18-02944-E

Madison, Wilton

From: Mark Edwards <medwards@biosciadvisors.com>
Sent: Saturday, March 03, 2018 11:55 AM
To: foiapa
Subject: FOIA Request

I would like to request access to Exhibit 10.32 to the 12/31/14 10-K, filed by Genocea Biosciences, Inc. on 2/27/2015. Confidential treatment was sought as to certain portions when initially filed with the Commission.

In the event that confidential treatment has not expired or has been extended, I further request that you send me the expiration date(s) from the relevant CT order(s) so I will know when I should resubmit my request.

I authorize up to $61 in search and retrieval fees. Please send the exhibit(s) by PDF if possible.

Sincerely,

Mark

Mark G Edwards
Managing Director
Bioscience Advisors
2855 Mitchell Dr., Suite 103
Walnut Creek, CA 94598
medwards@biosciadvisors.com
925 954-1397

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

Office of FOIA Services

March 29, 2018

Mr. Mark G. Edwards
Bioscience Advisors
2855 Mitchell Dr.
Suite 103
Walnut Creek, CA 94598

RE: Freedom of Information Act (FOIA), 5 U.S.C. § 552
Request No. 18-02944-E

Dear Mr. Edwards:

This letter is in response to your request, dated March 3, 2018 and received in this office on March 5, 2018, for access to Exhibit 10.32 to the December 31, 2014 Form 10-K, filed by Genocea Biosciences, Inc. on February 27, 2015.

The search for responsive records has resulted in the retrieval of 31 pages of records that may be responsive to your request. They are being provided to you with this letter.

As shown on the enclosed invoice, the processing fee is $30.50 in accordance with our fee schedule. You may use our new *Online Payment* option to pay by debit or credit card. If paying by mail, checks or money orders should be made payable to the SEC and a copy of the invoice should be mailed to our payment address: Enterprise Services Center, HQ Bldg, Room 181, AMZ-341, 6500 South MacArthur Boulevard, Oklahoma City, OK 73169. Please refer to the following link for detailed instructions on how to remit payments. http://www.sec.gov/about/offices/ofm.htm

If you have any questions, please contact me at osbornes@sec.gov or (202) 551-8371. You may also contact me at foiapa@sec.gov or (202) 551-7900. You also have the right to seek assistance from Ray J. McInerney 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,

Sonja Osborne

Sonja Osborne
FOIA Lead Research Specialist

Enclosures

PRODUCT DEVELOPMENT AND CLINICAL SUPPLY AGREEMENT

THIS PRODUCT DEVELOPMENT AND CLINICAL SUPPLY AGREEMENT (this **"Agreement"**) is made effective as of the 23rd day of October, 2014 (the **"Effective Date"**) by and between **BAXTER PHARMACEUTICAL SOLUTIONS LLC**, a Delaware limited liability company having a place of business at 927 South Curry Pike, Bloomington, Indiana 47403 (**"Baxter"**), and **GENOCEA BIOSCIENCE, INC.**, a Delaware corporation having a principal place of business at Cambridge Discovery Park, 100 Acorn Park Dr., 5th Floor, Cambridge, MA, 02140 (**"Client"**).

RECITALS

1. Client is engaged, directly or through partners and contractors, in the development, bulk production, formulation, sale and distribution of pharmaceutical products;

2. Baxter is, among other pharmaceutical activities, engaged in the formulation, filling, inspection, labeling and packaging of pharmaceutical products for various pharmaceutical companies;

3. Client and Baxter desire to have Baxter formulate, fill, inspect, package, label, and test Product for Client for clinical supply.

NOW, THEREFORE, in consideration of the mutual covenants and agreements contained herein, Client and Baxter, hereinafter referred to as **"Party"** or **"Parties"**, agree as follows:

Article 1, DEFINITIONS

1.1. As used in this Agreement, the following words and phrases shall have the following meanings:

"Affiliate" shall mean any corporation or other business entity directly or indirectly controlled by, controlling, or under common control with a Party or its parent corporation. The term "control" (including, with correlative meaning, the terms "controlled by," "controlling" and "under common control with") means the possession, directly or indirectly, of the power to direct or cause the direction of the management and policies of such Party, whether through the ownership of voting securities, by contract or otherwise, or such other relationship as, in fact, constitutes actual control.

"Batch" shall mean a specific quantity of Product comprising a number of Units mutually agreed upon between Client and Baxter, and that (a) is intended to have uniform character and quality within specified limits, and (b) is Produced according to a single manufacturing order during the same cycle of manufacture.

"Baxter SOPs" shall mean Baxter's standard operating procedures applicable to the Production of Product.

"Bill of Materials" or **"BOM"** shall mean the listing of Materials, part numbers, and relative quantities to be used in the Production of Product.

"Bulk Drug Substance" or **"BDS"** shall mean the active pharmaceutical ingredient, as set forth in the Development Plan and/or Project Plan, to be supplied by Client for use in the Production of Product.

"Certificate of Analysis" or **"CofA"** shall mean a document prepared by Baxter in a Baxter standard format certifying the Batch of the Product release tests performed by Baxter, or Qualified Subcontractors, the specifications and test results for each Batch, as further specified in the Quality Agreement.

"cGMP Batch" shall mean a Batch of Product Produced from a cGMP production run conducted in accordance with the Master Batch Record that is used to create Product for research and development or for clinical use.

"Claims" means any and all claims, demands, actions, suits by a third party including claims of property damage, death or personal injury for which the Indemnified Parties otherwise would be strictly liable.

"Completion," "Completed" and correlatives shall mean the completion by Baxter of a Batch or other milestone, all as defined in the Project Plan.

"Completion Timeline" shall mean the timeline of Completion of an event as defined in the Project Plan (as may be amended by mutual agreement from time to time as set forth in this Agreement).

"Components" shall mean the primary packaging components (e.g. vial, stopper and seal) used by Baxter in the Production of Product under this Agreement. Components are listed in the Bill of Materials.

"Confidential Information" shall be defined as set forth in Article 18.

