Gentium S.p.A.
Form 6-K
December 01, 2009

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, 2009.

Commission File Number 000-51341

Gentium S.p.A.
(Translation of registrant's name into English)

Piazza XX Settembre 2, 22079 Villa Guardia (Como), Italy
(Address of principal executive office)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F.
Form 20-F x 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 x

If "Yes" is marked, indicate below the file number assigned to the registrant in connection with Rule 12g3-2(b):
82-_____.

The Registrant's press release regarding its quarterly financial results for the period ended September 30, 2009 and clinical research agreement with US Oncology are attached hereto as Exhibits 1 and 2, respectively, and incorporated by reference herein in their entirety. This report and the exhibits attached hereto are incorporated by reference into the registration statements of Gentium S.p.A. on Forms F-3: File No. 333-135622, File No. 333-137551, File No. 333-138202, File No. 333-139422 and File No. 333-141198 and on Forms S-8: File No. 333-137534 and File No. 333-146534.

Exhibit	Description
1	Press release, dated November 30, 2009.
2*	Clinical Research Agreement, effective September 29, 2009.

* Portions of this exhibit have been omitted and filed separately with the Securities and Exchange Commission pursuant to a request for confidential treatment.

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: December 1, 2009

INDEX TO EXHIBITS

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Exhibit 1

PRESS RELEASE

Gentium Reports Third Quarter Financial Results;
Provides Financial Update

VILLA GUARDIA (Como), Italy, November 30, 2009 (BUSINESS WIRE) — Gentium S.p.A. (NASDAQ: GENT) (the "Company") today reported financial results for the quarter ended September 30, 2009.

Financial Highlights

Gentium S.p.A., or the Company, reports its financial condition and operating results using U.S. Generally Accepted Accounting Principles (GAAP). The Company's financial statements are prepared using the Euro (€) as its functional currency. On September 30, 2009, €1.00 = $1.4643.

For the third quarter ended September 30, 2009 compared with the prior year's third quarter:

- Total revenues were €2.50 million, compared with €1.85 million. The increase was primarily attributable to named-patient sales of Defibrotide throughout the European and Asia-Pacific markets, offset by a decrease in other revenues, mainly cost sharing revenues from Sigma-Tau.
- Operating costs and expenses were €3.49 million, compared with €8.86 million. Operating costs and expense for the three-month period ended September 30, 2008 included a write down of acquired assets of €3.05 million.
- Research and development expenses, which are included in operating costs and expenses, were €0.85 million, compared with €2.51 million. Lower costs were due to the completion in enrollment in both the pediatric prevention and treatment studies as well as cost-reduction initiatives.
- Operating loss was €0.99 million, compared with €7.02 million. Operating losses in 2008 included a write down of acquired assets of €3.05 million. The lower operating loss for the nine months ended September 30, 2009 was due to the higher revenues and gross margins attributable to named-patient sales and lower general and administrative and research and development expenses.
- Net loss was €1.02 million, compared with €5.85 million.
- Basic and diluted net loss per share was €0.07 compared with €0.39 per share.

For the nine-month period ended September 30, 2009 compared with the comparable prior-year period:

- Total revenues were €6.12 million, compared with €6.40 million.
- Operating costs and expenses were €10.66 million, compared with €22.89 million.
- Research and development expenses, which are included in operating costs and expenses, were €2.66 million, compared with €7.87 million. Research and development expenses for the nine-month periods ended September 30, 2009 and 2008 are net of €0.76 million and €0.79 million, respectively, of government grants in the form of a tax credit, accrued as a reduction of research and development expenses.

- Operating loss was €4.54 million, compared with €16.49 million.
- Interest income (expense), net, was (€0.09) million, compared with €0.17 million.
- Net loss was €4.48 million, compared with €16.46 million.
- Basic and diluted net loss per share was €0.30, compared with €1.10 per share.

Cash and cash equivalents and short term available for sale securities as of September 30, 2009 were €0.97 million compared with €11.49 million as of December 31, 2008. In March 2009, the Company made a final installment payment of €4.0 million related to the acquisition of marketing authorizations and trademarks for Prociclide and Noravid (previous forms of Defibrotide sold only in Italy). Net cash used in operating activities for the nine-month period ended September 30, 2009 was €5.68 million compared with €11.09 million for the same period in 2008. The reduction in net cash used in operating activities between the two periods reflects a decrease in spending on development activities coupled with increased cash flows from the named-patient program. The Company also utilized Cassa Integrazione, a mechanism available to companies in Italy to temporarily lay-off employees, with the Italian government funding a portion of the costs of the employees during the lay-off period.

In light of increased revenues from the named-patient program and cost-reduction initiatives, among other factors, the Company currently anticipates that its cash will meet its operating requirements through June 2010. However, in order for the Company to continue as a going concern beyond this point, the Company will likely need to obtain capital from external sources.

“We are pleased with the revenue that continues to be generated through the named-patient program.” said Gary Gemignani, Executive Vice-President and Chief Financial Officer. “We have also initiated a cost recovery program, which is being administered by US Oncology, for distribution of Defibrotide through our expanded access program in the U.S., which we believe, along with the named-patient program, continues to demonstrate the demand that exists for Defibrotide. We continue to evaluate our strategic options and look forward to continuing our efforts toward obtaining regulatory approval to market Defibrotide.”

Company Update

Gentium reported top-line results from a historically controlled, multicenter, open label, Phase III trial designed to evaluate the safety and efficacy of 25 mg/kg/day of Defibrotide for the treatment of severe veno-occlusive disease (sVOD) in hematopoietic stem cell transplant (SCT) patients. The results demonstrated strong trends in favor of the Defibrotide-treated patients for complete response and survival, but did not reach the protocol-specified levels of significance for the primary and secondary endpoints at 100 days. Gentium will announce final results from this trial and the Company's Phase II/III Pediatric Prevention trial in two oral presentations at the American Society of Hematology Conference (ASH) on December 7, 2009 in New Orleans.
In the third quarter, Gentium also announced that five of the eight members of its Board of Directors resigned, thereby triggering automatic termination of its entire Board of Directors under Italian law. Following an ordinary meeting of shareholders, the Company recently announced the election of a new Board of Directors and the appointment of Dr. Khalid Islam as Interim CEO.

Operating Results

Net product sales for the nine-month period ended September 30, 2009 were €5.99 million compared with €4.12 million for the same period in 2008, an increase of €1.87 million or 45%. The increase was primarily due to the initiation of a named-patient program in April 2009 to distribute Defibrotide throughout the European and Asia-Pacific markets. Named-patient program gross sales for the period from April 21, 2009 through September 30, 2009 amounted to €2.82 million or €2.43 million net of related service payments. Through October 30, 2009, the Company has generated €3.54 million in gross revenue, or €3.05 million in net revenue, through the named-patient program.

Sales to a related party, Sirton, for the nine-month periods ended September 30, 2009 and 2008 represented 3% and 13% of the total product sales, net, respectively. The decrease in sales to Sirton is primarily due to the fact that the Company entered into direct agreements with Sirton's customers in order to mitigate the risk associated with Sirton's poor financial condition.

Sales to third parties decreased to €3.37 million for the nine-month period ended September 30, 2009 compared with €3.57 million for the same period in 2008. The nine-month period ended September 30, 2009 does not includes sales of Prociclide and Noravid (due to discontinuation of such sale), which in the prior period amounted to €1.72 million. The discontinuation of sales of Prociclide and Noravid was offset for the current nine-month period due to higher volume of sales to third parties and price increase.

Other revenues, primarily cost-sharing revenues from Sigma-Tau, were €0.13 million for the nine-month period ended September 30, 2009, compared with €2.28 million for the same period in 2008. Fluctuation versus the prior period is primarily due to timing on the recognition of reimbursement of certain costs incurred for the Company's Phase III clinical trial of Defibrotide to treat Severe VOD.

Cost of goods sold was €3.13 million for the nine-month period ended September 30, 2009 compared with €4.32 million for the same period in 2008. Cost of goods sold as a percentage of product sales was 52% for the nine-month period ended September 30, 2009 compared with 105% for the same period in 2008. The percentage decrease is primarily due to (i) higher margins on Defibrotide sold through the named-patient program, (ii) price increases in the active pharmaceutical ingredient business, and (iii) discontinuation of negative margins associated with Prociclide and Noravid. The Company has fully expensed, during the prior nine-month period, costs associated with the production of Defibrotide; therefore, costs of goods sold do not reflect the full costs of production, because a portion of the active pharmaceuticals ingredients, conversion and labor and overhead costs incurred to produce Defibrotide sold through the named-patient program were previously expensed. Additionally, the higher percentage for the nine-month period ended in 2008 was primarily due to the fact that product sales to Sirton were not recognized after March 2008, due to Sirton's poor financial condition and concerns over the collectability of such receivables. Cost of goods sold as of September 30, 2009 and 2008 include an allowance on inventory of €0.1 million and €0.06 million, respectively.

The Company incurred research and development expenses of €2.66 million for the nine- month period ended September 30, 2009 compared with €7.87 million for the same period in 2008. Research and development expenses for the nine-month periods ended September 30, 2009 and 2008 are net of €0.76 million and €0.79 million, respectively, of government grants, in the form of a tax credit, which have been accrued as a reduction of expense. Research and development expenses were primarily for the development of Defibrotide to treat and prevent VOD. The decrease from the comparable period in 2008 is primarily due to lower stock based compensation costs and development expenses (including contract research organization expenses and regulatory activities) following the completion of enrollment of the treatment trial, as well as cost-reduction initiatives.

General and administrative expenses were €3.96 million for the nine-month period ended September 30, 2009 compared with €6.36 million for the same period 2008. General and administrative expenses from the prior nine-month-period reflect the establishment of an allowance for doubtful accounts of €1.77 million, which was partially released for €0.41 million in 2009. The decrease in general and administrative expense is also attributable to lower stock based compensation costs and a decrease in payroll costs due to the temporary layoffs under the Cassa Integrazione program during the nine-month period ended September 30, 2009. For the nine-month period ended September 30, 2009, general and administrative expenses include recognition of service fees for named-patient program of €0.39 million.

Foreign currency exchange gain (loss) is primarily due to remeasurement of U.S. dollar cash balances. The positive result between 2009 and 2008 is due to a more favorable exchange rate in 2009 between the Euro and U.S. dollar and a lower cash balance in 2009 versus 2008.

Interest income (expense), net amounted to (€0.09) million and €0.17 million for the nine- month periods ended September 30, 2009 and 2008, respectively. Gross interest income amounted to €0.03 million and €0.43 million for the nine-month periods ended September 30, 2009 and 2008, respectively, a decrease of €0.40 million. The decrease is a result of a lower amount of invested funds in the nine-month period ended September 30, 2009 and a decrease in interest rates. Interest expense totalled €0.12 million and €0.26 million for the nine-month periods ended September 30, 2009 and 2008, respectively, a decrease of €0.13 million attributable to a fluctuation in interest rate and decrease of principal debt outstanding.

Net loss was €4.48 million for the nine-month period ended September 30, 2009 compared with €16.46 million for the same period in 2008. The difference was primarily due to lower research and development expenses, general and administrative expenses, and other income and revenues, as well as no write-down of acquired assets, which in 2008 amounted to €3.5 million, offset by an increase in margin from product sales through the named-patient program.

About VOD

Veno-occlusive disease is a potentially life-threatening condition, which typically occurs as an important complication of stem cell transplantation (SCT). Certain high-dose chemo-radiation therapy regimens used as part of SCT can damage the lining cells of hepatic blood vessels and so result in VOD, a blockage of the small veins of the liver that leads to liver failure and can result in significant dysfunction in other organs such as the kidneys and lungs (so-called severe VOD). SCT is a frequently used treatment modality following chemotherapy or radiation treatments for hematologic cancers and other conditions in both adults and children. There is currently no approved agent for the treatment or prevention of VOD in the U.S. or the EU.

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, is an investigational drug that has been granted Orphan Drug status by the U.S. Food and Drug Administration and EMEA to prevent and to treat VOD and Fast Track designation by the U.S. FDA for the treatment of severe VOD in recipients of stem cell transplants.

Cautionary Note Regarding Forward-Looking Statements

This press release contains “forward-looking statements.” In some cases, you can identify these statements by forward-looking words such as “may,” “might,” “will,” “should,” “expect,” “plan,” “anticipate,” “believe,” “estimate,” “pred or “continue,” the negative of these terms and other comparable terminology. These statements are not historical facts but instead represent the Company's belief regarding future results, many of which, by their nature, are inherently uncertain and outside the Company's control. It is possible that actual results, including cash and other financial projections and potential regulatory approval, may differ 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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GENTIUM S.p.A.
Balance Sheets
(Amounts in thousands, except share and per share data)

	December 31, 2008	September 30, 2009 (unaudited)
ASSETS		
Cash and cash equivalents	€ 11,491	€ 704
Available for sale securities		263
Accounts receivable	625	2,196
Accounts receivable from related parties, net of allowance of € 1,783 and € 1,370 as of December 31, 2008 and September 30, 2009, respectively	320	12
Inventories, net	907	919
Prepaid expenses and other current assets	2,178	2,014
Total Current Assets	15,521	6,108
Property, manufacturing facility and equipment, at cost	21,019	21,395
Less: Accumulated depreciation	10,268	11,223
Property, manufacturing facility and equipment, net	10,751	10,172
Intangible assets, net of amortization	95	78
Available for sale securities	510	261
Other non-current assets	24	171
Total Assets	€ 26,901	€ 16,790
LIABILITIES AND SHAREHOLDERS' EQUITY		
Accounts payable	€ 5,823	€ 4,389
Accounts payable to Crinos	4,000	-
Accounts payable to related parties	325	162
Accrued expenses and other current liabilities	810	706
Current portion of capital lease obligations	65	67
Current maturities of long-term debt	1,346	1,224
Total Current Liabilities	12,369	6,548
Long-term debt, net of current maturities	3,268	2,487
Capital lease obligation	158	108
Termination indemnities	655	601
Total Liabilities	16,450	9,744
Share capital (no par value; 18,605,492 shares authorized; 14,956,317 shares issued at December 31, 2008 and September 30 2009)	14,956	14,956
Additional paid in capital	90,619	91,676
Accumulated other comprehensive loss	(17)	(2)
Accumulated deficit	(95,107)	(99,584)
Total Shareholders' Equity	10,451	7,046
Total Liabilities and Shareholders' Equity	€ 26,901	€ 16,790

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

	Three months ended September 30,		Nine months ended September 30,	
	2008	2009	2008	2009
Revenues:				
Product sales to related party	€ -	€ -	€ 555	€ 195
Product sales to third parties	1,210	1,070	3,565	3,367
Name patient program sales, net	-	1,391	-	2,426
Total product sales, net	1,210	2,461	4,120	5,988
Other revenues	635	34	2,278	131
Total revenues	1,845	2,495	6,398	6,119
Operating costs and expenses:				
Cost of goods sold	1,363	1,130	4,317	3,130
Research and development	2,505	849	7,873	2,657
General and administrative	1,560	1,197	6,360	3,958
Charges from related parties	95	69	444	210
Depreciation and amortization	286	241	845	706
Write-down of acquired assets	3,052	-	3,052	-
	8,861	3,486	22,891	10,661
Operating loss	(7,016)	(991)	(16,493)	(4,542)
Interest income (expense), net	15	(26)	173	(98)
Foreign currency exchange gain/(loss), net	1,152	(6)	(137)	163
Loss before income tax expense	(5,849)	(1,023)	(16,457)	(4,477)
Income tax expense	-	-	-	-
Net loss	€ (5,849)	€ (1,023)	€ (16,457)	€ (4,477)
Net loss per share:				
Basic and diluted net loss per share	(0.39)	(0.07)	(1.10)	(0.30)
Weighted average shares used to compute basic and diluted net loss per share	14,956,317	14,956,317	14,956,245	14,956,317

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

	Nine Months Ended September 30,	
	2008	2009
Cash Flows From Operating Activities:		
Net loss	€ (16,457)	€ (4,477)
Adjustments to reconcile net loss to net cash used in operating activities:		
Unrealized foreign exchange loss	(326)	(248)
Write-down of acquired assets	3,051	-
Depreciation and amortization	1,364	970
Stock based compensation	1,594	1,057
Loss on fixed asset disposal	7	-
Inventory allowance	6	101
Allowance (release) for doubtful accounts	1,767	(413)
Changes in operating assets and liabilities:		
Accounts receivable	(638)	(1,594)
Inventories	(526)	(113)
Prepaid expenses and other current and noncurrent assets	(392)	17
Accounts payable and accrued expenses	(542)	(982)
Net cash used in operating activities	(11,092)	(5,682)
Cash Flows From Investing Activities:		
Capital expenditures	(432)	(373)
Intangible assets expenditures	(166)	-
Acquisition of Crinos Assets	-	(4,000)
Net cash used in investing activities	(598)	(4,373)
Cash Flows From Financing Activities:		
Proceeds stock option exercises, net	38	-
Repayments of long-term debt	(731)	(903)
Proceeds from short term borrowings	(279)	-
Principal payment of capital lease obligations	(86)	(48)
Net cash used by financing activities	(1,058)	(951)
Decrease in cash and cash equivalents	(12,748)	(11,006)
Effect of exchange rate on cash and cash equivalents	363	219
Cash and cash equivalents, beginning of period	25,964	11,491
Cash and cash equivalents, end of period	€ 13,579	€ 704

Exhibit 2

CONFIDENTIAL TREATMENT REQUESTED BY GENTIUM S.p.A.

