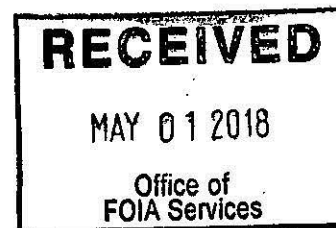




18-04226-E



FOIA / PA Officer John Livornese
U.S. Securities & Exchange Commission
FOIA Office
100 F Street NE, Mail Stop 5100
Washington, DC 20549

May 1, 2018

Dear Mr. Livornese:

I request pursuant to the Freedom of Information Act (FOIA) 5 U.S.C. § 552. As Amended by Public Law No. 104-231, 110 Stat. 3048, copies of the following agreements, based on the **CT Order File No. 0-19635 - CF# 22440**.

Exhibit 10.1 to Form 10-Q filed on 08/07/2008 by Genta Inc DE/.

Exhibit Title: Supply Agreement

CIK: 880643

Sectilis will pay up to \$61 for research, copies and review fees for all of the abovementioned agreements. Please forward all releasable material for copying. My daytime telephone number is 202-798-8809. Please call me or e-mail at research@sectilis.com to discuss the total cost or estimated cost of this research/copies should the amount exceed the price indicated in this request.

Sincerely,

Stella Vasconcellos
Research Assistant
Sectilis LLC
6931 Arlington Rd. # 580
Bethesda, MD 20814



UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
STATION PLACE
100 F STREET, NE
WASHINGTON, DC 20549-2465

Office of FOIA Services

May 17, 2018

Ms. Stella Vasconcellos
Sectilis LLC
6931 Arlington Rd. # 580
Bethesda, MD 20814

RE: Freedom of Information Act (FOIA), 5 U.S.C. § 552
Request No. 18-04226-E

Dear Ms. Vasconcellos:

This letter is in response to your request, dated and received in this office on May 01, 2018, for information regarding Exhibit 10.1 to the Form 10-Q filed on August 07, 2008, by Genta, Inc., DE.

The search for responsive records has resulted in the retrieval of 38 pages of records that may be responsive to your request. They are being provided to you with this letter.

If you have any questions, please contact me at smithLR@sec.gov or (202) 551-8328. You may also contact me at foiapa@sec.gov or (202) 551-7900. You also have the right to seek assistance from Lizzette Katilius as a FOIA Public Liaison or contact the Office of Government Information Services (OGIS) for dispute resolution services. OGIS can be reached at 1-877-684-6448 or Archives.gov or via e-mail at ogis@nara.gov.

Sincerely,

A handwritten signature in black ink, appearing to read "L. Smith".

La Kisha R. Smith
FOIA Research Specialist

Enclosure

SUPPLY AGREEMENT

This Agreement is effective as of May 1, 2008 and is made by and between Genta Incorporated, a corporation of the State of Delaware, with an address at 200 Connell Drive, Berkeley Heights, New Jersey 07922 (together with its Affiliates, "Customer") and Avecia Biotechnology, a corporation of the State of Delaware, with an address at 125 Fortune Boulevard, Milford, Massachusetts 017567 ("Avecia"). Customer and Avecia are sometimes referred to herein individually as a "Party" or collectively as "Parties".

WHEREAS, Avecia has knowledge and experience with regard to the GMP manufacture of oligonucleotides with significant expertise in process technologies, research and development and process scale-up;

WHEREAS, Customer conducts research and development in relation to certain oligonucleotides with a view to conducting clinical trials and seeking registration of the oligonucleotides in drug products for the treatment of human diseases;

WHEREAS, Customer has an oligonucleotide compound, identified by the trademark "Genasense," which is currently in Phase 3 clinical trials; and

WHEREAS, Customer and Avecia desire to enter into this Agreement to set forth the terms and conditions upon which Avecia will supply certain of Customer's requirements for API.

NOW, THEREFORE, intending to be legally bound, it is hereby agreed as follows:

1. Definitions.

"Affiliate" means any person, organization, corporation or other business entity, controlling, controlled by or under common control with Customer.

"Agreement Year" means any period of twelve consecutive calendar months beginning with the first full calendar month following the Effective Date.

"Applicable Laws" means applicable laws and regulations of the United States of America, including all such federal, state and local laws, rules, regulations and ordinances.

"Customer Partner" means any third party to whom Customer has granted the right to distribute, market or sell API (or any drug product which contains API).

"Confidential Information" means any technical, business, financial and other commercial information of a confidential nature disclosed (whether disclosed in writing, orally, by way of sample or by any other means and whether directly or indirectly) by either Party (the "Disclosing Party") to the other Party (the "Receiving Party").

"Current Process" means the process validated by Avecia in 2003 for the manufacture of API.

"Delivery" or "Delivered" as used in Sections 7 and 10 means ex-works Avecia's facility located in Milford, MA.

“Effective Date” means the date of this Agreement.

“Facility” means Avecia’s cGMP facility located in Milford, MA, which currently consists of the facilities designated as M1 and M2.

“cGMP” means current good manufacturing practice and standards as provided for (and as amended from time to time) in the European Community Directive 91/356/EEC (Principles and guidelines of good manufacturing practice for medicinal products) and the Current Good Manufacturing Practice Regulations to the US Code of Federal Regulations, Title 21 (21 CFR 210 and 211) in relation to the production of pharmaceutical intermediates and active pharmaceutical ingredients, as interpreted by ICH Harmonized Tripartite Guideline, Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients, Q7, and subject to any arrangement, additions or clarifications agreed from time to time between the Parties in the Quality Agreement.

“FDA” means the U.S. Food and Drug Administration, or any successor entity thereto or foreign counterpart thereof.

“Governmental Authority” means any (1) nation, state, county, city, town, village, district or other jurisdiction of any nature, (2) federal, state, local, municipal, foreign or other government, (3) governmental or quasi-governmental authority of any nature (including any governmental agency, branch, department, official or entity and any court or other tribunal, including an arbitral tribunal), (4) multi-national organization or body, or (5) body exercising, or entitled to exercise, any administrative, executive, judicial, legislative, police, regulatory or taxing power of any nature.

“Independent Intellectual Property” shall have the meaning set forth in Section 13.

“Intellectual Property” means patents, patent applications, all provisional, divisional, continuations, renewals, continuations in part, reexaminations, patents of addition, supplementary protection certificates, extensions, letters of patent, registration or confirmation patents and reissues with respect to any patents described in the foregoing clauses, any know how, trade secrets, data, technology and technical information.

“Latent Defect” means an impurity in API caused by Avecia, other than an impurity which is an intrinsic feature of API as produced by Avecia and present in numerous historic batches, which would not be expected by Customer to be in such API, either by type or degree of impurity, and which is not known to Customer or not readily discoverable by Customer at the time of delivery of such API, using commercially reasonable inspection procedures.

“New Process” means process changes to the Current Process as contemplated in Section 3 and Appendix 3.

“New Process Strategy” is the strategy for implementing a New Process as set forth in Appendix 3.

“New Process Validation” is the release by Avecia QA of three batches of API produced in accordance with the New Process, with the milestone time point being the release of the final batch.

“PAI” means “Pre Approval Inspection” which is the formal inspection of the Facility by a Regulatory Authority for the purpose of approving the Facility for manufacture of commercial quantities of API.

“API” means G3139 (AAC), that certain all-phosphorothioate oligonucleotide consisting of 18 modified nucleic acid bases with the sequence and chemical structure set forth in Appendix 1, and currently referred to under the trademark “Genasense.”

“API Requirements” means conformance with (a) cGMP, (b) API Specifications, (c) the current validated process and (d) the Quality Agreement.

“API Release Date” means, with respect to any API sold by Avecia to Customer hereunder, (i) the Avecia QA release date, if Avecia is responsible for all API release testing; or otherwise (ii) the date of the completion of manufacturing and sign off by Avecia QA on the executed batch records and the analytical report for all API release testing under Avecia control.

“API Specifications” means the specifications for the API as agreed and attached hereto as Appendix 4, as may be modified from time to time by the Parties.

“Quality Agreement” means the document agreed to by the Parties in the form attached hereto as Appendix 5, as amended, supplemented or restated from time to time.

“Recall” shall have the meaning set forth in Section 18.6.

“Regulatory Authority” means the FDA or any court, tribunal, arbitrator, agency, commission, official or other instrumentality of any federal, state, county, city or other political subdivision, domestic or foreign, that performs a function for such political subdivision similar to the function performed by the FDA for the United States with regard to the approval, licensing, registration or authorization to test, manufacture, promote, market, distribute, use, store, import, transport or sell a product in the defined territory or political subdivisions.

“Regulatory Authority Approval” means the first marketing approval by any Regulatory Authority for the drug product containing API.

“Regulatory Requirements” means (i) any and all permits, licenses, filings and certifications required by the US Food and Drug Administration (FDA), US Occupational Safety and Health Administration (OSHA), US Environmental Protection Agency (EPA), The International Conference of Harmonization Q7 (ICH Q7), The United States Pharmacopeia, (USP), The European Pharmacopeia (EP), the European Medicines Agency (EMA), and compliance with the cGMP of the FDA, ICH Q7, USP, EP and EMA, applicable to any manufacturing or processing activities hereunder or facilities at which any of the manufacturing or processing activities hereunder are performed, and (ii) any Laws, rules, guidelines, regulations, and standards of any governmental authority within the United States (including, without limitation, EPA, OSHA, the Drug Enforcement Administration (DEA) and state and local authorities), that apply to any manufacturing or processing activities hereunder or the Facility or other facilities at which any of the manufacturing or processing activities hereunder are performed.

“Requalification Plan” means the plan submitted to the FDA in writing in 2006, which describes the actions which will be taken to reestablish manufacture of API using the Current Process at the Facility.

“Rolling Forecast” shall have the meaning set forth in Section 6.2.

“Seizure” shall have the meaning set forth in Section 18.6.