"Current Good Manufacturing Practices" or **"cGMP"** shall mean the current good manufacturing practices required by the FDA and set forth in the FD&C Act or FDA regulations (including without limitation 21 CFR 210 and 211) as in effect from time to time.

"Demonstration Batch" shall mean a Batch used for process demonstration and engineering of some or all of the Process Services and/or demonstration and engineering of Production in Baxter's cGMP facility.

"Development Plan" shall mean the document containing the parameters for the Process Services which shall be developed by Baxter and Client and agreed to in writing by Client and Baxter for each Product under this Agreement as set forth in Section 2.1.

"Disposition Date" shall mean Baxter's disposition of the Executed Batch Record.

"Effective Date" shall mean the date set forth above.

"Executed Batch Record" shall mean the completed batch record (dispositioned by Baxter as released, rejected or aborted) and associated deviation reports, and if applicable, a Lot QC Data Packet for each Batch of Product.

"FDA" shall mean the United States Food and Drug Administration or any successor entity thereto.

"FD&C Act" shall mean the United States Federal Food, Drug and Cosmetic Act, as may be amended from time to time.

"Latent Defect" means any non-conformity of a Product with the Product Requirements that could not reasonably have been expected to have been revealed by review of the Released Executed Batch Record by Client and/or testing performed by Client during the applicable time period for acceptance as provided for in Section 7.1 herein, but is discovered within the time period as provided for in Section 7.1.1.

"Losses" shall mean any and all liabilities, obligations, penalties, claims, judgments, demands, actions, disbursements of any kind and nature, suits, losses, damages, costs and expenses (including, without limitation, reasonable attorney's fees).

"Lot QC Data Packet" shall mean the listing of the analytical testing and Product Specifications performed on the Product and the results of such tests and shall contain a CofA for each Batch delivered.

"Master Batch Record" or **"MBR"** shall mean, with respect to each Presentation of Product to be Produced hereunder, a mutually agreed formal set of instructions for the Production of each Presentation of such Product. The MBR shall be developed and maintained in Baxter's standard format by Baxter, using Client's master formulation and technical support.

"Materials" as used in this Agreement shall collectively mean the BDS, Components, Secondary Packaging Materials and Raw Materials as required for Production of Product.

"Materials Specifications" shall mean the specifications and testing to be performed on the Materials, as specified in the QCMD.

"Non-Conforming Batch" shall mean:

(1) a cGMP Batch that has not been Produced in accordance with the Product Requirements.

(2) A Demonstration Batch that has not been Produced in accordance with the Project Plan.

"Presentation" shall mean the specific formulation and Components for the Product as specified in the applicable Master Batch Record and Product Specifications.

"Process Services" shall mean those research and development services performed by Baxter to optimize the manufacturing process related to Client's process to Produce Product. Process Services activities shall be identified in the Development Plan.

"Produce" or "Production" shall mean the formulation, filling, packaging, inspecting, labeling, and testing of Product by Baxter during the manufacture and finishing of Product in finished dosage form for research and development and/or clinical use as specified in the applicable Master Batch Record or finishing specification sheet.

"Product" shall mean product as specified in the Development Plan, if applicable, and the Project Plan for use in Process Services and/or clinical trials.

"Product Requirements" shall mean cGMPs, Baxter SOPs, the Product Specifications and the Master Batch Record.

"Product Specifications" shall mean, with respect to Product, the specifications and testing to be performed for the Product (and the BDS to the extent that Baxter is required to test the BDS) and/or the stability program that are set forth in the Baxter SOPs and the Master Batch Records. The Product Specifications include all tests that Baxter is required to conduct or cause to be conducted as specified in the QCMD. The Product Specifications may be modified from time to time only by a written agreement of Client and Baxter.

"Production Price" shall be defined in Section 5.1.

"Project Plan" shall mean the document(s) containing the parameters, timelines, milestones, Completion and Product Specifications for the Production of each Presentation of Product which shall be developed by Baxter and Client and mutually agreed to in writing by Client and Baxter for each Presentation of Product under this Agreement as set forth in Section 2.2. In addition, the Project Plan may include, without limitation, the Product, Materials, the countries where such Product will be sold, and Presentations for such Product.

"Quality Agreement" shall mean an addendum to this Agreement under which the Parties allocate the pharmaceutical responsibilities, as further set forth in Section 2.4.

"Quality Control Master Document" or "QCMD" shall mean a listing of the analytical testing and corresponding Specifications, and the results of such testing, to be performed on the Bulk Drug Substance, Raw Materials and in some instances, Product and shall contain a CofA for each Batch delivered.

"Qualified Subcontractor" shall mean a subcontractor with whom Baxter has a signed agreement, with provisions that protect Client Confidential Information and intellectual property at least as stringent as the provisions of this Agreement, and that has been audited and approved as a supplier by Baxter's quality assurance department to provide the services to be subcontracted.

"Raw Materials" shall mean all excipients, inactive ingredients and other substances used by Baxter in the Production of Product under this Agreement with the exception of BDS, Components and Secondary Packaging Materials. All Raw Materials are listed in the Bill of Materials.

"Regulatory Approval" shall mean all authorizations by the appropriate Regulatory Authority necessary for use of Product in clinical trials in a jurisdiction, including without limitation, approval of labeling and Production.

"Regulatory Authority" shall mean those agencies or authorities responsible for regulation of the Products in the United States and such other Regulatory Authorities expressly agreed upon by the Parties in the Quality Agreement. Baxter will have no obligation to Produce Product in compliance with the requirements of a Regulatory Authority not specified in the applicable Quality Agreement.

"Regulatory Plan" shall mean the document(s) containing regulatory services and support for the development and maintenance of regulatory submissions and supporting documentation as set forth in Section 2.3.

"Released Executed Batch Record" shall mean the completed batch record and associated exception reports, and Lot QC Data Packet or QCMD created for each Batch of Product.

"Reschedule Fees" shall have the meaning given in Section 4.2.

"Secondary Packaging Materials" as used in this Agreement shall mean any material employed in the secondary packaging of the Product (e.g. leaflet, label and folded box), but excluding any outer packaging used for transportation or shipment. All Secondary Packaging Materials are listed in the Bill of Materials.