MASTER CONTRACT CLINICAL RESEARCH AGREEMENT

THIS CONTRACT CLINICAL RESEARCH AGREEMENT ("Agreement"), effective as of this 29th day of September, 2009 (the "Effective Date") by and between Gentium S.p.A., with offices located at Piazza XX Settembre, 222079, Villa Guardia (Co) Italy ("Gentium") and US Oncology Clinical Development, with its principal place of business located at 10101 Woodloch Forest, The Woodlands, Texas 77380 ("CRO"). GENTIUM and CRO are each individually referred to as a "Party" and collectively as the "Parties".

WHEREAS, GENTIUM is engaged in the research and development of pharmaceutical and biologics products for the treatment of human diseases and conditions;

WHEREAS, CRO is engaged in the business of providing services relating to conducting and managing clinical research investigations;

WHEREAS, CRO agrees to assist GENTIUM in managing certain clinical research activities, with such activities including but not limited to distribution of its investigational product, billing and invoicing for the investigation product, safety management, data management and patient registration on one or more of GENTIUM sponsored studies as set forth herein; and

WHEREAS, CRO and GENTIUM to enter into this Agreement in order to set forth definitively their respective rights and obligations with respect to the conduct of each Study (as that term is defined below).

NOW, THEREFORE, in consideration of the foregoing premises and mutual covenants and agreements provided herein, the Parties agree as follows:

SECTION 1
RETENTION OF CRO; STUDY WORK ORDERS

1.1 Retention of CRO. The Parties acknowledge that, from time to time during the Term (as that term is defined below) of this Agreement, GENTIUM may request that CRO assist GENTIUM in the conduct of a clinical research investigation (each, a "Study" or collectively, the "Studies") in accordance with this Agreement and a contract clinical research work order, substantially on the terms set forth on Exhibit A (the "Study Work Order"). The services to be provided by CRO with respect to a Study (the "Services") shall be set forth in a Study Work Order and shall include, without limitation, a detailed description of the Services required for a Study (the "Scope of Services"), a protocol for the applicable Study (each, a "Protocol") and information regarding the conditions for the compounding, storage and handling of the applicable investigational product or other agent, antibody or compound that is the subject of evaluation in such Study (each, a "Investigational Product").

1.2 Study Work Orders.

1.2.1 Binding Effect; Interpretation. A Study Work Order shall become effective on the effective date of any such Study Work Order as defined therein and shall constitute a binding agreement between the Parties regarding the Study or Studies covered thereby. The terms and conditions of this Agreement shall apply to all Study Work Orders. In the event of a conflict between the terms of this Agreement and the terms of a Study Work Order, the terms of this Agreement shall prevail.

Confidential treatment has been requested for portions of this exhibit. The copy filed herewith omits the information subject to the confidentiality request. Omissions are designated as ***. A complete version of this exhibit has been filed with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Act of 1934, as amended.

1.2.2 Modification. Either party may request changes to the Services set forth in a Study Work Order by submitting a written request detailing the proposed changes to the other party. Upon receipt or development of such written request, CRO shall advise GENTIUM of any adjustment in fees or other changes to a Study Work Order (e.g., to project timelines or personnel) that would result from the requested change. Except as otherwise contemplated in this Section 1.2.2, no change in any Study Work Order shall be made by CRO, GENTIUM or any Investigator (as that term is defined below) and no amendment or waiver of any term or provision of a Study Work Order shall be effective unless in writing and executed by the Party against whom such amendment or waiver is sought to be enforced. In the event that the safety of Study subjects shall require a deviation from a Study Work Order, then CRO shall immediately notify GENTIUM's Clinical Operations lead representative for the Study of the nature of the required deviation and the facts necessitating such deviation and obtain from GENTIUM prior verbal approval for such deviation, which approval shall be promptly thereafter confirmed by written notice given by GENTIUM to CRO; provided, however, in the event of an emergency with respect to the safety and/or health of Study subjects and prior notice is not possible, CRO and the applicable Investigators (as that term is defined below) shall effect the required deviation without GENTIUM's consent, but shall notify GENTIUM's Clinical Operations lead representative for the Study immediately thereafter.

1.3 Scope of Services. Each Study Work Order shall include a Scope of Services setting forth the specific Services that CRO shall provide for each Study. Such Services may include some or all of the following: clinical trials management, Study initiation, Study conduct, Study Site (as defined below) monitoring, biometrics, data management, medical report writing, regulatory records management, support for safety reporting, pharmacy distribution, billing and invoicing for the investigation product. local sponsor representation, Study site contracting and payment negotiation and administration, regulatory interface, translation services and such other services as the Parties may specify in writing. CRO shall initiate Study enrollment and to complete the Services in accordance with the terms and timelines set forth in the Scope of Services and the Protocol.

1.4 Affiliates.

1.4.1 GENTIUM Affiliates. In addition to GENTIUM, CRO agrees to provide Services to GENTIUM Affiliates (as that term is defined below) pursuant to validly executed Study Work Orders by and between CRO and a GENTIUM Affiliate. A GENTIUM Affiliate that executes a Study Work Order shall be entitled to all of the rights and benefits afforded to GENTIUM under this Agreement and may independently enforce such rights and benefits; provided, however, such GENTIUM Affiliate shall be solely liable to CRO for any obligations or liabilities undertaken as a result of a properly executed Study Work Order. Where the context requires, any references to "GENTIUM" in this Agreement shall be deemed to include an "GENTIUM Affiliate" with respect to any Study Work Order validly executed by any such GENTIUM Affiliate. For purposes of this Agreement an GENTIUM Affiliate means any entity that, now or in the future, directly or indirectly, controls, is controlled by, or is under common control with GENTIUM S.p.A (or any successor entity or permitted assignee of GENTIUM S.p.A.. For purposes of this Section 1.4.1, "control", whether used as a noun or a verb, means the possession, directly or indirectly, of the power to affirmatively direct, or affirmatively cause the direction of, the management and policies of an entity, whether through the ownership of voting securities, by contract, or otherwise.

Confidential treatment has been requested for portions of this exhibit. The copy filed herewith omits the information subject to the confidentiality request. Omissions are designated as ***. A complete version of this exhibit has been filed with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Act of 1934, as amended.

1.4.2 CRO Affiliates. GENTIUM agrees that CRO may use their affiliate(s) to provide the Services under this Agreement (each a "CRO Affiliate"), subject to GENTIUM's prior approval. CRO Affiliate(s) so used shall be subject to all of the terms and conditions applicable to this Agreement. Where the context requires, any references to "CRO" in this Agreement or in any Study Work Order shall be deemed to include any CRO Affiliate identified hereunder or with respect to such Study Work Orders. For purposes of this Agreement, a CRO Affiliate shall mean any entity that, now or in the future, directly or indirectly is controlled by, or is under common control under CRO's parent company US Oncology, Inc.. For purposes of this Section 1.4.2, "control", whether used as a noun or a verb, means the possession, directly or indirectly, of the power to affirmatively direct, or affirmatively cause the direction of, the management and policies of an entity, whether through the ownership of voting securities, by contract, or otherwise.

1.5 Non-Exclusive Arrangement. The Services contemplated under this Agreement shall be provided on a non-exclusive basis and GENTIUM reserves the right to undertake all work on its own behalf or to obtain similar services from any third party. Neither GENTIUM nor any GENTIUM Affiliate is obligated to purchase any minimum or specific volume or dollar amount of Services hereunder.

1.6 Pre-Existing Arrangements. GENTIUM and CRO hereby agree that any clinical study services which GENTIUM has contracted with CRO to perform prior to the Effective Date of this Agreement and which services are being provided to GENTIUM on an ongoing basis at the Effective Date of this Agreement, shall be independent of and the terms and conditions of this Agreement.

1.7 Other Services. GENTIUM acknowledges that certain individual employees or groups of employees of CRO possess significant business experience and technical expertise in many general areas of clinical drug development. In the event GENTIUM desires to retain the services of any such individuals or groups of individuals employed by CRO on a consultantship basis it is hereby agreed that such consulting services shall be undertaken under the terms and conditions of a separate Study Work Order between GENTIUM and CRO.

1.8 Supplemental Staffing. In some cases, GENTIUM will have requests for supplemental staffing for a Study. CRO agrees to use its best efforts to provide supplemental staffing to GENTIUM on an as needed basis. Such staff shall be utilized by GENTIUM as agreed upon in writing, documenting the services to be provided at mutually agreed rates.

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SECTION 2
SUB-CONTRACTORS, CONSULTANTS AND AGENTS

2.1 Use of Sub-Contractors, Consultants and Agents. Subject to Section 2, CRO shall perform all of the Services and discharge all its obligations under this Agreement or any Study Work Order through its own employees. CRO shall not subcontract any such Service or obligation through sub-contractors, consultants, agents or any third party without first obtaining the prior written approval of GENTIUM. CRO shall enter into a separate contract with the approved sub-contractors, consultants, agents or any third party containing terms consistent with this Agreement and any applicable Study Work Order. CRO shall ensure that any such contract shall contain the specific, detailed Services to be performed by any sub-contractor, consultant, agent or third party. CRO shall add GENTIUM as a third party beneficiary to such contract to allow GENTIUM to exercise and enforce similar rights as the CRO may have under its contract with sub-contractors, consultants, agents or any third party, including without limitation the right to audit and inspect the sub-contractors, consultants, agents or any third party's financial affairs, facilities, processes and procedures. Such provisions shall also specifically include an assignment to CRO of rights to any Property (as defined hereafter) arising from the performance by such sub-contractor, consultant, agent or any third party of any obligations subcontracted thereto pursuant to this paragraph. CRO understands and agrees that all such Property described in the immediately preceding sentence shall be assigned to GENTIUM as contemplated hereunder and as necessary CRO shall apprise each sub-contractor, consultant, agent or any third party of such fact. CRO represents and covenants that it shall use best efforts to ensure that any sub-contractor, consultant, agent or third party has the capability to perform the Services to GENTIUM's standards under this Agreement and in compliance with applicable laws and regulations. Investigators shall not be considered a sub-contractor, consultant or agent for purposes of this Section.

2.2 Performance and Liability. In the event that GENTIUM approves of the use of a sub-contractor, consultant, agent or third party to perform any Service or discharge any obligation of CRO under this Agreement or a Study Work Order, CRO shall (i) remain primarily responsible to GENTIUM for the performance of such Service or obligations; and (ii) accept all liability arising from the acts and omissions of any such sub-contractor, consultant, agent or third party.

2.3 Indemnification of GENTIUM. Consistent with CRO's indemnification obligations under Section 16, CRO agrees to indemnify, defend and hold GENTIUM harmless for any and all losses, claims, judgment, suits and liability against GENTIUM (including reasonable attorney's fees) arising out of the acts and omissions of any contractor, consultant, agent or third party engaged by CRO or by a sub-contractor to perform any Service or discharge any obligation of CRO under this Agreement or any Study Work Order including CRO's failure or delay in paying such sub-contractors, consultants or third party.

SECTION 3
BUDGET

3.1 Budget. With respect to each Study Work Order, in consideration of CRO and each Investigator's participation in a Study, GENTIUM shall pay to CRO such amounts as set forth and more fully described in the budget set forth in the Scope of Services ("Budget"). CRO agrees that it shall not incur any cost or expense in excess of the amounts set forth in the Budget for any item, without the prior written approval of GENTIUM. CRO shall use its best efforts to control and limit the costs and expenses associated with this Agreement and any Study Work Order and to obtain and pass along to GENTIUM all available discounts rebates and allowances.

3.2 Payments to Investigators. Where provided in the relevant Study Work Order, CRO shall be responsible for negotiating clinical grants with each participating Study Site ("Investigator Fees") in accordance with the Budget. GENTIUM agrees to reimburse CRO on a cost pass-through basis for Investigator Fees paid by

CRO. GENTIUM shall provide CRO with adequate funds for Investigator Fee payments and Project Management Charges (as that term is defined below) in accordance with the Payment Schedule (as that term is defined below) described in Section 4.1. If requested in the applicable Study Work Order, CRO will pay Investigator Fees and amounts due to any third party vendors contracted by the CRO as detailed in the Scope of Services and as approved by GENTIUM pursuant to Section 1.4.2.

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3.3 Indemnification of GENTIUM. CRO shall indemnify, defend and hold GENTIUM harmless for all third party claims, suits, liabilities, damages and expenses (including attorneys' fees and litigation costs) arising out of CRO's failure or delay in making any such payments; provided, however, that CRO shall have no obligation to indemnify GENTIUM under this Section 3.3 to the extent GENTIUM has failed to provide adequate funding as set forth in the Budget under Section 3.1 and the Payment Schedule under Section 4.

SECTION 4
PAYMENT SCHEDULE

4.1 General.

4.1.1 Amounts Due. With respect to each Study, GENTIUM shall pay CRO amounts due under the applicable Study Work Order as provided in this Section 4 and in accordance with the Budget and payment schedule attached thereto ("Payment Schedule").

4.1.2 Invoices. All payments shall be made against invoices issued by CRO to GENTIUM. All charges must be in compliance with the stated terms and conditions of this Agreement. In order to facilitate payment, the invoices will describe all services performed for which payment is sought, including a description of the scope and nature of services performed, billing period (time period of charges) and CRO's tax identification number ***, and shall be accompanied by appropriate supporting documentation. CRO's invoices will also include a statement of amounts paid to date by GENTIUM in connection with the Study, the manner in which such amounts have been applied and credited, as well as fees and expenses claimed to have been incurred by CRO. When applicable, with each invoice, CRO shall certify that charges submitted for each properly enrolled Study subject reflect visits and procedures actually completed pursuant to the Protocol. CRO shall submit a final invoice to GENTIUM for each applicable Study after GENTIUM's receipt and approval of all Study data and documents required or contemplated by Sections Section 8 and Section 9 of this Agreement.