“Shelf Life” means, with respect to particular quantities of API, the total time from date of such API’s manufacture (such date of manufacture determined by reference to Avecia’s approved master batch records) until the latest point in time at which such API’s conformance with API Specifications can, in consideration of the passage of time, continue to be assured.

“Special Mechanism” shall have the meaning set forth in Section 4.2.

“Waste” shall mean any “hazardous substance” and/or “hazardous material” as provided under the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA), any “hazardous waste” as provided under the Resource Conservation and Recovery Act (RCRA), and/or any other waste material, pollutant and/or contaminant of any kind including, without limitation, any routine process waste or any by-product arising from any activities conducted pursuant to this Agreement.

2. Residual Commitments.

Within three (3) months of issuance of the first Regulatory Authority Approval, Customer will reimburse Avecia for those materials (Amidites and Solid Support) purchased by Avecia in accordance with the 2004 forecasts given by Customer to Avecia in the first calendar quarter of 2004, provided that (a) Avecia has already consumed these raw materials where possible, so the original total of \$2,693,000 has been mitigated to a residual liability of \$1,700,000 and (b) Avecia will continue to consume these materials where commercially reasonable, and if the materials are consumed in manufacture for Customer or any other third party the benefit will be credited to Customer. Other than a maximum liability of \$1,700,000 for residual raw materials owed by Customer to Avecia as expressly set forth above, neither Party shall owe the other Party any consideration or compensation for anything arising prior to the Effective Date.

3. Current Process; New Process Implementation; Other Process Improvements.

3.1 The initial pricing, campaign size and capacity availability for API formulated for this Agreement are based upon the Current Process. In anticipation of the possibility for significant beneficial changes to the Current Process, the Parties have developed a strategy for implementing a New Process, which strategy is attached hereto as Appendix 3 (the “New Process Strategy”). The New Process Strategy establishes three milestones or stages: (a) definition and demonstration of the New Process (stage 1); (b) investigation of the New Process robustness and critical parameters in

- preparation for the New Process validation manufacture (stage 2); and (c) New Process Validation (stage 3). The Parties shall verify that the New Process Strategy complies with all Regulatory Requirements prior to its implementation.
- 3.2 In the event that the Parties agree to implement the New Process Strategy, Customer shall make the following payments to Avecia: (a) an initial payment of \$100,000 at the time that the Parties agree to proceed with stage 1; (b) \$1,900,000 upon the completion of stage 1 and agreement to proceed with stage 2; and (c) \$2,000,000 payable twelve (12) months following the completion of stage 3.
- 3.3 Other improvements to the Current Process not constituting a New Process and improvements to the New Process after implementation of the New Process shall be implemented consistent with the provisions of the Quality Agreement, with the assumption that the Parties shall share equally in the costs and benefits of any such improvements. Prior to moving forward with any such proposed improvement, the Parties shall agree on the type of costs to be so shared, it being anticipated that such shared costs would include, without limitation, the costs of Avecia's development effort, stability studies, any essential engineering batches and third party consultants. Costs which would not be shared include, without limitation, the cost of any revalidation batches and Customer costs associated with necessary regulatory filings. At Customer's request, Avecia shall provide to Customer detailed documentation sufficient to verify the shared costs and benefits relating to any such improvement.
- 3.4 The costs and benefits associated with any process improvements or changes which do not require the approval of Customer under the Quality Agreement shall be for the account of Avecia.

4. Capacity; Capital or Other Investment.

- 4.1 As of the Effective Date, Avecia has at the Facility installed equipment and assets with the technical capability to produce API at the rate of 164 kilograms per year using the Current Process, which could be increased to 300 kilograms per year with the implementation of the New Process (the "Facility Capacity"). The actual available capacity for the supply of API to Customer is determined by the number of full time equivalent employees available for the production of API for Customer (the "Available Capacity". The Available Capacity as of the Effective Date is a maximum rate of 11 kilograms per year. If an increase in Available Capacity is required by Customer forecasts, the Available Capacity shall be increased by Avecia to: the maximum rate of 22 kilograms per year during the seventh through the twelfth month after the first formal forecast and firm purchase order; the maximum rate of 84 kilograms per year during the thirteenth through the twenty-fourth month; and the maximum rate of 164 kilograms per year thereafter. In the event of the implementation of the New Process, the applicable Available Capacity would be approximately double that applicable under the Current Process.
- 4.2 In the event that Customer anticipates that its requirements for API will be in excess of the Available Capacity set forth in Section 4.1, Avecia and Customer will work together, in good faith, to agree on special mechanisms to accommodate such excess requirements. Such "Special Mechanisms" might include, among other things, a

ramp-up in manufacturing resources, new plant investment and process scale-up. Special Mechanisms might require, among other things, changes in API forecasting and manufacturing lead times, binding commitments to purchase API and advance payments by Customer to support one time costs and investments. This Section 4.2 is intended, simply, to indicate the good faith intention of the Parties to seek solutions to the possible changing circumstances of Customer resulting in a need for API in excess of Avecia's ability to supply. For the avoidance of doubt, if Customer's requirements fall within the Available Capacity pursuant to Section 4.1, then no Special Mechanisms will apply and no further accommodations or payments will be required by Customer.

5. Term.

This Agreement shall take effect as of the Effective Date and shall remain in effect until the date which is the earlier of (i) December 31, 2017 and (ii) the seventh anniversary of the date of Regulatory Authority Approval (the "Initial Term"). Either Party may terminate this Agreement as of the end of the Initial Term upon the giving of at least two (2) years prior written notice to the non-terminating Party; provided that such notice must be given during the month of December; provided, further, that the first time either Party may give such two (2) year notice is the date which is the earlier of (i) December 1 of the fifth year following Regulatory Authority Approval and (ii) December 1, 2015. In the absence of such notice, this Agreement shall continue in effect thereafter on a year to year basis, with either Party having the right thereafter to terminate this Agreement upon the giving of at least two (2) years prior written notice to the non-terminating Party.

6. Sale and Purchase; Forecasts; Minimum Order Size.

- 6.1 During the term of this Agreement, Avecia shall sell and Customer shall purchase, and Customer shall cause Customer's Affiliates and Customer Partners to purchase, a minimum of eighty percent (80%) of the combined global requirements of Customer and such Affiliates and Customer Partners of API during the term of this Agreement; provided, however, that, during any single Agreement Year, Avecia shall sell and Customer shall purchase, and, if applicable, shall cause Customer's Affiliates and Customer Partners to purchase, (i) when the Rolling Forecast for such Agreement Year is 100 kilograms or less of API, a minimum of seventy percent (70%) of the global requirements of Customer and its Affiliates and Customer Partners and (ii) when such Rolling Forecast is greater than 100 kilograms a minimum of seventy five percent (75%) of such requirements.
- 6.2 Within the first three working days of each calendar month during the term of this Agreement, Customer shall provide to Avecia a written forecast of the requirement for API of Customer (and, if applicable, of its Affiliates and Customer Partners) during such calendar month and the next succeeding seventeen-month period (the "Rolling Forecast"). The forecasted quantity with respect to the first six months of each Rolling Forecast shall constitute a firm commitment by Avecia to sell and

Customer (and, if applicable, Customer shall cause its Affiliates and Customer Partners) to purchase such forecasted quantity. The forecasted quantity with respect to the seventh through the ninth month of such Rolling Forecast shall be a firm commitment by Avecia to sell and Customer (and, if applicable, Customer shall cause its Affiliates and Customer Partners) to purchase a minimum of fifty percent (50%) of such forecasted quantity up to a maximum of one hundred twenty five percent (125%) of such forecasted quantity. The forecasted quantity with respect to the tenth through the eighteenth month of the Rolling Forecast shall be an indicative quantity with no commitment on either Avecia or Customer.

- 6.3 Upon either Party's request, the Parties will work together, in good faith, to permit Avecia to increase the Available Capacity and, if applicable, agree upon a Special Mechanism. Notwithstanding any provision of this Section 6, in no event shall Avecia be required to supply API under this Agreement in an amount greater than the Available Capacity (unless the Parties have agreed to increase the Available Capacity using a Special Mechanism pursuant to Section 4.2, in which case the Parties will work together, in good faith, to permit Avecia to increase the Available Capacity). If Avecia has not increased the Available Capacity, Customer may purchase its API requirements in excess of the Available Capacity from a third party until Avecia can meet such requirements and such purchases shall count towards Customer's minimum purchase requirements referred to in this Section 6; provided, however, that, if Customer fails to negotiate in good faith, notwithstanding Avecia's willingness to do so, a Special Mechanism to increase the Available Capacity, any such purchases by Customer of API from a third party shall not count towards Customer's minimum purchase requirements referred to in this Section 6.
- 6.4 Customer shall order API in quantities of at least ten kilograms per campaign, provided that Customer may request campaign volumes of less than ten kilograms and the price of such campaign volumes shall be determined through good faith negotiation of the Parties.
- 6.5 No Rolling Forecasts will be issued prior to Regulatory Authority Approval. The first Rolling Forecast following Regulatory Authority Approval will be for zero kilograms in the first six months. Avecia is allowed complete discretion to bring forward the timing of the first 11Kg campaign forecast in the seventh to ninth month period to any point within the third through the sixth month period of the first Rolling Forecast.
- 6.6 If due to unusual or unanticipated circumstances, Customer has a requirement for API prior to Regulatory Authority Approval, the Parties shall work together, in good faith, to fulfill and otherwise accommodate such requirement.

7. Delivery; Title; Invoices; Payment Terms.

- 7.1 API will be Delivered ex-works, the Facility. Notwithstanding any actions taken by Avecia on behalf of Customer as hereinafter set forth in this Section 7, title and risk of loss in the API shall pass to Customer on the earlier of (i) transfer at the Facility to Customer's designated agent or carrier and (ii) Avecia's placement of such API in its cGMP storage area at the Facility at Customer's request.
- 7.2 Avecia shall arrange, on behalf of Customer, for the shipment of API to the location as stated on the relevant purchase order. Avecia shall package API in a manner

consistent with good commercial practices, validated shipping procedures that comply with Regulatory Requirements (including, without limitation, shipment in approved containers), and any agreed-upon shipping specifications and the Quality Agreement.