"Specifications" shall mean the Materials Specifications and/or the Product Specifications as the context requires.

"Start Timeline" shall mean the timeline for starting a particular milestone or Batch run set forth in the Project Plan (as may be amended by mutual agreement from time to time as set forth in this Agreement).

"Unit" shall mean an individually packaged dose of Product, including by way of example only, a vial or prefilled syringe, as specified in the Project Plan.

Article 2, PLANS/QUALITY AGREEMENT

2.1. Development Plan. Prior to commencing Process Services for any Product, the Parties shall agree in writing upon a Development Plan and/or Project Plan, as applicable. Baxter will not be required to commence Process Services for development of a Product, and Client will not be required to pay for services or costs, until Client has (i) executed and returned the Development Plan and/or Project Plan for such Process Services to Baxter or (ii) issued to Baxter a purchase order or some other written approval by a Genocea Vice President or Genocea officer senior to a Vice President for such services or costs. Upon execution of the Development Plan, Baxter shall commence Development of such Product pursuant to the timeline and otherwise in accordance with the Development Plan.

2.2. Project Plan/Production. For Product to be Produced hereunder, the Parties shall agree in writing upon a Project Plan. Baxter has agreed to schedule Production prior to completion and approval of a Project Plan. However, Baxter will not be required to commence any Production, and Client will not be required to pay for services or costs, until (i) a Project Plan for such Product has been approved in writing by both Baxter and Client or (ii) Client has issued to Baxter a purchase order or some other written approval by a Genocea Vice President or Genocea officer senior to a Vice President for such services or costs. Product-specific Master Batch Records shall be reviewed and approved by Baxter and by Client prior to commencement of Production. Any material change to an approved Product-specific Master Batch Record will be reviewed and approved by Baxter and by Client prior to said change being implemented. Upon execution of the Quality Agreement and the corresponding Project Plan for each Product, Baxter shall commence Production of such Product pursuant to the timeline and otherwise in accordance with the Project Plan. Each Batch of Product shall be Produced by using a copy of the Master Batch Record. Each copy of the Master Batch Record for such Batch of Product shall be assigned a unique Batch number. Any deviation from the manufacturing process specified in the Master Batch Record must be documented in the copy of the Master Batch Record for that Batch. Baxter shall provide Client with required supporting development and Production documentation in a form reasonably suitable for Client's submission to the FDA.

2.3. Regulatory Plan. If requested by Client, Baxter shall provide regulatory services in connection with obtaining Regulatory Approval for a Product. Baxter will not be required to conduct regulatory services for a Product, and Client will not be required to pay for services or costs, until (i) the Regulatory Plan for such Product has been agreed upon by the Parties or (ii) Client has issued to Baxter a purchase order or some other written approval by a Genocea Vice President or Genocea officer senior to a Vice President for such services or costs.

2.4. Quality Agreement. The Parties will agree in writing on a Quality Agreement. Baxter will not be required to schedule any Production, and Client will not be required to pay for services or costs, until (i) a Quality Agreement has been duly signed by both Baxter and Client or (ii) with respect to payment for services or costs, Client has issued to Baxter a purchase order or some other written approval by a Genocea Vice President or Genocea officer senior to a Vice President for such services or costs.

2.5. Amendment. This Agreement and each Development Plan, Project Plan, Regulatory Plan and Quality Agreement may be amended from time to time, only upon mutual

written agreement of Client and Baxter. Upon execution of any Development Plan, Project Plan, Regulatory Plan or Quality Agreement, such executed document shall be deemed to be incorporated herein by reference and made a part of this Agreement. In the event that the terms of any Development Plan, Project Plan, Regulatory Plan or purchase order, acknowledgment, invoice or other standard commercial documents are inconsistent with the terms of this Agreement, this Agreement shall control, unless otherwise explicitly agreed to in writing by the Parties. No Development Plan, Project Plan, Regulatory Plan, Quality Agreement or purchase order, acknowledgment, invoice or other standard commercial documents shall be deemed to amend this Agreement. In the event of a conflict between this Agreement and the Quality Agreement, the Quality Agreement will prevail for matters of quality and this Agreement will prevail for all business, legal, and financial issues.

2.6. Effect of Failure to Execute Plans. Failure to execute a Development Plan, Project Plan or Regulatory Plan with respect to the Product will not relieve either Party of any obligation accruing with respect to services or costs for such Product prior to such failure to execute provided Client has issued to Baxter a purchase order or some other written approval by a Genocea Vice President or Genocea officer senior to a Vice President for such services or costs.

Article 3, PURCHASE AND SUPPLY OF MATERIALS

3.1. Client Supplied Materials. Client, at its expense (including, without limitation, shipping costs), shall supply to Baxter, in a timely manner, all Materials listed in the Bill of Materials as Client supplied. On receipt of the Client supplied Materials, Baxter's sole obligation with respect to evaluation of the Client supplied Materials shall be to (i) review the accompanying certificate of analysis to confirm that the Client supplied Materials conform with the specifications, and (ii) perform testing on the BDS in accordance with the Project Plan. Client shall be liable for the conformance of the BDS and Client supplied Materials to their respective specifications, and Client shall be responsible for any liability arising out of any such nonconformance, including without limitation, Non-Conforming Batches of Product, unless Baxter is required to test the Client supplied Materials and such nonconformance was not detected by Baxter as a result of its negligence or willful misconduct. Unless specifically set forth otherwise in this Agreement, Baxter disclaims any and all liability with respect to Client's BDS. The responsibility for vendor/supplier qualification is set forth in the Quality Agreement. Baxter shall only use Qualified Subcontractors.

3.2. Baxter Supplied Materials. Baxter will purchase, at Baxter's expense, in a timely manner, all Materials listed in the Bill of Materials as Baxter supplied. Baxter shall test such Materials in accordance with the Quality Agreement and QCMD. Baxter shall be liable for the conformance of the Baxter supplied Materials to their respective specifications if such nonconformance is due to Baxter's negligence or willful misconduct as specifically set forth in this Agreement. In addition, Baxter will use commercially reasonable efforts to assist Client in recovering from Baxter's suppliers for indemnification and warranty obligations for purposes of flow through to Client. Baxter shall control packaging materials listed in the Bill of Materials and shall assist Client with evaluation and purchase of modified materials in the event that Client

requests a change in Presentation. Baxter shall not initiate any changes to Materials without prior written approval from Client, in its sole discretion.