4.1.3 Payment Terms. Unless expressly provided for otherwise in the Payment Schedule, and except as provided for otherwise in this Section 4.1.3, all invoices properly submitted in accordance with this Agreement by CRO shall be due and payable within thirty (30) days of GENTIUM's receipt. If any portion of an invoice is disputed, then GENTIUM shall pay the undisputed amounts as set forth in the preceding sentence and the Parties shall use good faith efforts to reconcile the disputed amount as soon as possible.

4.1.4 Submission of Invoices. Except as otherwise specified in this Agreement or as otherwise instructed in writing by GENTIUM, CRO will send all invoices to GENTIUM at the address provided for notices in Section 6.3.2, to the attention of Salvatore Calabrese, with a copy to other GENTIUM employees specified on the applicable Study Work Order.

4.1.5 Form of Payment. Except as otherwise specified in the applicable Study Work Order, GENTIUM shall effectuate all payments due hereunder in U.S. Dollars by wire transfer payable to the order of CRO, sent to the address provided for in Section 6.3.1.

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4.2 Reimbursement of Expenses. In order to facilitate payment of invoices for CRO's expenses, CRO will submit to GENTIUM a report containing at least the following details: (i) photocopies of expense reports and receipts for Study-related travel expenses, including lodging, air travel (coach class only), ground transportation, meals and other miscellaneous expenses, such as overnight courier charges and photocopying, (ii) task reference, (iii) date, travel destination and itinerary, (iv) employee name and title, and (v) purpose of trip/expense. All discounts, rebates and allowances obtained under Section 3.1 will be properly reflected in invoices to GENTIUM.

SECTION 5
COMPLIANCE WITH APPLICABLE LAWS AND REGULATIONS

5.1 Applicable Provisions. At all times during the Term of this Agreement or during the term of a Study Work Order, the Parties shall comply with all relevant federal and local laws statutes and regulations of any country or territory where the Study is being conducted and/or where the Study Site is located ("Applicable Laws").

5.1.1 Applicable Laws in the United States. Applicable Laws in the United States shall include all applicable federal, state and local laws, statutes and regulations, including but not limited to the following federal statutes and sections of the United States Code of Federal Regulations ("CFR") and associated applicable regulatory guidance:

5.1.1.1 The Federal Food, Drug & Cosmetic Act ("FDCA");

5.1.1.2 Part 312—Investigational New Drug Application;

5.1.1.3 Part 50—Informed Consent;

5.1.1.4 Part 54 - Financial Disclosure by Clinical Investigators;

5.1.1.5 Part 56—Institutional Review Board;

5.1.1.6 Health Information Portability and Accountability Act of 1996 ("HIPAA");

5.1.1.7 42 U.S.C. §§ 1320a-7, 7a, and 7b, which are commonly referred to as the "Federal Fraud Statutes;"

5.1.1.8 31 U.S.C. §§ 3729-3733, which is commonly referred to as the "Federal False Claims Act

5.1.1.9 the International Conference for Harmonization's Harmonised Tripartite Guidelines for Good Clinical Practice, including all good clinical practice requirements as are specified in Directive 2001/20/EC of the European Parliament and the Council of 4 April 2001 relating to medicinal products for human use and in guidance published by the European Commission pursuant to such Directive;

5.1.1.10 the World Medical Association Declaration of Helsinki entitled 'Ethical Principles for Medical Research Involving Human Subjects' (1996 version); and

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5.1.1.11 the NHS Research Governance Framework for Health and Social Care (version 2, April 2005).

5.2 Definition of Regulatory Authority. As used in this the Agreement the term ”Regulatory Authority” shall include the U.S. Food and Drug Administration (“FDA”), the European Medicines Agency (“EMA”) and any competent local authority regulating the medical profession or the conduct of clinical trials in a country or territory where a Study is being conducted and/or where the Study Site is located.

5.3 Allocation of Responsibility. With respect to a Study, responsibility for filing and maintaining compliance with certain provisions of 21 CFR. Part 312 may be transferred to CRO as agreed between the Parties and documented in this Agreement or in a Study Work Order, and CRO shall be responsible for compliance with such allocated provisions for such Study. To the extent responsibility for compliance with provisions of such Part 312 is not transferred to CRO for a Study under the terms of this Agreement and the applicable Study Work Order, GENTIUM shall remain responsible for compliance with such provisions of Part 312. Each Party shall provide such reasonable cooperation as the other may request in connection with the other Party’s compliance with the applicable provisions of Part 312.

5.4 Compliance with Anti-Corruption Acts.

5.4.1 General. CRO is aware of and understands the U.S. Foreign Corrupt Practices Act ("FCPA"), the U.S. Export Administration Act ("EAA"), the U.S. Anti-Boycott regulations (“Anti-Boycott Regulations”) and the ADB/OECD Anti-Corruption Initiative for Asia-Pacific (“OECD Anti-Corruption Initiative”) and agrees to refrain from any activity in connection with this Agreement that would constitute a violation by CRO of the Anti-Corruption Statutes (as defined below). For purposes of this Agreement, the FCPA, EAA, Anti-Boycott Regulations and OECD Anti-Corruption Initiative shall collectively be referred to as “Anti-Corruption Statutes”)

5.4.2 Compliance with Anti- Corruption Statutes.

5.4.2.1 At all times during the Term of this Agreement or a Study Work Order, CRO and its employees, CRO Affiliates, agents, sub-contractors or representatives (together, “CRO Representatives”) shall not offer, promise or give, directly or indirectly, anything of value to any government official, political party official, political candidate, or any relative, business associate or employee thereof, or to any other third party while knowing that such item of value or portion thereof may be offered, promised or given to a government official, political party official, political candidate or employee thereof for the purpose of obtaining or retaining business. In particular, CRO agrees that no part of the payments for fees under Section 4 of this Agreement shall be paid to or shared with, directly or indirectly, any government or political party official for the purpose of obtaining or retaining any business under this Agreement;

5.4.2.2 CRO represents that neither CRO nor any CRO Representative is an employer, officer, or agent of a foreign government or a candidate for a foreign public office, and CRO undertakes to inform GENTIUM immediately if any CRO Representative becomes a foreign government official during the term of this Agreement;

5.4.2.3 CRO represents that CRO has read and understands all applicable Anti-Corruption Statutes, and at all times during this Agreement shall keep apprised of any amendments, changes or other modifications to such Anti-Corruption Statutes and that all CRO Representatives have been appropriately trained on and made aware of their responsibilities and obligations under all applicable Anti-Corruption Statutes.

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SECTION 6
CONTACT PERSONS AND NOTICES

6.1 Contact Persons.

6.1.1 CRO Contact Persons. For each Study, during the term of an applicable Study Work Order, the CRO shall provide the services of a Study project manager ("Project Manager") and Study support staff (collectively, the "Project Team"; each individually a "Project Team Member"), as described in Section 7.1. No change in the Project Manager or in Project Team Members shall be effected by CRO without the prior written consent of GENTIUM; provided, however, that in the event of death, disability, illness, termination or resignation of a Project Manager or Project Team Member, CRO shall have the right to replace such personnel upon notice to GENTIUM and GENTIUM's prior approval of replacement Project Team members. Upon notice to GENTIUM, CRO shall have the right to immediately replace a Project Manager or Project Team Member in the event that: (1) a Project Manager or Project Team Member breaches any provision of this Agreement; or (2) a Project Manager or Project Team Member is not performing his/her duties according to a Protocol or Study Work Order hereunder.

6.1.2 GENTIUM Contact Persons. For each Study, during the term of an applicable Study Work Order, GENTIUM shall designate a contact person to receive all information required under this Agreement and the Study Work Order.

6.2 Serious Adverse Events In the event of any "Serious Adverse Drug Experience" as such term is defined in 21 CFR 312.32, CRO shall comply with the reporting procedure provided for in the Protocol and herein and, if so provided in a Study Work Order, shall be responsible on behalf of GENTIUM for collecting and submitting to GENTIUM's contact for receiving reports of adverse drug events and drug experiences as specified in the Protocol, and all relevant adverse event information, including causality assessments by reporting Investigators. CRO shall use its reasonable efforts to ensure compliance by the Investigators (as that term is defined below) with such reporting procedure. Unless GENTIUM notifies CRO otherwise and, except as provided otherwise under Section 11.4, serious adverse drug experience reports shall be, in all cases, forwarded within one business day from study sites to CRO's Drug Safety Department in accordance with the Protocol and subsequently sent to GENTIUM within one business day.

6.3 Notices. Except as otherwise provided, all communications and notices required under this Agreement shall be in writing and shall be either delivered personally (as evidenced by a signed receipt), mailed by first class certified mail, postage prepaid to the addresses set forth below.

6.3.1 If to CRO:

Attn: Vice President and General Manager
US Oncology Clinical Development, LLC
10101 Woodloch Forest

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The Woodlands, Texas 77380

With a copy to

Attn: Contracts Manager/Paralegal
US Oncology Research, LLC
10101 Woodloch Forest
The Woodlands, Texas 77380

6.3.2 If to GENTIUM:

Gentium S.p.A.

Attn: Timothy Hillman
Business Development and Strategic Planning
45 Rockefeller Plaza, Suite 2000
New York, NY 10111

With a copy to

Attn: Massimo Iacobelli
Scientific Director
Piazza XX Settembre, 222079
Villa Guardia (Co) Italy

The above addresses are subject to change from time to time by notice in accordance herewith.

SECTION 7
PROJECT MANAGEMENT, MANUAL AND FORMS

7.1 Project Management. For each Study, a Project Manager and senior and key Project Team Members shall be identified on the applicable Study Work Order and attached thereto. GENTIUM reserves the right to pre-approve such Project Manager and Project Team Members. CRO represents that all Project Team Members are true employees of CRO. It is understood that the goal is to maintain CRO staff who are trained and experienced on GENTIUM processes, systems, templates, etc. assigned to GENTIUM Studies. GENTIUM will not be charged for time or efficiencies lost due to personnel changes at CRO.

7.1.1 Project Manager Responsibilities. The Project Manager will supervise and manage the conduct of each Study by the Project Team and is the primary CRO contact for GENTIUM with respect to the conduct and operational aspects of each Study.

7.1.2 Project Team Responsibilities. The responsibilities of the Project Team shall include: administrative assistance, pharmacy distribution and billing, accounting, collections, data management and any other related service described in the Study Plan and this Agreement. The Project Team will also be responsible for assisting GENTIUM in managing the Study to meet the requirements of all Applicable Laws.

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7.1.3 CRO Management Responsibilities. CRO will ensure that CRO, the Project Manager and Project Team comply with the applicable Protocol and all Applicable Laws related to the Study, including but not limited to all local laws and regulations governing the protection of human subjects and the conduct of clinical research by monitors and clinical investigators. CRO shall immediately report to GENTIUM any violations of Applicable Laws or any deviations or omissions from the Protocol by a Study Site. CRO shall investigate any such violations, deviations and omissions and interface with the applicable IRB (defined below). CRO will certify that Study records are authentic, complete and accurate. CRO will ensure that all Project Team Members are also trained on relevant requirements applicable to the conduct of clinical research under Applicable Laws.

7.1.4 CRO Performance Standards.

7.1.4.1 CRO shall have full responsibility for compliance with Applicable Laws and all local laws and regulations affecting any duties and obligations specifically delegated to CRO in this Agreement or under any Study Work Order.

7.1.4.2 CRO will make its best efforts to follow GENTIUM's travel policy for all travel arrangements associated with a Study (e.g., monitoring visits, Investigator meeting attendance). Every effort will be made to make travel arrangements at least two weeks in advance of travel. The costs of Study travel will be passed through by CRO to GENTIUM so that all travel undertaken on a specific Study can be reconciled.

7.1.4.3 CRO agrees to complete the Services according to the timelines specified in the applicable Study Work Order. If at any time CRO anticipates a delay in meeting any timelines or target completion dates, CRO shall promptly notify GENTIUM of such delay.

7.1.4.4 CRO shall implement appropriate quality controls in order to monitor CRO and Study Site compliance with the Protocol and any applicable Study Work Order, including but not limited to CRO's standard operating procedures. CRO shall train and monitor those personnel associated with the Study Work Orders to ensure compliance with such standard operating procedures.

7.2 Manual. As applicable under a Study Work Order, GENTIUM will provide a copy of an investigator's brochure or other reference manual and/or product package insert for the Investigational Product ("Manual") for distribution to each Investigator and each IRB or EC. CRO shall be responsible for giving each Investigator a copy of the Manual and case report form completion guidelines before the Study begins and for giving each Investigator a copy of any updates to the Manual provided by GENTIUM to CRO. CRO may not duplicate or reproduce the Manual, in whole or in part, for any purpose unless first authorized in writing by GENTIUM.

7.3 Informed Consents.

7.3.1 Informed Consent Forms. As applicable under a Study Work Order, for each Study, GENTIUM shall provide a separate standard form of informed consent (each an "Informed Consent" or collectively, the "Informed Consents") for Study Subjects to sign prior to their participation in a Study. All such Informed Consents shall comply with the requirements of each Protocol and all Applicable Laws including but not limited to 21 CFR Part 50. The approved form of Informed Consents shall include language intended to serve as appropriate authorization for the disclosure Study subject protected health information to CRO and GENTIUM.

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7.3.2 CRO Responsibilities Regarding Informed Consent Forms.

As applicable under a Study Work Order, with respect to Informed Consents, CRO shall:

7.3.2.1 advise each Investigator and each Study Site and their respective IRBs of GENTIUM's Informed Consent form that contains the appropriate language regarding the protection of personal data, information relative to the Investigational Product and proper Study procedures under the Protocol;

7.3.2.2 prior to the commencement of a Study, remind each Investigator and Study Site of their respective obligations;

7.3.2.3 ensure that all consents, approvals and permissions from Study subjects as required under Applicable Laws governing the confidentiality and privacy of individually-identifiable health information are obtained prior to their participation in the Study;

7.3.2.4 ensure that necessary authorizations are in place allowing GENTIUM to have access to and the ability to disclose Study information and data as GENTIUM deems necessary for a Study and as contemplated under this Agreement and each Investigator Agreement;

7.3.2.5 advise all Investigators and Study Sites, that any Study subject who withdraws his or her authorization shall be promptly discontinued from participation in the Study; and

7.3.2.6 provide GENTIUM with copies of all Informed Consents from the Study Sites for approval prior to being put into effect.

7.3.3 Modification of Informed Consents. The Informed Consents and any modifications thereto shall be subject to the prior approval of GENTIUM and the IRB prior to any use thereof. CRO will confirm that IRB approval of any GENTIUM-approved modified Informed Consent is obtained at each Study Site prior to any use thereof. If an Informed Consent is modified prior to signature by the Study subject, it shall nonetheless contain the provision dealing with compensation for research related injuries in unaltered form and shall comply with all Applicable Laws.

7.3.4 Transfer of Responsibilities. For each Study, GENTIUM and CRO shall determine which Party shall be responsible for obtaining Informed Consent from each Study subject as required under Section 7.3 and Applicable Law. Any transfer of responsibility for obtaining Informed Consent as required under Applicable Laws shall be set forth in each Study Work Order.

7.4 Case Report Forms. As applicable under a Study Work Order, GENTIUM shall design the Case Report Forms ("CRFs") for the Study. GENTIUM shall provide adequate quantities of CRFs to CRO for distribution to Study Sites as required by each Protocol. CRO shall review and provide comments on the CRFs prepared by GENTIUM to confirm that the CRFs include all data elements required by each Protocol. CRO's comments shall be provided promptly to GENTIUM in a single written communication. Any revisions to the CRFs shall be subject to GENTIUM's prior written approval.

