixed on the due date for the above mentioned payment) exceed the maximum rate permitted by law no. 108 of March 7, 1996 (“*Disposizioni in materia di usura*”) and related implementation regulations as subsequently amended and/or repealed, such interest rate will be automatically reduced to such permitted interest rate.

(B) Cure Period. Notwithstanding any other provision of this Agreement, GENTIUM shall have a period of 45 days to cure a payment default with respect to the Second Installment and the Third Installment.

(C) Consequences of Payment Default. If GENTIUM is obligated to pay the Second Installment or Third Installment to CRINOS or to the Escrow Account, as the case may be, and fails to do so within the 45 day default periods set forth above, the Parties agree that (a) the AICs will be retransferred by GENTIUM to CRINOS according to the AIC Transfer Agreement (if the AICs have been transferred to GENTIUM by such date), (b) CRINOS will be entitled to retain the First Installment, (c) GENTIUM shall have no obligation to pay the Second Installment or the Third Installment, (d) the Future License Agreements will become effective, enforceable and binding upon the Parties, (e) SFI and SFS shall not be obligated to transfer Procyclide to GENTIUM, (f) SFI shall not be obligated to transfer Noravid to GENTIUM, (g) CRINOS shall not continue to be bound by its obligation to not sell the Ampoules as set forth in Paragraph 2.3(A), (h) CRINOS shall not be bound by its obligation to not sell the Capsules after 31 December 2008 as set forth in Paragraph 2.4(D) and (i) the royalty set forth in Paragraph 3.2 shall remain in effect.

#### **Article 4**

#### **Representations and Warranties of CRINOS**

4.1 Representations and Warranties of CRINOS. CRINOS makes the representations and warranties in this Article 4 to GENTIUM (it being understood that there shall not be any other representation or warranty, whether express or implied, on the part of CRINOS in any other Paragraph or clause of this Agreement or anywhere else) and acknowledges that they are true, correct and accurate as of the date of this Agreement.

#### 4.2 Legal Power; Authorization; Enforceability.

(A) CRINOS is a corporation duly constituted and validly existing under the laws of Italy and has full power and authority to (i) execute and deliver this Agreement, (ii) perform its obligations hereunder and (iii) consummate the transactions contemplated hereby.

(B) The execution, delivery and performance of this Agreement by CRINOS and the consummation of the transactions contemplated hereby by CRINOS do not and on the Second Closing will not violate or conflict with (i) any provision of the CRINOS's organizational documents; (ii) any applicable law, statute, regulation, injunction, order or decree of any government agency or authority or court to which CRINOS or any of the Products are subject; or (iii) any contract to which CRINOS is bound or (iv) the terms of any Permit to which CRINOS is bound.

(C) The execution and delivery of this Agreement and the consummation of the transactions contemplated hereby have been duly and validly authorized and approved by the competent corporate bodies of CRINOS.

(D) This Agreement constitutes a valid and legally binding obligation of CRINOS, enforceable against it in accordance with the terms set forth herein, subject to mandatory provisions of applicable law.

4.3 Rights and Assets Related to the Products. CRINOS acknowledges that the intent of this Agreement is for GENTIUM to purchase all of CRINOS's right, title and interest to all of CRINOS's and its affiliates' rights and assets related to the Products. CRINOS has no rights or assets related to the Products other than the CRINOS Assets and the Ampoule Inventory. No affiliate of CRINOS (other than SFI and SFS) has any rights or assets with respect to the Products. SFI and SFS have no rights or assets related to the Products other than Procyclide and Noravid. Prior to the date of this Agreement, CRINOS has delivered to GENTIUM true and complete copies of all trademark registrations, other registrations and licenses known to CRINOS that are applicable to the CRINOS Assets and to Procyclide and Noravid, and there are no other rights, approvals and agreements known to CRINOS that are applicable to the CRINOS Assets, the Ampoule Inventory, Procyclide and Noravid.



4.4 Title to Assets. CRINOS is the current, sole and exclusive owner of all of the CRINOS Assets and the Ampoule Inventory.

4.5 Condition and Location of CRINOS Assets and Ampoule Inventory. Except for the fees payable as set forth on Exhibit 4.5 attached hereto, CRINOS has and is hereby conveying to GENTIUM good and valid title to the CRINOS Assets and the Ampoule Inventory free and clear of all Liens and without the obligation, on the part of CRINOS, to pay any royalties (except to GENTIUM), fees, or commissions with respect to the use thereof. The Ampoule Inventory is located at De Salute S.r.l., Via Biasini 26, 26015 Sorresina (CR), Italy.

4.6 Legal and Contractual Obligations. Attached hereto as Exhibit 4.6 is a list of all oral or written contracts and legal obligations of CRINOS and its affiliates to deliver or sell the Ampoules and the Capsules. Prior to the date of this Agreement, CRINOS has delivered to GENTIUM true and complete copies of all such contracts and legal obligations referred to in this Paragraph 4.6.

4.7 Litigation and Claims. Other than as set forth on Exhibit 4.7, there are no actions, suits, claims or proceedings pending or, to CRINOS's knowledge, threatened against or by CRINOS or its affiliates relating to the Products, at law or in equity, in, before, or by, any court, arbitrator, or governmental agency or authority. In particular, except as set forth above, CRINOS has no knowledge of any current intention of the MOH or AIFA to withdraw the AICs prior to 31 December 2008. There are no unsatisfied judgments or outstanding orders, injunctions, decrees, stipulations or awards (whether rendered by a court or administrative agency or by arbitration) against CRINOS or its affiliates relating to the Products. To CRINOS's knowledge, CRINOS and its affiliates have not, during the last five (5) years, (a) incurred any uninsured or insured liability related to the Products, or (b) been threatened with a claim based upon alleged liability related to the Products and, to CRINOS's knowledge, no reasonable basis for any such claim exists.

4.8 Infringement. Except for any possible infringements that occurred prior to 17 May 2002, CRINOS represents and warrants that in carrying out its business with respect to the CRINOS Assets and the Products it does not infringe any model or design (whether registered or not), copyright, patent, trademark, or any other intellectual property right belonging to third parties. No person has, in any judicial or administrative proceeding, challenged the ability of CRINOS to use any of the CRINOS Assets or engage in the business relating to the Products. No person, product or business has infringed, or is infringing, upon CRINOS's rights in or to the CRINOS Assets.

4.9 Consent, Approvals and Permits. Except for the publication process required to transfer the AICs to GENTIUM and with respect to the Distribution and Promotion Agreement, no consent by, approval of or filing with any third party and/or authority is required to be obtained or made on the part of CRINOS in connection with the execution and delivery of this Agreement.

4.10 No Finders. No act of CRINOS has given or will give rise to any claim against any of the parties hereto for a brokerage commission, finder's fee or other like payment in connection with the transactions contemplated by this Agreement.

## **Article 5**

### **Representations and Warranties of SFI and SFS**

5.1 Representations and Warranties of SFI and SFS. SFI and SFS make the representations and warranties in this Article 5 to GENTIUM (it being understood that there shall not be any other representation or warranty, whether express or implied, on the part of SFI or SFS in any other Paragraph or clause of this Agreement or anywhere else) and acknowledge that they are true, correct and accurate as of the date of this Agreement.

5.2 Legal Power; Authorization; Enforceability regarding SFI.

(A) SFI is a corporation duly constituted and validly existing under the laws of Ireland and has full power and authority to (i) execute and deliver this Agreement, (ii) perform its obligations hereunder and (iii) consummate the transactions contemplated hereby.

(B) The execution, delivery and performance of this Agreement by SFI and the consummation of the transactions contemplated hereby by SFI do not and on the Second Closing will not violate or conflict with (i) any provision of the SFI's organizational documents; or (ii) any applicable law, statute, regulation, injunction, order or decree of any government agency or authority or court to which SFI or any of the Products are subject; (iii) any contract to which SFI is bound or (iv) the terms of any Permit to which SFI is bound.

(C) The execution and delivery of this Agreement and the consummation of the transactions contemplated hereby have been duly and validly authorized and approved by the competent corporate bodies of SFI.

(D) This Agreement constitutes a valid and legally binding obligation of SFI, enforceable against it in accordance with the terms set forth herein, subject to mandatory provisions of applicable law.

5.3 Legal Power; Authorization; Enforceability regarding SFS.

(A) SFS is a corporation duly constituted and validly existing under the laws of Ireland and has full power and authority to (i) execute and deliver this Agreement, (ii) perform its obligations hereunder and (iii) consummate the transactions contemplated hereby.

(B) The execution, delivery and performance of this Agreement by SFS and the consummation of the transactions contemplated hereby by SFS do not and on the Second Closing will not violate or conflict with (i) any provision of the SFS's organizational documents; or (ii) any applicable law, statute, regulation, injunction, order or decree of any government agency or authority or court to which SFS or any of the Products are subject; (iii) any contract to which SFS is bound or (iv) the terms of any Permit to which SFS is bound.

(C) The execution and delivery of this Agreement and the consummation of the transactions contemplated hereby have been duly and validly authorized and approved by the competent corporate bodies of SFS.

(D) This Agreement constitutes a valid and legally binding obligation of SFS, enforceable against it in accordance with the terms set forth herein, subject to mandatory provisions of applicable law.

5.4 Rights and Assets Related to the Products. SFI and SFS acknowledge that the intent of this Agreement is for GENTIUM to purchase all of SFI's and SFS's right, title and interest to all of SFI's, SFS's and their affiliates' rights and assets related to the Products. SFI and SFS have no rights or assets related to the Products other than Procyclide and Noravid. No affiliate of SFI or SFS other than CRINOS has any rights or assets with respect to the Products. CRINOS has no rights or assets related to the Products other than the CRINOS Assets and the Ampoule Inventory. Prior to the date of this Agreement, SFI and SFS have delivered to GENTIUM true and complete copies of all trademark registrations, other registrations and licenses known to SFI and SFS that are applicable to Procyclide and Noravid, and there are no other rights, approvals and agreements known to SFI and SFS that are applicable to Procyclide and Noravid.

5.5 Title to Procyclide and Noravid. SFI will be the sole and exclusive owner of Noravid on the Second Closing and is and, on the Second Closing, will be, the current, sole and exclusive owner of Procyclide, except that Procyclide is registered in the name of SFS.





5.6 Condition of Prociclide and Noravid. Except for the fees payable as set forth on Exhibit 5.6 attached hereto, SFI on the Second Closing will be conveying to GENTIUM good and valid title to Noravid free and clear of all Liens and without the obligation, on the part of SFI or SFS, to pay any royalties, fees, or commissions with respect to the use thereof, except to GENTIUM. Except for the fees payable as set forth on Exhibit 5.6 attached hereto, SFI has and on the Second Closing will be conveying to GENTIUM good and valid title to Prociclide free and clear of all Liens and without the obligation, on the part of SFI or SFS, to pay any royalties, fees, or commissions with respect to the use thereof, except to GENTIUM.

5.7 Litigation and Claims. Other than as set forth on Exhibit 4.7, there are no actions, suits, claims or proceedings pending or, to SFI's or SFS's knowledge, threatened against or by SFI, SFS or their affiliates relating to Prociclide or Noravid, at law or in equity, in, before, or by, any court, arbitrator, or governmental agency or authority. In particular, except as set forth above, SFI and SFS have no knowledge of any current intention of the MOH or AIFA to withdraw the AICs. There are no unsatisfied judgments or outstanding orders, injunctions, decrees, stipulations or awards (whether rendered by a court or administrative agency or by arbitration) against SFI, SFS or their affiliates relating to Prociclide or Noravid. To SFI's and SFS's knowledge, SFI, SFS and their affiliates have not, during the last five (5) years, (a) incurred any uninsured or insured liability related to Prociclide and Noravid, or (b) been threatened with a claim based upon alleged liability related to Prociclide or Noravid and, to SFI's and SFS's knowledge, no reasonable basis for any such claim exists.

5.8 Infringement. Except for any possible infringements that occurred prior to 17 May 2002, SFI and SFS represent and warrant that in carrying out their businesses with respect to Prociclide and Noravid they do not infringe any model or design (whether registered or not), copyright, patent, trademark, or any other intellectual property right belonging to third parties. No person has, in any judicial or administrative proceeding, challenged the ability of SFI or SFS to use any of Prociclide or Noravid or engage in the business relating to Prociclide or Noravid. No person, product or business has infringed, or is infringing, upon SFI's or SFS's rights in or to Prociclide or Noravid.

5.9 Consent, Approvals and Permits. No consent by, approval of or filing with any third party and/or authority is required to be obtained or made on the part of SFI or SFS in connection with the execution and delivery of this Agreement.

5.10 No Finders. No act of SFI or SFS has given or will give rise to any claim against any of the parties hereto for a brokerage commission, finder's fee or other like payment in connection with the transactions contemplated by this Agreement.

## **Article 6**

### **Representations and Warranties of GENTIUM**

6.1 Representations and Warranties of GENTIUM. GENTIUM makes the representations and warranties in this Article 6 to CRINOS, SFI and SFS (it being understood that there shall not be any other representation or warranty, whether express or implied, on the part of GENTIUM in any other Paragraph or clause of this Agreement or anywhere else) and acknowledges that they are true, correct and accurate as of the date of this Agreement.

6.2 Legal Power; Authorization; Enforceability.

(A) GENTIUM is a corporation duly constituted and validly existing under the laws of Italy and has full power and authority to (i) execute and deliver this Agreement, (ii) perform its obligations hereunder and (iii) consummate the transactions contemplated hereby.

(B) The execution, delivery and performance of this Agreement by GENTIUM and the consummation of the transactions contemplated hereby by GENTIUM do not and on the Second Closing will not violate or conflict with (i)

any provision of the GENTIUM's organizational documents; or (ii) any applicable law, statute, regulation, injunction, order or decree of any government agency or authority or court to which GENTIUM is subject; (iii) any contract to which GENTIUM is bound or (iv) the terms of any Permit to which GENTIUM is bound.

(C) The execution and delivery of this Agreement and the consummation of the transactions contemplated hereby have been duly and validly authorized and approved by the competent corporate bodies of GENTIUM.

(D) This Agreement constitutes a valid and legally binding obligation of GENTIUM, enforceable against it in accordance with the terms set forth herein, subject to mandatory provisions of applicable law.

6.3 Consent, Approvals and Permits. Except for the authorization required in order to transfer the AICs from CRINOS to GENTIUM and with respect to the Distribution and Promotion Agreement, no consent by, approval of or filing with any third party and/or authority is required to be obtained or made on the part of GENTIUM in connection with the execution and delivery of this Agreement.

6.4 No Finders. No act of GENTIUM has given or will give rise to any claim against any of the parties hereto for a brokerage commission, finder's fee or other like payment in connection with the transactions contemplated by this Agreement.

## **Article 7 Covenants of the Parties**

7.1 Actions to Satisfy Closing Conditions. To the maximum extent permitted under applicable law, each of the Parties shall take all such reasonable actions within its power that are necessary to ensure compliance by such Party with all of the terms of this Agreement.

7.2 Expenses.

(A) Except as otherwise set forth in this Paragraph 7.2, each Party shall each pay its own expenses (including, but not limited to, all compensation and expenses of counsel, financial advisors, consultants, actuaries and independent accountants) incident to the negotiation, preparation and consummation of the transactions provided for herein.

(B) All charges and expenses relating to any notary public fees shall be borne on a 50% basis by each of GENTIUM and CRINOS.

(C) All charges and expenses relating to the Escrow Agreement, including the charges and expenses of the Escrow Agent, shall be borne on a 50% basis by each of GENTIUM and CRINOS.

(D) Any tax relating to the consummation of the transactions contemplated herein other than VAT shall be borne on a 50% basis by each of GENTIUM and CRINOS.

7.3 Registration Formalities. CRINOS, SFI and SFS hereby grant to GENTIUM any and all powers and authority necessary for GENTIUM to register the Noravid Assignment of Trademarks and the Procyclide Assignment of Trademarks. CRINOS, SFI and SFS hereby undertake to execute any document which may be required by the competent authorities for the purposes of such registration.

## **Article 8 Indemnification**

8.1 Indemnification by CRINOS. CRINOS agrees to indemnify and hold harmless GENTIUM and each of its subsidiaries, affiliates, officers, directors, employees and shareholders (each a "**GENTIUM Indemnified Party**") from and against any actual loss, damage, liability, cost or expense, including, without limitation, reasonable legal fees and disbursements incurred in connection with seeking indemnification for and any other reasonable amounts or expenses required to be paid or incurred in connection with any action, suit, proceeding, claim, appeal, demand, assessment or

judgment, but otherwise excluding loss of profit, consequential (other than the legal fees and disbursements referenced above) or indirect loss or damage (hereinafter, a “**Loss**”) suffered or incurred by a GENTIUM Indemnified Party as a result of any breach of (i) the representations and warranties rendered by CRINOS pursuant to Article 4 above; or (ii) any obligation undertaken by CRINOS under this Agreement or any Collateral Agreement.

8.2 Indemnification by SFI and SFS. SFI and SFS each agrees to indemnify and hold harmless each GENTIUM Indemnified Party from and against any Loss suffered or incurred directly by a GENTIUM Indemnified Party as a result of any breach of (i) the representations and warranties rendered by SFI or SFS, as applicable, pursuant to Article 5 above; or (ii) any obligation undertaken by SFI or SFS, as applicable, under this Agreement or any Collateral Agreement.

8.3 Indemnification by GENTIUM. GENTIUM agrees to indemnify and hold harmless CRINOS, SFI and SFS and each of their subsidiaries, affiliates, officers, directors, employees and shareholders (each a “**CRINOS Indemnified Party**”) from and against any Loss suffered or incurred by a CRINOS Indemnified Party as a result of any breach of (i) the representations and warranties rendered by GENTIUM pursuant to Article 6 above; or (ii) any obligation undertaken by GENTIUM under this Agreement or any Collateral Agreement.

8.4 Noravid Indemnification. In addition the above, irrespective of any other provision of this Agreement, CRINOS, SFI and SFS agree to indemnify and hold harmless each GENTIUM Indemnified Party from and against any Loss arising from a liability suffered or incurred by a GENTIUM Indemnified Party in respect of VAT (including as a consequence of any assessment issued by the tax authorities and including any interest and penalties related thereto) as a result of GENTIUM’s acquisition of Noravid under this Agreement or any Collateral Agreement. Without prejudice of the foregoing, in case of a tax assessment, in accordance with following Paragraph 8.6 GENTIUM will follow reasonable CRINOS instructions, including appointing a tax lawyer chosen by CRINOS, in order to handle the tax assessment and deciding whether appeal before the competent tax court.