3.3. Material Delivery Delays. Timely delivery of Client supplied Materials and Baxter supplied Materials shall mean that the respective Materials and the required cGMP-related documents reach Baxter prior to the scheduled manufacturing date of such Product per the timing set forth in the Project Plan. A delay in delivery of the Client supplied Materials by the vendor shall not be considered to be a delay by Baxter. A delay in delivery of the Baxter supplied Materials by the vendor shall not be considered to be a delay by Client. Notwithstanding anything in this Agreement to the contrary, in the event that Baxter receives the Client supplied Materials and associated cGMP documents for the Production of Product from Client with less time than requested in the Project Plan, but within sufficient time to Produce such Product on such scheduled date, Baxter shall charge Client an additional fee of [Five Thousand and no/100 Dollars ($5,000.00)], which shall be paid promptly to Baxter prior to Production, and Baxter shall Produce such Product as per the original schedule. Notwithstanding anything in this Agreement to the contrary, in the event that Baxter receives the Client supplied Materials for Production of Product from Client with less time than requested in the applicable Project Plan prior to the scheduled date of Production of such Product, and without sufficient time to Produce such Product on the scheduled date or in the event Client cancels or reschedules Production of Product, Baxter shall reschedule Production of such Product and shall charge Client the applicable Reschedule Fee pursuant to Section 4.2.

3.4. Importer of Record. In the event any material or equipment to be supplied by Client, including without limitation Client supplied Materials, is imported into the United States for delivery to Baxter (**"Imported Goods"**), such Imported Goods shall be imported DDP Bloomington, IN (Incoterms 2010). Client shall be the "Importer of Record" of such Imported Goods. As the Importer of Record, Client shall be responsible for all aspects of the Imported Goods including, without limitation (a) customs and other regulatory clearance of Imported Goods, (b) payment of all tariffs, duties, customs, fees, expenses and charges payable in connection with the importation and delivery of the Imported Goods, and (c) keeping all records, documents, correspondence and tracking information required by applicable laws, rules and regulations arising out of or in connection with the importation or delivery of the Imported Goods.

Article 4, PURCHASE AND SUPPLY OF PRODUCT

4.1. Agreement to Purchase and Supply. Pursuant to the terms and conditions of this Agreement, Client will purchase the Product from Baxter, and Baxter will Produce the Product for Client in accordance with this Agreement.

4.2. Reschedule Fees.

4.2.1 If Client unilaterally cancels or reschedules (other than where the Parties mutually agree to reschedule through a change order or to extend the Start Timeline or due to breach or default by Baxter) Production of any Batch set forth in a Project Plan, Client shall pay, as liquidated damages and not as a penalty, the following fees

("**Reschedule Fees**") calculated based on the date of Baxter's receipt of Client's notice, and payable within thirty (30) days after the invoice date:

(i) for cancellation or rescheduling [ninety (90) days] or more in advance of the scheduled Start Timeline for any Demonstration Batch run or cGMP Batch run, no Reschedule Fees shall be due;

(ii) a charge of [thirty] percent ([30]%) of the Production Price of the Batch if the Batch is canceled or rescheduled [less than ninety (90) days] from the scheduled Start Timeline but [more than forty-five (45) days] from the scheduled Start Timeline;

(iii) a charge of [fifty] percent ([50]%) of the Production Price of the Batch if the Batch is canceled or rescheduled [forty-five (45) days or less] from the scheduled Start Timeline but [more than ten (10) business days] from the scheduled Start Timeline;

(iv) a charge of [one hundred] percent ([100]%) of the Production Price of the Batch if the Batch is canceled or rescheduled [ten (10) days or less] from the scheduled Start Timeline.

Such damages set forth in this Section 4.2.1 are in lieu of all other remedies.

4.2.2 As further set forth in the Project Plan, Baxter will timely provide Client with milestones, Product and other deliverables, including BDS testing, within the time periods specified in the Project Plan unless the Parties agree to extend such time periods in writing. Delays in providing Product conforming to the Product Requirements caused by Baxter's [negligence will, to the extent of Baxter's negligence, and delays in providing Product conforming to the Product Requirements caused by Baxter's unilateral act or omission in re-allocating resources to other customers for Baxter's greater economic benefit] will, result in liquidated damages, and not as a penalty, as follows:

(i) for rescheduling the Start Timeline [more than forty-five (45) days] after the scheduled Start Timeline or, if applicable under Section 7.2, the date Baxter receives replacement BDS from Client, [twenty] percent ([20]%) of the Production Price shall be deducted;

(ii) for rescheduling the Start Timeline [more than thirty (30) days], but [forty-five days or less] after the scheduled Start Timeline or, if applicable under Section 7.2, the date Baxter receives replacement BDS from Client, [ten] percent ([10]%) of the Production Price shall be deducted;

(iii) for rescheduling the Start Timeline [more than five (5) days], but [thirty days or less] after the scheduled Start Timeline or, if applicable under Section 7.2, the date Baxter receives replacement BDS from Client, [five] percent ([5]%) of the Production Price shall be deducted, and

(iv) for rescheduling the Start Timeline [five (5) days or less] after the scheduled Start Timeline or, if applicable under Section 7.2, the date Baxter receives replacement BDS from the Client, no fee shall be due.

Such damages set forth in this Section 4.2.2 are in addition to all other remedies as specified in Section 7.2, including termination under Section 8.2.

Article 5, PRICE

5.1. Product Production Price. The price to be paid by Client for the Production of Product (the "**Production Price**") shall be set forth in the Project Plan.

5.2. Regulatory Services Price. The price to be paid by Client for regulatory services shall be set forth in the Regulatory Plan.

5.3. Process Services Price. The price to be paid by Client for Process Services shall be set forth in the Development Plan/Project Plan.