- 7.3 Subject to the proviso to this Section 7.3, if Avecia Delivers any portion of API later than the date of Delivery set out in the relevant purchase order then:
- 7.3.1 a 2.5% reduction in price shall be made with respect to that portion of the shipment that is Delivered more than thirty (30) days but no more than sixty (60) days late;
 - 7.3.2 a 5% reduction in price shall be made with respect to that portion of the API that is Delivered more than sixty (60) days but no more than ninety (90) days late; and
 - 7.3.3 a 7.5% reduction in price shall be made with respect to that portion of the API that is Delivered more than ninety (90) days late; provided, however, that no such reduction in purchase price shall be applicable to the extent that any such delay (i) results from an event of force majeure as set forth in Section 15 or (ii) is caused by Customer.
- 7.4 Avecia shall seek, in good faith, to make Delivery of amounts ordered by Customer in each purchase order within seven days of the Delivery Date agreed to by the Parties in such purchase order. Avecia shall promptly notify Customer of any occurrence expected to inhibit Avecia's ability to provide on-time Delivery of API meeting the terms and conditions of this Agreement. In addition, Avecia shall promptly inform Customer of any notice, written or oral, received from any of its subcontractors regarding a possible shortage or inability to obtain or supply API raw materials or any components or materials used in the manufacture of API.
- 7.5 To the extent that Customer obtains quantities of API from an alternative source as a result of a delay of ninety (90) days or more, then Customer shall be relieved from its obligations to purchase any quantities of API identified in any outstanding forecasts or orders to the extent that and for so long as Avecia has failed or is reasonably anticipated to fail to supply such quantities as a result of the delay, provided that the amount of API in such firm orders shall count toward Customer's percentage purchase requirements herein.
- 7.6 Until Customer, its Affiliates and Customer Partners shall have purchased an aggregate of fifty (50) kilograms of API pursuant to this Agreement, Avecia shall issue invoices for API three (3) months in advance of the API Release Date for such API, as estimated by Avecia, and Customer shall pay, or arrange to have paid, to Avecia: (i) thirty percent (30%) of the amount due under each such invoice by no later than thirty (30) business days after Customer's receipt of such invoice and (ii) the remaining seventy percent (70%) of such amount by no later than five (5) business days after such API Release Date. After Customer, its Affiliates and Customer Partners shall have purchased an aggregate of fifty (50) kilograms of API pursuant to this Agreement, Avecia shall issue invoices for API on the API Release Date for such API and Customer shall pay, or arrange to have paid, to Avecia one hundred percent (100%) of the amount due under each such invoice by no later than five (5) business days after such API Release Date. If Avecia is not responsible for all API release testing, then the invoicing point will be the completion of

manufacturing and sign off by Avecia QA on the executed batch records and the analytical report for all API release testing under Avecia's control.

- 7.7 In addition to the supply of API as contemplated hereunder, the Parties may develop and agree to documents, each entitled a scope of work, setting forth the terms and conditions pursuant to which Avecia would undertake for Customer development work or other service projects coming within the terms of this Agreement (such as, for example, service projects related to the matters set forth in Sections 17.7 and 17.8). Changes to any such scope of work shall be agreed to in writing between the Parties. Invoices for services under any such scope of work will be issued as follows: an initial invoice in the amount equal to fifty percent (50%) of the fee for such services shall be issued by Avecia to Customer on agreement to the scope of work; and a final invoice for the remainder of such fee shall be issued by Avecia to Customer on completion of the services under such scope of work. Unless otherwise stated in the scope of work, "completion" will be defined as delivery of the draft report. Customer shall pay such invoices within thirty (30) days of Customer's receipt of any such invoice.

8. Exclusivity.

During the term of this Agreement, neither Avecia nor its Affiliates shall develop, manufacture, supply or commercialize API or any generic equivalent of API other than for Customer, its Affiliates or Customer Partners. In the event that Avecia terminates this Agreement for any reason other than the material breach by Customer of this Agreement, neither Avecia nor its Affiliates shall develop, manufacture, supply or commercialize API or any generic equivalent of API, for a period of two (2) years following the later of the termination of this Agreement or the end of the Initial Term. In the event that Customer terminates this Agreement for any reason other than a material breach by Avecia of this Agreement, Avecia shall not be subject to the provisions of this Section 8 following the date of such termination, but otherwise the restrictions of this Section 8 shall continue in effect for a period of two (2) years following the later of the termination of this Agreement or the end of the Initial Term. For clarity, the foregoing shall not be construed as granting Avecia any rights under Customer's Intellectual Property.

9. Price.

- 9.1 The price for API shall be determined in accordance with Appendix 2.
- 9.2 The price for API hereunder excludes any applicable sales, use, consumption, value added or excise taxes, duties, tariffs and other similar assessments which may be imposed by any Governmental Authority as a result of the sale of API hereunder. The Parties shall cooperate and take any reasonable steps to reduce or eliminate such charges.

10. Acceptance of API.

- 10.1 Within thirty (30) days of Delivery of API to Customer and except in the case of a Latent Defect, Customer shall notify Avecia of any claim for shortage of API or that all or some of such API does not meet API Requirements. In the absence of such notification, such API shall be deemed accepted by Customer as complete and in accordance with API Requirements. In the event of a Latent Defect, Customer shall have forty-five (45) days from the earlier of (i) the date that Customer becomes aware of such Latent Defect, (ii) the date that the applicable API is used by Customer (or its Affiliate or Customer Partner, if applicable) in the manufacture of its drug product and (iii) nine (9) months after the API Release Date of the applicable API to notify Avecia of any claim with respect thereto. In the absence of such notification, such API shall be deemed accepted by Customer as in accordance with API Requirements even as to Latent Defects.
- 10.2 If Customer notifies Avecia in accordance with the provisions of Section 10.1 that API does not conform to API Requirements or that the amount of API is less than the amount set forth in the applicable invoice, Customer shall advise Avecia of the manner in which API does not conform to API Requirements or shall document the shortage. In the event that Avecia accepts such determination, Avecia shall, at Customer's option, process free of charge sufficient API or reimburse the price to Customer, to make up such shortage or replace defective API and shall dispose of the defective API at Avecia's cost.
- 10.3 If a dispute arises between the Parties as to any failure of API to meet API Requirements which dispute is not resolved by the Parties within thirty (30) days of notice to Avecia as set forth in Section 10.1, either Party shall be entitled to require that the matter in dispute be referred to an independent laboratory or other appropriate expert nominated by agreement of the Parties. Such referral shall be solely for the purpose of establishing whether or not there is any failure of the relevant API to meet API Requirements. The decision of such independent laboratory or expert shall be binding upon the Parties, and the Party against which the decision is made shall be responsible for the costs of such independent laboratory or expert. If the decision shows that Avecia failed to supply API in accordance with API Requirements, then Avecia shall process free of charge sufficient API to replace the defective API and shall dispose of the defective API at its own cost.
- 10.4 All API supplied to Customer shall at the time of Delivery have the longest remaining Shelf Life reasonably practicable, but in any event a minimum of (i) six (6) months if the total Shelf Life from the date of manufacture is equal to or greater than twelve (12) months and (ii) eighteen (18) months if the total Shelf Life from the date of manufacture is equal to or greater than twenty-four (24) months; provided, however, that Avecia shall be permitted to supply API with shorter Shelf Life on a case-by-case basis where Customer so agrees in writing in advance of the shipment of such API.

11. Representations and Warranties.

- 11.1 Avecia represents and warrants to Customer as follows:
- 11.1.1 Avecia is a corporation validly existing and in good standing under the laws of the State of Delaware, with the power to own all of its properties and assets and to carry on its business as it is currently being conducted.
 - 11.1.2 Avecia has the power to execute and deliver this Agreement and to perform its obligations under this Agreement.
 - 11.1.3 Avecia has obtained all necessary consents and authorizations to execute and deliver this Agreement and to perform its obligations under this Agreement, and no other corporate proceedings of Avecia or third party consents are necessary with respect thereto.
 - 11.1.4 Avecia shall handle, accumulate, label, package, store, transport and dispose of all Wastes generated through performance of the manufacturing and processing activities hereunder in accordance with all Regulatory Requirements.
 - 11.1.5 All API conforms to and is produced in accordance with API Requirements.
 - 11.1.6 Avecia has, and will remain in material compliance with, all Applicable Laws, including permits, licenses and other authorizations (the "Permits") which are required under USA federal, state and local laws, rules and regulations applicable to the manufacture of API.
 - 11.1.7 No person performing services on behalf of Avecia under this Agreement has been debarred under Section 306 of the United States Federal Food, Drug and Cosmetic Act nor otherwise (i) disqualified or debarred by the FDA or any other Regulatory Authority for any purpose pursuant to 21 U.S.C. § 355a or any foreign counterparts thereof; or (ii) charged with or convicted under United States federal law, or foreign counterparts thereof, for conduct relating to the development or approval of, or otherwise relating to the regulation of, any drug product under the Generic Drug Enforcement Act of 1992 or any other relevant statute, law or regulation.
 - 11.1.8 Manufacture of API will be performed consistent with standards then customary in the oligonucleotide and API industry, and, in any event, with at least the degree of care and quality that Avecia uses to perform similar activities for other parties.
 - 11.1.9 To the best of Avecia's knowledge, Avecia's manufacture of API in the performance of this Agreement will not infringe the Intellectual Property or other rights of third parties.
 - 11.1.10 API manufactured using the New Process (i) will be of a quality equal to or better than that of API manufactured using the Current Process, (ii) will have no new impurities, as determined using the same analytical methods and (iii) will contain significantly less adduct than API manufactured using the Current Process.
- 11.2 Customer represents and warrants to Avecia that (i) Customer is a corporation validly existing and in good standing under the laws of the State of Delaware, with the power to own all of its properties and assets and to carry on its business as currently being conducted, (ii) Customer has the power to execute and deliver this

Agreement and to perform its obligations under this Agreement, (iii) Customer has obtained all necessary consents and authorizations to execute and deliver this Agreement and to perform its obligations under this Agreement, and no other corporate proceedings of Customer or third party consents are necessary with respect thereto, (iv) Customer has all rights necessary to permit Avecia to manufacture API as contemplated in this Agreement and (v), to the best of Customer's knowledge, Avecia's use of Customer's Intellectual Property in the performance of this Agreement will not infringe the Intellectual Property or other rights of third parties.