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7.5 Investigators' Meetings. As applicable under a Study Work Order, CRO shall ensure a reasonable number of its personnel, as determined by GENTIUM, attend any scheduled Investigators meeting and prepare in conjunction with GENTIUM, meeting presentations on relevant Study topics, meeting materials, training materials and Study Site trainers. If requested by GENTIUM, CRO shall coordinate all activities associated with any Investigators' meeting, including selection of an appropriate meeting site, scheduling Study Site personnel travel, making hotel arrangements, preparing in conjunction with GENTIUM meeting presentations on relevant Study topics and managing all meeting events.

7.6 Study Subject Privacy. CRO shall treat all individually-identifiable health information as confidential in accordance with all Applicable Laws, including the Health Information Portability and Accountability Act of 1996, as amended from time to time, and any regulation and official guidelines (as amended from time to time) promulgated under that Act ("HIPAA") and the Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data and any local jurisdiction data protection legislation enacting Directive 95/46/EC as appropriate. CRO shall comply with the information protection requirements set forth in Attachment 7 in a Study Work Order; to the extent such terms are applicable to the services performed by CRO.

SECTION 8
IDENTIFICATION, SELECTION AND RETENTION OF STUDY SITES AND CLINICAL INVESTIGATORS

8.1 Study Sites. As applicable under a Study Work Order, for each Study, CRO shall make investigational site (each investigational site, a "Study Site") initiation visits and subsequent (i.e. periodic) monitoring and close out visits to each Study Site ("Study Site Visits") as described in each Scope of Services to ensure that the Study Sites are in compliance with this Agreement, the relevant Investigator Agreement, the Protocol and all Applicable Laws. Enrollment of Study Sites and Study subjects shall be as directed by the Scope of Services. GENTIUM shall have the right at any time to increase or decrease the number of investigators and Study subjects to be involved in a Study, including by modifying or amending the Protocol and/or the Scope of Services and providing CRO with copies of such modified or amended document(s), subject to the provisions of Section 10. If GENTIUM decides to increase or decrease the number of Study Sites and/or study Subjects, CRO shall adjust the Budget and Payment Schedule in accordance with Section 3 and Section 4, subject to prior written approval of GENTIUM.

8.2 Initial Study Site Contact. Either CRO or GENTIUM shall make initial contact with potential investigators identified by GENTIUM (or by CRO, with GENTIUM's approval). If both GENTIUM and a potential investigator are interested in continuing discussions after the initial contact, GENTIUM will conduct, or designate CRO to conduct, a Study Site evaluation and CRO shall complete a study site evaluation report in the form attached as Attachment 3 to an applicable Study Work Order ("Study Site Evaluation Report") specifying the name, address, telephone number and other information relating to the potential investigator. Upon GENTIUM's receipt and approval of the Study Site Evaluation Report for each Study Site, CRO will then endeavor to qualify the potential investigator and to obtain for delivery to GENTIUM, as GENTIUM shall require, the necessary documents, as provided for in Sections 8.3, 8.4, and 8.6 of this Agreement. If CRO as incurred past negative experiences with any GENTIUM named Investigator, CRO will bring this to the attention of GENTIUM for final disposition.

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8.3 Qualification of Investigators. As applicable under a Study Work Order, CRO is responsible for the recruitment of all Study Sites for the conduct of each Study. CRO will do all things necessary under Applicable Laws to qualify each potential investigator on a Study, including:

8.3.1 satisfying the requirements set forth in 21 CFR 312.53 for obtaining sufficient accurate financial disclosure information required pursuant to 21 CFR Part 54;

8.3.2 obtaining completed FDA Forms 1572 for all relevant individuals at the Study Site and obtaining IRB approval of the potential investigator, Study Site and the Protocol by an appropriate IRB in accordance with the regulations established by the FDA in 21 CFR Part 56; and

8.3.3 ensuring that each potential investigator has not been (i) debarred or voluntarily excluded or convicted of a crime for which a person can be debarred under § 335a (defined below), nor (ii) threatened to be debarred or voluntarily excluded or indicted for a crime or otherwise engaged in conduct for which a person can be debarred under § 335a (collectively, (i) and (ii) above, ("Debarred"), or subject to any governmental sanction that would prevent the rendering of services hereunder in any jurisdiction in which the Study is to be conducted, nor (iii) excluded from participation in any federally-funded health-care program ("Excluded").

8.3.4 GENTIUM shall have final approval as to whether a particular Study Site or potential investigator are enrolled in the Study. All potential investigators on a Study who become qualified as herein described are referred to herein as "Investigators".

8.4 Delivery of Documents. From time to time or at the request of GENTIUM, CRO will provide GENTIUM with an up-to-date list of Study Sites that have agreed to participate in a Study, including the names and addresses of the Investigators. For each Investigator (and sub-investigators), CRO will provide GENTIUM with all documentation (originals where appropriate) required under Applicable Laws, including under 21 CFR 312.53(c) including: a completed and signed FDA Form 1572, a Curriculum Vitae, State Medical License Numbers, and a signed Protocol. With respect to each Study, CRO shall provide GENTIUM with all written approvals of the applicable Protocol and Informed Consent from the IRB, IRB roster, DHHS number for each Study Site, Informed Consent forms, financial disclosure information (including any changes and post-Study updates) to the extent received by CRO, the name and address of each clinical laboratory approved by GENTIUM (if any) and a copy of the laboratory license containing the accreditation/certification number for each such clinical laboratory and the laboratory reference ranges, and all other documents required by GENTIUM to obtain approval of the Study by the Regulatory Authority with jurisdiction over the Study. An Investigator's signature on the Protocol signifies the Investigator's understanding of, and agreement to comply with, the terms of the Protocol.

8.5 Transfer of Responsibilities. For each Study, GENTIUM and CRO shall determine which Party shall be responsible for obtaining information from each Investigator as described above in Section 8.4 and required under Applicable Laws (including 21 CFR 312.53(c)). Any transfer of responsibility for obtaining the information described in Section 8.4 shall be set forth in each Study Work Order.

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8.6 Agreements with Investigators; Negotiation Plan.

8.6.1 Investigator Agreements. As applicable under a Study Work Order, each Study Site and Investigator proposed by CRO for participation in a Study must be approved by GENTIUM in writing prior to initiation of any on-site Study-related activities involving that Study Site or Investigator. Following receipt of such approval by GENTIUM, CRO will enter into a clinical trial agreement with each such Study Site and Investigator in a form mutually approved by GENTIUM and CRO ("Investigator Agreement"). CRO shall submit the signed Investigator Agreement to GENTIUM prior to the shipment of any Investigational Product to the Investigator; provided, however, that if GENTIUM has an effective agreement in place with the Investigator or Study Site, GENTIUM and CRO will determine whether such existing agreement will be used. Any Investigator, or any permitted sub-Investigator, that prior to the commencement of a Study, fails to (i) sign an Investigator Agreement, (ii) provide adequate financial disclosure to GENTIUM as required under Applicable Laws or (iii) provide written certification that they are not Debarred nor Excluded may not be permitted by CRO to participate in the Study.

8.7 Notification of Audit. CRO shall cause and require each Investigator to inform GENTIUM within one business day of being notified of an audit by any Regulatory Authority with proper jurisdiction over the Study, whether or not advance notice is given by the Regulatory Authority. GENTIUM or its representatives, or at GENTIUM's option, CRO or a CRO Representative, shall be permitted to be present and directly communicate with such Regulatory Authority representatives concerning any matters arising in connection with any audit of any Investigator or the CRO. GENTIUM shall have the right to delegate to CRO its rights to be present during Regulatory Authority visits as described in the preceding sentence.

8.8 Delivery of Documents to CRO. GENTIUM will promptly send to CRO copies of all correspondence between GENTIUM and Investigators pertaining to the Study that GENTIUM determines are necessary in order for CRO to perform effectively the services to be performed by it hereunder.

8.9 GENTIUM Visits to Sites. GENTIUM will inform CRO in writing of the results of any visits by GENTIUM and/or its representatives to Study Sites that result in corrective actions being suggested or recommended by GENTIUM. GENTIUM personnel or designees may visit Study Sites to inspect facilities where the Study is conducted and Study documents, records and materials (including Investigational Product storage areas). All Investigator Agreements will so provide.

SECTION 9
MONITORS, MONITORING SITE VISITS, AND DATA DELIVERY

9.1 Transfer of Responsibilities. For each Study, GENTIUM and CRO shall determine which Party shall be responsible for monitoring the progress of a Study as required under Applicable Laws, including compliance with 21 CFR. 312.53(d) and 312.56(a) and (b). Any transfer of responsibility for Study monitoring shall be set forth in each Study Work Order. In the event that Study monitoring is transferred to CRO, CRO shall designate sufficient, trained qualified monitors ("Monitors") to monitor the progress and conduct of each Study, each of whom shall meet all qualification requirements established under Applicable Laws and as set forth in this Agreement. GENTIUM shall have the option to review all Monitors' qualifications and approve them prior to CRO designating them to a Study.

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9.2 Monitoring Visits. CRO Monitors will monitor the progress of the Study, and will closely monitor the Investigators and Study Sites enrolled for compliance with all requirements of the Protocol, GENTIUM, CRO (including pursuant to any Investigator Agreement) any applicable Regulatory Authority and all Applicable Laws. In each Monitor's report, CRO shall supply its certification that to the best of its knowledge (i) each Study subject has met the entry criteria set forth in the Protocol; and (ii) each Investigator in the Study has complied with the Protocol, the relevant Investigator Agreement and all Applicable Laws. CRO shall immediately report to GENTIUM any instance in which subjects do not meet applicable entry criteria and the facts and circumstances related any such ineligibility.

9.3 Monitoring Reports. For each Study CRO shall submit to GENTIUM on a monthly basis or as otherwise agreed between the parties, comprehensive written reports in an agreed upon format regarding Study Site Visits and receipt by CRO of completed CRFs with copies of Monitoring Report Forms.

9.4 GENTIUM Visits. GENTIUM, in its sole discretion, may join the Monitors or conduct separate visits to Study Sites and may also conduct independent document audits at such Study Sites.

9.5 Completed CRFs. A completed CRF shall be delivered by CRO to GENTIUM for each Study subject enrolled in a Study, whether or not such Study subject completes his or her participation in the Study or is discontinued before completion. CRO shall subject each CRF to a primary and secondary quality control review process. The original CRFs for a Study shall be delivered to GENTIUM upon completion of the entire Study, or upon earlier discontinuation or termination of the Study for any reason or as specified in the applicable Study Work Order. Any questions or comments concerning any CRF shall be directed to GENTIUM or to the CRO Project Manager who shall provide prompt written clarification and confirmation to GENTIUM. If applicable, CRO will coordinate and cooperate with GENTIUM or its designee with respect to any data management issues regarding Study data.

9.6 Clinical Trial Reports. If contemplated under the applicable Study Work Order, CRO shall prepare and submit to GENTIUM for review and approval, draft and final clinical trial reports for the Study which shall include a discussion of all aspects of the Study and any additional matters reasonably requested by GENTIUM. All final reports will be audited and will include appendices and such other elements as GENTIUM may require.

SECTION 10
INSTITUTIONAL REVIEW BOARD

10.1 Constitution. As applicable under a Study Work Order, CRO will ensure that each Study Site engages an independent, properly constituted Institutional Review Board ("IRB") or Ethics Committee ("EC") which is in compliance with all Applicable Laws including 21 CFR Part 56 for the purpose of reviewing and approving the Protocol and Informed Consents as required by 21 CFR 312.66. The IRB shall be subject to all requirements under Applicable Laws regarding its conduct and constitution in a timely manner. CRO will ensure that all necessary IRB approvals are obtained, documented, and delivered in a timely manner to GENTIUM.

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10.2 Protocol and Informed Consent. If after using its reasonable efforts to obtain approval, the IRB does not approve the Protocol or the Informed Consents for a Study, or any amendment thereof as described in Section 10.3, CRO shall bear no liability for any loss or damage that may be incurred by GENTIUM, provided that no Study Site with respect to which a validly constituted IRB has withheld such approval shall be utilized for such Study and provided that such loss or damage does not result from CRO's negligence, misconduct, or breach of this Agreement or Applicable Law.

10.3 Amendment of Protocol and Informed Consents. GENTIUM shall have the right to amend the Protocol and Informed Consents for a Study at any time. If GENTIUM amends the Protocol or the Informed Consents after the initial IRB approval has been granted, CRO shall ensure that the amended Protocol or amended Informed Consent is submitted to and approved by the applicable IRB(s) prior to implementation by the Investigators. CRO acknowledges that prior IRB approval is required for the following changes:

(a) Change in principal investigator (except as set forth in clause (y) below);
(b) Change in and/or addition of Study Site;
(c) Change in the Protocol; and
(d) Change in Informed Consent after initial IRB approval.

CRO further acknowledges and agrees that written notification to the IRB, with a copy of such notice sent to GENTIUM within ten (10) business days, is required for the following changes:

(x) Change in and/or addition of clinical laboratory (subject to GENTIUM's prior written approval); and
(y) Replacement of a principal investigator by a previously IRB-approved sub-investigator for that Study Site.

A new Form FDA 1572 is required for each of the above changes.

SECTION 11
PERIODIC PROJECT STATUS REPORTS

11.1 Investigator Status. For each Study, CRO's Project Managers shall submit to GENTIUM weekly or monthly written reports regarding the status of Investigators in hard copy and electronic form.

11.2 Study Subject Enrollment. For each Study, CRO's Project Manager shall submit to GENTIUM in hard copy and electronic form, weekly written reports regarding the status of Study subject enrollment, enrollment statistics and projections, and overall Study progress in an agreed upon format. The specific data elements to be included in such weekly reports are described in Attachment 10 to the applicable Study Work Order.

11.3 Monitoring Reports. For each Study, CRO shall submit to GENTIUM on a monthly basis, comprehensive written reports in an agreed upon format regarding Study Site Visits and receipt by CRO of completed CRFs with copies of Monitoring Report Forms.

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11.4 Adverse Experiences. As applicable under a Study Work Order, for each Study, CRO will provide to GENTIUM cumulative quarterly and annual serious adverse drug experience reports in an agreed upon format. In addition, all adverse events will be provided for investigational new drug application ("IND") progress reports on a predesignated date in an agreed upon format. As provided for in a Protocol, all serious adverse experiences shall be reported by CRO to GENTIUM pursuant to Section 6.2 on a "Serious Adverse Drug Event Report" form approved by GENTIUM via telefax or overnight courier within one (1) business day of its occurrence. Adverse events that are fatal or life-threatening must be reported immediately to GENTIUM's Drug Safety Department by telefax or telephone.

11.5 Response to Inquiries. CRO will respond promptly to oral and written inquiries by GENTIUM concerning the conduct or progress of a Study.

SECTION 12
INVESTIGATIONAL PRODUCT SUPPLIES AND REGULATIONS

12.1 Terms pertaining to Supply of Investigational Product, Investigational Product Disposal, and Investigational Product Documentation shall be addressed in each Study Work Order.

12.2 Investigational Product Quality. GENTIUM is responsible for the quality and composition of any Investigational Product and other test articles delivered to CRO for distribution to Investigators and Study Sites, including but not limited to the labeling, packaging and shipping of such material used in the course of a Study to the Study Sites, except to the extent otherwise specified in a Study Work Order.