Article 6, SHIPMENT AND INVOICING

6.1. Delivery Terms. Product shall be delivered to Client or its designee EXW (Incoterms 2010) at Baxter's facility in Bloomington, Indiana, freight collect, by a common carrier designated by Client; provided, however, Baxter shall be responsible for the loading of the Product on departure and shall bear all costs of such loading. Client shall procure, at its cost, insurance covering damage or loss to the Product during shipping.

6.2. Storage.

6.2.1 Product Storage. Baxter will store Product free of charge for up to [thirty (30) calendar days] after Baxter's release (the **"Storage Period"**). After the Storage Period, if Baxter agrees to store Product longer, then Baxter may charge the storage fees as set forth in the Project Plan.

6.2.2 BDS and Material Storage. Baxter will not be required to store quantities of BDS more than required to Produce one (1) Batch(es) of Product without the prior written consent of Baxter and Client's agreement. If Baxter agrees to store quantities of BDS in excess of the amount set forth above, the Parties will reach written agreement on the terms of such storage which shall be set forth in a Project Plan, including without limitation the cost of storage fees.

6.2.3 Storage Conditions. Baxter shall store all Materials and Product in safe and secure storage under its control in the Baxter Bloomington, Indiana facility in accordance with the mutually agreed storage guidelines.

6.2.4 Third Party Storage. Baxter shall be permitted to store Product and Client supplied Materials in third party storage facilities with the prior written consent of Client in each case, provided that Baxter shall remain fully responsible for compliance with its obligations under this Agreement.

6.3. Subsequent Export. Client agrees and represents that Client is the owner of the goods that are consigned to Baxter for contract manufacturing services and warrants that Client is responsible for any subsequent export or re-export and will comply with all applicable US laws and regulations relating to the export or re-export, including the prohibition against

unlawful transshipments. Further, where such goods are destined for export or re-export, Client agrees and accepts that it is the Foreign Principal Party in Interest (**"FPPI"**) and warrants that as the FPPI, it will duly authorize and retain a U.S. agent who will act on its behalf, assuming all attendant responsibilities associated with the export or re-export, including obtaining any necessary export licenses, pursuant to 15 C.F. R. §758.3. The Client's responsibilities as FPPI include, but are not limited to, cooperating with its U.S. agent in providing the U.S. government with a detailed description and accurate valuation and classification of the goods, bills of lading, and all other required documentation. Client further agrees to defend Baxter against any action, civil or criminal, private or public, in connection with the subsequent export or re-export by Client of the goods.

6.4. Foreign Corrupt Practices Act. Client acknowledges that it is not the agent of Baxter and represents and warrants that it has not, and covenants that it will not pay anything of value to any government employee in connection with the sale of the Product.

6.5. Payment Terms. The following invoicing and payment terms apply:

Status	Invoice Date	Payment Due
[Development Plan deposit [none anticipated]]	[Execution of Development Plan]	Invoice date + 30 days*
[Project Plan deposit]	[Execution of Project Plan]	Invoice date + 30 days*
[Process Services]	Monthly	Invoice date + 30 days*
[Demonstration Batch(es), cGMP Batch(es)]	100% [less deposit, if any] of Production Price at [Baxter's disposition of the manufacturing (filling portion) Released Executed Batch Record]	Invoice date + 30 days*
[TSS/Validation and TSS Packaging]	100% [less deposit, if any] at Baxter's Completion as specified in the Project Plan	Invoice date + 30 days*

*All days specified above are calendar days.

Payments shall be made in U.S. dollars by check delivered to Baxter by overnight delivery with a reputable overnight delivery service or by wire transfer as set forth in Baxter's invoice. Each invoice shall be payable by Client in accordance with the terms noted above. Any payment due under this Agreement not received within the times noted above shall incur finance charges at the lesser of (a) the maximum rate permitted by law, or (b) [one] percent ([1]%) per month on the outstanding balance.

6.6. Default in Payment Obligations. In addition to all other remedies available to Baxter in the event of a Client default, if Client does not make payments as required hereunder of amounts that are not subject to a good faith dispute by Client, Baxter may refuse to Produce any Product until Client's account in regard to such undisputed payments is paid in full, suspend deliveries of Product until Client provides assurance of performance reasonably satisfactory to Baxter, and/or take other reasonable means as Baxter may determine. In the event Client

disputes, in good faith, an invoice amount, Client agrees to provide Baxter with written notification of such dispute within [thirty (30) days] from the date of the invoice and the Parties shall use good faith efforts to resolve the dispute within [forty-five (45) days] from the date of the invoice. In the event the Parties are unable to resolve the dispute, the dispute shall be promptly elevated to senior management of each Party for resolution.

Article 7, ACCEPTANCE OF PRODUCT

7.1. Product Conformity. Within [twenty (20) calendar days] after the manufacturing of any Batch pursuant to the Project Plan, Baxter shall promptly forward to Client, or Client's designee, samples of such Batch. Within [sixty (60) calendar days] from the Receipt (as defined below) of such samples of Product or [fifteen (15) calendar days] from the date of Receipt of the Released Executed Batch Record, whichever is later (the **"Inspection Period"**), Client will determine whether the Batch of Product was Produced according to the Product Requirements and reject such Batch if such Batch was not Produced in accordance with the Product Requirements ("Non-Conforming") or accept such Batch if such Batch was Produced in accordance with the Product Requirements. If Client believes a Batch is Non-Conforming, it shall notify Baxter as set forth in Section 7.1.2. For purposes of this Section 7.1, "Receipt" shall occur on the first business day following the date of confirmed transmission if Baxter sends by facsimile or email, and on the second business day following the date of delivery to the overnight delivery service if Baxter sends by overnight delivery.

7.1.1 If Client does not notify Baxter in writing within the Inspection Period that the Batch of Product is Non-Conforming, then such Batch will be deemed to have been accepted and Client will have waived its right to revoke acceptance (other than for Latent Defects, in which case, the Inspection Period for such Product shall be [twelve (12) months] and the Parties shall then follow the procedures set forth in Section 7.1.2).