8.5 Indemnification Procedure, Set-off.

(A) In the event that one of the Parties to this Agreement seeks indemnification hereunder, such indemnified party will give written claim notice (to be sent by registered mail) to the indemnifying party indicating the amount, to the extent known, of the claim asserted (“**Claim Notice**”). Notwithstanding anything contained in this Paragraph 8.5, the right of the indemnified party to be indemnified hereunder shall not be adversely affected by a failure to give the Claim Notice.

(B) The indemnifying party shall pay the amount claimed by the indemnified party within 30 (thirty) Business Days following receipt of the Claim Notice unless the indemnifying party has replied within above term with a written notice of disagreement to be sent by registered mail. Should the indemnifying party however not reply within above 30 days-term and not proceed to payment within such 30-day-term, the indemnified party shall be entitled to set-off the relevant amount from any other amount due to the indemnifying party pursuant to this Agreement. In case the indemnifying party has sent the mentioned notice of disagreement, the indemnified party’s right to set off the relevant claim however shall apply only to the extent such claim is finally ascertained by the arbitration panel according to Article 9.

(C) In the event that there shall be, with respect to any party claim covered by this Paragraph 8.5, more than one indemnifying party, this Paragraph 8.5 shall apply to all such indemnifying parties and their rights hereunder shall be exercised by them, if at all, jointly.

8.6 Third-Party Claim Procedures.

(A) If a claim by a third party is made against any indemnified party, such indemnified party shall promptly give notice of such claim (“**Third Party Claim Notice**”) to each other party hereto who has, or might reasonably be expected to have, an obligation to indemnify the indemnified party hereunder with respect to such claim; provided, however, that failure to give timely notice shall not affect the rights of the indemnified party except to the extent that the failure to give timely notice adversely affects the indemnifying party’s ability to defend such claim against a third party.

(B) The indemnifying party shall be entitled to settle or assume the defense of such claim, including the employment of counsel satisfactory to the indemnified party (whose approval shall not reasonably be withheld), as provided below, unless such assumption would adversely affect insurance coverage or an ability to recover from insurance by the indemnified party. If the indemnifying party elects to settle or defend such claim, it shall notify the indemnified party within 30 days of the date on which it receives the Third Party Claim Notice of its intent to do so; provided, however, that if such notice is given within 20 days of the date on which any material pleading, filing or response on behalf of the indemnified party is due, such assumption of the defense shall not be effective until after the filing or giving of such pleading, filing or request. If the indemnifying party elects not to defend such claim or fails to notify the indemnified party of its election within such 30 day period, the indemnified party shall have the right to contest, settle or compromise the claim (subject in any event to the other terms and conditions hereof) without prejudice to any rights to indemnification hereunder. Regardless of which party is controlling the settlement or defense of any claim, (i) both the indemnified party and the indemnifying party shall act in good faith, (ii) the controlling party shall permit the non-controlling party to participate in such settlement or defense through counsel chosen by the non-controlling party, provided that all fees, costs and expenses of such counsel shall be borne by the non-controlling party, (iii) no entry of judgment or settlement of a claim may be agreed to without the written consent of both the indemnified party and the indemnifying party, which consents shall not be unreasonably withheld. The controlling party shall deliver, or cause to be delivered, to the other party copies of all correspondence, pleadings, motions, briefs, appeals or other written statements relating to or submitted in connection with the settlement or defense of any such claim, and timely notices of, and the right to participate pursuant to clause (ii) above in any hearing or other court proceeding relating to such claim.

(C) In the event that there shall be, with respect to any third party claim covered by this Paragraph 8.6 , more than one indemnifying party, this Paragraph 8.6 shall apply to all such indemnifying parties and their rights hereunder shall be exercised by them, if at all, jointly.

8.7 No Rescission or Other Remedy. Except as elsewhere in this Agreement provided, anything in any applicable law to the contrary notwithstanding, no breach or inaccuracy of any representation, warranty or obligation of CRINOS, SFI, SFS or GENTIUM, as the case may be, set forth herein shall give rise to any right on the part of CRINOS, SFI, SFS or GENTIUM, respectively, to rescind or terminate this Agreement.

**Article 9**  
**Dispute Resolution**

9.1 Arbitration. Any dispute among the Parties arising out of or in connection with this Agreement shall be referred to and finally settled by arbitration under the “**Regolamento della Camera Arbitrale Nazionale e Internazionale di Milano**”, hereinafter, “Rules of Arbitration”, attached hereto as Exhibit 9.1 by three (3) arbitrators appointed by the Parties as provided herein, it remaining understood that, for the purposes of this Article 9 only, CRINOS, SFI and SFS will be considered as a sole Party.

9.2 Appointment of the Arbitrators. The first Arbitrator will be appointed by the Party initiating the arbitration, the second Arbitrator will be appointed by the other Party within ten (10) Business Days from the date of receipt of the arbitration notice and the third Arbitrator (who shall act as Chairman of the arbitration panel) will be designated upon

mutual agreement of the two Arbitrators already appointed by the Parties or, failing such agreement within ten (10) Business Days from the appointment of the second Arbitrator, by the Arbitration Council in accordance with paragraph 15.4.b of Rules of Arbitration, as promptly as practicable thereafter. The Arbitration Council will also designate (i) the second Arbitrator in the event that the Party required to make such designation will have failed to do so within the above referenced ten-Business Day period, in accordance with paragraph 15.4.a of Rules of Arbitration; and (ii) the replacement of any Arbitrator who is unable or unwilling to serve or to continue to serve as such, in the event that such replacement has not been designated by the Party who had originally appointed such Arbitrator within ten (10) Business Days following the date on which such Arbitrator resigned or otherwise ceased from office or, in case of the Chairman, upon agreement of the other two Arbitrators.

9.3 Conflicts of interest. Should a conflict of interest between CRINOS, SFI or SFS arise whereby they can not jointly appoint an Arbitrator, the multilateral dispute deriving from it shall be settled by three (3) Arbitrators, all jointly appointed by the disputing Parties, or, failing such agreement within 10 (ten) Business Days from the request made to the other disputing Parties by any Party, they shall be appointed, upon the request of any Party, by the “**Camera Arbitrale Nazionale ed Internazionale di Milano**”.

9.4 Determination of the Arbitrators. The determination of the Arbitrators will be made in accordance with applicable principles of law and shall have the force and effect of a judicial decision between the Parties in accordance with Article 806 et seq. of the Italian Civil Procedure Code. The arbitration proceedings shall take place in Milan (Italy) and shall be conducted in the English language.

9.5 Arbitration Award. Under paragraph 36 of Rules of Arbitration, the Arbitration Panel will submit its final arbitration Award to the General Secretary within 6 months from the date of its appointment, thus bringing the proceedings to an end.

## **Article 10 Miscellaneous**

### 10.1 Notices.

(A) Any notice or other communication required or permitted to be given hereunder shall be in writing and shall be transmitted by fax or registered mail, return receipt requested, addressed as follows:

If to GENTIUM, to:

Gentium S.p.A.  
Piazza XX Settembre, 2  
Villa Guardia (Como)  
Fax: 39-031-385-241  
Att.: Dr. Laura Ferro

With copies (which shall not constitute notice) to:

Gianni, Origoni, Grippo & Partners  
Via delle Quattro Fontane, 20  
00184 Roma  
Italy  
Fax: 39-06-487-1101  
Att.: Raimondo Premonte - Andrea Aiello



And

Epstein Becker & Green, P.C.  
250 Park Avenue  
New York, New York 10177  
United States of America  
Fax: 1-212-878-8759  
Att.: Christopher M. Locke, Esq.

If to CRINOS, to:

CRINOS S.p.A.  
Via Pavia, 6  
Milan  
Italy  
Phone: 39-02-8310371  
Fax: 39-02-83103  
Att: Enrique Häusermann

With a copy (which shall not constitute notice) to:

STADA Arzneimittel AG  
Stadastrasse 2-18  
61118 Bad Vilbel  
Germany  
Fax: 49-6101-603  
Att.: Luc Slegers

If to SFI, to:

Stada Financial Investments Ltd.  
Clonmel Healthcare,  
Waterford Road,  
Clonmel,  
Ireland  
Phone: 353 52 77777  
Fax: 353 52 77799  
Att: Jim Hanlon

With a copy (which shall not constitute notice) to:

STADA Arzneimittel AG  
Stadastrasse 2-18  
61118 Bad Vilbel  
Germany  
Fax: 49-6101-603 (to be completed)  
Att.: Luc Slegers

If to SFS, to:

SFS Stada Financial Services International Ltd.

Clonmel Healthcare,

Waterford Road,

Clonmel,

Ireland

Phone: 353 52 77777

Fax: 353 52 77798

Att: James Hanlon

With a copy (which shall not constitute notice) to:

STADA Arzneimittel AG  
Stadastrasse 2-18  
61118 Bad Vilbel  
Germany  
Fax: 49-6101-603  
Att.: Luc Slegers

(B) Any such notice or other communication shall be deemed to have been given on the day on which it is received (or, if such day is not a business day, on the next following business day). A positive fax confirmation report shall be a valid proof of receipt of a fax communication.

(C) Any Party may at any time change its address for service by giving notice to the other Parties in accordance with this Paragraph 10.1.

10.2 Assignment, No Third Party Beneficiaries.

(A) This Agreement and all of the provisions hereof shall be binding upon and inure to the benefit of each of the Parties hereto and their respective successors and permitted assigns, and such successors and permitted assigns shall have the benefit of the indemnities set forth in Paragraph 9 hereof. This Agreement and the rights, interests or obligations hereunder shall not be assigned by any Party without the prior written consent of the other Party, and any attempt to assign this Agreement without such consent shall be void and of no effect.

(B) Except as otherwise expressly provided for herein, nothing in this Agreement shall confer any rights upon any person which is not a Party or a successor or permitted assignee of any Party to this Agreement.

10.3 Governing Law. This Agreement shall be governed by, construed and enforced in accordance with the Laws of Italy.

10.4 Confidentiality.

(A) Neither Party shall disclose any information received from the other Party or pursuant to this Agreement or to any previous agreements between the Parties relating to the Products without the other Party's written consent. Such information is confidential and proprietary. This obligation of confidentiality does not apply to:

- (i) information which is or was known to the receiving Party at the time of its disclosure pursuant to this Agreement or any previous agreement, as established by such Party's written records;
- (ii) information disclosed to the receiving Party by a third party having the right to disclose such information;
- (iii) information which becomes patented, published or otherwise part of the public domain, as a result of acts of the disclosing Party or of a third party obtaining such information and having the right to disclose the same;
- (iv) information that have to be disclosed by virtue of any applicable disposition of law or by a decision of a competent court or public authority.

(B) Each Party agrees that it shall not use confidential information obtained pursuant to this Agreement, for any purpose other than that indicated in this Agreement, without the prior written approval of the other Party.

(C) The Parties agree that the provision set forth in this Paragraph 11.4 survives after expiration and/or termination for any reason of this Agreement, until the confidential information becomes of public knowledge, without any breach of this clause made by the Parties hereto.

(D) Except for the draft of press release, which has been agreed by the Parties and attached hereto as Exhibit 10.4 (D), no Party to this Agreement shall make any announcement concerning the provisions or subject of this Agreement and/or the Collateral Agreements, without the prior written approval of the other Parties (which shall not be unreasonably withheld or delayed). Such restriction shall not apply if and to the extent that the announcement is required by law or by any authority having jurisdiction over it, provided that the disclosing Party shall give notice and, if requested by the other Parties, a draft of the announcement to the other Parties.

(E) Notwithstanding the foregoing, CRINOS, SFI and SFS hereby agree that GENTIUM may disclose the existence and terms of this Agreement and the Collateral Agreements in and file copies of the same as exhibits to registration statements and reports filed with the United States Securities and Exchange Commission pursuant to the Securities Act of 1933, as amended and the Securities Exchange Act of 1934, as amended, with any securities exchange or listing upon which GENTIUM's securities may be listed or trading or pursuant to applicable law or regulations, provided that GENTIUM shall give notice and, if requested, a draft of the applicable portion of such registration statement or report (and also a copy of the final version which has been filed).

(F) Notwithstanding the foregoing, on the other hand, GENTIUM hereby agrees that the mother company of CRINOS, STADA Arzneimittel AG, which is listed at the Frankfurt Stock Exchange, may disclose the existence and terms of this Agreement and the Collateral Agreements in and file copies of the same as exhibits to registration statements and reports filed with the competent German Authorities pursuant to the requirements provided for in German Law, provided that CRINOS shall give notice and, if requested, a draft of the applicable portion of such registration statement or report (and also a copy of the final version which has been filed).

10.5 Integration. This Agreement, together with the Schedules and Exhibits hereto, the documents and agreements delivered or to be delivered in connection herewith, constitutes the entire agreement of the Parties and supersedes all prior agreements and understandings, both written and oral, of the Parties with respect to the subject matter hereof.

10.6 Amendments and Waivers. No amendment of any provision of this Agreement shall be binding on any Party unless agreed to in writing by all Parties. No waiver of any provision of this Agreement shall constitute a waiver of any other provision, nor shall any waiver constitute a continuing waiver unless otherwise expressly provided.

10.7 English Language to Prevail. In case of any translation of this Agreement and the Exhibits which are in the English language or any dispute arising over the meaning of any provision hereof or thereof, the English language versions shall prevail. In case of any translation of the Exhibits which are in the Italian language or any dispute arising over the meaning of any provision thereof, the Italian language versions shall prevail.

[Remainder of page left blank intentionally]

IN WITNESS WHEREOF, the Parties have executed this Agreement as of the date first written above.

GENTIUM S.p.A.

By: */s/ Laura Ferro, M.D.*  
Name: Dr. Laura Ferro  
Title: Chairperson, Chief Executive Officer  
and President

CRINOS S.p.A.

By: */s/ Enrique Hausermann*  
Name: Enrique Hausermann  
Title: Managing Director

SFI STADA FINANCIAL SERVICES LTD.

By: */s/ Enrique Hausermann*  
Name: Enrique Hausermann  
Title: Attorney-in-Fact

SFS STADA FINANCIAL SERVICES INTERNATIONAL LTD.

By: */s/ Enrique Hausermann*  
Name: Enrique Hausermann  
Title: Attorney-in-Fact

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**Exhibit 2.3(B)**

**Clinical Data**

Intentionally omitted.

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**Exhibit 2.3(C)**

**AIC Transfer Agreement**

See Exhibit 3 to Form 6-K of Gentium S.p.A. dated January 3, 2007.

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**Exhibit 2.3(D)**

**Distribution and Promotion Agreement**

See Exhibit 3 to Form 6-K of Gentium S.p.A. dated January 3, 2007.

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**Exhibit 2.3(E)**

**Escrow Agreement**

See Exhibit 5 to Form 6-K of Gentium S.p.A. dated January 3, 2007.

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**Exhibit 2.3(F)**

**Noravid License of Trademarks**

See Exhibit 7 to Form 6-K of Gentium S.p.A. dated January 3, 2007.

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**Exhibit 2.3(G)**

**Procicide License of Trademarks**

See Exhibit 8 to Form 6-K of Gentium S.p.A. dated January 3, 2007.

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**Exhibit 2.3(L)**

**Future License Agreements**

Intentionally omitted.

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**Exhibit 2.5(A)**

**Noravid Assignment of Trademarks**

Intentionally omitted.

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**Exhibit 2.5(B)**

**Procicide Assignment of Trademarks**

Intentionally omitted.

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**Exhibit 4.5****Fees Payable by CRINOS****INVENTORY PROCICLIDE AMPOULES**

| CODE  | LOT NUMBER | EXPIRY DATE | DE SALUTE | MEDIFARMA | ORVED S.R.L | PULEO | TOTAL  |
|---|------------|-------------|-----------|-----------|-------------|-------|--------|
| 0330202 Prociclide - 10 amp 200 mg hospital         | D031-      | 6/30/2009   | 4,425     | 0         | 0           | 0     | 4,425  |
|   | D033-      | 9/30/2009   | 4,614     | 0         | 0           | 0     | 4,614  |
| 0330202 Prociclide - 10 amp 200 mg hospital - Total |            |             | 9,039     | 0         | 0           | 0     | 9,039  |
| 0330201 Prociclide - 10 amp 200 mg public           | C023-      | 11/30/2008  | 0         | 12        | 0           | 0     | 12     |
|   | C024-      | 11/30/2008  | 0         | 0         | 0           | 10    | 10     |
|   | D027-      | 3/31/2009   | 0         | 0         | 5           | 0     | 5      |
|   | D029-      | 6/30/2009   | 0         | 216       | 0           | 0     | 216    |
|   | D030-      | 6/30/2009   | 0         | 0         | 0           | 550   | 550    |
|   | D032-      | 9/30/2009   | 6,518     | 0         | 0           | 0     | 6,518  |
|   | D033-      | 9/30/2009   | 2,880     | 0         | 0           | 0     | 2,880  |
| 0330201 Prociclide - 10 amp 200 mg public - Total   |            |             | 9,398     | 228       | 5           | 560   | 10,191 |
|   |            |             |           |           |             |       |        |
| <b>TOTAL PROCICLIDE</b>                             |            |             | 18,437    | 228       | 5           | 560   | 19,230 |

**INVENTORY NORAVID AMPOULES**

| CODE                                    | LOT NUMBER | EXPIRY DATE | DE SALUTE | FD    | ORVED S.R.L | PULEO | TOTAL |
|---|------------|-------------|-----------|-------|-------------|-------|-------|
| 80000910 Noravid - 10 amp 200 mg public | D001-      | 4/30/2009   | 0         | 0     | 0           | 11    | 11    |
|   | D002-      | 9/30/2009   | 4,831     | 2,563 | 0           | 0     | 7,394 |
| <b>TOTAL NORAVID</b>                    |            |             | 4,831     | 2,563 | 0           | 11    | 7,405 |