11.3 EXCEPT AS EXPRESSLY PROVIDED HEREIN, NEITHER PARTY MAKES ANY WARRANTY OF ANY KIND, EXPRESS, IMPLIED, STATUTORY OR OTHERWISE, WITH RESPECT TO THE SUBJECT MATTER OF THIS AGREEMENT. AVECIA EXPRESSLY DISCLAIMS ANY WARRANTY OF MERCHANTABILITY OR FITNESS OF API FOR ANY PARTICULAR PURPOSE.

12. Indemnification; Remedies; Limitation of Liability.

12.1 Avecia shall indemnify and hold Customer harmless from all losses, liabilities, damages and expense (including reasonable attorneys' fees and costs) incurred as a result of any claim, demand, action or other proceeding by a third party to the extent caused by (i) any breach by Avecia of the covenants, representations or warranties hereunder, (ii) the infringement of the Intellectual Property rights of a third party arising from Avecia's manufacture of API hereunder other than to the extent arising out of Avecia's use of Customer's Intellectual Property in its manufacture of API hereunder, (iii) claims for personal injury or death, damage to property, for failure to comply with operating permits or Regulatory Requirements relating to the operation of the Facility during the course of Avecia's manufacturing and processing activities or (iv) arising out of gross negligence or willful misconduct on the part of Avecia or any of its agents or employees; in each case (i) through (iv) above, other than to the extent caused by (a) any breach of the covenants, representations or warranties of Customer hereunder or (b) the gross negligence or willful misconduct of Customer hereunder.

12.2 Customer shall indemnify and hold Avecia harmless from all losses, liabilities, damages and expense (including reasonable attorneys' fees and costs) incurred as a result of any claim, demand, action or other proceeding by a third party to the extent caused by (i) any breach by Customer of the covenants, representations or warranties of Customer hereunder, (ii) the infringement of the Intellectual Property rights of a third party arising out of Avecia's use of Customer's Intellectual Property in Avecia's manufacture of API or the provision of other services for Customer hereunder, (iii) the use or sale of API by Customer, Customer's Affiliates and Customer Partners, or by any other third party or (iv) any use of Avecia's Intellectual Property in the manufacture of API by Customer, a Customer Partner or any other third party appointed a sub-licensee of Customer pursuant to rights granted to Customer pursuant to Section 13; in each case (i) and (ii) other than to the extent caused by (a) a breach of the covenants, representations or warranties of Avecia hereunder, (b) the gross negligence or willful misconduct of Avecia hereunder or (c) any API supplied

hereunder that does not conform to API Requirements, provided, however, that, in such case, Customer shall have notified Avecia of such non-conformance within the applicable time period prescribed in Section 10.1.

- 12.3 NOTWITHSTANDING ANYTHING TO THE CONTRARY IN THIS AGREEMENT, EXCEPT FOR WILLFUL MISCONDUCT AND RECKLESS DISREGARD, (A) AVECIA'S AGGREGATE LIABILITY FOR ANY AND ALL LOSSES OR DAMAGES RESULTING FROM ANY CAUSE WHATSOEVER OR WITH RESPECT TO ANY API SUPPLIED HEREUNDER, INCLUDING, WITHOUT LIMITATION, ANY LIABILITY RELATING TO A RECALL, WITHDRAWAL OR SEIZURE AS SET FORTH IN SECTION 18, SHALL IN NO EVENT EXCEED TWO HUNDRED PERCENT (200%) OF THE PRICE PAID BY CUSTOMER FOR THE API IN QUESTION OR AFFECTED, AND (B) IN NO EVENT SHALL EITHER PARTY BE LIABLE FOR SPECIAL, INCIDENTAL PUNITIVE OR CONSEQUENTIAL DAMAGES, WHETHER THE CLAIM IS IN CONTRACT, NEGLIGENCE, STRICT LIABILITY OR OTHERWISE.

13. Intellectual Property.

- 13.1 Nothing in this Agreement shall affect the ownership by either Party of any Intellectual Property or process owned by or in the possession of that Party as of the Effective Date or Intellectual Property developed independently of the work undertaken pursuant to this Agreement by any employee of that Party without reference to any of the Confidential Information disclosed by the other Party ("Independent Intellectual Property"). Other than giving Avecia the right to manufacture API for Customer, nothing in this Agreement shall give either Party the right to use the other Party's Independent Intellectual Property.
- 13.2 Intellectual Property generated, developed, discovered or invented in connection with work conducted pursuant to this Agreement by the Parties relating to the composition of API or other product-specific invention shall belong to Customer. Intellectual Property generated, developed, discovered or invented in connection with work conducted pursuant to this Agreement relating to Avecia's process to manufacture API or other process-related invention shall belong to Avecia.
- 13.3 Avecia hereby grants to Customer a non-exclusive, worldwide, royalty-free license, with the right to grant sublicenses, to Avecia's interest in any Intellectual Property generated, developed, discovered or invented during work conducted pursuant to this Agreement with general application to manufacturing processes (including as specifically applicable to the manufacture of API) to the extent that such Intellectual Property can be used to enhance the manufacture of API.
- 13.4 During the term of this Agreement, Avecia hereby grants to Customer a non-exclusive, worldwide, royalty-free license, with the right to grant sublicenses, to Avecia's process to manufacture API with respect to the manufacture of API (i) in an amount up to twenty five or thirty percent (25 or 30%) of Customer's requirements for API during any Agreement Year commensurate with the minimum volume requirements of Section 6.1 or (ii) for such greater amount to the extent that Avecia does not supply Customer its requirements for API in excess of such 25 or 30%

during any such Agreement Year for any reason other than a breach of this Agreement by Customer.

- 13.5 Avecia hereby grants to Customer a non-exclusive worldwide license, with the right to grant sublicenses, to Avecia's process to manufacture API (the "Licensed Process"), such license to take effect after termination of this Agreement, subject to payment to Avecia of the following royalties: Twelve dollars (\$12) per gram for each of the first fifty (50) kilograms of API or portion thereof manufactured during any license year using the Licensed Process; six dollars (\$6) per gram for each kilogram of API or portion thereof so manufactured during such license year in excess of three hundred (300) kilograms; with such royalty being prorated linearly for such kilograms of API or portion thereof so manufactured during such license year between fifty (50) and three hundred (300) kilograms.
- 13.6 Each Party shall be the sole owner of all regulatory filings and all governmental approvals obtained by such Party from any Regulatory Authority with respect to the API.

14. Confidentiality.

- 14.1 In consideration of the Disclosing Party (Avecia or Customer, as the case may be) disclosing Confidential Information to the Receiving Party (Avecia or Customer, as the case may be), the Receiving Party hereby undertakes to maintain as confidential all such Confidential Information, and it will not use or disclose any of such Confidential Information in whole or in part save for purposes envisaged in this Agreement.
- 14.2 The foregoing restrictions on the Receiving Party shall not apply to any Confidential Information which:
- (a) was already in the Receiving Party's possession and at its free disposal before the disclosure hereunder to it;
 - (b) is hereafter disclosed to, purchased or otherwise legally acquired by the Receiving Party by or from a third party who has not derived it, directly or indirectly, from the Disclosing Party;
 - (c) is or becomes available to the public or otherwise in the public domain through no act or default on the part of the Receiving Party, its agents or employees; or
 - (d) has been developed by the Receiving Party independently of the Disclosing Party without reference to any of the Confidential Information disclosed by the Disclosing Party.
- 14.3 In order to secure the obligations under this Section 14, the Receiving Party agrees to exercise reasonable precautions to prevent and restrain the unauthorized disclosure and use of information subject to confidentiality, including restricting access to such information to such of its employees and representatives (i) as are bound to keep such information confidential and (ii) who need to have such access for the purposes of this Agreement.

- 14.4 The confidentiality obligations under this Section 14 shall not apply to the extent that a Party is required to disclose information by Applicable Law, regulation or order of a governmental agency or a court of competent jurisdiction or otherwise required by a Governmental Authority (including, without limitation, the requirement to announce and file a copy of this Agreement with the U.S. Securities and Exchange Commission). In connection with such disclosure, such Party shall provide written notice thereof to the other Party, use reasonable efforts to consult with the other Party with respect to such disclosure and use reasonable efforts to provide the other Party sufficient opportunity to object to any such disclosure, to request confidential treatment thereof or to redact any of such information not required to be so disclosed, provided that each of the foregoing are subject to such Party's legal obligations and to the extent practical under the circumstances.
- 14.5 Any of Customer's Affiliates and any Customer Partner shall have access to Confidential Information of Avecia as reasonably necessary in connection with its agreement with Customer provided that it is bound by confidentiality terms in connection therewith which are no less onerous than those set forth herein.
- 14.6 The terms of this Section 14 shall not be construed to limit either Party's right to independently make, develop or acquire products, processes or concepts without use of the other Party's Confidential Information, even if similar. Neither Party shall have any obligation to limit or restrict the assignment of its employees or consultants as a result of their having had access to Confidential Information of the other Party.
- 14.7 The provisions of this Section 14 shall survive termination or expiry of this Agreement and shall continue for a period of five (5) years from the date of such termination or expiry.
- 14.8 From time to time during the term of this Agreement, Customer may have employees assigned to work full-time at the Facility. For clarification purposes, Customer shall treat all Confidential Information disclosed to or learned by such employees at the Facility as Confidential Information of Avecia for purposes of this Section 14. Furthermore, Customer shall require that such Customer employees review and sign an employee acknowledgement of confidentiality agreement in form and substance reasonably satisfactory to Avecia.