7.1.2 If Baxter released a Batch of Product and Client believes such Batch is Non-Conforming, it will provide to Baxter a detailed explanation of the non-conformity within the Inspection Period. Such notice of non-conformity shall be confirmed in writing via overnight delivery to Baxter. Upon receipt of such notice, Baxter will investigate such alleged non-conformity and, (a) if Baxter agrees such Batch is Non-Conforming, deliver to Client a corrective action plan within [thirty (30) calendar days] after receipt of Client's written notice of non-conformity, or such additional time as is reasonably required and mutually agreed if such investigation or plan requires data from sources other than Client or Baxter (the "Response Period"), or (b) if Baxter disagrees that the Batch of Product is Non-Conforming, Baxter will so notify Client in writing and provide to Client a detailed explanation of the conformity within the Response Period.

7.1.3 If the Parties dispute whether the Batch of Product is conforming or Non-Conforming, samples of the Batch will be submitted to a mutually acceptable laboratory or consultant for resolution, whose determination of conformity or non-conformity, and the cause thereof if Non-Conforming, shall be binding upon the Parties for purposes of determining financial liability. Notwithstanding the foregoing, Client cannot release a

Batch of Product that Baxter has rejected. The costs of such laboratory or consultant are to be borne by the Party whose determination was incorrect.

7.2. Remedies for Non-Conforming Batch of Product. In the event Baxter determines or agrees that a Batch of Product is a Non-Conforming Batch as a result of Baxter's [negligence or willful misconduct], or such mutually acceptable laboratory or consultant determines that such Batch of Product is a Non-Conforming Batch as a result of Baxter's [negligence or willful misconduct], then: (i) within a reasonable time after either such determination, Baxter will[, to the extent of its negligence or willful misconduct,] reimburse Client for the cost of the BDS used in such Non-Conforming Batch, with such reimbursement not to exceed an amount equal to (a) with respect to a Demonstration Batch, [one (1) times] the Production Price of the Non-Conforming Batch, or (b) with respect to a cGMP Batch, [one and one-half (1½) times] the Production Price of the Non-Conforming Batch; and (ii) Baxter will[, to the extent of its negligence or willful misconduct], at Client's option, (a) if Client has paid for such Non-Conforming Batch, either refund or credit the Production Price of the Non-Conforming Batch or replace the Non-Conforming Batch, at Baxter's expense, within [forty-five (45) calendar days] from receipt of sufficient BDS to be provided by Client, at Client's expense, and in due time to carry out the Production, or (b) if Client has not paid for the Non-Conforming Batch, Baxter will not invoice for the Non-Conforming Batch and shall replace the Non-Conforming Batch, at Client's expense, within [forty-five (45) calendar days] from receipt of sufficient BDS to be provided by Client, at Client's expense, and in due time to carry out the Production.

Article 8, TERM AND TERMINATION

8.1. Term. This Agreement shall commence on the Effective Date and shall continue for seven (7) years unless earlier terminated in accordance with Sections 8.2, 8.3 or 8.4 of this Agreement (the "**Term**").

8.2. Termination for Breach. Either Party may terminate this Agreement upon the material breach of any provision of this Agreement by the other Party if such breach is not cured by the breaching Party within [thirty (30) calendar days] for monetary defaults, and [sixty (60) calendar days] for non-monetary defaults (or such additional time as is reasonably necessary to cure such non-monetary default provided that such longer period of time for cure shall in no case exceed [ninety (90) calendar days)] after receipt by the breaching Party of written notice of such default. At the option of the non-breaching Party, such termination may be with respect to the entire Agreement, or only with respect to the Product which is subject to the breach.

8.3. Termination for Financial Matters. Either Party may terminate this Agreement immediately by giving the other Party written notice thereof in the event such other Party shall become judicially adjudged insolvent or unable to pay its debts when due, or in the event that proceedings are commenced against, or voluntarily by, such Party relating to its bankruptcy or insolvency and not dismissed within [ninety (90) days].

8.4. Termination by Client. Client may terminate this Agreement at any time effective on notice, subject to Section 4.2.1 (Reschedule Fees) and Section 8.6 (Non-cancelable Costs and Expenses).

8.5. Additional Rights and Remedies. Subject to Section 13.1, termination under this Article 8 shall be in addition to the other rights and remedies of the terminating Party as specified herein.

8.6. Non-cancelable Costs and Expenses. In the event of the termination (but not expiration) of this Agreement, Baxter will immediately cease performance, cancel all commitments, and take all reasonable steps to mitigate further expenses, and except in the event of termination by Client as a result of a breach by Baxter under Section 8.2 or under Section 8.3, Client will (a) reimburse Baxter for all Materials and equipment ordered prior to termination and not cancelable at no cost to Baxter or will pay Baxter the cost of cancellation, and (b) pay Baxter for any work-in-process commenced by Baxter under any outstanding approved Development Plans and/or Project Plans. In addition, in the event of termination or expiration for any reason, subject to Section 7.2, Client will pay the prices described in Article 5 for all finished Product Produced prior to expiration or termination. Within [sixty (60) calendar days] after the effective date of termination or expiration, Baxter will ship such Materials, equipment, work-in-process and Product to Client pursuant to Section 6.1 at Client's cost and per Client's instructions. Client will make payments for all expenses described in this Section 8.6 no later than [thirty (30) calendar days] from the later to occur of the shipment of such Materials, equipment, work-in-process and Product or the invoice date. Baxter will provide a final accounting and credit any prepayments (if any) on its final invoice, and refund any outstanding balance to Client, no later than [sixty (60) calendar days] from the effective date of termination or expiration.

8.7. Survival. Termination or expiration of this Agreement through any means or for any reason shall be without prejudice to the rights and remedies of either Party with respect to any antecedent breach of any of the provisions of this Agreement, subject to Article 13. The provisions of Articles/Sections 1, 2.5, 2.6, 8, 9.2, 9.3, 9.8, 10, 12, 13, 14, 15, 16, 17, 18, 20, 21, 24, 25, 26, 27, 29, 30 and 31 hereof shall survive expiration or termination of this Agreement. Termination of this Agreement for any reason shall not relieve any Party of any obligations or affect any rights accruing prior to such termination.