**Exhibit 4.6****Oral and Written Contracts and Legal Obligations to Deliver Products****Obligations to deliver products (Prociclide and Noravid)****HOSPITAL TENDERS****PROCICLIDE - 10 AMPOULES 200 MG**

| CODE | CUSTOMER   | CITY                    | PRICE € | DISCOUNT % (*) | STARTING DATE | CLOSING DATE |
|------|--|-------------------------|---------|----------------|---------------|--------------|
| 66   | AZIENDA REGIONALE U.S.L. 4<br>CdC VILLA MARIA PIA  | TORINO                  | 11.93   | 54.12          | 01/10/2005    | 31/01/2008   |
| 117  | HOSPITAL   | TORINO                  | 12.0016 | 53.84          | 07/04/2006    | 31/03/2007   |
| 300  | A O S.CROCE E CARLE<br>AZIENDA U.S.L. N. 3         | CUNEO<br>GENOVA         | 6.6     | 73.11          | 07/07/2004    | 6/30/2007    |
| 422  | GENOVESE<br>IST.NAZ.RICERCA SUL                    | QUARTO                  | 13      | 50             | 15/02/2005    | 30/06/2007   |
| 434  | CANCRO   | GENOVA<br>GENOVA        | 12.688  | 51.2           | 24/02/2006    | 31/05/2009   |
| 461  | ISTITUTO GIANNINA GASLINI<br>IST.NAZ.STUDIO E CURA | QUARTO                  | 11.973  | 53.95          | 01/08/2005    | 31/12/2007   |
| 809  | TUMORI   | MILANO                  | 13      | 50             | 31/01/2005    | 31/05/2007   |
| 942  | A.O. OSPEDALE TREVIGLIO<br>CARAVAGGIO              | TREVIGLIO               | 13      | 50             | 28/02/2005    | 30/06/2008   |
| 999  | A O SPEDALI CIVILI                                 | BRESCIA                 | 6.621   | 74.53          | 01/03/2006    | 30/06/2008   |
| 1019 | A O MELLINO MELLINI                                | CHIARI                  | 13      | 50             | 01/09/2006    | 30/06/2008   |
| 1020 | AZIENDA PROVINCIALE                                | BRESCIA                 | 13      | 50             | 28/02/2005    | 30/06/2008   |
| 1022 | AZIENDA OSPEDALIERA<br>A.S.L. DI                   | DESENZANO<br>DEL GARDA  | 13      | 50             | 28/02/2005    | 30/06/2008   |
| 1028 | VALLECAMONICA-SEBINO                               | BRENO                   | 13      | 50             | 28/02/2005    | 30/06/2008   |
| 1127 | AO ISTITUTI OSPITALIERI                            | CREMONA                 | 13      | 50             | 28/02/2005    | 30/06/2008   |
| 1144 | A O OSPEDALE MAGGIORE                              | CREMA                   | 13      | 50             | 28/02/2005    | 30/06/2008   |
| 1145 | ASL PROV. CREMONA                                  | CREMONA                 | 13      | 50             | 28/02/2005    | 30/06/2008   |
| 1200 | A O CARLO POMA<br>AZIENDA SANITARIA                | MANTOVA                 | 13      | 50             | 28/02/2005    | 30/06/2008   |
| 1229 | LOCALE   | BOLZANO                 | 13      | 50             | 01/02/2005    | 31/01/2007   |
| 1319 | AZIENDA U.L.S.S. N. 5 OVEST<br>VICENTINO           | ARZIGNANO               | 7.3126  | 63.96          | 01/10/2004    | 30/10/2007   |
| 1422 | CASA DI CURA PAPA G. XXIII                         | MONASTIER<br>REGGIO     | 13      | 50             | 10/03/2006    | 31/03/2007   |
| 1740 | SALUS HOSPITAL<br>GAMBRO HEALTHCARE                | EMILIA                  | 12.0016 | 53.84          | 07/04/2006    | 31/03/2007   |
| 1752 | ITALIA S.p.A                                       | MEDOLLA                 | 13      | 50             | 20/09/2006    | 30/09/2007   |
| 1786 | A O UNIV. POLICLINICO<br>S.ORSOLA-MALPIGHI         | BOLOGNA                 | 12.87   | 50.5           | 09/02/2006    | 30/06/2009   |
| 1787 | AZIENDA U.S.L. BOLOGNA<br>NORD                     | SAN GIORGIO<br>DI PIANO | 12.87   | 50.5           | 09/02/2006    | 30/06/2009   |
| 1813 | ISTITUTI ORTOPEDICI<br>RIZZOLI                     | BOLOGNA                 | 12.87   | 50.5           | 09/02/2006    | 30/06/2009   |



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|      |                                 |         |         |       |            |            |
|------|---------------------------------|---------|---------|-------|------------|------------|
| 1832 | AZIENDA U.S.L.                  | IMOLA   | 12.87   | 50.5  | 09/02/2006 | 30/06/2009 |
| 1852 | AZIENDA U.S.L.                  | RAVENNA | 13      | 50    | 01/06/2006 | 30/05/2007 |
| 1854 | CASA DI CURA CITTA' DI<br>LECCE | LECCE   | 12.0016 | 53.84 | 01/04/2006 | 31/03/2007 |

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| CODE | CUSTOMER                               | CITY                           | PRICE € | DISCOUNT % (*) | STARTING DATE | CLOSING DATE |
|------|--|--------------------------------|---------|----------------|---------------|--------------|
| 1859 | SAN PIER DAMIANO<br>HOSPITAL           | FAENZA                         | 12.0016 | 53.84          | 07/04/2006    | 31/03/2007   |
| 1864 | VILLA MARIA CECILIA<br>HOSPITAL        | COTIGNOLA                      | 12.0016 | 53.84          | 07/04/2006    | 31/03/2007   |
| 1909 | AZIENDA U.S.L. N. 3                    | FANO                           | 13      | 50             | 19/05/2006    | 31/08/2008   |
| 1910 | AZIENDA U.S.L. N.1                     | PESARO                         | 13      | 50             | 19/05/2006    | 31/08/2008   |
| 1923 | AZIENDA U.S.L. N. 2                    | URBINO                         | 13      | 50             | 19/05/2006    | 31/08/2008   |
| 1928 | ZONA TERRITORIALE 7                    | ANCONA                         | 13      | 50             | 19/05/2006    | 31/08/2008   |
| 1930 | AZIENDA U.S.L. N. 5                    | JESI                           | 13      | 50             | 19/05/2006    | 31/08/2008   |
| 1953 | AZIENDA U.S.L. N.6                     | FABRIANO                       | 13      | 50             | 19/05/2006    | 31/08/2008   |
| 1955 | AZIENDA U.S.L. N.4                     | SENIGALLIA                     | 13      | 50             | 19/05/2006    | 31/08/2008   |
| 1965 | AZIENDA U.S.L. N. 10                   | CAMERINO                       | 13      | 50             | 01/07/2006    | 31/08/2008   |
| 1966 | AZIENDA U.S.L. N. 8                    | CIVITANOVA<br>MARCHE           | 13      | 50             | 19/05/2006    | 31/08/2008   |
| 1967 | AZIENDA U.S.L. N.9                     | MACERATA                       | 13      | 50             | 01/07/2006    | 31/08/2008   |
| 1991 | AZIENDA U.S.L. N.11                    | FERMO                          | 13      | 50             | 19/05/2006    | 31/08/2008   |
| 1992 | AZIENDA U.S.L. N.13                    | ASCOLI<br>PICENO               | 13      | 50             | 12/07/2006    | 31/08/2008   |
| 2013 | AZIENDA U.S.L. N.12                    | SAN<br>BENEDETTO<br>DEL TRONTO | 13      | 50             | 01/07/2006    | 31/08/2008   |
| 2019 | AZIENDA U.S.L. N.1                     | MASSA<br>CARRARA               | 6.984   | 71.54          | 14/04/2004    | 31/03/2008   |
| 2039 | AZIENDA U.S.L. N.2                     | LUCCA                          | 6.984   | 73.14          | 14/04/2004    | 31/03/2008   |
| 2040 | AZIENDA U.S.L. N.12                    | VIAREGGIO                      | 6.984   | 73.14          | 14/04/2004    | 31/03/2008   |
| 2063 | AZIENDA U.S.L. N.3                     | PISTOIA                        | 7.015   | 71.42          | 01/04/2004    | 31/07/2008   |
| 2094 | AZIENDA U.S.L.                         | FIRENZE                        | 7.015   | 71.42          | 01/04/2004    | 31/08/2007   |
| 2095 | A O CAREGGI                            | FIRENZE                        | 7.015   | 71.42          | 01/04/2004    | 31/07/2008   |
| 2096 | AZIENDA U.S.L. N. 4                    | PRATO                          | 7.015   | 71.42          | 01/04/2004    | 31/07/2008   |
| 2097 | AZIENDA U.S.L. N. 11                   | EMPOLI                         | 7.015   | 71.42          | 01/04/2004    | 31/07/2008   |
| 2100 | A O MEYER                              | FIRENZE                        | 7.015   | 71.42          | 01/04/2004    | 31/07/2008   |
| 2162 | AZIENDA U.S.L. N.6                     | LIVORNO                        | 6.984   | 73.14          | 14/04/2004    | 31/03/2008   |
| 2185 | AZIENDA U.S.L. N.5                     | PISA                           | 6.984   | 71.54          | 14/04/2004    | 31/03/2008   |
| 2208 | AZIENDA U.S.L. N.8                     | AREZZO                         | 12.2728 | 50             | 01/01/2006    | 31/03/2008   |
| 2227 | AZIENDA U.S.L. N.7                     | SIENA                          | 12.2728 | 50             | 04/10/2004    | 31/12/2007   |
| 2228 | A O SENESE                             | SIENA                          | 8.2     | 66.59          | 24/02/2004    | 31/03/2007   |
| 2238 | AZIENDA U.S.L. N.9                     | GROSSETO                       | 12.2728 | 50             | 01/05/2005    | 31/12/2007   |
| 2595 | G.I.O.M.I. S.P.A.<br>AZIENDA SANITARIA | ROMA                           | 13      | 50             | 01/04/2005    | 31/01/2007   |
| 3003 | LOCALE BN/1                            | BENEVENTO                      | 11.95   | 54.04          | 01/10/2005    | 7/31/2007    |
| 3210 | A O CARDARELLI                         | NAPOLI                         | 12.2728 | 50             | 01/06/2005    | 7/31/2007    |
| 3214 | A O<br>SANTOBONO-PAUSILLIPON           | NAPOLI                         | 13      | 50             | 01/12/2004    | 31/03/2007   |
| 3241 | CASA DI CURA VESUVIO                   | NAPOLI                         | 13      | 50             | 20/02/2006    | 28/02/2007   |
| 3498 | AZIENDA U.S.L. AV/1                    | AVELLINO                       | 13      | 50             | 01/06/2006    | 30/06/2008   |

| CODE | CUSTOMER  | CITY               | PRICE € | DISCOUNT % (*) | STARTING DATE | CLOSING DATE |
|------|---|--------------------|---------|----------------|---------------|--------------|
| 3707 | AZIENDA U.S.L.  | CHIETI             | 13      | 50             | 19/07/2006    | 30/06/2008   |
| 3766 | AZIENDA U.S.L. FG/1                                     | SAN SEVERO         | 8.347   | 64.43          | 11/04/2003    | 1/31/2007    |
| 3770 | OSPEDALI RIUNITI  | FOGGIA             | 13      | 50             | 01/11/2006    | 6/30/2009    |
| 3843 | ANTHEA SRL  | BARI               | 12.0016 | 53.84          | 07/04/2006    | 31/03/2007   |
| 3846 | AZIENDA U.S.L. BARI/5                                   | PUTIGNANO          | 13      | 50             | 01/05/2006    | 31/03/2007   |
| 3847 | AZIENDA U.S.L. BARI/4                                   | BARI               | 7.67    | 68.75          | 23/03/2004    | 3/30/2007    |
| 3848 | AZIENDA U.S.L. BARI/2                                   | BARLETTA           | 7.9     | 67.81          | 29/06/2004    | 30/04/2007   |
| 3857 | AZIENDA OSPEDALIERA -<br>POLICLINICO                    | BARI               | 8.1309  | 65             | 28/05/2003    | 15/06/2007   |
| 3889 | CONGREG.ANCELLE DIVINA<br>PROVVIDENZA                   | BISCEGLIE          | 13      | 50             | 06/10/2004    | 31/05/2007   |
| 3950 | AZIENDA U.S.L. 1  | BRINDISI           | 12.2728 | 50             | 01/09/2004    | 31/12/2007   |
| 3989 | AZIENDA U.S.L. LE/2                                     | MAGLIE             | 7.749   | 66.98          | 01/01/2004    | 31/03/2007   |
| 3990 | AZIENDA U.S.L. LE/1                                     | LECCE              | 13      | 50             | 24/03/2006    | 12/31/2008   |
| 4153 | AZIENDA SANITARIA N. 2                                  | CASTROVILLARI      | 11.96   | 54             | 15/04/2005    | 31/08/2008   |
| 4155 | AZIENDA OSPEDALIERA                                     | COSENZA            | 11.97   | 53.96          | 01/06/2006    | 31/05/2008   |
| 4157 | AZIENDA U.S.S.L. N. 3                                   | ROSSANO<br>CALABRO | 13      | 50             | 01/07/2006    | 1/31/2008    |
| 4293 | A O PUGLIESE-CIACCIO                                    | CATANZARO          | 13      | 50             | 01/02/2005    | 31/03/2007   |
| 4294 | A O MATER DOMINI  | CATANZARO          | 13      | 50             | 19/01/2005    | 30/09/2009   |
| 4295 | AZIENDA U.S.L.  | LAMEZIA<br>TERME   | 7.1452  | 72.52          | 11/04/2003    | 31/03/2007   |
| 4296 | AZIENDA U.S.L. N. 5                                     | CROTONE            | 7.44    | 69.68          | 25/05/2004    | 31/08/2007   |
| 4297 | AZIENDA U.S.S.L. N. 8                                   | VIBO VALENTIA      | 13      | 50             | 01/06/2006    | 10/31/2009   |
| 4434 | AZIENDA U.S.S.L. N. 9                                   | LOCRI              | 13      | 50             | 31/01/2005    | 31/05/2008   |
| 4494 | AZIENDA U.S.L. N. 9                                     | TRAPANI            | 12.2728 | 50             | 07/09/2004    | 31/12/2007   |
| 4543 | C.d.C. IGEA   | PARTINICO (PA)     | 13      | 50             | 18/05/2006    | 31/05/2007   |
| 4562 | CASA DI CURA VILLA<br>MARIA ELEONORA                    | PALERMO            | 12.0016 | 53.84          | 07/04/2006    | 31/03/2007   |
| 4569 | A O CERVELLO  | PALERMO            | 13      | 50             | 01/07/2006    | 01/06/2009   |
| 4578 | A O UNIVERSITARIA PAOLO<br>GIACCONE                     | PALERMO            | 7.1893  | 70.71          | 29/03/2004    | 30/04/2007   |
| 4694 | AZIENDA U.S.L. N. 5                                     | MESSINA            | 10      | 59.25          | 07/04/2004    | 31/07/2007   |
| 4696 | A O PIEMONTE  | MESSINA            | 7.44    | 68.3           | 17/12/2003    | 30/06/2007   |
| 4763 | AZIENDA U.S.L. N. 1                                     | AGRIGENTO          | 7.7413  | 67.01          | 01/03/2004    | 30/06/2007   |
| 4766 | A O OSPEDALI RIUNITI<br>A O V.EMANUELE                  | SCIACCA            | 11.9912 | 53.88          | 01/12/2005    | 31/03/2008   |
| 4910 | FERRAROTTO  | CATANIA            | 13      | 50             | 13/06/2006    | 31/12/2009   |
| 4911 | A O OSPEDALE GARIBALDI<br>S.LUIGI CURRO'<br>POLICLINICO | CATANIA            | 13      | 50             | 01/01/2007    | 31/12/2009   |
| 4915 | UNIVERSITARIO   | CATANIA            | 13      | 50             | 01/05/2005    | 30/06/2007   |
| 5019 | AZIENDA USL N. 8  | SIRACUSA           | 12.3    | 50             | 10/09/2004    | 31/12/2007   |
| 5197 | AZIENDA U.S.L. N. 7                                     | CARBONIA           | 13      | 50             | 01/07/2005    | 3/31/2007    |
| 5735 | ISTITUTO NEUROLOGICO<br>CARLO<br>BESTA                  | MILANO             | 13      | 50             | 31/01/2005    | 31/05/2007   |



| CODE | CUSTOMER                                   | CITY                 | PRICE € | DISCOUNT % (*) | STARTING DATE | CLOSING DATE |
|------|--|----------------------|---------|----------------|---------------|--------------|
| 5745 | CDC VILLA MARIA<br>BEATRICE                | FIRENZE              | 12.0016 | 53.84          | 07/04/2006    | 31/03/2007   |
| 5753 | IST. CODIVILLA - PUTTI                     | CORTINA<br>D'AMPEZZO | 13      | 50             | 01/04/2005    | 31/01/2007   |
| 6844 | AZIENDA USL DELLA<br>CITTA' DI BOLOGNA     | BOLOGNA              | 12.87   | 50.5           | 09/02/2006    | 30/06/2009   |
| 6851 | AZ. OSP. UMBERTO I<br>-LANCISI -<br>SALESI | ANCONA               | 11.921  | 54.15          | 15/10/2005    | 31/07/2007   |
| 6922 | AZIENDA U.S.L. 8                           | SELARGIUS            | 6.6     | 74.62          | 21/01/2004    | 30/06/2007   |
| 6964 | AZIENDA U.S.L. FG/2                        | CERIGNOLA            | 11.73   | 54.88          | 01/07/2005    | 31/10/2007   |
| 6982 | OSP.MAGGIORE DI<br>MILANO                  | MILANO               | 13      | 50             | 31/01/2005    | 31/05/2007   |
| 6991 | A O PISANA                                 | PISA                 | 6.984   | 73.14          | 14/04/2004    | 31/03/2008   |
| 7001 | AZIENDA U.S.L. BAT/1                       | ANDRIA               | 11.973  | 53.95          | 01/08/2005    | 31/08/2008   |
| 7012 | CLINIC CENTER NAPOLI                       | NAPOLI               | 13      | 50             | 10/03/2006    | 31/03/2007   |
| 7014 | VILLA AZZURRA<br>HOSPITAL                  | RAPALLO              | 12.0016 | 53.84          | 10/03/2006    | 31/03/2007   |
| 7015 | VILLALBA HOSPITAL                          | BOLOGNA              | 12.0016 | 53.84          | 07/04/2006    | 31/03/2007   |
| 7029 | CENTRO NEFROLOGICO<br>E DIALISI            | PALERMO              | 13      | 50             | 18/05/2006    | 30/05/2007   |
| 7030 | AZIENDA SANITARIA<br>REG.MOLISE            | ISERNIA              | 12.2727 | 50             | 05/10/2004    | 31/12/2007   |

(\*) Discount is calculated on public price less  
VAT

**Exhibit 4.7**

CRINOS believes that GENTIUM in July 2005 was been verbally and unofficially informed that AIFA was reviewing the AICs. GENTIUM informed verbally CRINOS about said review, which CRINOS verbally and unofficially confirmed. No official communication has been sent by the MOH or AIFA to CRINOS and no official information has been received by CRINOS on this issue after that date.