SECTION 13
RECORD RETENTION AND AUDITS

13.1 Record Retention.

13.1.1 Record Retention Requirements for Study Period. With respect to each Study, CRO will retain all Study records and documents for a period of at least five (5) years following the last to occur of the following dates: (a) the date on which a marketing application for the indication studied hereunder for a Investigational Product is approved by the Regulatory Authority, if approved; (b) the date of completion of a Study (which shall include the date of any notification to a Regulatory Authority), if completed; or (c) if a Study is discontinued before its completion, the date on which the Regulatory Authority is so notified. In any event, CRO shall at all times comply with all Applicable Laws, including 21 CFR 312.57 and 21 CFR 312.62(c). Upon the reasonable request of GENTIUM, CRO will make all such records and documents available in electronic and documentary form to GENTIUM or its designee from the execution date of a Study Work Order through the last day of the above-mentioned five (5) year period. In addition, CRO will make available its employees to consult with GENTIUM or its designee with respect to such records and documents. CRO shall notify GENTIUM six (6) months prior to the expiration of the above referenced document retention period to determine whether GENTIUM plans to take delivery of the Study records and document or require post Study record and document retention services.

13.1.2 Post Study Record Retention Requirements. Upon the expiry of the record retention period described above in Section 13.1.1, CRO shall, if requested by GENTIUM and at GENTIUM's cost and upon an acceptable archiving contract being signed by CRO and GENTIUM, archive all GENTIUM specified Study records. In addition, CRO shall make available all retained employees to consult with GENTIUM or their respective representatives or designees with respect to such records and documents.

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13.2 Regulatory Authority Audits. CRO shall make all records of a Study in its possession, including CRFs and supporting notes and other documentation, available to all Regulatory Authorities with jurisdiction over the Study. CRO will inform GENTIUM within one business day of being notified by any Regulatory Authority of an audit (if advance notice is given) or within one business day of the beginning of an audit by a Regulatory Authority (if no notice is given). CRO shall encourage each Investigator, to the extent possible, to promptly notify CRO about all Regulatory Authority audits. CRO shall forward GENTIUM copies of correspondence from any Regulatory Authority relating to a the Services or a Study Work Order, involving GENTIUM. Without limiting the foregoing, CRO shall provide GENTIUM with a copy of any written correspondence to a Regulatory Authority regarding a the Services or a Study Work Order for GENTIUM's input prior to submitting it to such Regulatory Authority.

13.3 GENTIUM Right to Audit. CRO will permit GENTIUM and its representatives to audit CRO and its facilities used to perform the Services, Study documentation, financial records, and other documents and materials that relate to the Services performed under this Agreement. GENTIUM shall provide reasonable notice of its intent to audit and shall conduct the audit during regular business hours. CRO agrees to remediate audit findings to ensure compliance with Applicable Laws, this Agreement, and Study Work Orders and agrees to provide objective evidence to GENTIUM of such remediation upon GENTIUM's request.

13.4 Definition of "Records" and "Documents". For purposes of this Agreement "records" and "documents" shal include, but not be limited to, all medical reports related to a Study (including Case Report Forms), all Monitoring Reports and all financial records relating to fees and expenses incurred in the discharge of CRO's responsibilities under an applicable Study Work Order.

SECTION 14
TERM OF AGREEMENT

14.1 Term. Upon execution by both Parties, this Agreement is effective as of the Effective Date and shall continue in force for a period concluding on the two (2) year anniversary of such date ("Term") unless terminated earlier by either Party in accordance with Section 15. The parties may renew this Agreement for two (2) year periods or other periods they deem adequate prior to the previous term's scheduled expiration.

14.2 Term of Study Work Order. Upon execution by both Parties, a Study Work Order is effective as of the execution date and automatically expires on the date on which GENTIUM has received all the documents for the applicable Study referred to in Sections 9.5 and 9.6 and CRO has received from GENTIUM all of the payments due pursuant to Section 4, unless terminated earlier by either Party in accordance with Section 15.

14.3 Surviving Provisions. Notwithstanding the expiration or termination of this Agreement, the provisions of the following sections of this Agreement will survive and remain in full force and effect: Sections 3, 5, 5, 6.2, 7, 8.7, 8.8, 8.9, 9, 10, 11, 12, 13, 15, 17, 18, 19, 20, 21, 22 and 23.

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SECTION 15
TERMINATION

15.1 Termination of Agreement.

15.1.1 By GENTIUM. This Agreement may be terminated at any time by GENTIUM, with or without cause, upon thirty (30) days advance written notice to CRO; provided, however, that if in GENTIUM's discretion GENTIUM deems it necessary to terminate the Agreement (and all Study Work Orders hereunder) due to health concerns of Study subjects, or if GENTIUM is required to terminate all Studies hereunder by order of a competent Regulatory Authority, or elects to terminate this Agreement for a breach of CRO's obligations under Section 21, this Agreement may be terminated by GENTIUM immediately upon written notice to CRO of such circumstances.

15.1.2 By CRO. Subject to Section 15.1.3, this Agreement may be terminated by CRO if GENTIUM commits a material breach of this Agreement and fails to cure such breach within ninety (90) days after receiving written notice from CRO (or fails to commence to cure such breach within such ninety (90) day period where such breach is not susceptible to cure within ninety (90) days). CRO has the right to give notice of termination at any time after expiration of the ninety (90) day period. The notice of termination is effective sixty (60) days after its receipt by GENTIUM.

15.1.3 Effect of Termination on Study Work Orders. In the event this Agreement is terminated by either Party pursuant to Section 15.1 or 15.1.2, then GENTIUM, in its sole discretion, may specify in writing which activities and Study Work Orders must be completed by CRO, and the effective date of termination shall be extended only with respect to those activities and Study Work Orders specified by GENTIUM until they are completed in accordance with the terms of this Agreement and the Study Work Order; provided, however, that in the event that CRO has elected to terminate the Agreement due to a material breach by GENTIUM pursuant to Section 15.1.2, subject to its obligations under this Section 15.1.3 to perform its obligations on a "phase out" basis, CRO, in its discretion, may elect not to complete the Study Work Order which gave rise to the uncured material breach by GENTIUM. GENTIUM shall not be liable to CRO for any lost profits or loss of business opportunity.

15.2 Termination of Study Work Orders.

15.2.1 By GENTIUM. A Study Work Order may be terminated at any time by GENTIUM, with or without cause, upon thirty (30) days advance written notice to CRO; provided, however, that if in GENTIUM's discretion GENTIUM deems it necessary to terminate a Study Work Order due to health concerns of Study subjects, or if GENTIUM is required to terminate a Study associated by a Study Work Order by a legal or Regulatory Authority, or elects to terminate a Study Work Order under Section 21, a Study Work Order may be terminated by GENTIUM immediately upon written notice to CRO of such circumstances.

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15.2.2 By CRO. A Study Work Order may be terminated by CRO if GENTIUM commits a material breach of this Agreement with respect to such Study Work Order and fails to cure such breach within sixty (60) days after its receipt of written notice describing the breach (or fails to commence to cure such breach within such 60 day period where such breach is not susceptible to cure within sixty (60) days). CRO has the right to give notice of termination at any time after expiration of the sixty (60) day period. The notice of termination is effective thirty (30) days after its receipt by GENTIUM.

15.2.3 Cessation of Work Upon Termination of Study Work Order. Unless specified otherwise by GENTIUM in its termination notice, CRO will stop work on each Study that is the subject of a Study Work Order termination notice immediately upon receipt of such a notice of termination from GENTIUM and will, as applicable, commence to wind up or transfer responsibility for the Study to GENTIUM or its designee in an orderly and medically responsible manner. If CRO gives notice of termination of a Study Work Order to GENTIUM, GENTIUM has the right to require CRO to continue work on the Study on a "phase out" basis during the termination period. Upon receipt of notice of termination from GENTIUM, CRO will use its best efforts to avoid incurring any additional costs or expenses with respect to the Study, to cancel any outstanding costs and obligations relating thereto, and will promptly inform Investigators immediately to stop enrolling new Study subjects. GENTIUM shall not be liable to CRO for any lost profits or loss of business opportunity.

15.3 Payments Upon Termination.

15.3.1 Outstanding Invoices. With respect to each Study Work Order that is terminated, GENTIUM will pay to CRO the amounts properly due under invoices outstanding at the time of termination for services properly performed in accordance with this Agreement and the applicable Study Work Order pursuant to Section 4.1.

15.3.2 Early Termination of a Study Work Order By GENTIUM. With respect to each Study Work Order that is terminated, CRO shall promptly invoice GENTIUM for all services properly performed through the date of termination which have not been previously invoiced. If GENTIUM terminates a Study Work Order for any reason other than a material breach by CRO, GENTIUM will pay CRO for all documented direct costs already incurred up to the date of termination, less any payments made to date, and limited by any maximum specified in any Scope of Services. Direct costs will include any noncanceleable expenses other than personnel costs so long as they were properly incurred and prospectively approved by GENTIUM, and only to the extent they cannot reasonably be mitigated. GENTIUM shall pay to CRO the amounts properly due under this Section 15.3.2 pursuant to Section 4.1.

15.3.3 Refund of Overpayments to GENTIUM. Any amounts paid by GENTIUM to CRO prior to any termination of a Study Work Order to which such payment relates, will be applied towards payments due under such Study Work Order and the balance, if any, of amounts not so applied or not earned relating to such Study Work Order will be promptly refunded to GENTIUM.

15.4 Delivery of Documents and Cooperation. Upon any termination of a Study Work Order or this Agreement, CRO will promptly deliver to GENTIUM or its designee all materials, documents, data and other information in its possession or under its control relating to each Study relating to a Study Work Order that has been terminated as well as any related Investigational Product or other test materials. CRO will cooperate reasonably with GENTIUM or its designee in the event of GENTIUM or its designee assumes control of a Study or upon termination of the Study. This cooperation includes, but is not limited to, assigning Investigator Agreements and other agreements entered into by CRO in connection with such Study to GENTIUM or its designee, at GENTIUM's request, and using the period following issuance of a termination notice to wind up or transition such Study or any portion of services to be performed by CRO hereunder in an orderly manner.

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SECTION 16
INDEMNIFICATION

16.1 Indemnification by GENTIUM.

16.1.1 CRO Indemnified Parties. The term "CRO Indemnified Parties" shall mean each of CRO, CRO Affiliates and their respective officers, directors and employees, but not the Study Sites. GENTIUM will indemnify individual Study Sites in accordance with the terms of the Investigator Agreements, if any, entered into with individual Study Sites.

16.1.2 Indemnification by GENTIUM. Upon the request of CRO, GENTIUM will indemnify the CRO Indemnified Parties against and will assume the defense and related expense (including attorneys' fees) of any and all third party claims for damages arising out of services performed by a CRO Indemnified Party pursuant to this Agreement or a Study Work Order, except to the extent that such claims or damages are the result of (i) any CRO Indemnified Party breaching or acting outside the scope of this Agreement, Protocol or any applicable Study Work Order; (ii) negligence or willful misconduct by a CRO Indemnified Party; (iii) the failure of a CRO Indemnified Party to adhere to the terms of the Protocol; or (iv) the failure of a CRO Indemnified Party to comply with Applicable Laws.

16.1.3 Conditions of GENTIUM Indemnification. CRO agrees (i) to notify GENTIUM immediately of a claim that is subject to GENTIUM's indemnification obligation under this Section 16.1; (ii) to authorize GENTIUM and/or its insurers to carry out the sole management and defense of the claim, including without limitation, while taking into reasonable consideration the business interests and possible related liabilities of CRO, the settlement thereof at the sole option of GENTIUM and/or its insurers; and (iii) to cooperate in the management and the defense by GENTIUM and/or its insurers of the claim. CRO agrees that no CRO Indemnified Party will compromise or settle any claim that is subject to GENTIUM's indemnification obligation under this Section 16.1.

16.2 Indemnification by CRO.

16.2.1 GENTIUM Indemnified Parties. The term "GENTIUM Indemnified Parties" shall mean GENTIUM, an GENTIUM Affiliate, and their respective officers, directors and employees

16.2.2 Indemnification by CRO. CRO will indemnify the GENTIUM Indemnified Parties against and will assume the defense and related expense (including attorneys' fees) of any and all third party claims for damages arising out of (i) any CRO Indemnified Party or any of their sub-contractors, consultants, CRO Representatives and agents breaching or acting outside the scope of this Agreement, a Protocol or a Study Work Order; (ii) negligence or willful misconduct by a CRO Indemnified Party or their sub-contractors, consultants, CRO Representatives and agents; (iii) the failure of a CRO Indemnified Party or their sub-contractors, consultants, CRO Representatives and agents to adhere to the terms of the Protocol; or (iv) the failure by a CRO Indemnified Party or their sub-contractors, consultants, CRO Representatives and agents to comply with any Applicable Law.

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16.2.3 Conditions of CRO Indemnification. If any GENTIUM Indemnified Party elects to exercise its indemnification rights under this Section 16.2, such GENTIUM Indemnified Party shall (i) notify CRO of the subject claim as soon as reasonably practicable; (ii) authorize CRO and/or its insurers to carry out the sole management and defense of the claim; and (iii) cooperate in the management and defense by CRO and/or its insurers of the claim. GENTIUM agrees that no GENTIUM Indemnified Party will compromise or settle any claim for which GENTIUM has elected to exercise its indemnification rights under this Section 16.2 without the prior written approval of CRO, which approval shall not unreasonably be withheld. CRO agrees not to compromise or settle any claims on behalf of an GENTIUM Indemnified Party without the prior written consent of such GENTIUM Indemnified Party.

16.3 Material Errors or Omissions. In the event of a material error or omission by CRO or their sub-contractors, consultants or agents in the performance of its obligations under this Agreement or Study Work Order, CRO agrees: (i) that the GENTIUM Indemnified Parties will not be obligated to pay for work not performed in accordance herewith, with any Study Work Order or with the Protocol, (ii) that CRO or their sub-contractors, consultants, CRO Representatives or agents will re-perform the services detrimentally impacted by such error or omission at the sole cost and expense of CRO, or (iii) that CRO will reimburse such GENTIUM Indemnified Party for the reasonable costs related to a third-party's re-performance of such services or reimburse the GENTIUM Indemnified Party for the reasonable internal costs allocated for the re-performance of such services, as the GENTIUM Indemnified Party may elect.

16.4 Limitation of Liability. EXCEPT AS OTHER WISE PROVIDED FOR IN THIS AGREEMENT, NEITHER PARTY SHALL BE LIABLE TO THE OTHER PARTY FOR LOSS OF PROFITS OR SPECIAL, PUNITIVE, CONSEQUENTIAL, INCIDENTAL OR SIMILAR DAMAGES (EVEN IF SUCH DAMAGES WERE FORESEEABLE OR IN CONTEMPLATION OF EITHER PARTY). However, the limitations of liability in the immediately preceding sentence shall not apply to the Parties' indemnification obligations in Section 16; any breach of Section 17 (Confidentiality), Section 19 (Ownership of Existing Property and Data) and Section 20 (Ownership of Future Property and Data); or to the negligence, recklessness or willful misconduct of either Party or their employees or agents.

16.5 Insurance. During the Term of this Agreement and for the duration of any applicable Study Work Order, the Parties shall maintain liability insurance with policy limits sufficient to meet their indemnification obligations under this Section 16.