15. Force Majeure.

Neither Party is liable for any failure to perform or delay in performing any obligation under this Agreement, if such failure or delay is due to fire, flood, strike or any other industrial disturbance, war, embargo, legal prohibition, terrorism, insurrection, regulatory delay or any other cause beyond the reasonable control of such defaulting Party preventing or delaying the performance of such obligations. The Party so affected will, upon giving notice thereof to the other Party, be excused from such performance to the extent of such prevention, restriction or delay. Except in the case of strike or similar work stoppage, the affected Party is obligated to use its commercially reasonable efforts to

avoid or remove such causes of non-performance and to continue performance with the utmost dispatch whenever such causes are removed.

Neither Party shall be entitled to relief under this Section 15 for any delay or failure in performing any of its payment obligations under this Agreement.

16. Termination; Consequences of Termination.

16.1 Without prejudice to any other rights or remedies which may be available to them, the Parties may terminate this Agreement at any time by mutual agreement of both Parties in writing.

16.2 Without prejudice to any other rights or remedies which may be available to them, either Party may terminate this Agreement with immediate effect by giving written notice of termination to the other Party if the other commits a material breach of any of the provisions of this Agreement and, in the case of a breach capable of being remedied, fails to remedy such breach within ninety (90) days of receiving notice from the non-breaching Party specifying such and requiring the same to be remedied, provided, however, if, for any reason other than an event of force majeure referred to in Section 15 or a failure of Customer to meet its obligations under this Agreement, Avecia fails to Deliver the API set out in the applicable purchase order within ninety (90) days following the date of Delivery set out in such purchase order, Customer may terminate this agreement for material breach effective upon written notice if Avecia fails to cure such breach within thirty (30) days of receiving notice of such breach from Customer.

16.3 Without prejudice to any other rights or remedies which may be available to Customer, Customer may terminate this Agreement by giving written notice of termination to Avecia if Customer, in its sole discretion, determines that the drug product containing API shall not be further developed or marketed by Customer, Customer's Affiliates and Customer Partners.

16.4 Subject to Section 16.5 and without prejudice to any other rights or remedies which a Party may have, upon termination of this Agreement, howsoever the same occurs, each Party shall:

- (a) immediately pay to the other all sums which at the date of termination are due and payable to the other hereunder;
- (b) immediately cease all use of any property of the other, including, without limitation, any Intellectual Property of the other Party, except as permitted under Section 13; and
- (c) at the expense of the requesting Party, promptly return to the other Party any property of the other in its possession, custody or control.

16.5 If (i) the Parties terminate this Agreement pursuant to Section 16.1, (ii) Avecia terminates this Agreement in accordance with Section 16.2 or (iii) Customer terminates this Agreement in accordance with Section 16.3, Customer shall purchase

all amounts of API which have been manufactured but not yet delivered and pay to Avecia Avecia's costs related to any API which is in the process of being manufactured or is in the Avecia manufacturing schedule as of the date of such termination to fulfill Customer's firm commitment portion of the effective Rolling Forecast, including, without limitation, Avecia's cost for any raw materials purchased in anticipation of meeting the firm commitment portion of the effective Rolling Forecast, subject to Section 25. Customer shall have the right to take possession of any such raw materials or unfinished API at its expense.

- 16.6 If it is determined by the final decision of an arbitrator pursuant to Section 26.3 that Customer has committed a material breach of this Agreement and has not cured such breach within thirty (30) days after notice thereof, Avecia shall thereafter have the right to revoke any licenses granted to Customer pursuant to Section 13 by giving written notice to Customer (except with respect to the license and rights Avecia has granted to Customer pursuant to Section 13.3, which license and rights shall survive), it being understood, however, that, in the event that this Agreement is terminated for any other reason, Avecia shall not have the right thereafter to revoke any such licenses granted to Customer pursuant to Section 13.
- 16.7 Sections 12, 13, 14, 17 to 19, and 21 to 26 shall survive the termination of this Agreement howsoever the same occurs.

17. Regulatory; Facility Access; Audits.

- 17.1 Except as otherwise set forth in the proviso to this sentence, Avecia shall be responsible for obtaining at its own expense all permissions, licenses and approvals necessary to discharge its obligations under this Agreement; provided, however, that Customer shall pay for, or reimburse Avecia for, all reasonable work carried out by Avecia in support of regulatory filings and preparation for any PAI, including, without limitation, Avecia staff participation in the PAI or practice PAIs. If, however, Avecia fails a PAI due to its gross negligence or willful misconduct, or a failure in the Avecia general Quality systems not related specifically to API, then Customer will not be required to pay for the PAI or reimburse Avecia. Once the cumulative total of API produced under this Agreement reaches 50 kilograms, Customer will no longer be charged for additional PAIs.
- 17.2 If Customer requests that Avecia adopt any approach to cGMP or Avecia operating standards which is different from Avecia's operating norms, the change will only be implemented if Avecia agrees to the change, and Avecia will charge Customer for Avecia's cost to deliver the request, except when Customer makes such a request because Avecia is operating outside industry norms (as reasonably demonstrated by Customer), Regulatory Requirements, cGMP requirements or contractual commitments.
- 17.3 Avecia shall promptly furnish Customer with such information and documentation as Customer may request relating to any regulatory filings or

submissions for API. Avecia shall provide Customer with a copy of all proposed submissions to any regulatory agency associated with the manufacture of API hereunder for Customer's review and approval.

- 17.4 Avecia shall permit Customer's employees, consultants and/or representatives to have reasonable access to the Facility for the purpose of verifying quantities of Customer supplied materials and API and observing manufacturing and related activities, including access to certain agreed documents ("Reasonable Access"); provided that such persons agree to be bound by a mutually acceptable confidentiality agreement.
- 17.5 Customer shall have the right to conduct, upon reasonable notice and at its own expense, periodic technical, quality, and environmental health and safety audits. Avecia shall give Reasonable Access to Customer for purposes of auditing the Facility. Preferably four (4) (but no less than two (2)) calendar weeks' notice should be reasonable, but Avecia will provide Customer immediate access in case of rejections or emergency conditions.
- 17.6 Avecia, if it is so aware (or as soon as it becomes aware) will promptly advise Customer if any regulatory agency intends to inspect the Facility and the nature of the inspection. Customer shall have the right to observe such inspection relating to the manufacture of API. Avecia shall promptly provide a report of the results of such inspection to Customer. In addition, Avecia shall promptly notify Customer of any notice of deficiencies by any regulatory agency, and provide Customer with a copy of the unredacted copies of any FDA 483(s) and Establishment Inspection Reports or their equivalents issued as a result of said inspection and any follow-up written communications between Avecia and the relevant Government Authority if, and only if, such reports or FDA 483(s) do not contain third party confidential information. Avecia will use best efforts to correct all identified deficiencies in a timely manner and advise Customer periodically of progress being made, as well as when all deficiencies are corrected.
- 17.7 Avecia will complete the Requalification Plan, including the engineering runs, within 6 months of receipt of a purchase order if the scope of the Requalification Plan remains unaltered from the current scope (i.e. as provided to the FDA in 2006).
- 17.8 The Parties shall cooperate to obtain approval for Avecia to become responsible for all API release testing. As part of such cooperation, it is intended that quality control methods will be validated at the Facility and Avecia's quality control laboratory will be included in the next Regulatory Authority Approval.
- 17.9 Customer Partners shall have the same rights as Customer under this Section 17, subject to reasonable confidential obligations.
- 17.10 Avecia shall not have the right to subcontract, sublicense or otherwise delegate all or any portion of its obligations under this Agreement without Customer's prior written approval. For the avoidance of doubt, Customer has already granted such

approval for the subcontractors approved as part of the process validation and subsequent production conducted in 2004.

18. Recalls.

- 18.1 Each Party shall keep the other Party fully informed of any notification, or other information of which it has actual knowledge, which might result in the Recall, Seizure or other enforcement action relating to the API.
- 18.2 If Avecia independently believes that a withdrawal of API or Recall of drug product containing API or field corrective action may be necessary or appropriate, Avecia shall so notify Customer of Avecia's conclusion within twenty-four (24) hours and the Parties shall cooperate with each other to ascertain the necessity and nature of such action.
- 18.3 Promptly after Customer notifies a Regulatory Authority of a withdrawal of API or Recall of drug product containing API, Customer shall so notify Avecia as soon as possible and, to the extent related to Avecia's supply of API pursuant to this Agreement, no later than within twenty-four hours. If requested by Customer, Avecia shall reasonably assist Customer, and, if applicable the Customer Partner(s), in the investigation to determine the cause and extent of the problem. In such case, Customer shall reimburse Avecia for any costs incurred by Avecia with respect thereto.
- 18.4 Notwithstanding anything to the contrary in the foregoing, Customer shall make the final decision as to whether API or drug product containing API is withdrawn or Recalled.
- 18.5 If any Governmental Authority withdraws its approval to sell the API or drug product containing API or issues a directive or request that all or specified quantities of the API or drug product containing API be Recalled for product safety reasons or Customer reasonably determines that all or specified quantities of the API or drug product containing API should be withdrawn or Recalled, Avecia shall pay all costs associated with the withdrawal or Recall to the extent resulting from the delivery of non-conforming API.
- 18.6 For purposes of this Section 18, "Recall" shall mean any action by Customer or Customer Partner to recover title to or possession of drug products containing API sold or shipped to third parties. For purposes of this Section 18, "Seizure" shall mean any action by any Governmental Authority to detain or destroy API. For the purposes of this Section 18, (a) neither "Recall" nor "Seizure" shall mean any actions taken by Customer or Customer Partner that are solely related to nonpayment or contract issues and are not related to any toxicity, safety, efficacy or Regulatory Requirements-related issues; and (b) references to "API" include drug product containing API.