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**Exhibit 5.6**

**Fees Payable by SFI**

Fees for registration, renewal and maintenance of the trademarks Noravid and Prociclide.

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**Exhibit 9.1**

**Regolamento della Camera Arbitrale Nazionale e Internazionale di Milano**

Intentionally omitted.

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**Exhibit 10.4(D)**

**Press Release**

See Exhibit 1 to Form 6-K of Gentium S.p.A. dated January 3, 2007.

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**AIC TRANSFER AGREEMENT**

**BY AND BETWEEN**

**CRINOS S.p.A.** with the registered offices in Milan, Via Pavia no. 6, share capital equal to € 21,700,000.00, fully paid-in, registration number with the Register of Enterprises of Milan 03481280968, tax number/VAT code no. 03481280968, SIS code 2454, (hereinafter, "CRINOS"), represented for the purposes hereof by the managing director Mr. Enrique Hausermann, born in Barcelona (Spain), on December 31, 1945, tax code: HSR NRQ 45T31 Z131J, domiciled for the purpose of his office with CRINOS' registered office and granted with the relevant power

**AND**

**GENTIUM S.p.A.** with the registered office in Villaguardia (Province of Como), Piazza XX Settembre, 2, share capital equal to € 11,688,013, fully paid-in, registration number with the Register of Enterprises of Como 02098100130, tax number/VAT code no. 02098100130, SIS code 1247, (hereinafter, "GENTIUM") represented for the purposes hereof by the Chairman and Managing Director Mrs. Laura Iris Ferro, born in Milan, on August 3, 1951, tax code no. FRR LRS 51M43 F205L, domiciled for the purpose of her office with GENTIUM's registered office and granted with the relevant power

**WHEREAS**

CRINOS declares to be the sole owner and beneficiary of all the rights relating to the *Autorizzazione all'Immissione in Commercio* (hereinafter, the "AIC") of the patent medicines indicated hereinafter and identified by means of the relevant codes released by the Italian Ministry of Health (hereinafter, collectively, the "Medicines")

**PROCICLIDE** in the following packages:

|                    |                    |
|--------------------|--------------------|
| 10 ampoules 200 mg | code no. 026111029 |
| 21 capsules 400 mg | code no. 026111056 |

**NORAVID** in the following packages:

|                           |                    |
|---------------------------|--------------------|
| 10 ampoules 2.5 ml 200 mg | cod. no. 026086025 |
| 21 capsules 400 mg        | code no. 02608052  |

GENTIUM, by virtue of two license agreements entered into as of the date hereof, is the exclusive licensee of the trademarks relating to Procyclide and Noravid.

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**having stated the above, the Parties agree as follows:**

**1. PRELIMINARY STATEMENTS**

- 1.1 Whereas, clauses and the annexes AIC transfer agreement (hereinafter, the “Agreement”).
- 1.2 The annexes hereto (hereinafter, the “Annexes”) are identified by means of the number of the article or section in which are referenced for the first time.

**2. PURPOSE OF THE AGREEMENT AND GUARANTEE**

- 2.1 By the entering into of this Agreement, CRINOS transfers and sells to GENTIUM, which accepts and purchases, all the property rights relating to the AIC relating to the Medicines. For such a purpose, CRINOS transfers and sells to GENTIUM the right to register in its favor the AIC, in the pharmaceutical formulations indicated above and authorized with respect to the territory of the Republic of Italy, the Republic of San Marino and the Vatican City.
- 2.2 CRINOS authorizes GENTIUM to carry out all the activities necessary in order to obtain the transfer to GENTIUM of the AIC relating to the Medicines by the Italian ministry of Health, it remaining understood that:
- Ø CRINOS shall cooperate in this respect and shall provide, without delay, all the necessary documentation within its province;
  - Ø GENTIUM shall carry out all the activities necessary in order to cause the AIC to be transferred as soon as possible and, in any event, no later than December 31, 2007.
- 2.3 CRINOS declares that the composition and the validity of the Medicines comply with the declarations made to the Italian Ministry of Health and that CRINOS, as of today, is not aware of any other contraindication, side effect or use restriction of the Medicines other than those indicated in the relevant Dossiers e PSURs. At the same time, GENTIUM declares to have acknowledged the effects of the therapeutic indications of the Medicines hereby transferred and to be aware of the side effects, use restrictions, contraindications and possible uses of the Medicines, including what is indicated in the PSUR.

**3. CONSIDERATION**

- 3.1 The consideration agreed by the Parties for the transfer of the rights indicated in Article 2 of this Agreement (hereinafter, the “Price”) is equal to Euro 10,500,000.00 (tenmillionfivehundredthousand/00 Euro) plus VAT, equal to 20%.
- 3.2 The transfer of the rights indicated in Article 2 above is part of more complex agreements between the Parties to this Agreement, which agreements provide, *inter alia*, that in case GENTIUM is in breach of certain obligations, this Agreement will be terminated (the “Resolatory Events”).

**4. EXPRESS TERMINATION CLAUSE**

- 4.1 This Agreement will be deemed automatically terminated, pursuant to section 1456 of the Italian Civil Code, in the event a Resolatory Event occurs.
- 4.2 In the event of termination of this Agreement due to the occurrence of a Resolatory Event:
- 4.2.1 CRINOS shall transmit to GENTIUM a declaration to exercise the above mentioned termination clause in the form attached hereto under Annex 4.2.1(hereinafter, the “Declaration of Termination”), following to which, in case the event triggering the termination has not been challenged by GENTIUM pursuant to section 4.3 below, (i) the Agreement is terminated, pursuant to article 1456 of the Italian Civil Code, and (ii) the ownership of the AIC is returned to CRINOS with retroactive effect between the Parties. In case of challenge by GENTIUM, CRINOS will be entitled to carry out the activities set forth under Section 4.2.2 below, after a favourable decision issued by the Arbitration Panel in compliance with Section 5 below.
- 4.2.2 Following the termination of the Agreement pursuant to Section 5.2.1 above, CRINOS will be entitled - also in the name and on behalf of GENTIUM - to obtain the termination of this Agreement to be ascertained by any third party and, in particular, by any public authority. In particular, CRINOS will be entitled to:
- § request and obtain the transfer of the AIC for the pharmaceutical indications indicated above, and authorized with respect to the territory of the Republic of Italy, the Republic of San Marino and the Vatican City;
  - § carry out any activity necessary in order to obtain the transfer to CRINOS of the AIC relating to the Medicines with the Italian Ministry of Health. For such a purpose, GENTIUM hereby undertakes to cooperate in this respect and to provide all the necessary documentation within its province;
- all the above, with dispensation to provide the interested authorities (which are hereby manleved from any consequent liability) any documents or recognitive deeds, with respect to the execution of which, also in the name and on behalf of GENTIUM, CRINOS is hereby expressly authorized.
- 4.3 GENTIUM, however, has the right to start arbitration proceedings as set forth in the following article 5 in order to verify the correctness of the utilization of the express termination clause or better the existence of the Resolatory Event.

## 5. ARBITRATION

- 5.1 **Arbitration.** Any dispute among the Parties arising out of or in connection with this Agreement, i.e. comprising disputes regarding the validity, interpretation, execution or resolution or any controversy concerning a default of one of the Parties, shall be referred to and finally settled by arbitration under the “Regolamento della Camera Arbitrale Nazionale e Internazionale di Milano”, hereinafter, “Rules of Arbitration”, attached hereto as Exhibit 5.1 by three (3) arbitrators appointed by the Parties as provided herein.
- 5.2 **Appointment of the Arbitrators.** The first Arbitrator will be appointed by the Party initiating the arbitration, the second Arbitrator will be appointed by the other Party within ten (10) Business Days from the date of receipt of the arbitration notice and the third Arbitrator (who shall act as Chairman of the arbitration panel) will be designated upon mutual agreement of the two Arbitrators already appointed by the Parties or, failing such agreement within ten (10) Business Days from the appointment of the second Arbitrator, by the Arbitration Council in accordance with paragraph 15.4.b of Rules of Arbitration, as promptly as practicable thereafter. The Arbitration Council will also designate (i) the second Arbitrator in the event that the Party required to make such designation will have failed to do so within the above referenced ten-Business Day period, in accordance with paragraph 15.4.a of Rules of Arbitration; and (ii) the replacement of any Arbitrator who is unable or unwilling to serve or to continue to serve as such, in the event that such replacement has not been designated by the Party who had originally appointed such Arbitrator within ten (10) Business Days following the date on which such Arbitrator resigned or otherwise ceased from office or, in case of the Chairman, upon agreement of the other two Arbitrators.
- 5.3 **Determination of the Arbitrators.** The determination of the Arbitrators will be made in accordance with applicable principles of law and shall have the force and effect of a judicial decision between the Parties in accordance with Article 806 et seq. of the Italian Civil Procedure Code. The arbitration proceedings shall take place in Milan (Italy) and shall be conducted in the English language.
- 5.4 **Arbitration Award.** Under paragraph 36 of Rules of Arbitration, the Arbitration Panel will submit its final arbitration Award to the General Secretary within 6 months from the date of its appointment, thus bringing the proceedings to an end.
- 5.5 Notwithstanding the above, the Court of Milan will have the jurisdiction over any dispute relating to this Agreement which may not be deferred to the arbitration.

## 6. NOTICES

Any notice, required or allowed pursuant to the provisions of this Agreement will be made in writing, by registered letter anticipated via telefax, and will be deemed as validly carried out upon receipt thereof (*i.e.*, the receipt of the registered letter) at the following addresses:

CRINOS S.p.A.  
Via Pavia 6, Milan  
Telefax: +39 02 83103  
Attention: Mr. Enrico Hausermann

GENTIUM S.p.A.  
Piazza XX Settembre 2, Villa Guardia (CO)  
Telefax: +39 031 385241  
Attention: Mrs. Laura Iris Ferro

## 7. MISCELLANEOUS

- 7.1 The notarial expenses, the registration duties, as well as any other costs relating to and transfer of the ownership of the AIC will be equally borne by the Parties.
- 7.2 The Parties declare that this Agreement does not have any novative effects on the previous and/or further agreements by and between the Parties.
- 7.3 The undersigned Parties request the Notary Public to release four originals of this Agreement.

Milan, December 28, 2006

CRINOS S.p.A.

GENTIUM S.p.A.

By: /s/ Mr. Enrique Hausermann

By: /s/ Dr. Laura Iris Ferro

Managing Director

Chairman and Managing Director

Annexes:

4.2.1 Declaration of termination

5.1 Arbitration Rules

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Annex 4.2.1 Declaration of termination

GENTIUM S.p.A.  
Via XX Settembre 2,  
Villaguardia (CO)  
Telefax: \_\_\_\_\_  
Attention: Mrs. Laura Iris Ferro

Milan, \_\_\_\_\_

**Re: Termination of the AIC Transfer Agreement**

WHEREAS

**a)** on \_\_\_ CRINOS S.p.A. and GENTIUM S.p.A. (hereinafter, the “Parties”) entered into an agreement (hereinafter, the “Agreement”) relating to the transfer of the ownership of the *Autorizzazione all'Immissione in Commercio* (hereinafter, the “AIC”) relating to the Medicines indicated therein;

**b)** the transfer of the AIC is part of more complex agreements between the Parties to this Agreement, which agreements provide, *inter alia*, that in case GENTIUM is in breach of certain obligations, this Agreement will be terminated pursuant to section 1456 of the Italian Civil Code (the “Resolutive Events”);

IN CONSIDERATION OF THE FACT THAT

a Resolutive Event is occurred, since [ ]

NOW, THEREFORE

CRINOS S.p.A., represented for the purpose hereof by the managing director and legal representative, Mr. Enrico HAUSERMANN, hereby **declares** to intend to benefit from the express termination clause set forth under Article 4 of the Agreement. As a consequence thereof, the Agreement will be deemed as **automatically terminated** pursuant to article 1456 of the Italian Civil Code.

CRINOS S.p.A. **does invite** GENTIUM S.p.A. (i) if necessary to attend the meeting with the Notary Public indicated by CRINOS in order to formalize the transfer of the AICs relating to the Medicines in favor of CRINOS S.p.A., and (ii) to cooperate and to provide all the possible documentation, within its province, in order to obtain the transfer of the AIC.

Best regards,

CRINOS S.p.A.

Mr. Enrique HAUSERMANN





Milan, December 28, 2006

Gentium S.p.A.  
Piazza XX Settembre 2  
22079 Villa Guardia (Como)  
Italy

**Re: Integration of the AIC Transfer Agreement**

Dear Sirs:

With reference to the agreement entered into as of the date hereof by and between Crinos S.p.A. (“**CRINOS**”) and Gentium S.p.A. (“**GENTIUM**”, and, jointly with CRINOS, the “**Parties**”) relating to the transfer of the property right relating to the *autorizzazioni all'immissione in commercio* (the “**AIC**”) from CRINOS to GENTIUM (the “**Agreement**”), we would like to state and specify as follows.

**WHEREAS**

- The Agreement is part of a more complex transaction (the “**Transaction**”) between the Parties and two Irish companies named Stada Financial Investments/SFI (“**SFI**”) and SFS Stada Financial Services International Ltd. (“**SFS**”), which Transaction is regulated by separate deeds, contracts and agreements, which provide, *inter alia*, that in case GENTIUM is in breach of certain provisions thereof, the Agreement will be terminated (the “**Resolutive Events**”).
- Section 4 of the Agreement provides for the immediate termination thereof, pursuant to section 1456 of the Italian Civil Code, in case a Resolutive Event occurs.

**NOW THEREFORE**, it is necessary to provide an exact and unquestionable definition of Resolutive Event, so that no doubt may arise on whether the Agreement is terminated or not.

**1. Preliminary Statements and definitions.**

- 1.1 The preliminary statements shall be considered as an integral part of this Supplementary Letter.
  - 1.2 Capitalized terms used in this letter (hereinafter, the “**Supplementary Letter**”) but not expressly defined herein, shall have the meaning given to them by the Agreement.
-

## **2. Payment of the Consideration**

2.1 Pursuant to the provisions of the master agreement entered into as of the date hereof by the Parties, SFI and SFS (the “**Master Agreement**”), the payment of the entire consideration due by GENTIUM in connection with the Transaction, equal to Euro 16,000,000.00 (sixteen million) plus VAT (the “**Consideration**”) will be paid as follows:

- i) Euro 8,000,000.00 (eightmillion), paid concomitantly to the entering into of this Agreement (the “**First Instalment**”);
- ii) Euro 4,000,000.00 (fourmillion), to be paid no later than December 31, 2007; and
- iii) Euro 4,000,000.00 (fourmillion), to be paid no later than December 31, 2008.

2.2 The payment of the First Instalment is carried out by GENTIUM,

Ø with respect to an amount equal to Euro 4,000,000.00 (fourmillion), by wire transfer on 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. (hereinafter, the “**CRINOS Account**”);

Ø with respect to an amount equal to Euro 4,000,000.00 (fourmillion), by wire transfer on the bank account no. 821291 held by GENTIUM/CRINOS with Deutsche Bank, ABI 3104, CAB 1600, IBAN IT68Q0310401600000000821291 (hereinafter, the “**ESCROW Account**”).

2.3 The Euro 4,000,000.00 (fourmillion) paid on the ESCROW Account pursuant to Paragraph 2.2 above will be released in favor of CRINOS no later than 3 (three) Working Days (*i.e.*, any day other than Saturday, Sunday or a day on which banking institutions both in Milan are authorized or obliged to close) following the date on which the AIC are transferred to GENTIUM (*i.e.*, the date on which such a transfer is published on the Italian Official Gazette).

2.4 GENTIUM shall execute the payments of the other two instalments of the Consideration on the relevant dates by wire transfer on the CRINOS Account.

## **3. Claims**

3.1 In the event, prior to the deadlines set forth under Paragraph 2.1, points ii) and iii) above, GENTIUM claims a material breach by CRINOS, relating to one or more obligations of the latter under the Master Agreement, the Agreement and/or the other agreements relating to the Transaction, GENTIUM will be entitled to start, within the upmentioned deadlines, an arbitration procedure pursuant to the provisions of Article 5 of the Agreement (hereinafter, the “**Arbitration**”). In such a case, however, GENTIUM shall pay the amounts under Paragraph 2.1, points ii) and iii) above in the same terms and conditions provided therein, by wire transfer of the relevant amounts, on the ESCROW Account.

3.8 The amounts paid by GENTIUM on the ESCROW Account may be released therefrom, in whole or in part, in favor of CRINOS or, in the opposite case, released and returned, in whole or in part, to GENTIUM only upon the final award of the Arbitration, pursuant to the terms and the instructions, and in the measure indicated in the arbitrators’ award.



#### **4. Breaches relating to the Arbitration**

- 4.1 It remains understood that, in the event at the deadlines mentioned under points ii) and iii) of Paragraph 2.1 above GENTIUM has paid the relevant amount(s) on the ESCROW Account but has not started the Arbitration, such failure will represent a contractual breach and, as a consequence thereof, the amounts paid by GENTIUM on the Escrow Account will be fully released and corresponded to CRINOS.
- 4.2 For the purposes of Paragraph 4.1 above, GENTIUM will be deemed in breach of the provisions of the Agreement in the event, within the deadlines indicated under points ii) and iii) of Paragraph 2.1 above, GENTIUM has not:
- Ø filed the arbitration request (the “**Arbitration Request**”) with the of the Secretariat of the Chamber of Arbitration, in compliance with Article 10 of the Arbitration Rules;
  - Ø served the Arbitration Request to CRINOS by means of a bailiff;
  - Ø served the Arbitration Request to the representative of the depository bank of the ESCROW Account (the “**Escrow Agent**”).