Article 9, PRODUCTION OF PRODUCT

9.1. Reprocessing, Rework or Reproduction. If reprocessing, rework or reproduction is allowed pursuant to Client's regulatory submissions or approved by Client, it shall be performed in accordance with the Quality Agreement and Client shall be responsible for and promptly reimburse Baxter for all Client approved costs and expenses incurred in connection with such reprocessing, rework or reproduction, unless such reprocessing, rework or reproduction is due to [any negligent or willful act or omission of Baxter], in which case Baxter will[~~, to the extent of its negligent or willful act or omission,~~] pay for all costs and expenses incurred in connection with such reprocessing, rework or reproduction, which payment will not exceed [the Production Price of the affected Batch of Product].

9.2. Audits.

9.2.1 Quality Audits. Client shall have the right to audit Baxter's facilities to determine compliance with (i) cGMP, (ii) the Project Plan, (iii) Baxter SOPs, and (iv) applicable laws and regulations. Such audits shall be scheduled at mutually agreeable times upon reasonable advance written notice to Baxter. Audits shall be at Client's expense as detailed in the Project Plan, if it occurs more than one (1) time every calendar year unless required by Baxter's compliance status. If Client requests additional audits which are not due to Baxter's compliance status and Baxter agrees to such audits, Client will incur fees as set forth in the Project Plan. Such fees shall be paid promptly upon completion of such audits. In connection with performing such audits, Client shall comply with all reasonable rules and regulations promulgated by Baxter. All information disclosed or reviewed in such inspections shall be deemed to be the property of Baxter and Baxter Confidential Information.

9.2.2 Other Audits. Except as provided in Section 9.2.1, any audit shall be at the expense of Client and the prior written consent of Baxter.

9.3. Stability Testing. At Client's expense, Client or a party selected by Client shall perform all stability testing required to be performed on Product. If performed by Baxter, such testing shall be performed in accordance with the procedures set out in the Product-specific Baxter SOPs for the stability protocol and the Project Plan. If Baxter is not performing stability testing, then Baxter requires at a minimum that Baxter perform the sterility testing as part of the stability program. Such stability protocol shall contain a listing of the analytical testing and corresponding Product Specifications, to be performed on the Product in connection with the stability testing program under 21 CFR § 166.

9.4. Permits and Licenses. Client will be responsible, at its expense, for obtaining, maintaining, updating and remaining in compliance with all permits, licenses and other authorizations during the Term of this Agreement, which are necessary or required under federal, state, and local laws, rules and regulations which are applicable to the use and sale of Product Produced by Baxter hereunder, in addition to any permits, licenses and other authorizations that are specific to the Production of Product, if any. Baxter will be responsible, at its expense, for obtaining, maintaining, updating and remaining in compliance with all generally required permits and licenses applicable to production of pharmaceutical products generally which are required for Baxter to carry out its regulatory and Production obligations hereunder. Baxter will have no obligation to obtain permits relating to the sale, marketing, distribution or use of BDS or Product or with respect to the content of any Product labeling.

9.5. Regulatory Requirements. Each Party promptly shall notify the other of new regulatory requirements of which it becomes aware which are relevant to the Production of Product under this Agreement and which are required by an applicable Regulatory Authority or other applicable laws or governmental regulations, and shall confer with each other with respect to the best means to comply with such requirements. Baxter shall notify Client of and require prior written approval from Client for material changes to Product-specific Master Batch Records and Product Specifications prior to the Production of subsequent Batches of Product. Baxter shall have no obligation to Produce Product in compliance with the requirements of a

Regulatory Authority not explicitly specified in the Quality Agreement. Client shall supply to Baxter a copy of its license submission prior to Baxter's Production of Product. Client will be responsible for the final release of each Batch of Product for use in clinical trials as set forth in the Quality Agreement. Baxter shall be responsible for compliance with all federal, state and local laws and regulations of Regulatory Authorities (the "**Regulations**") as they apply generally to production of pharmaceutical products. Client shall be responsible for compliance with all Regulations as they apply specifically to all other aspects of the Production, use, and sale of Product or BDS, which responsibility shall include, without limitation, all contact with the FDA, and other regulatory authorities, regarding the foregoing.

9.6. Changes in Manufacturing.

9.6.1 Product-Specific Changes. If facility, equipment, process or system changes are required of Baxter as a result of requirements set forth by a Regulatory Authority, and such regulatory changes apply solely to the Production and supply of one or more Products, then Client and Baxter will review such requirements and agree in writing to such regulatory changes, and Client shall bear [one hundred] percent ([100]%) of the reasonable costs thereof.

9.6.2 General Changes. If such regulatory changes apply generally to one or more Products as well as to one or more other products produced by Baxter for itself or for third parties, then Client shall pay a pro rata amount of the reasonable cost of such regulatory changes based upon the proportion of time that such facility is dedicated to the Production of Products relative to the production of such other products.

9.7. Equipment Expenses. If Baxter is required to obtain specialized equipment in order to Produce Product for Client, the price of such equipment shall be paid by Client. Baxter shall advise Client of the specialized equipment required and the estimated price associated with the purchase and installation of such equipment. Client shall be invoiced for all approved costs as specified in the Project Plan. Baxter shall be responsible for such equipment while at the Baxter facility.

9.8. Ownership of Equipment. Upon termination or expiration of this Agreement, Baxter upon the agreement of Client shall either (i) transfer possession of the specialized equipment paid for by Client to Client, or (ii) purchase such equipment by paying Client the then current book value of such equipment. Depreciation of such equipment shall be calculated in accordance with applicable generally accepted accounting principles.

9.9. Manufacturing Compliance. Baxter shall advise Client immediately if an authorized agent of any regulatory body visits Baxter's manufacturing facility and makes an inquiry specifically regarding Baxter's Production of Product for Client. Client shall advise Baxter immediately if an authorized agent of any regulatory body plans to visit or accompany Client on a visit to Client's facility or Baxter's manufacturing facility.