19. Announcements and Publicity.

Except in connection with disclosures under Section 14.4, the Parties agree that they shall not make any official press release, announcement or other formal publicity relating to the transactions which are the subject of this Agreement, or any ancillary matter, without first obtaining in each case the prior written consent of the other Party, which consent shall not be unreasonably withheld.

20. Assignment and Change of Control.

This Agreement shall be binding upon and inure to the benefit of the Parties hereto and their respective legal successors but shall not otherwise be assignable by either Party without the prior written consent of the other Party; provided, however, that (i) either Party, without the need for consent, shall assign this Agreement and its rights and delegate its obligations hereunder in connection with the transfer or sale of all or substantially all of its business and assets to which this Agreement relates, or in the event of its merger, consolidation, change in control or similar transaction; and (ii) Customer, without the consent of Avecia, may assign this Agreement, in whole or in part, to a Customer Partner or Customer Affiliate; provided, however, that, in the event of any such assignment pursuant to this subsection (ii) but not subsection (i), unless such Customer Partner or Customer Affiliate has a market value of at least one billion dollars at the time of such assignment, Customer shall continue as a Party to the Agreement, subject to all of its terms and conditions. Any permitted assignee shall assume all obligations of its assignor (and in the case of assignment by Genta, be deemed a "Customer" hereunder) and otherwise be subject to all of the terms and conditions under this Agreement (and, to the extent applicable due to their ongoing activities, Genta and its Affiliates would each be deemed a "Customer Partner" of Genta's assignee). Any purported assignment in violation of this Section 20 shall be void. All Customer Partners or Customer's Affiliates purchasing API as provided herein shall be subject to all obligations, terms and conditions under this Agreement to the same extent as Customer.

21. Integration and Variation.

This Agreement shall constitute the sole and exclusive agreement between the parties regarding the subject matter hereof. Any other agreement or arrangement between the Parties relating to the sale of API by Avecia to Customer, including the Manufacturing and Supply Agreement dated December 20, 2002, as subsequently amended by the Parties, and any letter or side agreements relating thereto (the "December 20, 2002 Agreement"), is hereby superceded and terminated as of the Effective Date, and the provisions of this Agreement shall govern the rights, remedies and obligations of the Parties with respect to any sale of API by Avecia to Customer, provided that the terms of the letter agreements attached as Appendix 6 shall remain in full force and effect and are incorporated herein as part of this Agreement. No variation or amendment of this

Agreement shall bind a Party unless made in writing in the English language and agreed to in writing by duly authorized officers of both Parties.

22. Illegality.

If any provision of this Agreement is agreed by the Parties to be illegal, void or unenforceable under any Applicable Law or if any court of competent jurisdiction in a final decision so determines, this Agreement shall continue in full force save that such provision shall be deemed to be excised herefrom with effect from the date of such agreement or decision or such earlier date as the Parties may agree.

23. Waiver.

A failure by either Party to exercise or enforce any rights conferred upon it by this Agreement shall not be deemed to be a waiver of any such rights or operate so as to bar the exercise or enforcement thereof at any subsequent time or times.

24. Notices.

All notices and any other communications given or made in relation to this Agreement shall be in writing and delivered by hand, registered mail or recognized overnight mail service to the address of the Party set forth below:

If to Avecia:

Avecia Biotechnology Inc.
125 Fortune Boulevard
Milford, MA.
01757
Attention: President

If to Customer:

Genta Incorporated
200 Connell Drive
Berkeley Heights, NJ
07922
Attention: Vice President, Manufacturing Operations

cc: Senior Director, Legal Affairs

25. Duty to Mitigate.

Each of the Parties shall use all reasonable efforts to mitigate any costs, losses or expenses due to be incurred or suffered by the other Party in connection with the performance or non-performance of this Agreement.

26. Law and Jurisdiction.

- 26.1 This Agreement is governed by and shall be construed and interpreted in accordance with the laws of the State of Delaware.
- 26.2 The Parties shall use reasonable efforts, acting in good faith, to reach consensus on all matters as expeditiously as possible. Should the Parties be unable to reach consensus on an issue, such issue shall be elevated to the respective presidents of each Party for resolution.
- 26.3 Any dispute not disposed of in accordance with Section 26.2 shall be disposed of by binding arbitration under the rules of the American Arbitration Association. The arbitration shall take place in New York City, NY. The arbitrator shall be bound to follow the applicable provisions of this Agreement and Delaware law in adjudicating any dispute. It is agreed by the Parties that the arbitrator's decision is final, and that neither Party may take action, judicial or administrative, to overturn the decision. The judgment rendered by the arbitrator may be entered in any court having jurisdiction thereof.

EXECUTION COPY

IN WITNESS WHEREOF, this Agreement has been entered into the day and year first above written.

AVECIA BIOTECHNOLOGY INC

BY: _____
NAME:
TITLE:

EXECUTION COPY

IN WITNESS WHEREOF, this Agreement has been entered into the day and year first above written.

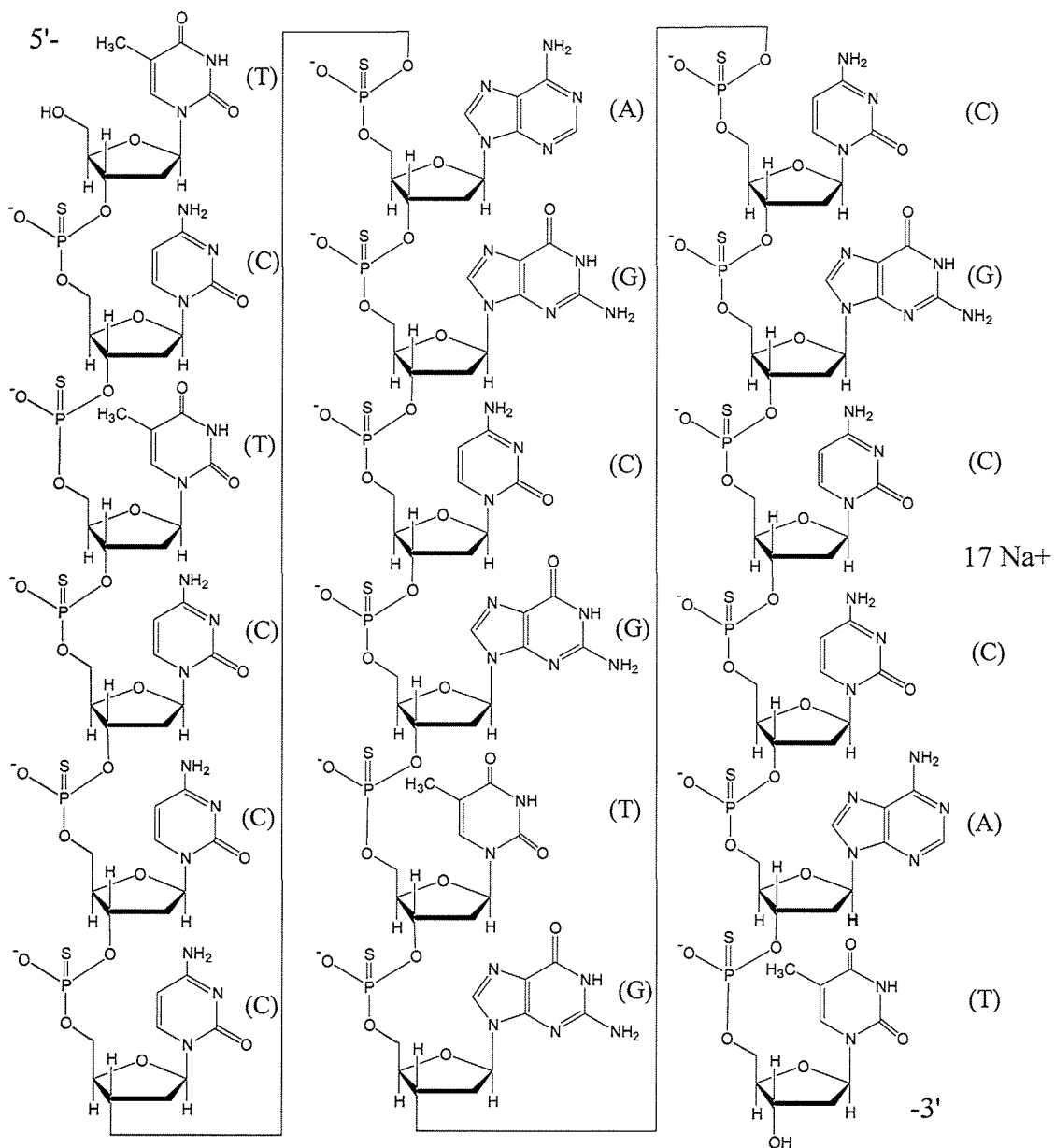
GENTA INCORPORATED

BY: _____
NAME:
TITLE:

Appendix 1

CHEMICAL STRUCTURE OF API

For clarity the chemical structure is redacted in its entirety



Appendix 2

API PRICE

Shown below are the pricing curves which will apply for this agreement for the Current Process and the New Process. The price for the Current Process assumes an HL30 price of \$15/g, variations from this in either direction will be to Customer's account (subject to Customer's audit right pursuant to Section 3.3 of the Supply Agreement).