#### **5. Resolutive Events**

- 5.1 A “Resolutive Event” of the Agreement will be deemed as “occurred” in the event:
- a) At the deadlines indicated under points ii) and iii) of Paragraph 2.1 above, GENTIUM has not paid the relevant amounts on the CRINOS Account or on the ESCROW Account, as the case may be;
  - b) By December 31, 2007, the transfer and register in the name of GENTIUM of the AIC has not been published in the Italian Official Gazette.
  - b) To the decree GENTIUM is required to do so by the Master Agreement, on December 31 of the calendar year following the calendar year in which GENTIUM validly acquires the ownership (*i.e., diritto di proprietà*) of the CRINOS Assets (as evidence by publication in the Italian Official Gazette), GENTIUM has not formalized the assignment of the VAT credit to CRINOS, in compliance with Paragraph 3.3(E)(iii)(c) of the Master Agreement.
- 5.2 CRINOS may not benefit from the express termination clause prior to a 45-day tolerance period (the “**Tolerance Period**”), starting from the deadlines respectively indicated under points ii) and iii) of Paragraph 2.1 above (with respect to the payment of the instalments) or, in any event:
- Ø not prior to February 15, 2008, in case the event determining the termination relates to the failure to pay the instalment mentioned under point ii) of Paragraph 2.1 above;
  - Ø not prior February 15, 2009, in case the event determining the termination relates to the failure to pay the instalment mentioned under point iii) of Paragraph 2.1 above;

- 5.3 Once the Tolerance Period mentioned under Paragraph 5.2 above is expired and a Resolutive Event is occurred, CRINOS shall have the faculty to declare the termination of this Agreement pursuant to the terms and conditions described in Article 4 of the Agreement.
- 5.4 In case of termination of the Agreement due to the occurrence of a Resolutive Event, the payments of the Consideration carried out by GENTIUM will be deemed acquired by CRINOS in compliance with the provisions of the Master Agreement as (i) indemnity for the exploitation of the AIC during the period in which GENTIUM has been owner and beneficiary thereof, and (ii) compensation for the damages suffered by CRINOS, except for the additional damages which may be separately claimed. For such a purpose, the Parties - and, in particular, GENTIUM - declare to have adequately and carefully valued the amount of the penalty clause set forth in this paragraph, having taken into account, *inter alia*, the economic prejudice suffered by CRINOS as a consequence of the transfer, even if temporary, of the ownership of the AIC and of the commercial, financial, strategic and industrial effects relating thereto.

## **6. Confidentiality**

- 6.1 In addition to the obligations binding the Parties under Italian law, and the undertaking of the Parties to provide the arbitrators with this Supplementary Letter in case an Arbitration is started, the Parties (i) shall keep and cause their executives, directors, and consultants to keep strictly confidential any information relating to this Supplementary Letter, and (ii) shall not communicate any of such confidential information to third parties without the written consent of the other Party, except as mandatorily required under Italian law.

## **7. Miscellaneous**

- 7.1 This Supplementary Letter represents a mere integration of the contents of the Agreement and does not amend, modify, suspend or terminate it in any way, nor in whole or in part. As a consequence thereof, the Agreement and this Supplementary Letter jointly contain the understanding among the Parties with respect to the subject matter thereof.
- 7.2 The provisions of this Supplementary Letter shall be modified only by the written consent of both the Parties.
- 7.3 This Supplementary Letter shall be governed by and construed in accordance with the Italian law.

\* \* \*

Please return copy of this letter duly signed for receipt and full acceptance thereof.

Best regards,

/s/ Enrique Hausermann

CRINOS S.p.A.

Mr. Enrique Hausermann

For acceptance:

/s/ Laura Iris Ferro, M.D.

GENTIUM S.p.A.

Dr. Laura Iris Ferro

**ESCROW AGREEMENT**

Between

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

and

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

and

- **DEUTSCHE BANK S.P.A.**, branch of Milan, Piazza del Calendario no. 3, acting through its Bank Manager and special procurator, Mr. Luigi Alberto Cairoli, who is domiciled for the purposes of this Agreement at the offices of the above mentioned bank (hereinafter, “DB” or “ESCROW AGENT”),

**Whereas**

- a) on December 28<sup>th</sup> 2006 (hereinafter, “Closing Date”), CRINOS and GENTIUM will execute, among other contracts, an agreement of transfer of Market Authorizations (i.e., the AICs) concerning “Procyclide” and “Noravid”, and a Supplementary Letter integrating such agreement (hereinafter, jointly, the “AIC Transfer Agreement”), attached hereto as Exhibit A;
  - b) under the terms and subject to the conditions provided under the above mentioned AIC Transfer Agreement, GENTIUM shall pay a total consideration of € 16.000.000,- (in letters: sixteen million), as follows:
    - § the First Instalment of € 8.000.000,- shall be paid, within the Closing Date, by two (2) wire transfers of equal amount of € 4.000.000,- (in letters: four million), which will be deposited respectively into a CRINOS’ Bank Account and into an Escrow Bank Account (hereinafter, ESCROW ACCOUNT);
    - § the remaining amount of € 8.000.000,- (in letters: eight million) shall be paid by GENTIUM in two instalments of equal amount, i.e. € 4.000.000,- (in letters: four million, hereinafter “Second Instalment”) within 31<sup>st</sup> December 2007 and € 4.000.000,- (in letters: four million, hereinafter “Third Instalment”) within 31<sup>st</sup> December 2008;
-

- c) under the terms and subject to the conditions of the AIC Transfer Agreement, the Second Instalment and the Third Instalment shall be paid by transfer into the CRINOS ACCOUNT;
- d) in the event of a breach of contract by CRINOS, GENTIUM shall be entitled to submit a claim to arbitration under the terms and conditions of the AIC Transfer Agreement; in this case, GENTIUM shall deposit the Second Instalment and/or the Third Instalment in accordance with the AIC Transfer Agreement into the ESCROW ACCOUNT;
- e) DB is willing to act as “ESCROW AGENT” upon the terms and conditions set forth in this Agreement,

Now, therefore, in consideration of the premises and the agreements herein, CRINOS, GENTIUM and DB agree as follows.

**1. Designation of Escrow Agent**

- 1.1 Within the Closing date, it will be opened an ESCROW ACCOUNT in which the escrowed funds shall be transferred and deposited according to the provisions of this Agreement.
- 1.2 DB is hereby appointed as ESCROW AGENT to hold and dispose of the escrowed funds provided for herein, in accordance with the terms and conditions set forth in this Agreement. The ESCROW AGENT accepts such designation and agrees to hold and dispose of such escrowed funds in compliance with the provisions of this Agreement.

**2. Management of the Escrow Account and condition for release**

**2.1 First Instalment**

- 2.1.1 On the Closing Date, GENTIUM will transfer into the ESCROW ACCOUNT the sum of € 4.000.000,- (hereinafter, “First Escrowed Sum”), according to the AIC Transfer Agreement. Such amount will remain in the ownership of GENTIUM until its release to CRINOS, if any, in accordance with the provisions of this Escrow Agreement.
- 2.1.2 The First Escrowed Sum will remain deposited on the Escrow Account, at the latest, until 31<sup>st</sup> December 2007.
- 2.1.3 The First Escrowed Sum shall be entirely released to CRINOS as soon as the ESCROW AGENT will receive the “Gazzetta Ufficiale Italiana”, certifying that the AICs have been transferred to and registered in the name of GENTIUM, document which can be provided to the ESCROW AGENT either by GENTIUM or by CRINOS.



**2.1.4** In the event that the Escrow Agent does not receive the “Gazzetta Ufficiale Italiana”, certifying that the AICs have been transferred to and registered in the name of GENTIUM by 31<sup>st</sup> December 2007 at the latest, the AIC Transfer Agreement will be considered terminated and the First Escrowed Sum shall be entirely released to GENTIUM.

## **2.2 Second Instalment**

**2.2.1** In the event of GENTIUM alleging a breach of contract by CRINOS, GENTIUM will be obliged to transfer by 31<sup>st</sup> December 2007 into the ESCROW ACCOUNT the Second Instalment of € 4.000.000,- (hereinafter, “Second Escrowed Sum”), according to the AIC Transfer Agreement. By the above mentioned expiry date, GENTIUM will be obliged to start to the arbitration procedure against CRINOS pursuant to Article 10 of the arbitration rules of the Chamber of Arbitration of Milan (the “Arbitration Rules”) under the terms and conditions of the AIC Transfer Agreement. A copy of the claim deposited before the Arbitration Court of Milan in compliance with Article 10 of the Arbitration Rules shall be served to the ESCROW AGENT.

**2.2.2** The Second Escrowed Sum will be deposited on the ESCROW ACCOUNT and will remain in the ownership of GENTIUM until the end of such arbitration and it shall be released, in full or partially, to CRINOS and/or to GENTIUM, in accordance with the Arbitration Award which will be produced to the ESCROW AGENT in authenticated copy thereof.

**2.2.3** If GENTIUM does not start an arbitration procedure in accordance with Article 10 of the Arbitration Rules and the AIC Transfer Agreement, the Second Escrowed Sum shall be entirely released to CRINOS, within 5 days commencing from 15<sup>th</sup> February 2008.

## **2.3 Third Instalment**

**2.3.1** In the event of GENTIUM alleging a breach of contract by CRINOS after the payment of the Second Instalment but before the 31<sup>st</sup> December 2008, GENTIUM will be obliged to transfer within 31<sup>st</sup> December 2008 into the ESCROW ACCOUNT the Third Instalment of € 4.000.000,- (hereinafter, “Third Escrowed Sum”), according to the provisions of the AIC Transfer Agreement. By the above mentioned expiry date, GENTIUM will be obliged to start an arbitration procedure against CRINOS pursuant to Article 10 of the Arbitration Rules under the terms and conditions of the AIC Transfer Agreement. A copy of the claim deposited before the Arbitration Court of Milan in compliance with Article 10 of the Arbitration Rules shall be served to the ESCROW AGENT.

**2.3.2** The Third Escrowed Sum will be deposited on the ESCROW ACCOUNT and will remain in the ownership of GENTIUM until the end of such arbitration and it shall be released, in full or partially, to CRINOS and/or to GENTIUM in accordance with the Arbitration Award which will be produced to the ESCROW AGENT in authenticated copy thereof.

**2.3.3** If GENTIUM does not start an arbitration procedure in accordance with the AIC Transfer Agreement, the Third Escrowed Sum shall be entirely released to CRINOS, within 5 days as from 15<sup>th</sup> February 2009.

**3. Payments by the Escrow Agent**

3.1 The Escrow Agent shall transfer the First Escrowed Sum, the Second Escrowed Sum and the Third Escrowed Sum (hereinafter, “Escrow Amount”), together with the relevant portion of the Accrued Interest, pursuant to and in strict accordance with the provisions of this Escrow Agreement and the management rules and conditions for release (hereinafter, “Instructions”) set forth on Section 2 of this Escrow Agreement, with value date not later than the second (2<sup>nd</sup>) Business Day following the applicable expiry date upon the Instructions, from the Escrow Account to the bank account of CRINOS and/or GENTIUM indicated in the letter attached hereto in draft as Exhibit B.

3.2 Any payment from the Escrow Account made by the Escrow Agent in accordance with the Escrow Agreement and the Instructions shall be a full and sufficient discharge to the Escrow Agent in respect of its obligation to CRINOS and GENTIUM.

**4. Activities and Liability of the Escrow Agent**

4.1 The Escrow Agent shall keep accurate books and records of the funds received and paid in connection herewith. The duties of the ESCROW AGENT are purely of administrative nature.

4.2 The Escrow Agent’s duties and obligations hereunder shall be determined solely by the express provisions of this Escrow Agreement. The Escrow Agent shall not be concerned with or bound by the terms of any other agreement related to this Escrow Agreement except as expressly provided herein, or obligated to ensure any party’s compliance with the terms thereof. The Escrow Agent shall not be under any obligation to take any action under this Agreement that it expects will result in any expense to, or liability for, it, the payment of which is not, in its opinion, assured to it within a reasonable time.

4.3 The Escrow Agent shall not be liable to anyone whatsoever by any reason of error of judgment or for any act done or step taken or omitted by it in good faith or for any mistake of fact or for anything which it may do or refrain from doing in connection herewith unless caused by or arising out of its own gross negligence or wilful misconduct. In particular, but without limiting the generality of the foregoing, the Escrow Agent shall not be liable to CRINOS or GENTIUM for any failure to maximize the amount of interest or other amounts earned on all or part of the Escrow Account. Under no circumstances shall the Escrow Agent be liable for any consequential or special loss, or indirect, consequential or punitive damages, however caused or arising (including loss of business, goodwill, opportunity or profit) even if advised of the possibility of such loss or damage.

- 4.4 The Escrow Agent shall be entitled to rely on and shall be protected in acting in reliance upon the Instructions pursuant to any provisions of this Escrow Agreement and shall be entitled to treat as genuine any letter, paper, or other document furnished to it and believed by it to be genuine and to have been signed and presented by the proper party or parties.
- 4.5 CRINOS and GENTIUM agree to indemnify the Escrow Agent for, and to hold it harmless against, any loss, cost or damage incurred or suffered by the Escrow Agent however arising in relation to or in connection with this Agreement or the discharge of its duties hereunder, other than those losses, costs or damages caused by its gross negligence or wilful misconduct.

## 5. Representations And Warranties

Each of CRINOS and GENTIUM hereby represents and warrants to the Escrow Agent that (i) it is a company duly organized and in good standing in the jurisdiction of its incorporation, (ii) it has the power and authority - having obtained all necessary authorizations - to sign and to perform this Agreement and all the obligations arising therefrom, (iii) its performance of this Agreement will not violate or breach any applicable law, regulation, contract or other requirement applicable to it or by which it is bound.

## 6. Termination of the Agreement

This Agreement shall automatically terminate upon payment by the Escrow Agent of the Escrow Amount and the Accrued Interest pursuant to Section 2 and 3 of this Agreement. The Escrow Account will be closed by 31 December 2011 at the latest.

## 7. Resignation

Each of CRINOS and GENTIUM agrees that the Escrow Agent shall have the right to resign its appointment hereunder upon two weeks prior written notice to be delivered at the same time to CRINOS and GENTIUM. Should such resignation occur, the Escrow Agent, in accordance to written directions given for this purpose by CRINOS and GENTIUM jointly (and not severally), shall transfer the Escrow Amount to CRINOS, GENTIUM or to such other person(s) so indicated, all the above subject to any costs, fees, charges, expenses or indemnities owed to the Escrow Agent or to such person(s) as CRINOS and GENTIUM may jointly (and not severally) direct in writing.

## 8. Fees and Expenses

- 8.1 For the services provided hereunder, the Escrow Agent shall charge a set up fee (the “**Acceptance Fee**”) of euro 5.000 (five thousand) and an administration fee (the “**Administration Fee**”) of euro 5.000 (five thousand), that shall be equally shared between CRINOS and GENTIUM. The Escrow Agent shall be reimbursed upon request for all properly and reasonably incurred expenses, disbursements and advances, incurred or made by it in connection with the preparation of this Agreement and the carrying out of its duties under this Agreement.

- 8.2 If any amount payable to the Escrow Agent under this Section 8 is not paid when due, the Escrow Agent shall be entitled to debit the Escrow Account to recover the amount which should have been paid to it, provided that any subsequent recovery of any such amount shall be credited to the Escrow Account.
- 8.3 All payments by CRINOS and GENTIUM under this clause shall be made free and clear of, and without withholding or deduction for, any taxes, duties, assessments or governmental charges of whatsoever nature imposed, levied, collected, withheld or assessed by any government having power to tax, unless such withholding or deduction is required by law. In that event, CRINOS or GENTIUM shall pay such additional amounts as will result in receipt by the Escrow Agent of such amounts as would have been received by it if no such withholding had been required.
- 8.4 The Acceptance Fee and Administration Fee shall be paid to the Escrow Agent within two (2) Business Days after the date of signing of this Agreement and the payment thereof shall be a condition precedent to the obligations of the Escrow Agent to receive and hold the Escrow Amount on the Escrow Account and to comply with any other provision under this Agreement. Any other payment under this Section 8 shall be made within 30 calendar days of the date of the relevant invoice.

**9. Jurisdiction and applicable law**

- 9.1 This Agreement shall be governed by, construed and enforced in accordance with the Italian Law.
- 9.2 The Court of Milan will have exclusive jurisdiction in respect of any dispute arising in relation thereto.

Milan, December 28<sup>th</sup> 2006

**CRINOS S.p.A.**  
By : /s/ Enrique Hausermann  
Mr. Enrique Hausermann

**GENTIUM S.p.A.**  
By: /s/ Laura Iris Ferro  
Laura Iris Ferro, M.D.

**DEUTSCHE BANK S.P.A.**  
By: /s/ Luigi Alberto Cairoli  
Mr. Luigi Alberto Cairoli

**Exhibit A**  
**AIC TRANSFER AGREEMENT**  
**(including Supplementary Letter)**

See Exhibit 3 to Form 6-K of Gentium S.p.A. dated January 3, 2007.

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**Exhibit B**  
**PAYMENT INSTRUCTION**

\_\_\_\_\_, 2006

To:  
Deutsche Bank  
Agenzia  
Attention:

Fax :

**Dear Sirs,**

**RE: CRINOS/GENTIUM ESCROW ACCOUNT**

Please pay the following amount \_\_\_\_\_, 2006 from the CRINOS and GENTIUM Escrow Account no. 1 pursuant to Section 2 of the Escrow Agreement dated December 28<sup>th</sup> 2006 between CRINOS and GENTIUM and Deutsche Bank as Escrow Agent, to the account specified below:

*Indication of CRINOS' or GENTIUMS' account details:*

Amount : [€\_\_\_\_\_ ]

Account Number : \_\_\_\_\_

Held with:\_\_\_\_\_

Branch Address:\_\_\_\_\_

Reference:\_\_\_\_\_

Yours faithfully,

Authorized signatory    Authorized signatory

**DISTRIBUTION & PROMOTION AGREEMENT**

Dated as of 28 December 2006

**between**

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 and 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**" or the "**Principal**")

**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**" or the "**Distributor**").

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

**RECITALS**

- A. GENTIUM is the current, sole and exclusive owner of the Know-How concerning the Products, the Patent and the AICs.
- B. CRINOS wishes to purchase the Products from GENTIUM, distribute and promote the Products in the Territory and license the Know-How related to the Products and the Patent from GENTIUM in accordance with the terms and conditions set forth in this Agreement.
- C. GENTIUM is willing to sell the Products to CRINOS, grant CRINOS the right to distribute and promote the Products in the Territory, and license the Know-How related to the Products and the Patent to CRINOS in accordance with the terms and conditions set forth in this Agreement.
- D. The Parties intend to set forth herein below the terms and conditions that shall govern their relationship.

**NOW, THEREFORE**, the Parties hereto agree as follows.

**ARTICLE 1**  
**INTERPRETATION**

- 1.1 Recitals and Exhibits.** The recitals and all Exhibits hereto are integral and substantial part of this Agreement.
- 1.2 Entire Agreement.** This Agreement, including any Exhibit, sets forth the entire understanding between the Parties. In order to be effective, any amendment, additional provision to or deletion from this Agreement shall be made in writing and be incorporated in an addendum, which shall be signed by the Parties.
- 1.3 Severability.** If one or more of the articles, sections, paragraphs or other subdivisions, or any other provision contained in this Agreement shall be or become illegal, invalid or unenforceable, it shall be severed from this Agreement and be ineffective, to the extent permitted by applicable law, and shall not affect or impair the validity, legality, or enforceability of the remaining provisions hereof.