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SECTION 17
CONFIDENTIALITY

17.1 Definition of Confidential Information. During the Term, it may be necessary for GENTIUM, or other persons or entities working with GENTIUM, to disclose certain information to CRO that GENTIUM considers proprietary and confidential ("Confidential Information"). "Confidential Information" shall mean (a) GENTIUM's business records, oral or electronic communications, financial information, business practices, trade secrets, know-how, intellectual property, materials, inventions, formulas, compounds, devices, specifications, plans, methods, software, data, technical information, concepts, procedures, processes, business plans, current and past distribution and production arrangements (oral or written), facilities, employees, marketing and sales strategies, business opportunities and strategic plans; (b) information related to or arising from any proprietary compounds of GENTIUM or GENTIUM Affiliates that is developed by CRO in connection with the performance of the Services hereunder; or (c) information that is generated or developed by or received from Study Sites or Investigators in connection with any Study or any Study Work Order or Scope of Services. Confidential Information includes, but is not limited to, the terms of this Agreement, any Manuals, Protocol(s), completed CRFs (and the data contained therein), the final statistical analyses and the final Study reports but shall not include CRO research methodologies and computer software and code. The terms of this Section 17 shall govern the exchange of Confidential Information between CRO and GENTIUM, CRO and any GENTIUM Affiliate, and in any meetings held for the purpose of exploring a potential business transaction between CRO and GENTIUM or its Affiliates.

17.2 Non-Disclosure and Non-Use. CRO agrees that neither CRO nor any CRO Affiliate will disclose to any third party or use any Confidential Information except as provided herein, subject to the following provisions of this Section 17.2. The foregoing obligations of confidentiality and non-use shall not apply to the extent that any information is (a) already known to CRO at the time of initial disclosure to CRO, or is developed by CRO in the course of work entirely independent of this Agreement or any disclosure hereunder, as evidenced by CRO's written records, and is not subject to any confidentiality obligation inuring to GENTIUM or any GENTIUM Affiliate or (b) publicly known prior to or after disclosure hereunder other than through acts or omissions of CRO, (c) disclosed in good faith to CRO or a CRO Affiliates by a third party under a reasonable claim of right, or (d) required by law to be disclosed, provided GENTIUM is promptly notified of such requirement in order for GENTIUM to take action it determines is necessary to protect the Confidential Information.

17.3 Return of Confidential Information. If any Study Site is terminated or elects not to participate in a Study, CRO will be responsible for ensuring that all Confidential Information is retrieved from the Study Site and returned promptly to GENTIUM as appropriate.

17.4 No Publication of Study Results. As provided for in the Investigator Agreements, all original CRFs and Study data will be the property of GENTIUM and CRO will have no right to publish the results of the Study. GENTIUM shall have the exclusive right to prepare and publish any paper for publication which utilizes data generated by a Study subject to the applicable provisions of the applicable Protocol and Investigator Agreement. CRO shall not have the right to publish any paper utilizing the Study data or any portion thereof.

17.5 Confidentiality of Agreement. CRO shall not disclose the terms of this Agreement or any applicable Study Work Order to any third party other than to CRO's legal and financial advisors and such information which is required to be disclosed by federal, state or municipal law or regulation, except that CRO may disclose the provisions of Section 16 (Indemnification) and Section 6.2 (Adverse Reactions) to the Investigators.

17.6 Restrictions on Announcements. CRO shall not make any announcement, oral presentation or publication relating to the Study or the Investigational Product without GENTIUM's prior written consent, except as required by law or by court or administrative order. CRO shall not employ or use the name of GENTIUM or an GENTIUM

Affiliate in any publication or promotional materials in any form for public distribution, without the prior written consent of GENTIUM, except as required by law or by court or administrative order.

Confidential treatment has been requested for portions of this exhibit. The copy filed herewith omits the information subject to the confidentiality request. Omissions are designated as ***. A complete version of this exhibit has been filed with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Act of 1934, as amended.

SECTION 18
REPRESENTATIONS AND WARRANTIES

18.1 GENTIUM Representations and Warranties. GENTIUM represents and warrants to CRO that:

18.1.1 GENTIUM is a duly incorporated and validly existing corporation under the laws of the country of Italy.

18.1.2 GENTIUM has the corporate power and authority to execute and deliver this Agreement and to perform its obligations hereunder. GENTIUM's execution and delivery of, and performance under, this Agreement have been duly and validly authorized by GENTIUM; and

18.1.3 upon execution and delivery of this Agreement, this Agreement shall constitute a legal, valid and binding agreement of GENTIUM, enforceable in accordance with its terms, except to the extent enforceability may be affected by applicable bankruptcy, reorganization, insolvency, and moratorium laws and other laws applicable generally to creditors' rights and debtors' remedies from time to time in effect.

18.2 CRO Representations and Warranties. CRO represents and warrants to GENTIUM that:

18.2.1 CRO is a duly incorporated and validly existing corporation under the laws of the State of Delaware;

18.2.2 CRO has the corporate power and authority to execute and deliver this Agreement and to perform its obligations hereunder and under each scope of work. CRO's execution and delivery of, and performance under, this Agreement have been duly and validly authorized by CRO;

18.2.3 CRO represents that it has personnel, equipment, experience and expertise sufficient in quality and quantity to provide all comprehensive services requested by GENTIUM hereunder and agrees to provide any and all such services in responsible and timely manner commensurate with the highest professional standards generally applicable to the conduct and management of clinical drug studies throughout the world.

18.2.4 upon execution and delivery of this Agreement and each Scope of Work, this Agreement and each such Scope of Work shall constitute a legal, valid and binding agreement of CRO, enforceable in accordance with its terms, except to the extent enforceability may be affected by applicable bankruptcy, reorganization, insolvency, and moratorium laws and other laws applicable generally to creditors' rights and debtors' remedies from time to time in effect;

18.2.5 neither the execution and delivery of this Agreement nor CRO's performance of its obligations hereunder will violate or breach, or otherwise constitute or give rise to a default under, the terms or provisions of CRO's Certificate of Incorporation or its By-Laws or of any material contract, commitment or other obligation to which CRO is a party, or violate or result in a breach of or constitute a default under any judgment, order, decree, rule or regulation of any court or governmental agency to which CRO is subject;

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18.2.6 CRO shall fully comply with the requirements of all Applicable Laws of any and all applicable federal, state, local and foreign laws, regulations, rules and orders of any governmental body having jurisdiction over the activities contemplated by this Agreement;

18.2.7 CRO shall render the services to be rendered by it hereunder in accordance with the highest professional standards and that such services shall be completed in conformance herewith and any applicable Scope of Services and the Protocol;

18.2.8 CRO has developed a business interruption and disaster recovery program and is executing such program to assess and reduce the extent to which CRO's hardware, software and embedded systems may be susceptible to errors or failures in various crisis (or force majeure) situations. In the event that any data, reports or materials that are delivered by CRO to GENTIUM are inaccurate as a result of such errors or failures then CRO will fix, or if necessary, re-perform the deliverables at its own expense within mutually agreeable time frames. If GENTIUM reasonably determines that CRO is not capable of timely re-performance, then CRO will reimburse GENTIUM for the reasonable costs related to a third party's re-performance of such services or reimburse GENTIUM for the reasonable internal costs allocated for the re-performance of such services;

18.2.9 if CRO uses electronic systems for creating, modifying, maintaining, archiving, retrieving or transmitting any records, including test results that are required by, or subject to inspection by an applicable Regulatory Authority (including the FDA), then CRO represents and warrants that CRO's systems for electronic records are in compliance with 21 CFR Part 11. CRO further represents and warrants that, in order to comply with Part 11, it will not use any electronic signatures on any documents required by, submitted to, or supporting a submission to the FDA unless CRO, as applicable, has certified to the FDA that it intends such electronic signatures to be the legally binding equivalent of a hand-written signature; and

SECTION 19
OWNERSHIP OF EXISTING PROPERTY AND DATA

19.1 CRO Ownership of Systems. All aspects of the software and hardware incorporated into CRO's processing and management systems which are owned by CRO shall remain the property of CRO; provided, however, that CRO shall notify GENTIUM prior to inclusion of any such proprietary software or hardware in any deliverable hereunder and, with respect to any software so included, or which is improved, modified or developed by CRO under or during the term of this Agreement, hereby grants to GENTIUM and all GENTIUM Affiliates, a perpetual, paid-up, non-exclusive license to use such software. CRO represents and warrants that it is entitled to deliver the material, data and information to be delivered as part of the services hereunder for GENTIUM and all GENTIUM Affiliates' use. CRO shall, without additional charge to GENTIUM and the GENTIUM Affiliates, provide GENTIUM and the GENTIUM Affiliates with a limited, royalty-free, paid-up, non-exclusive license to use such CRO proprietary software on the data to the extent reasonably necessary to permit GENTIUM and the GENTIUM Affiliates to utilize the full benefit of the Study data and all other rights, interests, inventions, know-how, data and Confidential Information inuring to them hereunder.

Confidential treatment has been requested for portions of this exhibit. The copy filed herewith omits the information subject to the confidentiality request. Omissions are designated as ***. A complete version of this exhibit has been filed with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Act of 1934, as amended.

19.2 Ownership of Data. Subject to Section 19.1, any material, information, documents and data (including without limitation, computer software and hardware and Confidential Information) furnished by or on behalf of GENTIUM or an GENTIUM Affiliate for use by CRO and all materials, information (other than general information the use of which by CRO in the normal course of CRO's operations would not impair GENTIUM or an GENTIUM Affiliates' interests in and to a Study, a Investigational Product, the Confidential Information or in any material, information, documents and data to which GENTIUM or the GENTIUM Affiliates have rights hereunder), documents and data (including without limitation Confidential Information and any data or other information stored or entered in or on any CRO software or hardware described under Section 19.1) which relates to a Study or a Investigational Product and not to CRO's research methodologies and which has been developed, gathered or compiled by, or disclosed to, CRO in connection with this Agreement or any Study Work Order shall be and remain the exclusive property of GENTIUM or an GENTIUM Affiliate, as the case may be, and shall be returned promptly to GENTIUM or an GENTIUM Affiliate, as appropriate, upon request.

SECTION 20
OWNERSHIP OF FUTURE PROPERTY AND DATA

20.1 Ownership of Inventions and other Intellectual Property. Except as specifically set forth in Section 19.1, all inventions, processes, know-how, trade secrets, data, improvements, copyrights, trademarks and/or patents or other intellectual property ("Property") relating to the Investigational Product or otherwise arising from a Study, Confidential Information, a Protocol, a Scope of Work or CRO's performance hereunder, that are conceived, generated or reduced to practice, as the case may be, during the term of this Agreement and subsequent to the termination or expiration of this Agreement will be the exclusive property of GENTIUM.

20.2 Assignment of Rights; Cooperation. CRO shall and shall require and use reasonable efforts to cause each Investigator and Study Site to assign and transfer any and all right, title and interest in any such party may have in and to any Property relating to the Investigational Product, or otherwise arising from the Study as described more completely in Section 20.1 above, to GENTIUM and the GENTIUM Affiliates, and take such other reasonable action to ensure ownership of such Property vests in GENTIUM and/or its GENTIUM Affiliates as directed.

SECTION 21
DEBARMENT

21.1 CRO and Employees. CRO (and each CRO Affiliate performing CRO's obligations hereunder) represents that it has never been and that neither its employees, nor its sub-contractors, consultants, CRO Representatives and agents, nor any Investigator who will be rendering services to GENTIUM hereunder or in connection herewith has ever been, (i) Debarred or voluntarily excluded or convicted of a crime for which a person can be Debarred under 21 U.S.C. § 335a, as amended, or any equivalent thereof, in any country in which any portion of the Study is conducted ("§ 335a") nor (ii) threatened to be Debarred or voluntarily excluded or indicted for a crime or otherwise engaged in conduct for which a person can be Debarred under § 335a, or subject to any governmental sanction that would prevent the rendering of services hereunder in any jurisdiction in which the Study is to be conducted, nor (iii) Excluded from participation in any federally-funded health-care program.

21.2 Notices. CRO agrees that it shall promptly notify GENTIUM in the event of any Debarment, voluntary exclusion, conviction, threat, indictment or Exclusion prohibited by Section 21.1 occurring during the term of this Agreement or the three (3) year period following the termination or expiration of this Agreement.

Confidential treatment has been requested for portions of this exhibit. The copy filed herewith omits the information subject to the confidentiality request. Omissions are designated as ***. A complete version of this exhibit has been filed with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Act of 1934, as amended.

21.3 Third Parties. During the term of this Agreement, CRO agrees not to knowingly, and agrees to conduct appropriate due diligence to ensure that it does not (i) employ or otherwise engage any individual who will be rendering services who has been Debarred or voluntarily excluded or convicted of a crime for which a person can be Debarred under § 335a, nor (ii) threatened to be Debarred or voluntarily excluded or indicted for a crime or otherwise engaged in conduct for which a person can be Debarred under § 335a, or subject to any governmental sanction that would prevent the rendering of services hereunder in any jurisdiction in which the Study is to be conducted, nor (iii) Excluded from participation in any federally-funded health-care program. CRO agrees that, before engaging or employing any individual, CRO shall obtain a written certificate signed by or for such third party stating that such third party is not Debarred, Excluded or voluntarily excluded or convicted of a crime for which a person can be Debarred, Excluded or voluntarily excluded.

Certification. Upon GENTIUM's reasonable request, CRO shall certify to GENTIUM in writing CRO's compliance with the foregoing provisions of this Section 21. GENTIUM has the right to terminate this Agreement upon written notice in the event of a breach of any of the provisions set forth in this Section 21.

SECTION 22
DISASTER RECOVERY

22.1 Appropriate Safeguards. CRO shall employ all reasonable and appropriate measures and processes to insure that all data collected and stored by it pursuant to this Agreement will be safeguarded against loss, damage and destruction arising from any cause including, but not limited to, theft, fire, flood, earthquake, lightening, and electrical disruption. Such measures and processes shall include, but not be limited to, (a) storage of hard-copy documents and computer storage disks in locked, fireproof containers, and (b) back-up and recovery systems (which are periodically tested) for computer-based systems.

22.2 GENTIUM Inspection. GENTIUM shall have the right, but not the obligation, upon reasonable advance notice and during normal business hours, to periodically inspect CRO's premises to determine whether the foregoing measures and processes are in effect and being implemented.

SECTION 23
MISCELLANEOUS

23.1 Modification. No modification of this Agreement, a Study Work Order or a Scope of Work shall be deemed effective unless in writing and signed by each of the Parties hereto (or an GENTIUM Affiliate, as the case may be). Emails, including emails that have an electronic "signature block" identifying sender, do not constitute a signed instrument for purposes of this Agreement.

23.2 Waiver. No waiver of any right set forth herein shall be deemed effective unless in writing and signed by the Party against whom enforcement of the waiver is sought. The waiver by either of the Parties of any breach of any provision of this Agreement by the other shall not be construed to be a waiver of any succeeding breach of such provision or of a waiver of the provision itself.

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23.3 Entire Agreement. The terms and provisions contained in the Agreement, including the Exhibits and Attachments annexed hereto represent the entire agreement between the Parties and supersede all prior negotiations, representations or agreements, written or oral, regarding the subject matter described herein.

23.4 Section and Attachment References. All references herein to Sections and Exhibits are to Sections of and Attachments to this Agreement, except as may be expressly specified otherwise.

23.5 Descriptive Headings. The descriptive headings of the sections of this Agreement are inserted for convenience only and shall not control or affect the meaning or construction of any provision hereof.

23.6 Incorporation by Reference. All Exhibits and Attachments hereto, including any Scope of Services, shall be deemed to be incorporated herein and made a part hereof. In the event of an inconsistency between the terms of this Agreement or any Scope of Services, the terms of this Agreement shall be dispositive except to the extent the terms of any such Scope of Services expressly supercede this Agreement.

23.7 Assignment. CRO shall not assign, delegate or subcontract its rights and obligations under this Agreement to any third party without the prior written consent of GENTIUM. Any permitted assignment by CRO will not relieve CRO of its obligations or liability incurred prior to assignment.