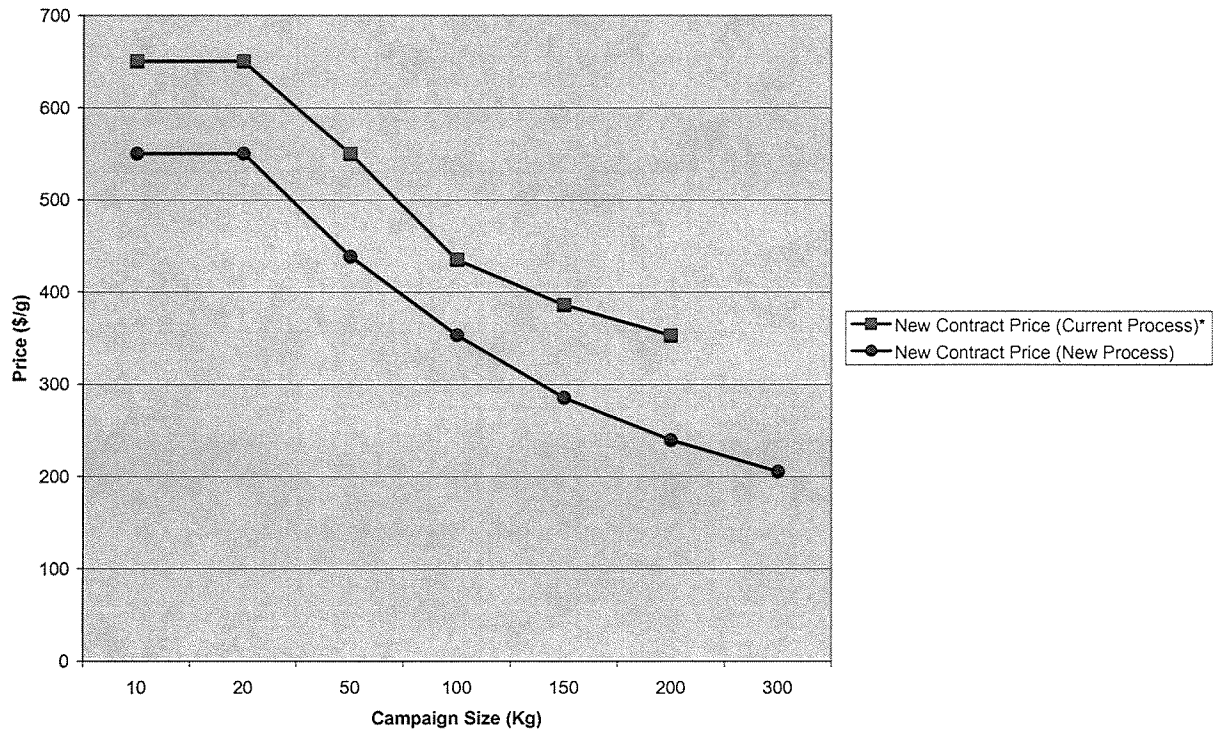
The weight basis for pricing is API containing 5% water. Gross weight of API will be adjusted to 5% water for the purpose of invoice.

Pricing will be on a "campaign basis" for calendar years where the forecast off take is <50Kg and will be on an "annual volume basis" for calendar years where the forecast off take is >50Kg. If in any given calendar year the forecast offtake triggers one pricing mechanism but the actual offtake is consistent with the other mechanism there will be a year-end pricing true-up.

When the New Process is implemented the price in that calendar year will be based upon the total number of grams produced in that calendar year. The quantity produced from the Current Process will be charged at the \$/g price for the total quantity on the Current Process curve, and the quantity produced from the New Process will be at the \$/g price for the total quantity on the New Process curve.

The price will be adjusted annually from January 1, 2011 based upon 50% of the annual change in the PPI for Pharmaceutical Preparation Manufacturing.

Price versus Campaign Size / Annual Output - 2008 Basis



Price versus Campaign Size / Annual Output - 2008 Basis							
Campaign Size (Kg)	10	20	50	100	150	200	300
New Contract Price (Current Process)*	650	650	550	435	386	353	N/A
New Contract Price (New Process)	550	550	438	353	285	239	205

*Current Process Price assumes HL30 @ \$15/g
Any variation +ve or -ve will be to Genta's account

Note: Pricing will be determined on the basis of straight-line interpolation.

This table is also highlighted for redaction

For clarity, this entire page should be redacted.

Appendix 3

NEW PROCESS STRATEGY

The process change strategy to move Customer from the Current Process to the New Process contains 3 main elements:

(i) Definition and demonstration of process.

Establish small scale model which accurately mimics proposed large scale process.

Carry out 3 manufacturing runs on small scale model through to final isolated API.

Execute comparability protocol; analytically compare API from New Process to material from Current Process, comparison using release purity tests plus additional characterization by LCMS. Determine if product is equivalent.

(ii) Investigation of process robustness and critical parameters in preparation for process validation manufacture.

Define process parameters/process controls/process specifications for each unit operation.

Perform pre-experimental parameter risk assessment; identify parameters to be experimentally assessed and appropriate responses to be measured.

Generate experimental protocol then conduct DOE investigation of selected process parameter for each unit operation, determine criticality of parameters.

Generate revised process description, process development history report and technical reports.

Generate and approve process validation protocol.

(iii) Process Validation

Carry out one full scale engineering run to demonstrate New Process at scale.

Validate New Process by conducting 3 manufactures at scale under a validation protocol.

Execute equivalence protocol to confirm product from the New Process at scale is equivalent to material from the Current Process.

This approach has been used by Avecia and their clients to support site technical transfers and major process change in late Phase clinical products, and it has been successfully reviewed by the regulators. At this stage the strategy is a good basis for planning to implement the new process. It is planned that Customer with Avecia support will seek specific regulatory advice/approval on the process change strategy.

Appendix 4

OBLIMERSEN SODIUM – G3139

DRUG SUBSTANCE TESTING SPECIFICATIONS

G3139-00-107

ACCEPTANCE TESTING AT TIME OF MANUFACTURING

Test	Method	GENTA SPECIFICATION	REPORTING
Appearance	PHR-111	White to off-white powder	Pass: White to off-white powder or Fail: Report description
Identification			
Molecular Weight	060401-001	5684.6± 3 Da	xxxx.x Da
Sequence Confirmation	060401-002	Confirms expected sequence	Confirms expected sequence /or/ Does not confirm expected sequence
Assay			
Free acid, anhydrous	PHR-110	865-960 mg/g	xxx mg/g
Potency (as is)		Report results mg/g	xxx mg/g
Structurally Related Impurities			
N-2 /Oxygenated	PHR-110	NMT 2.5%	x.x %
N-1		NMT 4.0%	x.x %
N+1		NMT 1.2%	x.x %
Each Other Individual Impurity ²		NMT 0.2%	x.x % with RRT of x.xx
Total Impurities		NMT 6.5%	x.x %
Water Content	PHR-104	NMT 11.0%	xx.x %
Heavy Metals	PHR 026	NMT 20 ppm total	Pass: NMT 20ppm total or Fail: Report ppm result
Volatile Organic Impurities			
Acetonitrile	PHR-105	NMT 200 ppm	xxx ppm or < LOQ (41ppm)
Toluene		NMT 300 ppm	xxx ppm or < LOQ (1.5 ppm)
Pyridine		NMT 100 ppm	xxx ppm or < LOQ (20 ppm)
Sodium Content	PHR-108	5.0-7.0% (w/w)	x.x % (w/w)
Bacterial Endotoxins	NV SOP 14B-15	NMT 6 EU/mg	< x EU/mg
Microbial Bioburden			
Total Aerobic Microbial count	NV SOP 13B-13	NMT 100 cfu/g	< xx cfu/g
Total Yeasts and Molds		NMT 100 cfu/g	< xx cfu/g
Absence of 4 Objectionable Organisms			
<i>Staphylococcus aureus</i>		Absent	Pass
<i>Pseudomonas aeruginosa</i>		Absent	or
<i>Salmonella species</i>		Absent	Fail: Report result
<i>Escherichia coli</i>		Absent	



Appendix 5

QUALITY AGREEMENT

1. OVERVIEW

- 1.1 This Quality Agreement (the “Quality Agreement”) serves to define the responsibilities of Genta and Avecia with regard to manufacturing, packaging, inventory management and/or testing of *[drug substance]* (the “API”). In addition, this Quality Agreement specifies a process to ensure the API complies with all applicable Specifications and other requirements and that the API will be released in accordance with the manufacturing process agreed to by both Parties (the “Manufacturing Process”).
- 1.2 It is the responsibility of Genta and Avecia to ensure that this Quality Agreement complies with Applicable Laws. Genta and Avecia will ensure that the respective Standard Operating Procedures (SOPs) utilized in the course of the Services comply with Applicable Laws. Any changes to this Quality Agreement must be contained in a written amendment signed by both parties.
- 1.3 Genta and Avecia will carry out this Quality Agreement in accordance with the Genta or Avecia identified and approved SOPs. In the event of a conflict between this Quality Agreement and the applicable SOP, the parties will confer and agree on a mutually acceptable solution.
- 1.4 This Quality Agreement is intended to comply with the requirements for quality agreements contained in Applicable Laws including, but not limited to, the applicable portions of the U.S. Code of Federal Regulations and applicable FDA guidance documents as well as ICH guidelines, USP, EP, and EMEA requirements (“Regulatory Requirements”).

2. DEFINITIONS

- 2.1 All capitalized terms used but not otherwise defined in this Quality Agreement shall have the same meaning given to such terms in the Supply Agreement.

3. SPECIFICATIONS

- 3.1 Genta is responsible for providing a controlled copy of the approved API Specifications for the API to Avecia. Genta is responsible for notifying Avecia of any revisions to approved API Specifications and providing controlled copies. Avecia is responsible for generating and maintaining any internal specifications as they relate to the Manufacturing Process.

4. FACILITIES, MANUFACTURING

- 4.1 Avecia is responsible for maintaining all licenses, registrations and other authorizations as are required to operate the Facility according to cGMP and Applicable Laws.
- 4.2 Avecia is responsible for maintaining and operating the Facility in accordance with cGMP and other Applicable Law. This includes, but is not limited to, conducting all activities associated with preventative maintenance, equipment and instrument calibration, and validation where applicable. Avecia is responsible for ensuring that qualified, trained individuals are assigned to the manufacturing and testing of each batch of the API.
- 4.3 Avecia is responsible for manufacturing each batch of the API in accordance with the requirements of this Quality Agreement.