**ARTICLE 2**  
**DEFINITIONS**

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

- 2.1** “**Agreement**” means this distribution and promotion agreement, including all its whereas clauses and Exhibits.
- 2.2** “**AICs**” means AIC no. 026111056 (Capsules) and AIC no. 026111029 (Ampoules) with respect to the Products marketed under Procyclide and AIC no. 02608052 (Capsules) and AIC no. 026086025 (Ampoules) with respect to the Products marketed under Noravid issued by the MOH.
- 2.3** “**AIFA**” means the *Agenzia Italiana del Farmaco*.
- 2.4** “**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 Procyclide and Noravid.
- 2.5** “**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 Procyclide and Noravid.
- 2.6** “**Defibrotide**” means a poli-desoxi-ribonucleotide extracted from swine mucose.
- 2.7** “**Gross Margin**” means the total Net Sales for the applicable Products sold by the Distributor during the given fiscal period minus the Prices paid by the Distributor to the Principal for such Products.
- 2.8** “**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 the Distributor in connection with the sale of such Product.
- 2.9** “**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.
- 2.10** “**MOH**” means the Italian Ministry of Health.
- 2.11** “**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; and (c) rebates under government programs to the extent customary in Italian 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.
- 2.12** “**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.

- 2.13 “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.
- 2.14 “Permits”** means the licences, authorizations and permits that are required by any authority for the Parties to carry out their business with respect to the Products as contemplated by this Agreement.
- 2.15 “Prices”** as defined in Paragraph 5.1 hereof.
- 2.16 “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.
- 2.17 “Products”** means the Ampoules and the Capsules.
- 2.18 “Territory”** means Italy, San Marino and Vatican City.

### **ARTICLE 3**

#### **APPOINTMENT OF THE DISTRIBUTOR; LICENSE**

- 3.1 Distributor Appointment.** The Principal hereby grants the Distributor, which accepts, the right, as specified in Article 4 below, to distribute, sell and promote the Products throughout the Territory. The Distributor shall sell the Products in its own name and on its own behalf. The right of the Distributor to sell the Ampoules is exclusively limited to the Distributor’s current legal and contractual obligations set forth on Exhibit 3.1 attached hereto. With regard to the Ampoules, the Distributor shall not enter into any new legal or contractual obligations or extend or renew such current legal and contractual obligations. After 31 December 2008, the right of the Distributor to sell the Capsules is exclusively limited to the Distributor’s current legal and contractual obligations set forth on Exhibit 3.1 attached hereto. With regard to the Capsules, the Distributor shall not enter into any new legal or contractual obligations binding him for a period exceeding 31 December 2008 or extend or renew such current legal and contractual obligations to a date later than 31 December 2008.
- 3.2 Independent Contractor.** In the performance of its obligations hereunder, the Distributor shall act as an independent contractor, and the Parties hereby expressly acknowledge that this Agreement does not and shall not be deemed to make one Party the agent or representative of the other Party for any purpose whatsoever, and neither Party shall have the right or authority to assume or create any obligation or responsibility whatsoever, on behalf of the other Party.
- 3.3 License.** The Principal hereby grants the Distributor a license, as specified in Article 4 below, to use the Know-How related to the Products and the Patent in sole and exclusive connection with the Distributor’s distribution, sale and promotion of the Products in the Territory in accordance with the terms of this Agreement. Except as provided in this Paragraph 3.3 and Article 4 below, the Parties agree that the Principal does not hereby assign or grant any license to the Distributor with respect to any intellectual or industrial property rights regarding the Products.
- 3.4 License Royalty.** It is expressly agreed that no royalties shall be owed by the Distributor for sales of the Products sold under Prociclide and/or Noravid.

**ARTICLE 4**  
**EXCLUSIVITY AND TERRITORY**

- 4.1 Exclusivity. The distribution and license rights with respect to the Products are granted in the Territory on an exclusive basis.
- 4.2 Sales outside the Territory. The distribution rights are limited to the Territory. Throughout the term of this Agreement, unless otherwise provided in this Agreement or in any subsequent amendment, the Distributor shall not actively sell the Products outside the Territory.

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**ARTICLE 5**  
**PRICES - TERMS OF PAYMENT**

**5.1 Prices.** The Parties agree that the initial prices (the “**Prices**”) for the Products are as follows, in each case plus VAT.

(A) The Prices for containers of Capsules sold until 31 December 2008 are (i) €6.70 per container of 21 Capsules and (ii) €0.84 per sample container of 4 Capsules.

(B) After 31 December 2008, the Prices for containers of the Capsules shall be 80% of the Distributor’s Gross Sales for such containers.

(C) The Price per container of 10 Ampoules sold starting from the date of execution of this **Agreement** is 80% of the Distributor’s Gross Sales for each such container. Sample containers of 2 Ampoules are not distributed to Hospitals.

**5.2** The Prices shall be revised if the Distributor requests changes to the packaging or composition of the Products or if the MOH provides for revision of the Prices.

**5.3** For sales of Products under Sections 5.1 (B) and (C) above, the Principal shall issue the Distributor with an invoice at the time of delivery of the Products, which shall be equal to € 7,50 per container of 21 Capsules, € 9,20 per container of 10 Ampoules times the number of applicable types of Products delivered. Such amounts are the Parties’ current estimates of 80% of the Distributor’s expected Gross Sales for such Products. The Distributor shall pay such invoices as set forth in Section 5.6 below. Within 60 days after the end of each fiscal quarter ended March 31, June 30, September 30 and December 31, the Distributor shall issue the Principal a statement of its actual Gross Sales during such quarter. Any excess of such actual Gross Sales and the applicable Prices set forth in Sections 5.1(B) and (C), as applicable, for Products delivered in such quarter, shall be paid by the Distributor to the Principal at the time of such invoice. Any excess of the applicable Prices set forth in Sections 5.1(B) and (C), as applicable, for Products delivered in such quarter over such actual Gross Sales shall be paid by the Principal to the Distributor within 60 days of receipt of such statement. The Principal shall have the right, one time per calendar year for a period of two (2) years after each payment of the Price is due, to examine or have its consultants examine the relevant books and records of the Distributor (after at least 20 business days prior written notice) during business hours to determine whether appropriate accounting and invoicing has been made by the Distributor. The Distributor shall retain any such books and records for the period of time subject to the Principal’s right of inspection. Once the Principal has examined the books and records of the Distributor for a particular period, it may not re-examine such books and records absent evident fraud on the part of the Distributor.

**5.4 Graphic Studies, Films and Clichés.** The preparation of graphic studies and films necessary for the printing of the packaging materials are under the responsibility of the Distributor. Costs for the realization of clichés of the printed material are at the Distributor’s charge.

**5.5 Taxes.** The Prices are net of any tax, which shall be the responsibility of the Distributor.

**5.6 Payment.** The Principal shall issue an invoice to the Distributor at the time the Products are delivered. The Distributor shall make payment for the Products within sixty (60) days from the date of invoice in Euro by means of wire transfer to the Principal’s account at the Villa Guardia (Como) branch of Banca Intesa S.p.A., ABI 03069, CAB 51841, CIN I, Account Number 000007500116 or any other bank account communicated to the Distributor by the Principal in the relevant invoice and the delivery of the Products shall be considered ex-works.



**ARTICLE 6**  
**ORDERS AND DELIVERIES**

- 6.1 Monthly Requirements.** Attached as Exhibit 6.1 is the Distributor's proposed monthly requirements for the Products for the next twelve (12) calendar months.
- 6.2 Binding Purchase Orders.** The first three (3) months of the monthly requirements attached as Exhibit 6.1 are binding purchase orders and the remaining nine (9) months shall be considered as forecasts. Deliveries shall be made on the last day of each applicable month.
- 6.3 Monthly Updates.** Before the last day of the first month of the monthly requirements attached as Exhibit 6.1 and the last day of each month thereafter, the Distributor shall issue a binding purchase order for an additional month and shall update the nine (9) month plan in order to guarantee a twelve (12) month rolling plan with three (3) months of binding purchase orders.
- 6.4 Limit on Purchase Orders and Forecasts.** The Distributor shall not issue purchase orders or update its forecasts to purchase more quantities of the Products than it reasonably expects to sell during such periods, and in no event shall issue purchase orders or update its forecasts to purchase more quantities of the Products than it reasonably expects to sell during the term of this Agreement. The Distributor may not increase the quantities of the Products ordered by more than thirty percent (30%) over any twelve month period, and may not increase the order for any month by more than twenty percent (20%) over the amount ordered for the preceding month.
- 6.5 Reimbursement for Failure to Deliver.** If the Principal fails to perform a binding purchase order of the Distributor within thirty (30) days of its scheduled delivery date, the Principal shall reimburse the Distributor for the damages and/or losses resulting from such failure, equal to the Distributor's not realised Gross Margin for the such purchase order, calculated based on the quantities ordered but not delivered multiplied by an amount equal to the Distributor's average Gross Margin for such Product realised during the 6 months prior to the month of failure. In such case, the Distributor shall provide the Principal with a statement of its Gross Sales of the applicable Product for such six month period. The Principal shall have the right, one time per calendar year for a period of two (2) years after such claim by the Distributor of a failure by the Principal to perform a binding purchase order, to examine or have its consultants examine the relevant books and records of the Distributor (after at least 20 business days prior written notice) during business hours to determine whether appropriate accounting has been made by the Distributor. The Distributor shall retain any such books and records for the period of time subject to the Principal's right of inspection. Once the Principal has examined the books and records of the Distributor for a particular period, it may not re-examine such books and records absent evident fraud on the part of the Distributor.
- 6.6 Delivery.** The Products shall be sold by the Principal "ex works" pursuant to INCOTERMS 2000 (EXW). The Distributor shall be responsible for the transportation of the Product.-
- 6.7 Transfer of Title.** Transfer of title on the Products and of the risks connected thereto shall vest in the Distributor upon delivery of the Products "ex works" pursuant to INCOTERMS 2000 (EXW).

**ARTICLE 7**  
**MANUFACTURE AND PRODUCT SPECIFICATIONS; INFORMATION**

- 7.1 Manufacture and Packaging.** The Principal shall cause the Products to be manufactured according to the Registration Technical Dossier of the applicable AIC, according to the AIC itself and in accordance with the Good Manufacturing Practices set forth in Exhibit 7.1(A). The Principal shall cause the Product, upon delivery at its facility, to comply with the packaging set forth in Exhibit 7.1(B). The Principal shall hold the Distributor

harmless from any damage claimed by third parties arising out of the use of the Products when such damages have been proven to have been caused by manufacturing defects and the Distributor submits claims for such damage to the Principal within thirty (30) days of delivery of the Products. The Distributor shall hold the Principal harmless from any damage claimed by third parties arising from the Distributor's use of the Know-How relating to the Product, the Distributor's use of the Patent or the AICS, Novarid, Prociclode or any defects other than manufacturing.

- 7.2 Certificate of Analysis. The Principal shall include an appropriate certificate of analysis with each delivery of the Products.
- 7.3 Updating. Any analytical, technical or International Conference on Harmonization updating which may be necessary after the date hereof by law or by other regulatory rules shall be borne by the Principal and the Principal shall inform the Distributor about such updating.
- 7.4 Information and Other Assistance. The Principal agrees to provide to the Distributor the existing technical information, Know-How and scientific assistance, reasonably required by the Distributor to market, promote and sell the Products and within the Principal's possession and knowledge.
- 7.5 Distributor's Study of the Products. Personnel designated by the Distributor shall be given a reasonable opportunity to study the Products and its scientific data and to discuss such information with the Principal's representatives, including experts and specialists. The Distributor shall provide the Principal with thirty (30) days notice in writing of such a request to study the Product, including the names, interests and qualifications of the aforesaid personnel in order for the Principal to have adequate time to organize and provide the reasonable information needed. The Distributor agrees to use such information solely in connection with distributing, selling and promoting the Products in the Territory under the terms of this Agreement, and agrees to treat such information as confidential information pursuant to Paragraph 17.1 hereof.
- 7.6 Maintenance of the AIC. The Principal hereby agrees to use all reasonable and customary efforts to maintain the AICs as long as the Distribution and Promotion Agreement is in force, including paying any required fees to the MOH and other official bodies. The Parties agree that such obligation shall not be extended to the maintenance of any clinical trials. In the event that, due to the negligence of the Principal, one or more of the AICs are withdrawn by the MOH, the Principal shall reimburse the Distributor for the damages and/or losses resulting from such withdrawal, equal to the Distributor's not realised Gross Margin for the period from the withdrawal through the earlier of any reinstatement of such AIC and the remainder of the term of this Agreement (not later than 31 December 2008), calculated proportionally on the basis of the Distributor's Gross Margin for such Product realised during the 6 months prior to the withdrawal. In such case, the Distributor shall provide the Principal with a statement of its Gross Sales of the applicable Product for such six month period. The Principal shall have the right, one time per calendar year for a period of two (2) years after such withdrawal of an AIC, to examine or have its consultants examine the relevant books and records of the Distributor (after at least 20 business days prior written notice) during business hours to determine whether appropriate accounting has been made by the Distributor. The Distributor shall retain any such books and records for the period of time subject to the Principal's right of inspection. Once the Principal has examined the books and records of the Distributor for a particular period, it may not re-examine such books and records absent evident fraud on the part of the Distributor.

**ARTICLE 8**  
**DISTRIBUTOR'S OBLIGATIONS**

- 8.1 Sales and Promotion. In addition to the obligations provided hereunder, the Distributor undertakes to use its best efforts to sell, distribute, market and promote the sales of the Products in the Territory.
- 8.2 No Development Activities. The Distributor shall not engage in any development activities, including, without limitation, clinical trials, with respect to the Products without the prior written consent of the Principal.



- 8.3 Tracking System.** The Distributor agrees to maintain at all time an effective tracking system, consistent with industry standards, of recalls of the Products within the Territory. The Distributor agrees to render all reasonable assistance necessary to the Principal to effectuate any recall (see also article 13), including, without limitation, making its relevant records available to the Principal.
- 8.4 Promotion Materials.** The Distributor shall promote the Products using only sales, advertising and promotional materials which are compatible with the determination of the Product's indications, and the use of which does not violate any applicable law. In any case the Distributor will submit any promotional material to the Principal in advance and the Principal will have the right to approve it, however such approval shall not be unreasonable withheld. The Principal shall provide the Distributor with specific reasons in case of its refusal.
- 8.5 Change of Ownership or Control.** The Distributor will inform the Principal within ten (10) days of any change in the ownership or control of the Distributor.

**ARTICLE 9**  
**OTHER AGREEMENTS OF THE PARTIES**

- 9.1 Notice of Safety Findings.** The Distributor will inform the Principal within one (1) business day about the occurrence of any direct report of an adverse drug reaction, including any report of lack of effect, overdose, drug abuse or misuse or negative experience during pregnancy or lactation.
- 9.2 Compliance with Laws, Including Obligations Deriving From Law no. 196/2003.** The Parties undertake and guarantee that they will comply with the all applicable laws in relation to their performance of this Agreement, including but not limited to provisions contained in Law Decree No. 196 of June 30, 2003, regarding the protection of personal data, making any communication which should be necessary and obtaining any authorization of the Italian authority for the protection of personal data ("*Garante della Privacy*") which should become necessary for the execution of this Agreement.

**ARTICLE 10**  
**DISTRIBUTOR REPRESENTATIONS AND WARRANTIES**

**10.1 Representations and Warranties of the Distributor.** The Distributor exclusively makes the representations and warranties in this Article 10 to the Principal (it being understood that there shall not be any other representation or warranty, whether express or implied, on the part of the Distributor in any other Paragraph or clause of this Agreement or anywhere else) and acknowledges that they are true, correct and accurate as of the date of this Agreement.

**10.2 Legal Power; Authorization; Enforceability.** (A) The Distributor is a corporation duly constituted and validly existing under the laws of Italy and has full power and authority to (i) execute and deliver this Agreement, (ii) perform its obligations hereunder and (iii) consummate the transactions contemplated hereby.

(B) The execution, delivery and performance of this Agreement by the Distributor and the consummation of the transactions contemplated hereby by the Distributor do not violate or conflict with (i) any provision of the Distributor's organizational documents; or (ii) any applicable law, statute, regulation, injunction, order or decree of any government agency or authority or court to which the Distributor or any of the Products are subject; (iii) any contract to which the Distributor is bound or (iv) the terms of any Permit to which the Distributor is bound.

(C) The execution and delivery of this Agreement and the consummation of the transactions contemplated hereby have been duly and validly authorized and approved by the competent corporate bodies of the Distributor.

(D) This Agreement constitutes a valid and legally binding obligation of the Distributor, enforceable against it in accordance with the terms set forth herein, subject to mandatory provisions of applicable law.

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- 10.3 Consent, Approvals and Permits.** No consent by, approval of or filing with any third party and/or authority is required to be obtained or made on the part of the Distributor in connection with the execution and delivery of this Agreement. The Distributor holds all Permits.
- 10.4 Compliance with Law.** The business operated by the Distributor regarding the Products is not in violation of any law, ordinance, regulation or interpretation of any governmental entity, except for any such violation which would not have a material adverse effect on the Distributor or the Products.

**ARTICLE 11**  
**PRINCIPAL REPRESENTATIONS AND WARRANTIES**

- 11.1 Representations and Warranties of the Principal.** The Principal exclusively makes the representations and warranties in this Article 11 to the Distributor (it being understood that there shall not be any other representation or warranty, whether express or implied, on the part of the Principal in any other Paragraph or clause of this Agreement or anywhere else) and acknowledges that they are true, correct and accurate as of the date of this Agreement.
- 11.2 Legal Power; Authorization; Enforceability.** (A) The Principal is a corporation duly constituted and validly existing under the laws of Italy and has full power and authority to (i) execute and deliver this Agreement, (ii) perform its obligations hereunder and (iii) consummate the transactions contemplated hereby.
- (B) The execution, delivery and performance of this Agreement by the Principal and the consummation of the transactions contemplated hereby by the Principal do not will not violate or conflict with (i) any provision of the Principal's organizational documents; or (ii) any applicable law, statute, regulation, injunction, order or decree of any government agency or authority or court to which the Principal or any of the Products are subject; (iii) any contract to which the Principal is bound or (iv) the terms of any Permit to which the Principal is bound.
- (C) The execution and delivery of this Agreement and the consummation of the transactions contemplated hereby have been duly and validly authorized and approved by the competent corporate bodies of the Principal.
- (D) This Agreement constitutes a valid and legally binding obligation of the Principal, enforceable against it in accordance with the terms set forth herein, subject to mandatory provisions of applicable law.
- 11.3 Consent, Approvals and Permits.** Except for the filing of the nomination of the Distributor as such *Concessionario di Vendita* to the AIFA and the relevant approval issued by AIFA, no consent by, approval of or filing with any third party and/or authority is required to be obtained or made on the part of the Principal in connection with the execution and delivery of this Agreement. The Principal holds all Permits.
- 11.4 Compliance with Law.** The business operated by the Principal regarding the Products is not in violation of any law, ordinance, regulation or interpretation of any governmental entity, except for any such violation which would not have a material adverse effect on the Principal or the Products.