23.8 Applicable Law. This Agreement shall be construed by and enforced in accordance with the law of the State of New York, without regard to its conflict of law provisions. All parties agree to submit to the personal jurisdiction of the State of New York and further agree that any cause of action arising under this Agreement or any Scope of Work hereunder must be brought in either federal or state court in New York.

23.9 Force Majeure. The performance by either Party of any covenant or obligation on its part to be performed hereunder shall be excused by floods, strikes or other labor disturbances, riots, fires, accidents, wars, embargoes, delays of carriers, inability to obtain materials, failure of power or natural sources to supply, acts, injunctions or restraints of government (including any Regulatory Authorities with jurisdiction over this Agreement), or any other act of God or other Force Majeure preventing such performance; provided, however, that the Party affected shall use all reasonable endeavors to eliminate or cure or overcome any such causes and to resume performance of its covenants with all possible speed. Notwithstanding the foregoing provision of this Section 23.9, in no event shall the occurrence of a Force Majeure Event excuse CRO from its obligations (i) under Section 22.1 and any liability in respect thereof or (ii) if such event was reasonably foreseeable and CRO did not take all reasonable measures to protect against its occurrence.

23.10 Severability. In the event that any provision of this Agreement is held to be unenforceable or invalid by a court of competent jurisdiction, the validity and enforceability of the remaining provisions will not be affected thereby.

23.11 Counterparts. This Agreement may be executed in several counterparts, each of which shall be deemed an original but all of which shall constitute one and the same document.

Confidential treatment has been requested for portions of this exhibit. The copy filed herewith omits the information subject to the confidentiality request. Omissions are designated as ***. A complete version of this exhibit has been filed with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Act of 1934, as amended.

IN WITNESS WHEREOF, the undersigned have duly executed this Agreement as of the Effective Date.

GENTIUM INC.		US Oncology Clinical Development, LLC	
By:	/s/ Gary G. Gemignani Name: Gary G. Gemignani Title: Executive Vice President and Chief Finance Officer	By:	/s/ Stephen Smith Name: Stephen Smith Title: Vice President and General Manager

Confidential treatment has been requested for portions of this exhibit. The copy filed herewith omits the information subject to the confidentiality request. Omissions are designated as ***. A complete version of this exhibit has been filed with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Act of 1934, as amended.

EXHIBIT A

FORM OF
STUDY WORK ORDER

THIS STUDY WORK ORDER, effective as the this 11th day of September 2009 (the "Effective Date"), is made by between Gentium S.p.A., a biotechnology corporation with its office and place of business at Piazza XX Settembre, 222079, Villa Guardia (Co) Italy ("GENTIUM"), and US Oncology Clinical Development, LLC, a Delaware corporation with an office and place of business located at 10101 Woodloch Forest, The Woodlands, Texas 77380 ("CRO").

Recitals

WHEREAS, GENTIUM and CRO have entered into a Master Contract Clinical Research Agreement dated September 29, 2009 (the "Master Agreement") pursuant to which CRO has agreed to provide ;

WHEREAS, GENTIUM desires CRO to provide services in connection with GENTIUM's clinical investigation (the "Study") of its Investigational Product to be conducted in accordance with protocol number 2006-05, entitled "Defibrotide for Patients with Hepatic Veno-Occlusive Disease (VOD)" (the "Protocol"); and

WHEREAS, GENTIUM desires CRO to provide management services and certain clinical research activities, with such activities including but not limited to distribution of its investigational product, billing, invoicing and collection services for the investigational product and this Study as set forth herein and CRO is willing to render such services in accordance with the terms and conditions of this Study Work Order.

NOW, THEREFORE, in consideration of the mutual covenants, payments, and agreements contained herein, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto, intending to be legally bound, hereby agree as follows:

1. Study Work Order. This document constitutes a Study Work Order entered into pursuant to Section 1.2 of the Master Agreement, and as such, this Study Work Order and the services contemplated herein shall be subject to all terms and conditions of the Master Agreement. Any capitalized terms not otherwise defined in this Study Work Order shall have the same meaning ascribed to them in the Master Agreement. In the event of any inconsistency between the terms contained in this Study Work Order with those contained in the Master Agreement, the terms contained in the Master Agreement shall govern.

2. Protocol. The Study to be performed is set forth in the Protocol, as may be amended by GENTIUM from time to time, a copy of which is attached hereto as Attachment 1.

3. Investigational Product. For purposes of this Study Work Order, the Investigational Product for the Study is defibrotide.

4. Study Related Services to be Provided by CRO. The services to be performed by CRO for this Study (the "Services") and the related payment terms and obligations are set forth on the following attachments, which are incorporated herein by reference:

Confidential treatment has been requested for portions of this exhibit. The copy filed herewith omits the information subject to the confidentiality request. Omissions are designated as ***. A complete version of this exhibit has been filed with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Act of 1934, as amended.

Attachment 1	Protocol
Attachment 2	Study Plan [Scope of Services]
Attachment 3	Budget and Payment Schedule
Attachment 4	Transfer of Obligations
Attachment 5	Investigational Product and Financial Management Plan

5. Payments.

5.1 Payments to CRO. In consideration for the CRO's performance under this Agreement, GENTIUM will pay CRO in accordance with the terms of Attachment 3 attached hereto.

5.2 Payments to GENTIUM: In consideration for the services provided under this Agreement, CRO shall make payments to Gentium in accordance with the terms of Attachment 3 attached hereto.

5.3 CRO shall invoice GENTIUM for the Services, in accordance with the Budget and payment schedule attached as Appendix B hereto, and all invoices shall reference this Work Order and be sent to the following address:

US Oncology Clinical Development, LLC
2899 Paysphere Circle
Chicago, Illinois 60674
Attention: US Oncology Research, Inc.
ResearchReceivables@usoncology.com

Tax ID#: ***

Wire Transfers:
Bank: ***
***
ABA No.: ***
Beneficiary: ***
Account No.: ***

Similarly, based on the information provided in the monthly sales and inventory report, Gentium will invoice CRO, and all invoices shall reference this Work Order and be sent to the following address:

Gentium S.p.A.
Piazza XX Settembre, 222079
Villa Guardia (Co) Italy
Attention: Salvatore Calabrese
scalabrese@gentium.com

Wire Transfers:
***
ABA Routing # ***
Swift: ***
Account name: ***
Account number : ***

Confidential treatment has been requested for portions of this exhibit. The copy filed herewith omits the information subject to the confidentiality request. Omissions are designated as ***. A complete version of this exhibit has been filed with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Act of 1934, as amended.

5.4 Expense/Fee Limitations; Discounts, Rebates and Allowances. CRO will not incur any cost or expense in excess of the amounts set forth in the Budget, without the prior written approval of GENTIUM. CRO will use its best efforts to control and limit the costs and expenses associated with this Study Work order and to obtain and pass along to GENTIUM all available discounts, rebates and allowances.

6. Term. The term of this Study Work Order shall commence on the Effective Date herein and shall continue until the Services described in Attachment 2 are completed, unless this Study Work Order is terminated in accordance with Section 15 of the Master Agreement. If the Master Agreement is terminated or expires, but this Study Work Order is not terminated or completed, then the terms of the Master Agreement shall continue to apply to this Study Work Order until the Study Work Order is either terminated or completed.

7. Representations and Warranties.

7.1 Representations, Warranties and Covenants of CRO. Without limitation of any representations or warranties in the Master Agreement, CRO represents and warrants to GENTIUM that:

(a) CRO has the corporate power and authority to execute and deliver this Study Work Order and to perform its obligations hereunder. CRO's execution and delivery of, and performance under, this Work Study Order have been duly and validly authorized by CRO;

(b) upon execution and delivery of this Study Work Order, such Study Work Order will constitute a legal, valid and binding agreement of CRO, enforceable in accordance with its terms, except to the extent enforceability may be affected by applicable bankruptcy, reorganization, insolvency, and moratorium laws and other laws applicable generally to creditors' rights and debtors' remedies from time to time in effect;

(c) neither the execution and delivery of this Study Work Order nor CRO's performance of its obligations hereunder will violate or breach, or otherwise constitute or give rise to a default under, the terms or provisions of CRO's Certificate of Incorporation or its By-Laws or of any material contract, commitment or other obligation to which CRO is a party, or violate or result in a breach of or constitute a default under any judgment, order, decree, rule or regulation of any court or governmental agency to which CRO is subject; and

(d) CRO will render the services to be rendered by it hereunder in accordance with the highest professional standards and that such services will be completed in conformance herewith and with the Study Plan and the Protocol.

7.2 Representations and Warranties of GENTIUM. GENTIUM represents and warrants to CRO that:

(a) the Study is being conducted with an investigational new drug application ("IND") for the Investigational Product has been submitted by GENTIUM to the U.S. Food & Drug Administration ("FDA") and is in effect.

Confidential treatment has been requested for portions of this exhibit. The copy filed herewith omits the information subject to the confidentiality request. Omissions are designated as ***. A complete version of this exhibit has been filed with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Act of 1934, as amended.

7.3 Disclaimers; Limitation of Liability. GENTIUM MAKES NO WARRANTIES, EXPRESS OR IMPLIED, INCLUDING AND WITHOUT LIMITATION ANY OF THE IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE REGARDING THE INVESTIGATIONAL PRODUCT OR ANY OTHER SUBJECT MATTER OF THIS AGREEMENT AND WITHOUT ANY REPRESENTATION OR WARRANTY THAT THE USE OF THE INVESTIGATIONAL PRODUCT WILL NOT INFRINGE ANY PATENT, COPYRIGHT, TRADEMARK OR OTHER RIGHT OF A THIRD PARTY. GENTIUM MAKES NO REPRESENTATION OF ANY KIND, EXPRESS OR IMPLIED, REGARDING THE SAFETY OR EFFICACY OF THE INVESTIGATIONAL PRODUCT OR ANY OTHER SUBJECT MATTER OF THIS AGREEMENT. GENTIUM SHALL NOT BE LIABLE TO STUDY SITE OR PRINCIPAL INVESTIGATOR FOR SPECIAL, PUNITIVE, CONSEQUENTIAL, INCIDENTAL OR SIMILAR DAMAGES.

7.3 Liability for Damaged Product. Gentium agrees that, if any Investigational Product is damaged during shipment through no fault of CRO or Research Pharmacy, Gentium shall be solely responsible for such damaged Investigational Product and any replacement of Investigational Product to site.

8. Investigational Product Supply.

8.1 Supply of Investigational Product. GENTIUM shall provide a sufficient supply of the investigational product to CRO to enable appropriate distribution by CRO of the investigational product.

8.2 Investigational Product Disposal. CRO shall be responsible for the control and disposal of the Investigational Product and other test articles, as set forth under Applicable Laws, including 21 CFR 312.53(b) and 312.59.

8.3 Investigational Product Documentation. CRO shall be responsible for maintaining adequate records regarding the dispensation of the Investigational Product and other test articles to each Investigator as set forth under Applicable Laws, including 21 CFR. 312.57. CRO shall be responsible for instructing and directing the Investigators to document during the course of the Study, the receipt of the Investigational Product and other test articles, their dispensation to Study subjects, and the return of the Investigational Product and other testing articles, in accordance with the Protocol and Applicable Laws. CRO will use its best efforts to ensure that the Investigational Product and other test articles are accounted for on a per subject basis by all participating Study Sites and shall use GENTIUM's drug return forms to document drug returns to GENTIUM or its designee upon the completion or discontinuation of a Study or upon the termination of the participation of a Study Site.

Liability for Fraud. Nothing in this Study Work Order or the Master Agreement is intended to limit or exclude either party's liability for fraud.

9. Notices. Except as otherwise provided, all communications and notices required under this Work Study Order shall be in writing and shall be either delivered personally (as evidenced by a signed receipt), mailed by first class certified mail, postage prepaid, or sent by telefax (confirmed by mail), to the addresses set forth below.

If to CRO:

Attn: Vice President and General Manager
US Oncology Clinical Development, LLC
10101 Woodloch Forest
The Woodlands, Texas 77380

Confidential treatment has been requested for portions of this exhibit. The copy filed herewith omits the information subject to the confidentiality request. Omissions are designated as ***. A complete version of this exhibit has been filed with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Act of 1934, as amended.

With a copy to

Attn: Contracts Manager/Paralegal
US Oncology Research, LLC
10101 Woodloch Forest
The Woodlands, Texas 77380

If to GENTIUM:

With a copy to:

Gentium S.p.A.
Attn: Timothy Hillman
Business Development and Strategic Planning
45 Rockefeller Plaza, Suite 2000
New York, NY 10111

With a copy to

Attn: Massimo Iacobelli
Scientific Director
Piazza XX Settembre, 222079
Villa Guardia (Co) Italy

The above addresses, telephone and telefax numbers are subject to change from time to time by notice in accordance herewith.

10. Exhibits. The Attachments attached hereto form an integral part of this Study Work Order and are hereby incorporated in this Study Work Order.

11. Entire Agreement. With respect to the Services performed under this Study Work Order, this Study Work Order, including the Attachments attached hereto and the terms of the Master Agreement, contains the full understanding of the parties with respect to the matters described herein. In the event of any inconsistency between this Study Work Order any Attachment attached hereto, the terms of this Study Work Order shall govern.

12. Modification. No modification, amendment, or waiver of this Work Study Order shall be effective unless in writing and duly executed and delivered by each party to the other.

13. Counterparts. This Work Study Order may be executed in several counterparts, each of which is deemed an original but all of which will constitute one and the same document.

Confidential treatment has been requested for portions of this exhibit. The copy filed herewith omits the information subject to the confidentiality request. Omissions are designated as ***. A complete version of this exhibit has been filed with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Act of 1934, as amended.

IN WITNESS WHEREOF, the parties hereto have executed this Study Work Order effective as of the Effective Date herein.

GENTIUM.	CRO
By: /s/ Gary G. Gemignani	By: Stephen Smith
Name: Gary G. Gemignani	Name: Stephen Smith
Title: Executive Vice President and Chief Finance Officer	Title: Vice President and General Manager

Confidential treatment has been requested for portions of this exhibit. The copy filed herewith omits the information subject to the confidentiality request. Omissions are designated as ***. A complete version of this exhibit has been filed with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Act of 1934, as amended.

Attachment 2

Scope of Services

US Oncology Clinical Development, LLC (the "CRO") shall perform the Services described below.

SERVICES:

Research Pharmacy

The Research Pharmacy will provide Investigational Product supply management and distribution services to all sites on this study. Gentium S.p.A. or their designee (i.e. Catalent) will provide Investigational Product in a bulk, packaged fashion to the Research Pharmacy which will distribute to individual sites as orders are placed. The Research Pharmacy will also provide the following services to better manage Investigational Product supply:

- Central Investigational Product stock storage
- Investigational Product order processing
- Investigational Product distribution
- Investigational Product information resource for sites
- Central inventory records per site
- Central supply QA monitoring
- Coordination with Research Finance for site invoicing

Investigational Product Distribution and Processing

The following is the process by which CRO will ship investigational product to research sites:

1. The Research Pharmacy staff receives a specific order form via fax and/or email from the study site or investigator and reviews the order for accuracy. CRO must confirm that the site is on active status.
2. Research Pharmacy personnel enter the number of boxes requested for distribution to the specific site into the inventory system.
3. The Investigational Product boxes are removed from the Research Pharmacy stock for that study, and all inventory is counted prior to distribution. A perpetual inventory is maintained.
4. Before an order is shipped, a research pharmacist completes a QA check by reviewing the order and comparing it to the Investigational Product ready for shipping.
5. Once the order is approved, the pharmacist generates a packing list that is included with the Investigational Product in the shipment to the site.
6. All Investigational Products are batched and shipped to the site. Investigational product will be shipped to the sites via 2-day tracked shipment (or more urgently at the site's request for an additional cost to the site).
7. All distributions are strictly shipped as bulk supply orders to the site.
8. Upon receipt of the investigational product at the site, the site confirms that the items were received in good condition.