5. RAW MATERIALS/COMPONENTS/LABELING

- 5.1 Avecia will qualify the raw material suppliers to ensure compliance with cGMP and other Applicable Laws prior to use of raw materials or components in a Genta campaign. Raw materials and components will be stored per Avecia specifications in accordance with cGMP, other Applicable Laws, and Genta's regulatory filings. The suppliers utilized for the currently validated process should remain consistent with Genta's regulatory filings.
- 5.2 Packaging and labeling specifications will be prepared by Avecia and forwarded to Genta's Quality Assurance group ("Genta QA") for approval prior to use in the Manufacturing Process.
- 5.3 Avecia is responsible for the verification and documentation of animal or human source raw materials and components associated with the manufacture of the API. Avecia is responsible for notifying Genta in

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writing of any raw materials, which are derived from animal or human sources.

6. SAMPLING AND TESTING

- 6.1 Avecia will generate and provide to Genta all batch documentation as required under the Supply Agreement including, but not limited to, an approved Certificate of Analysis (CofA) and copies of all relevant data used to generate the CofA. The CofA will list the results from all analytical testing required per the approved API Specification. Avecia will forward the approved CofA and associated documentation to Genta with the QA reviewed copy of the executed batch record.
- 6.2 Avecia is responsible for any method transfers and the reporting of results of these method transfers. Avecia will forward a copy of the method transfer report and associated results to Genta for review and approval.

7. BATCH NUMBERING

- 7.1 Avecia is responsible for assigning a unique lot/batch number to each batch per Avecia's internal SOP.

8. DEVIATIONS, OUT-OF-SPECIFICATIONS (OOS)

- 8.1 Avecia is responsible for investigating, resolving and documenting all deviations and investigations from the master batch record, SOP's and Specifications. Any deviations, which have the potential to impact API quality, will be documented per Avecia quality systems and reported to Genta QA. These deviations include, but are not limited to, issues arising from raw material handling, - manufacturing operations, API storage, sampling, labeling, packaging or distribution. In addition, any associated CAPA (Corrective Actions Preventive Actions) will also be provided to Genta QA.
- 8.2 Any Out-of-Specification (OOS) resulting from a failure to meet an in-process or release criteria as defined in an approved specifications will be documented per Avecia quality systems and must be reported to Genta QA.

9. CHANGE CONTROL

- 9.1 Any changes to the Facilities, equipment or Manufacturing Process utilized to manufacture the API for Genta which have the potential to

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impact API quality or any licenses required to operate the Facility, must be reported to Genta QA by Avecia.

- 9.2 Genta shall provide a turn around time of five (5) business days on all Avecia documents requiring Genta review, otherwise, agreement shall be implied and the documents made effective.

10. BATCH RECORDS

- 10.1 Avecia will generate, complete and maintain all relevant batch records related to the manufacture of the API. All master batch records must be approved by Genta QA prior to use in cGMP manufacturing. Any change to a previously approved batch record must be approved, in writing, by Genta QA prior to use. Genta agrees to review applicable batch records within five (5) business days of receipt and provide comments for Avecia correction or approval as applicable.
- 10.2 Copies of executed batch records and associated documentation will be forwarded to Genta for review prior to further processing and/or use of the API. All batch records must be reviewed and released by Avecia QA personnel prior to forwarding to Genta QA. The parties may review batch records at the same time if previously agreed to by both parties.
- 10.3 Avecia will maintain batch records and related documents as required under Avecia SOPs and cGMP. Express written approval from Genta is required prior to the destruction of any batch records and related documents.

11. API RELEASE

- 11.1 Subject to the Supply Agreement, Genta QA will be responsible for final release of the API for further processing and/or use in addition to any Qualified Person (QP) release as required. Genta will provide a release authorization document to Avecia upon resolution of any items that arise during Genta QA review.

12. STORAGE, PACKAGING AND DISTRIBUTION

- 12.1 Avecia will store the API at the Facility in accordance with the API Specifications and the Supply Agreement until shipment/distribution is approved by Genta QA. Genta QA will provide written authorization for shipment as applicable.

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- 12.2 Avecia will maintain an accurate release status and inventory of the API.
- 12.3 Avecia will package shipments of the API in containers and ship in conditions previously approved by both parties.

13. AUDITS, INSPECTIONS

- 13.1 Genta will be entitled to conduct one quality systems audit of Avecia biennially to evaluate quality and testing processes, as well as “for cause” audits resulting from facility changes, potential API quality issues or patient safety issue. In addition, Genta may monitor batch API activities as they relate to Genta APIs.
- 13.2 When quality systems audits are performed, Genta will issue a report within 30 calendar days of the audit completion. Avecia will respond to the audit findings within 30 calendar days of receipt of the audit report. Genta will be entitled to perform a follow-up assessment to ensure that critical/major items are corrected.
- 13.3 Each party agrees to notify the other of any communication with a Regulatory Authority or any planned or unplanned inspections related to manufacture or distribution of the API.
- 13.4 Each party agrees to provide copies of all pertinent documentation necessary for the other party to respond to inquiries and audits by Regulatory Authorities.
- 13.5 Genta may conduct QA reviews of documents (i.e. executed batch records, method transfer reports, etc.), as needed, at Genta or at Avecia.

14. COMPLAINTS, API WITHDRAWAL/PRODUCT RECALL, FIELD ALERTS

- 14.1 Avecia agrees to assist Genta in the investigation of any field alerts, API Recalls/withdrawal or API complaints. Genta agrees to notify Avecia of any relevant field alerts, API complaints or API Recalls/withdrawals.

15. THIRD PARTIES

- 15.1 Any third parties utilized by Avecia to perform analytical testing or other activities must be made known to and approved by Genta and must have been audited and approved by Avecia prior to initiation of activities by those third parties.

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APPROVALS:

Bonnie Pappacena
Senior Director
Quality Assurance
Genta Incorporated

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Director
Quality Assurance
Avecia Biotechnology, Inc.

ACKNOWLEDGEMENTS:

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Vice President
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Avecia Biotechnology, Inc.

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Appendix 6 Letter Agreements



This letter is
highlighted for
redaction

April 28, 2005

Michael McLean, PhD
President
Avecia Biotechnologies, Inc.
125 Fortune Blvd
Milford, MA 01757

Dear Mick:

This will confirm Genta's consent to Avecia's sale of the G3139 API from Lots 115-117 to another Avecia customer, as long as Avecia agrees to the conditions in this letter.

Genta understands that Avecia's customer is planning very preliminary dosage form development for their own oligo, and therefore the customer needs another oligonucleotide (in this instance, G3139 API) to use as a model compound for physical development purposes. Prior to selling such G3139 API to this customer, Avecia shall enter into a written letter-agreement with the customer in which the customer agrees to refrain from: (a) using the G3139 for any purpose other than the internal use described above; (b) using the G3139 in any animal or human studies or in connection with any efficacy or toxicology studies of any kind; (c) analyzing the composition of matter underlying G3139 in any manner; or (d) re-selling or otherwise providing the G3139 to any third party.

Avecia bears sole responsibility for such G3139 API as well as its customer's compliance with the restrictions above. Avecia shall defend, indemnify, and hold Genta harmless against any claims, actions, losses or harm that may arise in connection therewith. Genta shall have no liability or obligation to Avecia or its customer in connection with such G3139 API, and disclaims all representations or warranties that may apply, whether express or implied.

This letter relates only to G3139 API Lots 115-117.

Please confirm your agreement to this letter by returning a signed copy to my attention.

Best regards,

A handwritten signature in cursive script, appearing to read "Bharat M. Mehta".

Bharat M. Mehta, Ph.D.
Vice President, Manufacturing Operations

A handwritten signature in cursive script, appearing to read "Michael McLean".

Michael McLean, PhD
President, Avecia Biotechnologies Inc.

Avecia Lots115-117 ltr.doc

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This letter is
highlighted for
redaction

October 5, 2007

Mr. Detlef Rethage
President Avecia Biotechnologies, Inc.
125 Fortune Blvd
Milford, MA, 01757

Dear Detlef:

Re: AAC Lots 115-117

This will confirm our telephone conversation last week about Genta providing storage of the subject G3139 API lots, marked as AAC lots 115-117.

Avecia owns the three (3) G3139 API lots marked as AAC lots 115-117, and is currently storing them at its manufacturing facilities in Milford, MA. Avecia is in need of additional freezer capacity.

Avecia will ship AAC lots 115-117 to Halls Warehouse in NJ using suitable transport and shall adequately insure the shipment. Genta agrees to pay for storage of the lots at Halls and to reimburse Avecia for shipping cost to NJ. Title to, and ownership of, the lots shall remain with Avecia, and Avecia agrees to adequately insure AAC lots 115-117 while they are stored at Halls.

After completion of transfer to Halls, Avecia and Genta will negotiate in good faith the terms of sale of the lots to third parties or Genta for experimental (non-human) use.

In case that Genta at some point has no interest anymore to store AAC lots 115-117, Genta is responsible and will pay for shipment back to Avecia.

Avecia has the right, at it's own choice, to review Genta's and Halls' records and documentation to verify the AAC volume remaining from the lots 115-117

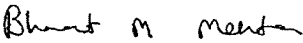
This letter relates only to AAC lots 115-117.

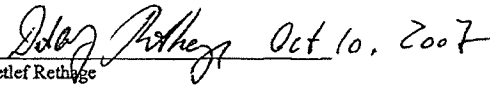
Please confirm your agreement effective as of the date of this letter, by returning a signed copy to my attention.

Best regards,

GENTA, INCORPORATED

Understood and Agreed
AVECIA BIOTECHNOLOGIES, INC.


Bharat M. Mehta, Ph.D.
Vice President, Manufacturing Operations


Detlef Rethage
President, Avecia Biotechnologies Inc.

For clarity, Appendix 6 should be redacted entirely