**ARTICLE 12**  
**PARTIES' LIABILITIES**

- 12.1 Parties' Liability.** Unless expressly agreed upon by the Parties in this Agreement, the Parties' liability for breach and damages to third parties shall be governed by the Italian Civil Code and the other applicable Italian laws, but shall include reasonable attorney fees and expenses.

**ARTICLE 13**  
**RETURNED PRODUCT / RECALLS**

- 13.1 Returns/Recalls.** In case of Product complaints and/or Products returned and/or a Product recall, the Distributor shall be required to notify in writing the Principal with regard to the complaint within 30 (thirty) working days from the date of delivery (in case of a defect detected by the Distributor itself) or within 5 (five) days after the date of receipt of the complaint from a third party or in case a hidden defect has been detected within 5 (five) days from the date the defect was detected. If possible with the notification the Distributor shall indicate the batch that is alleged to have failed to meet the technical specification. The Principal shall then use all reasonable efforts to replace the returned Product with a new Product within 60 (sixty) days from the date the Distributor notified the Principal.

In the event of a voluntary recall by the Distributor or a mandatory recall ordered by the MOH or the AIFA due to a manufacturing defect or safety issues, the cost for such recall, including the organization of the same, shall be borne by the Principal.

- 13.2 Reimbursement.** In the event that the Principal is unable to replace the returned Product within this 60 (sixty) days period or such Product is returned or recalled due to a breach by the Principal, then the Distributor may request the Principal to reimburse the Distributor the Price that the Distributor paid to the Principal for the affected Product.

**ARTICLE 14**  
**CONDITION PRECEDENT, TERM AND TERMINATION**

- 14.1 Condition Precedent.** The Parties acknowledge that this Agreement is subject to the filing of the appointment of the Distributor as such, *Concessionario de Vendita* to the AIFA and to the relevant approval issued by AIFA which, therefore, is a condition precedent to this Agreement. The Principal undertakes to perform the aforesaid filing with AIFA as soon as possible upon the signing of this Agreement.
- 14.2 Term.** This Agreement shall be effective as of the date of execution of this Agreement and shall remain in full force and effect until 31 December 2008 for sales of Capsules, unless earlier terminated as set forth below. For sales of Ampoules and Capsules pursuant to the Distributor's contractual and legal obligations set forth on Exhibit 3.1, this Agreement shall remain in effect until such contractual and legal obligations expire, unless earlier terminated as set forth below.
- 14.3 Early Termination.** This Agreement may be terminated prior to the expiration of the term set forth in Paragraph 14.1 in the event one of the following conditions occurs.
- (a) either Party's giving 60 days' notice to the other Party of a stated material breach of any of the terms and conditions of this Agreement or the Master Agreement dated [\_\_\_\_] between the Parties and the other signatories thereto by the other Party and the other Party's failure to cure its breach within the 60 days' notice period provided herein or the period in the Master Agreement, as applicable.

- (b) either Party's giving 60 days' notice to the other Party if an event of force majeure under Article 15 continues for more than twelve (12) months. A termination due to an event of force majeure may be made only by the Party that is not affected by the event of force majeure.
- (c) without notice by a Party in the event of any declaration of bankruptcy or insolvency, appointment of a receiver by a court of competent jurisdiction, assignment for the benefit of creditors, or institution of liquidation proceeding by or against the other Party.

**ARTICLE 15**  
**FORCE MAJEURE**

- 15.4 No Liability.** Except for the cases expressly referenced in this Agreement, failure of either Party to perform its obligations under this Agreement (excepting the obligation to make payments) shall not subject such Party to any liability to the other if such failure is caused or occasioned by act of God, or the public enemy, fire, explosion, flood, drought war, riot, sabotage, embargo, strikes, or other labor trouble, interruption of or delay in transportation, compliance with any order, regulation or request of any government of competent jurisdiction or any officer, department, agency or committee thereof, including requisition or allocation or establishment of priority, or by compliance with a request authorized by such governmental authority of any manufacturer for material to be used by it, or by any other event or circumstance of like or different character to the foregoing beyond the reasonable control of the Party so failing.
- 15.5 Notice and Cooperation.** The Party suffering an event of force majeure shall immediately notify the other Party and both parties shall co-operate in good faith in order to minimize the damages for both parties.

**ARTICLE 16**  
**EFFECTS OF TERMINATION OR EXPIRATION OF THIS AGREEMENT**

- 16.1 No Release of Obligation or Liability.** The termination or expiration of this Agreement, for any reason whatsoever, shall not relieve the Parties of any obligation or liability accrued hereunder prior to the time such termination or expiration becomes effective.
- 16.2 Effects on the Distributor.** In the event of termination of this Agreement according to Article 14, the Distributor shall stop distributing the Products and shall stop using and return to the Principal all confidential or proprietary information and material supplied by the Principal to the Distributor pursuant to this Agreement. The Distributor also shall not use Noravid or Procyclide or any trade name, trade dress, service marks or devices applied to or used in association with the Products.
- 16.3 Existing Stock.** As set forth in and subject to the terms of the Master Agreement, in the event of termination of this Agreement according to Article 14.1 or in accordance with Article 14.2 in case the Distributor is entitled to terminate, the Principal shall acquire (i) the remaining stock of Capsules existing in the warehouses of the Distributor on December 31, 2008 or on the date the Agreement is terminated and (ii) the Capsules returned to the Distributor from the market after December 31, 2008 (or the date the Agreement is terminated), in each case at the same price the Distributor paid to the Principal provided that, prior to December 31, 2008, the Distributor does not purchase more capsules than it reasonably expects to sell by December 31, 2008.

**ARTICLE 17**  
**CONFIDENTIALITY**

- 17.1 Confidentiality.** Neither Party shall disclose any information received from the other Party or pursuant to this Agreement or to any previous agreements between the Parties relating to the Products without the other Party's written consent. Such information is confidential and proprietary. This obligation of confidentiality does not apply to:
- (a) information which is or was known to the receiving Party at the time of its disclosure pursuant to this Agreement or any previous agreement, as established by such Party's written records;

- (b) information disclosed to the receiving Party by a third party having the right to disclose such information;
- (c) information which becomes patented, published or otherwise part of the public domain, as a result of acts of the disclosing Party or of a third party obtaining such information and having the right to disclose the same;
- (d) information that have to be disclosed by virtue of any applicable disposition of law.

**17.2 No Misuse of Confidential Information.** Each Party agrees that it shall not use confidential information obtained pursuant to this Agreement, for any purpose other than that indicated in this Agreement, without the prior written approval of the other Party.

**17.3 Survival.** The Parties agree that the provision set forth in this Article 17 survives after expiration and/or termination for any reason of this Agreement, until the confidential information becomes of public knowledge, without any breach of this clause made by the Parties hereto.

**17.4 Announcements.** Except for the draft of press release, which has been agreed by the Parties and attached hereto as Exhibit 17.4, No Party to this Agreement shall make any announcement concerning the provisions or subject of this Agreement without the prior written approval of the other Parties (which shall not be unreasonably withheld or delayed). Such restriction shall not apply if and to the extent that the announcement is required by law or by any authority having jurisdiction over it, provided that the disclosing Party shall give notice and, if requested by the other Parties, a draft of the announcement to the other Parties.

**17.5 Principal's Reports and Registration Statements.** Notwithstanding the foregoing, the Distributor hereby agrees that the Principal may disclose the existence and terms of this Agreement and the Collateral Agreements in and file copies of the same as exhibits to registration statements and reports filed with the United States Securities and Exchange Commission pursuant to the Securities Act of 1933, as amended and the Securities Exchange Act of 1934, as amended, with any securities exchange or listing upon which the Principal's securities may be listed or trading or pursuant to applicable law or regulations, provided that the Principal shall give notice and, if requested, a draft of the applicable portion of such registration statement or report to the Distributor.

#### **ARTICLE 18** **PREVAILING LANGUAGE**

In case of any translation of this Agreement and the Exhibits which are in the English language or any dispute arising over the meaning of any provision hereof or thereof, the English language versions shall prevail. In case of any translation of the Exhibits which are in the Italian language or any dispute arising over the meaning of any provision thereof, the Italian language versions shall prevail.

#### **ARTICLE 19** **JURISDICTION AND APPLICABLE LAW**

This Agreement shall be governed by and interpreted according to the Italian law; the Court of Milan will have exclusive jurisdiction in respect of any dispute arising in relation thereto and any other jurisdiction established by the law shall not apply.

#### **ARTICLE 20** **MISCELLANEOUS**

**20.1**

Assignment. None of the Parties shall be entitled to assign this Agreement or any of the rights or obligations hereunder, without the prior written consent of the other Party.



**20.2 Notices.** All notices or communication hereunder shall be given in writing and sent by fax or courier or registered mail, respectively to the fax numbers and addresses specified below or to such fax number and address that each Party will provide to the other Party from time to time pursuant to this article.

If to the Principal:

Gentium S.p.A.  
Piazza XX Settembre, 2  
Villa Guardia (Como)  
Italy  
Phone: 39-031-385-111  
Fax: 39-031-385-241  
Attn.: Dr. Laura Ferro

With copies (which shall not constitute notice) to:

Gianni, Origoni, Grippo & Partners  
Via delle Quattro Fontane, 20  
00184 Rome  
Italy  
Fax: 39-06-4871101  
Att.: Raimondo Premonte

And

Epstein Becker & Green, P.C.  
250 Park Avenue  
New York, New York 10177  
United States of America  
Fax: 1-212-878-8759  
Att.: Christopher M. Locke, Esq.

If to the Distributor:

CRINOS S.p.A.  
Via Pavia, 6  
Milan  
Italy  
Phone: 39-02-8310371  
Fax: 39-02-~~83103776~~  
Att: Enrique Häusermann,

With copy (which shall not constitute notice) to:

STADA Arzneimittel AG  
Stadastrasse 2-18  
61118 Bad Vilbel  
Germany  
Fax: 49-6101-603

Att.: Luc Slegers

[Remainder of page intentionally left blank]

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IN WITNESS WHEREOF, the Parties have executed this Agreement as of the date first written above.

(Principal) **GENTIUM S.p.A.**

By: /s/ Laura Ferro, M.D.

Name: Dr. Laura Ferro  
Title: Chairperson, Chief Executive Officer and President

(Distributor) **CRINOS S.p.A.**

By: /s/ Enrique Hausermann

Name: Enrique Hausermann  
Title: Managing Director

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**Exhibit 3.1****Oral and Written Contracts and Legal Obligations to Deliver Products****Obligations to deliver products (Prociclide and Noravid)****HOSPITAL TENDERS****PROCICLIDE - 10 AMPOULES 200 MG**

| CODE | CUSTOMER   | CITY                    | PRICE € | DISCOUNT % (*) | STARTING DATE | CLOSING DATE |
|------|--|-------------------------|---------|----------------|---------------|--------------|
| 66   | AZIENDA REGIONALE U.S.L. 4 TORINO<br>CdC VILLA MARIA PIA | TORINO                  | 11.93   | 54.12          | 01/10/2005    | 31/01/2008   |
| 117  | HOSPITAL   | TORINO                  | 12.0016 | 53.84          | 07/04/2006    | 31/03/2007   |
| 300  | A O S.CROCE E CARLE<br>AZIENDA U.S.L. N. 3               | CUNEO<br>GENOVA         | 6.6     | 73.11          | 07/07/2004    | 6/30/2007    |
| 422  | GENOVESE<br>IST.NAZ.RICERCA SUL                          | QUARTO                  | 13      | 50             | 15/02/2005    | 30/06/2007   |
| 434  | CANCRO   | GENOVA<br>GENOVA        | 12.688  | 51.2           | 24/02/2006    | 31/05/2009   |
| 461  | ISTITUTO GIANNINA GASLINI<br>IST.NAZ.STUDIO E CURA       | QUARTO                  | 11.973  | 53.95          | 01/08/2005    | 31/12/2007   |
| 809  | TUMORI   | MILANO                  | 13      | 50             | 31/01/2005    | 31/05/2007   |
| 942  | A.O. OSPEDALE TREVIGLIO<br>CARAVAGGIO                    | TREVIGLIO               | 13      | 50             | 28/02/2005    | 30/06/2008   |
| 999  | A O SPEDALI CIVILI                                       | BRESCIA                 | 6.621   | 74.53          | 01/03/2006    | 30/06/2008   |
| 1019 | A O MELLINO MELLINI                                      | CHIARI                  | 13      | 50             | 01/09/2006    | 30/06/2008   |
| 1020 | AZIENDA PROVINCIALE                                      | BRESCIA                 | 13      | 50             | 28/02/2005    | 30/06/2008   |
| 1022 | AZIENDA OSPEDALIERA                                      | DESENZANO<br>DEL GARDA  | 13      | 50             | 28/02/2005    | 30/06/2008   |
| 1028 | A.S.L. DI<br>VALLECAMONICA-SEBINO                        | BRENO                   | 13      | 50             | 28/02/2005    | 30/06/2008   |
| 1127 | AO ISTITUTI OSPITALIERI                                  | CREMONA                 | 13      | 50             | 28/02/2005    | 30/06/2008   |
| 1144 | A O OSPEDALE MAGGIORE                                    | CREMA                   | 13      | 50             | 28/02/2005    | 30/06/2008   |
| 1145 | ASL PROV. CREMONA  | CREMONA                 | 13      | 50             | 28/02/2005    | 30/06/2008   |
| 1200 | A O CARLO POMA<br>AZIENDA SANITARIA                      | MANTOVA                 | 13      | 50             | 28/02/2005    | 30/06/2008   |
| 1229 | LOCALE   | BOLZANO                 | 13      | 50             | 01/02/2005    | 31/01/2007   |
| 1319 | AZIENDA U.L.S.S. N. 5 OVEST<br>VICENTINO                 | ARZIGNANO               | 7.3126  | 63.96          | 01/10/2004    | 30/10/2007   |
| 1422 | CASA DI CURA PAPA G. XXIII                               | MONASTIER<br>REGGIO     | 13      | 50             | 10/03/2006    | 31/03/2007   |
| 1740 | SALUS HOSPITAL<br>GAMBRO HEALTHCARE                      | EMILIA                  | 12.0016 | 53.84          | 07/04/2006    | 31/03/2007   |
| 1752 | ITALIA S.p.A   | MEDOLLA                 | 13      | 50             | 20/09/2006    | 30/09/2007   |
| 1786 | A O UNIV. POLICLINICO<br>S.ORSOLA-MALPIGHI               | BOLOGNA                 | 12.87   | 50.5           | 09/02/2006    | 30/06/2009   |
| 1787 | AZIENDA U.S.L. BOLOGNA<br>NORD                           | SAN GIORGIO<br>DI PIANO | 12.87   | 50.5           | 09/02/2006    | 30/06/2009   |
| 1813 |  | BOLOGNA                 | 12.87   | 50.5           | 09/02/2006    | 30/06/2009   |