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Reconciliation

Upon completion of the trial, the Research Pharmacy will coordinate the return of any unused product from the sites back to the Research Pharmacy. The pharmacy will provide the sites with detailed shipping instructions and shipping labels. Once all un-used product is received, it will be destroyed by Research Pharmacy or returned as requested by Gentium. All shipping and destruction expenses will be provided t o Gentium as pass-through costs.

Research Pharmacy Reconciliation System-Central Accountability System

Accountability reports will be provided to Gentium at agreed-upon intervals. The Research Pharmacy Investigational Product reconciliation and accountability system permits Sponsor access to accountability and reconciliation reports, temperature logs, and study logs. Accountability Reports reflect all inventory information, including receipts, distributions and adjustments. A separate report can be provided for each patient ID number and for each lot of a study medication, if desired.

US Oncology Research Finance – Investigator Billing & Collections

Invoice & Payment Process
Research Finance will be notified by the Research Pharmacy once an order is completed and product is shipped to a site. Billing and collections services will be provided on a monthly basis over the course of 24 months as Investigational Product is shipped to the institutions/sites. Billing to Gentium will occur on the 16th of each month and invoices will be based on a monthly report of all distributions made by Research Pharmacy. Invoices to the sites will reflect Gentium's pricing agreement with each of the designated sites/institutions. Research Finance will provide a report of any outstanding balances as well as the current status of collections. Should balances remain outstanding beyond 30 days, Gentium will be notified immediately. Any site that does not pay within 60 days will be placed on administrative hold and no additional Investigational Product will be shipped until all past payments are made.

All payments received from sites/institutions will be submitted to Gentium per the terms of Attachment 3. Research Finance will also provide a monthly sales and inventory report reflecting shipments to the sites, amount billed and inventory information at Research Pharmacy and at the sites.

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Attachment 3

BUDGET
23.12 AND PAYMENT INFORMATION

COMPENSATION:

1. Gentium shall compensate CRO as follows:

2. CRO will be compensated fees in USD for Services provided as outlined below:

2.1 Drug Supply Management

- Project Set Up - $***
- Trial Set up
- Shipping
- Reporting
- Drug Accountability
- Billing & collections for each designated site/institution – Sites will be billed at $*** per unit
- Per Unit CRO Costs - $*** per unit for up to 1,000 units within a 24 month period (unit defined as 1 shipping unit)1

BILLING of GENTIUM:

1. CRO shall submit invoices to GENTIUM.

2. Invoices must reference the appropriate purchase order number and shall be sent to the attention of:

Gentium S.p.A
Salvatore Calabrese
Piazza XX Settembre, 222079
Villa Guardia (Co) Italy
scalabrese@gentium.it
+39 031 385287

3. Invoices will be paid by GENTIUM within thirty (30) days of receipt.

4. Payments will made based on the project set up costs as referenced in this Attachment-3.

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1 In the event the total units (over a 2 year time period) exceeds 1,000 units, each incremental unit will be charged at $*** per unit. The difference of the discounted rate between $*** and $*** per unit (or $***) will be applied as a credit toward towards the costs of future projects/agreements between GENTIUM and CRO if subsequent projects/agreements are executed within 2 years from execution of this agreement.

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SITE COLLECTION AND GENTIUM PAYMENT:

1. CRO will bill and collect from sites/institutions $*** per unit received. CRO will deduct $*** per unit shipped from amount received and pay the balance of $*** to Gentium.

2. Investigational Product will only be distributed to the individual sites that are approved by Gentium.

3. Any sites/institutions that do not remit payment in full within sixty (60) days of receipt of invoice from CRO will be placed on hold and not be allowed to receive additional shipments until account is reconciled.

4. All collections received will be processed at the end of the month and Gentium will bepaid in accordance with the electronic method outlined in Section 5.2 and 5.3 of theWork Order on the first week of the following month.

5. In the event of a dispute, CRO shall re-submit any undisputed amounts in a separate invoice for payment, containing all undisputed items while the parties are working toward resolving the disputed amounts. Disputed items will be paid upon resolution of said dispute.

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ATTACHMENT 5

Title: Investigational Drug and Financial Management Plan Version No 1.0
Effective Date: _____
Department: Research Pharmacy Protocol #: Gentium 2006-05

Contacts (Gentium S.p.A.):
In the event of an emergency, or if additional information is required, the following individuals should be contacted (in this order):

A. Robin Hume, M.S.; Director, Regulatory (Gentium) rhume@gentium.com
212-332-1669 (Phone) 646-705-1299 (mobile) 212-332-1668 (fax)

B. Alison Hannah, M.D.; Medical Monitor (Gentium) ahannah@gentium.it
707-824-4684 (Phone) 707-328-0808 (mobile) 707-824-4685 (Fax)

C. Massimo Iacobelli, M.D.; Senior Vice President (Gentium) miacobelli@gentium.it
011-39-031-385217 (Phone) 011-39-031-385241 (Fax)

Contacts (US Oncology):
A. ***, Associate Director ***
*** (Phone) *** (Fax) *** (Cell)

B. ***, PharmD, Clinical Manager ***
*** (Phone) *** (Fax)

C. ***, Research Finance - Accounts Receivable
*** (Phone) *** (Fax) ***

D. ***, Sr. Accountant
***
*** (Phone)

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Pharmacy Overview

Contents- Defibrotide VOD 24x kits
Shipping Container- Insulated box shipped at room temperature. Do not freeze.

Distribution and Processing by 8326016568US Oncology Research Pharmacy ("Research Pharmacy")

1. The Research Pharmacy will receive the order via fax or email from the site/ institution and will review for accuracy.
2. The pharmacy personnel will enter into the eDRAF inventory system the number of boxes requested for distribution to the specific site/ institution.
3. The investigational product boxes will then be pulled from the research pharmacy stock for that study. All inventory is counted at the time of each distribution. Only cartons containing 24 ampoules will be shipped; partial orders (fewer than 24 ampoules) will not be made.
4. After the order is pulled, a Pharmacist will complete a Quality Check ("QC") by reviewing the order and investigational product for accuracy.
5. Once reviewed, the pharmacy personnel will generate a packing list that will be included with the investigational product in the shipment to the site.
6. All investigational product will be batched and shipped to the site via 2-day Fed-Ex. At the site's request, if more urgent shipping is needed, shipments can be sent via Overnight Fed-Ex and the overnight shipment charges will be billed to the site's Fed-Ex account.
7. All distributions will be strictly as a bulk supply to the site/ institution. It is expected that they will maintain patient specific accountability records.

Receipt Confirmation
Upon receipt at the site, the site/ institution will confirm the items were received in good condition and appropriate temperature via fax return of Gentium Packing list to Research Pharmacy.

Reconciliation
In accordance with Attachment 2 of the Work Order dated September September 28, 2009, the Research Pharmacy will coordinate the return of any unused investigational product from the sites back to the Research Pharmacy. Research Pharmacy will account for and will destroy all unused Investigational Product at the completion of the trial. In the event that the Investigational Product becomes commercial, the Research Pharmacy will coordinate the return of any unused investigational product from the sites back to Research Pharmacy. Gentium or its designated vendor, will coordinate directly with the sites for replacement of the Investigational Product with commercialized drug.

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Investigational Product Management Plan

Receipt of Notification and Authorization to Ship:

1. Research Pharmacy's main point of contact at Gentium for this trial is Robin Hume and Alison Hannah.

2. Notification of approved sites/ institutions to receive Investigational Product will be provided by Gentium to Research Pharmacy via fax 832-601-6281or 877-714-4347 and/or via email (mailto:gentium@usoncology.com) to the attention of Son Han/ Jennifer Davis. The list of authorized sites will include the following information: Site or Institution name/ Site number/ Name of Principal Investigator/ Shipping Address/ Shipping Contact Person and phone number/ Site Fed-Ex number (if available). The active site list will be updated as changes occur and sent to US Oncology as changes occur. If a site contacts US Oncology that is not approved or is on administrative hold, US Oncology will inform the site of such and will also inform Gentium that such site has requested product.

3. Research Pharmacy will contact Research Finance to ensure site is in good payment standing. If site is 30 day delinquent in payments, Finance will notify site of this delinquency. If the site is 60 days delinquent in payments, Research Pharmacy will hold all further shipments until this is resolved.

4. If contacted by a site not on the approved listing, Research Pharmacy shall email Robin Hume and Alison Hannah at Gentium; Research Pharmacy will notify site that Gentium will contact them to process their approval to participate on the trial.

5. As new sites are identified by Gentium, Gentium will send Research Pharmacy an updated distribution listing. Research Pharmacy will provide an updated approved listing to Research Finance and Research Contracts on a monthly basis.

6. Sites may request an initial shipment of medication. Re-supplies will be sent as requests are submitted.

7. Research Pharmacy will NOT ship Investigational Product without receipt of a faxed or emailed Fax Order Request form from an authorized site/ institution.

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Order Request Process

8. Approved site/ institution will submit the Fax Order Request form either via fax to 832-601-6281 or 877-714-4347 or email to Gentium@usoncology.com.

9. Order requests submitted by 4:00pm CT will be shipped that day. All requests received after 4:00 p.m. cst time, will be processed the following day.

10. Supply shipments will be shipped out on Monday through Wednesday via 2 day Standard Fed-Ex. Overnight shipments, made only upon site request, can be shipped Monday through Thursday and will be charged to the site/ institution. No supplies will be shipped on Friday unless otherwise requested by site/ institution. In the event that a shipment must be dispatched on Friday, a request for this service must be made via email to Son Han/ Jennifer Davis.

Preparation of Documentation and Shipment:

11. For each Fax Order Request form received, Research Pharmacy will review request for accuracy and create a packing list. The request will then be processed through our electronic system to track inventory quantities shipped out. The information captured will include, but is not limited to, the following:

- Shipment number
- Site number
- Total number of boxes requested
- Investigator and/or contact name
- Site name, address, and telephone number
- Type of Shipment Requested
  - Initial stock supply
  - Initial pt supply (Pt ID)
  - Pt resupply (Pt ID)
  - Method of Delivery
  - Standard 2-day delivery
  - Overnight delivery
  - Site Fed-Ex number

12. Pharmacist will provide Investigational Product request to pharmacy personnel for fulfillment.

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13. Upon completion, the packing list(s) will be reviewed against the Fax Order Request form and items pulled by the Pharmacist. The Registered Pharmacists ("RPh") will ink-stamp the packing list as the final QC check. Copies of the Fax Order Request form and Gentium Packing list will be maintained within the appropriate study files.

14. Upon generation of the shipping label, a pharmacy representative will check the contents of the shipment, as well as the ship to address on the label, against the customer-supplied request. If all data matches, the representative will ink-stamp and date the bottom left hand corner of the Gentium packing list.

15. All sealed shippers will be transported to the designated pick-up area for shipment within Research Pharmacy.

Confirmation of Shipment:

16. Once the shipment has been completed, copies of the Fax Order Request form and Gentium Packing list that were sent with the shipment will be maintained in the study file at USON Investigational Pharmacy.

17. Confirmation of each shipment will be sent via e-mail to Gentium (rhume@gentium.com). Confirmation will include: Site name/site number, Number of boxes sent, Type of shipment requested.

18. Weekly reports of shipments sent out will be sent to the entire Gentium team via email to
thillman@gentium.com
rhume@gentium.com
miacobelli@gentium.it
scalabrese@gentium.it
ggemignani@gentium.com

Confirmation of Receipt:

19. Upon receipt, the site is required to sign, date the Gentium Packing list and fax back I immediately confirming receipt was in good condition.

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20. If received damaged or expired, site will need to contact Research Pharmacy for Investigational Product Return form. Once the form is complete, site will return Investigational Product as is referenced in Section 23 below.

21. As applicable, a replacement request utilizing the Fax Order Request form will be required either via fax to 832-601-6281 or 877-714-4347 or email to Gentium@usoncology.com.

Product Returns

22. In accordance with Section 7.3 terms of the Work Order dated September 28, 2009 Gentium acknowledges and agrees that they will be solely liable for any damaged Investigational Product damaged during shipment (through no fault of US Oncology) and its replacement to the site.

23. Sites/ institutions will be allowed to return damaged or expired unused whole boxes back to the Research Pharmacy. If product is being returned because it is damaged the site must contact US Oncology for shipping instruction of damaged product. Research Pharmacy will notify Gentium of any such returns. Gentium will send US Oncology a list of batch number and expiration dates. US Oncology should confirm batch number and expiration before any site is permitted to return product due to expiration.

24. Investigational product returns are received from the sites are sorted by pharmacy personnel.

a. Upon arrival, all Investigational Product returns will be segregated from incoming stock. Incoming shipments will be fully checked in and stocked before any returns are processed. All returns will be processed in the area specifically designated for returns.
b. All shipments will be inspected for damage. Any damaged Investigational Products will be quarantined in the returns cage. Damaged cartons should be replaced free of charge to the site.

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Financial Management Plan

Receipt of Site Authorizations:

25. List of approved sites/institutions on study able to receive Investigational Product will be provided by Research Pharmacy to US Oncology Research Finance ("Research Finance) via email to researchreceiveables@usoncology.com with a copy to Research Contracts at contractservices@usoncology.com. Gentium will maintain the approved site/institution list and will update Research Pharmacy as new sites are approved. Research Pharmacy will notify and update Research Finance with a copy to Research Contracts.

26. Site information required for invoicing will include Site name, billing address, billing contact name, phone number and email address, invoice preference of paper or electronic, Site PI name, and Site CRC name, phone and email.

Billing and Collections Process

27. Research Pharmacy will provide a monthly report of Investigational Product shipped to Research Finance on the 10th of each month.

28. Research Finance will generate invoices for all orders shipped to approved sites listed on the monthly report received from Research Pharmacy on the 16th of the month or next business day. US Oncology Research Finance will distribute invoices to the sites within 3 days in the site preferred method (electronic or paper).

29. Accounts not paid in full within thirty days of receipt of an invoice will receive notification from US Oncology requesting immediate payment. If the site/institution account is not current within 60 days Research Finance will notify Research Pharmacy and the site will not be allowed to order additional defibrotide. Copy of this notification will be sent to Gentium via email, and the site/institution will be placed on hold for new orders.

30. In the event site/institution does not agree with the outstanding balance due, Research Pharmacy will provide Research Finance with a copy of the confirmation of any receipt of Investigational Product, with a copy to Gentium. These items will be reconciled with the outstanding balance and sent to the site/institution by Research Finance with a copy of their invoice.

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Should any overcharges occur, Research Finance will reconcile the error with Research Pharmacy and the site/institution and a credit will be issued accordingly for the outstanding balance.

31. Research Finance will provide Gentium within one week of the end of each month a monthly report of outstanding balances due.

Payment Distribution Process to Gentium

32. All payments received will be processed at the end of the month and verified against outstanding invoices.

33. For services rendered by CRO, Accounts Payable will deduct $318 per unit shipped from the amount collected for each order processed.

34. Accounts Payable will distribute the remaining amount collected to Gentium by wire transfer the first week of the following month.

Approval Page:

Approved By:

/s/ Stephen Smith	09-29-09 Date
/s/ Gary G. Gemignani	10.1.2009 Date

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