ISTITUTI ORTOPEDICI  
RIZZOLI

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| CODE | CUSTOMER                         | CITY                           | PRICE € | DISCOUNT<br>% (*) | STARTING<br>DATE | CLOSING<br>DATE |
|------|----------------------------------|--------------------------------|---------|-------------------|------------------|-----------------|
| 1832 | AZIENDA U.S.L.                   | IMOLA                          | 12.87   | 50.5              | 09/02/2006       | 30/06/2009      |
| 1852 | AZIENDA U.S.L.                   | RAVENNA                        | 13      | 50                | 01/06/2006       | 30/05/2007      |
| 1854 | CASA DI CURA CITTA' DI<br>LECCE  | LECCE                          | 12.0016 | 53.84             | 01/04/2006       | 31/03/2007      |
| 1859 | SAN PIER DAMIANO<br>HOSPITAL     | FAENZA                         | 12.0016 | 53.84             | 07/04/2006       | 31/03/2007      |
| 1864 | VILLA MARIA CECILIA<br>HOSPITAL  | COTIGNOLA                      | 12.0016 | 53.84             | 07/04/2006       | 31/03/2007      |
| 1909 | AZIENDA U.S.L. N. 3              | FANO                           | 13      | 50                | 19/05/2006       | 31/08/2008      |
| 1910 | AZIENDA U.S.L. N.1               | PESARO                         | 13      | 50                | 19/05/2006       | 31/08/2008      |
| 1923 | AZIENDA U.S.L. N. 2              | URBINO                         | 13      | 50                | 19/05/2006       | 31/08/2008      |
| 1928 | ZONA TERRITORIALE 7              | ANCONA                         | 13      | 50                | 19/05/2006       | 31/08/2008      |
| 1930 | AZIENDA U.S.L. N. 5              | JESI                           | 13      | 50                | 19/05/2006       | 31/08/2008      |
| 1953 | AZIENDA U.S.L. N.6               | FABRIANO                       | 13      | 50                | 19/05/2006       | 31/08/2008      |
| 1955 | AZIENDA U.S.L. N.4               | SENIGALLIA                     | 13      | 50                | 19/05/2006       | 31/08/2008      |
| 1965 | AZIENDA U.S.L. N. 10             | CAMERINO                       | 13      | 50                | 01/07/2006       | 31/08/2008      |
| 1966 | AZIENDA U.S.L. N. 8              | CIVITANOVA<br>MARCHE           | 13      | 50                | 19/05/2006       | 31/08/2008      |
| 1967 | AZIENDA U.S.L. N.9               | MACERATA                       | 13      | 50                | 01/07/2006       | 31/08/2008      |
| 1991 | AZIENDA U.S.L. N.11              | FERMO                          | 13      | 50                | 19/05/2006       | 31/08/2008      |
| 1992 | AZIENDA U.S.L. N.13              | ASCOLI<br>PICENO               | 13      | 50                | 12/07/2006       | 31/08/2008      |
| 2013 | AZIENDA U.S.L. N.12              | SAN<br>BENEDETTO<br>DEL TRONTO | 13      | 50                | 01/07/2006       | 31/08/2008      |
| 2019 | AZIENDA U.S.L. N.1               | MASSA<br>CARRARA               | 6.984   | 71.54             | 14/04/2004       | 31/03/2008      |
| 2039 | AZIENDA U.S.L. N.2               | LUCCA                          | 6.984   | 73.14             | 14/04/2004       | 31/03/2008      |
| 2040 | AZIENDA U.S.L. N.12              | VIAREGGIO                      | 6.984   | 73.14             | 14/04/2004       | 31/03/2008      |
| 2063 | AZIENDA U.S.L. N.3               | PISTOIA                        | 7.015   | 71.42             | 01/04/2004       | 31/07/2008      |
| 2094 | AZIENDA U.S.L.                   | FIRENZE                        | 7.015   | 71.42             | 01/04/2004       | 31/08/2007      |
| 2095 | A O CAREGGI                      | FIRENZE                        | 7.015   | 71.42             | 01/04/2004       | 31/07/2008      |
| 2096 | AZIENDA U.S.L. N. 4              | PRATO                          | 7.015   | 71.42             | 01/04/2004       | 31/07/2008      |
| 2097 | AZIENDA U.S.L. N. 11             | EMPOLI                         | 7.015   | 71.42             | 01/04/2004       | 31/07/2008      |
| 2100 | A O MEYER                        | FIRENZE                        | 7.015   | 71.42             | 01/04/2004       | 31/07/2008      |
| 2162 | AZIENDA U.S.L. N.6               | LIVORNO                        | 6.984   | 73.14             | 14/04/2004       | 31/03/2008      |
| 2185 | AZIENDA U.S.L. N.5               | PISA                           | 6.984   | 71.54             | 14/04/2004       | 31/03/2008      |
| 2208 | AZIENDA U.S.L. N.8               | AREZZO                         | 12.2728 | 50                | 01/01/2006       | 31/03/2008      |
| 2227 | AZIENDA U.S.L. N.7               | SIENA                          | 12.2728 | 50                | 04/10/2004       | 31/12/2007      |
| 2228 | A O SENESE                       | SIENA                          | 8.2     | 66.59             | 24/02/2004       | 31/03/2007      |
| 2238 | AZIENDA U.S.L. N.9               | GROSSETO                       | 12.2728 | 50                | 01/05/2005       | 31/12/2007      |
| 2595 | G.I.O.M.I. S.P.A.                | ROMA                           | 13      | 50                | 01/04/2005       | 31/01/2007      |
| 3003 | AZIENDA SANITARIA<br>LOCALE BN/1 | BENEVENTO                      | 11.95   | 54.04             | 01/10/2005       | 7/31/2007       |
| 3210 | A O CARDARELLI                   | NAPOLI                         | 12.2728 | 50                | 01/06/2005       | 7/31/2007       |
| 3214 | A O<br>SANTOBONO-PAUSILLIPON     | NAPOLI                         | 13      | 50                | 01/12/2004       | 31/03/2007      |



| CODE | CUSTOMER                                 | CITY               | PRICE € | DISCOUNT % (*) | STARTING DATE | CLOSING DATE |
|------|--|--------------------|---------|----------------|---------------|--------------|
| 3241 | CASA DI CURA VESUVIO                     | NAPOLI             | 13      | 50             | 20/02/2006    | 28/02/2007   |
| 3498 | AZIENDA U.S.L. AV/1                      | AVELLINO           | 13      | 50             | 01/06/2006    | 30/06/2008   |
| 3707 | AZIENDA U.S.L.                           | CHIETI             | 13      | 50             | 19/07/2006    | 30/06/2008   |
| 3766 | AZIENDA U.S.L. FG/1                      | SAN SEVERO         | 8.347   | 64.43          | 11/04/2003    | 1/31/2007    |
| 3770 | OSPEDALI RIUNITI                         | FOGGIA             | 13      | 50             | 01/11/2006    | 6/30/2009    |
| 3843 | ANTHEA SRL                               | BARI               | 12.0016 | 53.84          | 07/04/2006    | 31/03/2007   |
| 3846 | AZIENDA U.S.L. BARI/5                    | PUTIGNANO          | 13      | 50             | 01/05/2006    | 31/03/2007   |
| 3847 | AZIENDA U.S.L. BARI/4                    | BARI               | 7.67    | 68.75          | 23/03/2004    | 3/30/2007    |
| 3848 | AZIENDA U.S.L. BARI/2                    | BARLETTA           | 7.9     | 67.81          | 29/06/2004    | 30/04/2007   |
| 3857 | AZIENDA OSPEDALIERA -<br>POLICLINICO     | BARI               | 8.1309  | 65             | 28/05/2003    | 15/06/2007   |
| 3889 | CONGREG.ANCELLE DIVINA<br>PROVVIDENZA    | BISCEGLIE          | 13      | 50             | 06/10/2004    | 31/05/2007   |
| 3950 | AZIENDA U.S.L. 1                         | BRINDISI           | 12.2728 | 50             | 01/09/2004    | 31/12/2007   |
| 3989 | AZIENDA U.S.L. LE/2                      | MAGLIE             | 7.749   | 66.98          | 01/01/2004    | 31/03/2007   |
| 3990 | AZIENDA U.S.L. LE/1                      | LECCE              | 13      | 50             | 24/03/2006    | 12/31/2008   |
| 4153 | AZIENDA SANITARIA N. 2                   | CASTROVILLARI      | 11.96   | 54             | 15/04/2005    | 31/08/2008   |
| 4155 | AZIENDA OSPEDALIERA                      | COSENZA            | 11.97   | 53.96          | 01/06/2006    | 31/05/2008   |
| 4157 | AZIENDA U.S.S.L. N. 3                    | ROSSANO<br>CALABRO | 13      | 50             | 01/07/2006    | 1/31/2008    |
| 4293 | A O PUGLIESE-CIACCIO                     | CATANZARO          | 13      | 50             | 01/02/2005    | 31/03/2007   |
| 4294 | A O MATER DOMINI                         | CATANZARO          | 13      | 50             | 19/01/2005    | 30/09/2009   |
| 4295 | AZIENDA U.S.L.                           | LAMEZIA<br>TERME   | 7.1452  | 72.52          | 11/04/2003    | 31/03/2007   |
| 4296 | AZIENDA U.S.L. N. 5                      | CROTONE            | 7.44    | 69.68          | 25/05/2004    | 31/08/2007   |
| 4297 | AZIENDA U.S.S.L. N. 8                    | VIBO VALENTIA      | 13      | 50             | 01/06/2006    | 10/31/2009   |
| 4434 | AZIENDA U.S.S.L. N. 9                    | LOCRI              | 13      | 50             | 31/01/2005    | 31/05/2008   |
| 4494 | AZIENDA U.S.L. N. 9                      | TRAPANI            | 12.2728 | 50             | 07/09/2004    | 31/12/2007   |
| 4543 | C.d.C. IGEA                              | PARTINICO (PA)     | 13      | 50             | 18/05/2006    | 31/05/2007   |
| 4562 | CASA DI CURA VILLA<br>MARIA ELEONORA     | PALERMO            | 12.0016 | 53.84          | 07/04/2006    | 31/03/2007   |
| 4569 | A O CERVELLO                             | PALERMO            | 13      | 50             | 01/07/2006    | 01/06/2009   |
| 4578 | A O UNIVERSITARIA PAOLO<br>GIACCONE      | PALERMO            | 7.1893  | 70.71          | 29/03/2004    | 30/04/2007   |
| 4694 | AZIENDA U.S.L. N. 5                      | MESSINA            | 10      | 59.25          | 07/04/2004    | 31/07/2007   |
| 4696 | A O PIEMONTE                             | MESSINA            | 7.44    | 68.3           | 17/12/2003    | 30/06/2007   |
| 4763 | AZIENDA U.S.L. N. 1                      | AGRIGENTO          | 7.7413  | 67.01          | 01/03/2004    | 30/06/2007   |
| 4766 | A O OSPEDALI RIUNITI                     | SCIACCA            | 11.9912 | 53.88          | 01/12/2005    | 31/03/2008   |
| 4910 | A O V.EMANUELE<br>FERRAROTTO             | CATANIA            | 13      | 50             | 13/06/2006    | 31/12/2009   |
| 4911 | A O OSPEDALE GARIBALDI<br>S.LUIGI CURRO' | CATANIA            | 13      | 50             | 01/01/2007    | 31/12/2009   |
| 4915 | POLICLINICO<br>UNIVERSITARIO             | CATANIA            | 13      | 50             | 01/05/2005    | 30/06/2007   |
| 5019 | AZIENDA USL N. 8                         | SIRACUSA           | 12.3    | 50             | 10/09/2004    | 31/12/2007   |
| 5197 | AZIENDA U.S.L. N. 7                      | CARBONIA           | 13      | 50             | 01/07/2005    | 3/31/2007    |



| CODE | CUSTOMER                                   | CITY                 | PRICE € | DISCOUNT % (*) | STARTING DATE | CLOSING DATE |
|------|--|----------------------|---------|----------------|---------------|--------------|
| 5735 | ISTITUTO<br>NEUROLOGICO CARLO<br>BESTA     | MILANO               | 13      | 50             | 31/01/2005    | 31/05/2007   |
| 5745 | CDC VILLA MARIA<br>BEATRICE                | FIRENZE              | 12.0016 | 53.84          | 07/04/2006    | 31/03/2007   |
| 5753 | IST. CODIVILLA - PUTTI                     | CORTINA<br>D'AMPEZZO | 13      | 50             | 01/04/2005    | 31/01/2007   |
| 6844 | AZIENDA USL DELLA<br>CITTA' DI BOLOGNA     | BOLOGNA              | 12.87   | 50.5           | 09/02/2006    | 30/06/2009   |
| 6851 | AZ. OSP. UMBERTO I<br>-LANCISI -<br>SALESI | ANCONA               | 11.921  | 54.15          | 15/10/2005    | 31/07/2007   |
| 6922 | AZIENDA U.S.L. 8                           | SELARGIUS            | 6.6     | 74.62          | 21/01/2004    | 30/06/2007   |
| 6964 | AZIENDA U.S.L. FG/2<br>OSP.MAGGIORE DI     | CERIGNOLA            | 11.73   | 54.88          | 01/07/2005    | 31/10/2007   |
| 6982 | MILANO                                     | MILANO               | 13      | 50             | 31/01/2005    | 31/05/2007   |
| 6991 | A O PISANA                                 | PISA                 | 6.984   | 73.14          | 14/04/2004    | 31/03/2008   |
| 7001 | AZIENDA U.S.L. BAT/1                       | ANDRIA               | 11.973  | 53.95          | 01/08/2005    | 31/08/2008   |
| 7012 | CLINIC CENTER NAPOLI<br>VILLA AZZURRA      | NAPOLI               | 13      | 50             | 10/03/2006    | 31/03/2007   |
| 7014 | HOSPITAL                                   | RAPALLO              | 12.0016 | 53.84          | 10/03/2006    | 31/03/2007   |
| 7015 | VILLALBA HOSPITAL<br>CENTRO NEFROLOGICO    | BOLOGNA              | 12.0016 | 53.84          | 07/04/2006    | 31/03/2007   |
| 7029 | E DIALISI<br>AZIENDA SANITARIA             | PALERMO              | 13      | 50             | 18/05/2006    | 30/05/2007   |
| 7030 | REG.MOLISE                                 | ISERNIA              | 12.2727 | 50             | 05/10/2004    | 31/12/2007   |

(\*) Discount is calculated on public price less  
VAT

**Exhibit 6.1**

**Monthly Requirements**

**Next 12 months of Proposed Product Requirements**

**PROCICLIDE - PROPOSED PRODUCT REQUIREMENTS - 2007**

**PUBLIC**

|                            | <b>Units</b> |
|----------------------------|--------------|
| PROCICLIDE - 21 cps 400 mg | 330,000      |

**HOSPITAL**

|                            | <b>Units</b> |
|----------------------------|--------------|
| PROCICLIDE - 21 cps 400 mg | 4,800        |
| PROCICLIDE -10 amp 200 mg  | 30,000       |

**SAMPLES**

|                           | <b>Units</b> |
|---------------------------|--------------|
| PROCICLIDE - 4 cps 400 mg | 15,000       |

**NORAVID - PROPOSED PRODUCT REQUIREMENTS - 2007**

**PUBLIC**

|                         | <b>Units</b> |
|-------------------------|--------------|
| NORAVID - 21 cps 400 mg | 37,000       |

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**Exhibit 7.1 (A)**

**Good Manufacturing Practises**

Intentionally omitted.

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**Exhibit 7.1 (B)**

**Packaging**

Intentionally omitted.

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**Exhibit 17.4**

**Press Release**

See Exhibit 1 to Form 6-K of Gentium S.p.A. dated January 3, 2007.

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**LICENSE OF  
TRADEMARK NORAVID**

by and between

SFI STADA FINANCIAL INVESTMENTS Ltd.

CRINOS S.p.A.

and

GENTIUM S.p.A.

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**LICENSE OF REGISTERED TRADEMARKS**

by and between

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

(hereinafter "SFI" or "LICENSOR 1")

**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" or "LICENSOR 2")

(LICENSOR 1 and LICENSOR 2 together also referred to as "LICENSORS")

and

**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" or "LICENSEE")

**PREAMBLE**

- A) Whereas the LICENSEE, in connection with the acquisition of the marketing authorizations regarding pharmaceutical specialities actually sold under the trademark "Noravid" which acquisition is planned for the end of year 2008, is interested in being officially invested as licensee of such trademark.
- B) Whereas SFI is the current, sole and exclusive owner of the trademark Noravid, having it acquired from CRINOS, although CRINOS for the moment remains the registered owner of Noravid, being such trademark registered as an international trademark for 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 (hereinafter the "Trademark").
- C) Whereas the LICENSOR 1 and LICENSOR 2 agree to grant LICENSEE a time limited gratuitous license with reference to the use of the Trademark in Italy.

**Now, therefore, in consideration of the covenants and agreements herein contained, the preamble forming an integral part of the present License Agreement, the Parties hereto agree as follows:**

**1. Assignment**

LICENSORS grant to LICENSEE the exclusive license to use the Trademark in Italy. The license is gratuitous and royalty free.





**2. Assignment and sublicense**

LICENSEE is not allowed to grant sublicenses or to assign this agreement, in toto or in part, to third parties.

**3. Costs and expenses**

As from the date of this Agreement, LICENSORS will bear the sole responsibility and all costs and expenses related to the registration, the maintenance, renewal and/or prosecution costs of the Trademark and any further applications in respect thereof.

**4. Effectiveness**

The present License Agreement shall become effective on the date of this Agreement and shall remain in force, with respect to the Trademark, until 31.12.2008 if not terminated before by LICENSORS in case of a breach of a contractual obligation LICENSEE has towards LICENSORS also on the basis of other agreements entered into between the Parties. LICENSORS expressly acknowledge such right of early termination of LICENSORS which has to be executed through the transmission of registered mail to the address of LICENSEE as given above and will be effective immediately upon receipt of such mail.

**5. Waiver**

The failure of a Party to insist upon strict performance of the terms, conditions and provisions of the present agreement by the other Party shall not constitute a waiver of any of the provisions hereof and no waiver by a Party of any of such provisions shall be deemed to have been made unless expressed in writing by such waiving Party.

**6. Language**

The language of the present Agreement is English. No translation into any other language shall be taken into account in the interpretation of the present Agreement.

**7. Governing Law**

This Agreement, its validity, its interpretation and performance shall be governed by Italian Law.

**8. Disputes**

Any disputes between the Parties arising out of or caused by this Agreement, including the validity, interpretation, execution and resolution of this Agreement, which are not settled as a result of negotiations between the Parties, shall be resolved under the exclusive jurisdiction of the Court of Milan.

IN WITNESS WHEREOF, each of the parties has caused this Agreement to be executed on its behalf by a duly authorised officer all as of the date first written above.

SFI Stada Financial Investments Ltd.

GENTIUM S.p.A.

By: /s/ Enrique Hausermann  
Enrique Hausermann

By: /s/ Laura Iris Ferro,  
M.D.  
Laura Iris Ferro, M.D.

CRINOS S.p.A.

By: /s/ Enrique Hausermann  
Enrique Hausermann



**LICENSE OF  
TRADEMARK PROCICLIDE**

by and between

SFI STADA FINANCIAL INVESTMENTS Ltd.

SFS STADA FINANCIAL SERVICES Ltd.

and

GENTIUM S.p.A.

---

**LICENSE OF REGISTERED TRADEMARKS**

by and between

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

(hereinafter "SFI" or "LICENSOR 1")

**SFS Stada Financial Services Ltd.**, a corporation organised and existing under the law of Ireland with its registered offices in Clonmel Healthcare, 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" or "LICENSOR 2")

(LICENSOR 1 and LICENSOR 2 together also referred to as "LICENSORS")

and

**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" or "LICENSEE")

**PREAMBLE**

- A) Whereas the LICENSEE, in connection with the acquisition of the marketing authorizations regarding pharmaceutical specialities actually sold under the trademark "Procyclide" which acquisition is planned for the end of year 2008, is interested in being officially invested as licensee of such trademark.
- B) Whereas SFI is the current, sole and exclusive owner of the trademark Procyclide, having it acquired from SFS, although SFS remains the registered owner of Procyclide, being such trademark registered in Italy for the trademark registration class 5, application date 5 October 2004, application number MI2004C009818, previous registration number 709684, expiring on 29 January 2015 (hereinafter the "Trademark").
- C) Whereas the LICENSOR 1 and LICENSOR 2 agree to grant LICENSEE a time limited gratuitous license with reference to the use of the Trademark in Italy.

**Now, therefore, in consideration of the covenants and agreements herein contained, the preamble forming an integral part of the present License Agreement, the Parties hereto agree as follows:**

**1. Assignment**

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LICENSEE is not allowed to grant sublicenses or to assign this agreement, in toto or in part, to third parties.

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SFI Stada Financial Investments Ltd.

GENTIUM S.p.A.

By: /s/ Enrique Hausermann  
Enrique Hausermann

By: /s/ Laura Iris Ferro,  
M.D.  
Laura Iris Ferro, M.D.

SFS Stada Financial Services Ltd.

By: /s/ Enrique Hausermann  
Enrique Hausermann