9.10. Lot QC Data Packet. At Client's cost and expense, Baxter shall test, or cause to be tested by third parties, in accordance with the Specifications, each Batch of Product Produced pursuant to this Agreement before delivery to Client. The Lot QC Data Packet shall contain a

certificate of analysis section for each Batch delivered and shall set forth the items tested, Specifications, and test results. Baxter shall also indicate on the final page of the Executed Batch Record that all Batch Production and control records have been reviewed and approved by the appropriate quality unit. Baxter shall send, or cause to be sent, such Lot QC Data Packet to Client prior to the shipment of Product. In the event Baxter is unable to send the Lot QC Data Packet due to technical difficulties, Baxter may send a QCMD in lieu of a Lot QC Data Packet, which QCMD shall contain all of the Lot QC Data Packet information.

Article 10, REGULATORY

10.1. Regulatory Approvals. Client will maintain all necessary Regulatory Approvals of marketing licenses for Product Produced by Baxter hereunder. As agreed upon by Client and Baxter in a Regulatory Plan, Baxter will provide documents and assist Client in preparation of submissions to US and foreign Regulatory Authorities designated by Client in support of Client's applications, and Client will advise Baxter of such document requirements in support of filings and similar applications required of US and foreign governments and agencies including amendments, license applications, supplements and maintenance of such. All regulatory submission preparation and maintenance performed by Baxter for Client shall be specified in the Regulatory Plan. Prior to submission to the Regulatory Authority, Client will provide Baxter with a copy of the applicable CMC section for review and comment. A final copy of the applicable CMC section will be provided by Client to Baxter upon submission to the Regulatory Authority.

Article 11, TRADEMARKS

11.1. Client grants to Baxter a non-exclusive, royalty-free license to use trademarks of Client for the sole purpose of allowing Baxter to fulfill its responsibilities under any Project Plan and this Agreement. Such license shall not be transferable in whole or in part.

11.2. Client shall be solely responsible for selecting, registering and enforcing trademarks of Client used to identify the Product and, except as set forth in Section 11.1, shall have sole and exclusive rights in such trademarks of Client.

Article 12, REPRESENTATIONS AND WARRANTIES

12.1. Mutual Representations. Each Party hereby represents and warrants to the other Party that (a) the person executing this Agreement is authorized to execute this Agreement; (b) this Agreement is legal and valid and the obligations binding upon such Party are enforceable by their terms; (c) the execution, delivery and performance of this Agreement does not conflict with any agreement, instrument or understanding, oral or written, to which such Party may be bound, nor violate any law or regulation of any court, governmental body or administrative or other agency having jurisdiction over it; and (d) it is not, and during the Term of this Agreement, shall not be debarred by any applicable governmental authority, including without limitation under subsections 306(a) or (b) of the U.S. Food, Drug and Cosmetic Act, and it will not use in any

capacity in the performance of this Agreement the services of any person or entity who is debarred by any applicable governmental authority. Each Party shall promptly notify the other Party in the event that it or any of its personnel becomes debarred or excluded during the Term of this Agreement.

12.2. Baxter Warranty. Baxter represents and warrants that Product shall be Produced in accordance with applicable cGMPs and all other Product Requirements, including without limitation, sterility and endotoxin (with no warranty that Product shall meet the Product Specifications). Except as provided in this Agreement, Baxter makes no representation or warranty with respect to the sale, marketing, distribution or use of the BDS, Product or to printed materials specified by Client or its consignee. Baxter further represents and warrants that (a) it has the right to give Client any information and materials provided by Baxter hereunder, and that Client has the right to use such information and materials for the Production of Product, and (b) Baxter has no knowledge of any (i) patents or other intellectual property rights that would be infringed by Baxter's Production of Product under this Agreement, or (ii) proprietary rights of third parties which would be violated by Baxter's performance hereunder, and (c) Baxter will Produce the Product and perform the Process Services in accordance with applicable laws, rules and regulations.

12.3. Disclaimer of Warranties. Except for those warranties set forth in Sections 12.1 and 12.2 of this Agreement, Baxter makes no warranties, written, oral, express or implied, with respect to Product or the Process Services and Production of Product. Except for those warranties set forth in Sections 12.1 and 12.4 of this Agreement, Client makes no warranties, written, oral, express or implied, with respect to Product, BDS or the sale, marketing, distribution or use of the BDS, Product or to printed materials specified by Client or its consignee. ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING, WITHOUT LIMITATION, THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE AND NONINFRINGEMENT HEREBY ARE DISCLAIMED BY BAXTER AND CLIENT. NO WARRANTIES OF BAXTER OR CLIENT MAY BE CHANGED EXCEPT IN WRITING AND SIGNED BY A DULY AUTHORIZED REPRESENTATIVE OF BOTH PARTIES.

12.4. Client Warranties. Client warrants that (a) it has the right to give Baxter any information and materials provided by Client hereunder, and that Baxter has the right to use such information and materials for the Production of Product, and (b) Client has no knowledge of any (i) patents or other intellectual property rights that would be infringed by Baxter's Production of Product under this Agreement, or (ii) proprietary rights of third parties which would be violated by Baxter's performance hereunder. Client warrants that the BDS provided to Baxter hereunder will (1) conform to the BDS specifications and (2) not be adulterated or misbranded within the meaning of the FD&C Act. Client will use and promote the Product in accordance with its regulatory filings and approvals.

Article 13, EXCLUSIVE REMEDIES, LIMITATION OF LIABILITY AND RISK OF LOSS

13.1. Exclusive Remedies. [A Party's] right to recover damages, losses or expenses from [the other Party], and [a Party's] liability under this Agreement, is limited to the amounts and remedies set forth in the applicable sections of this Agreement and subject to Section 13.2; [provided that nothing in this Agreement shall be construed to limit a Party's recovery or remedies for a breach of Article 17 by the other Party]. All claims by a Party under this Agreement (except claims seeking indemnity) shall be brought no later than [three (3) years] after the occurrence of the event giving rise to such claim; otherwise, such claim shall be deemed waived.

13.2. Limitation of Liability.

(a) Except [as otherwise provided in Article 4 and except] to the extent recoverable under Article 14, [and except for breach of Article 17 (Intellectual Property) or Sections 18.1, 18.2, 18.3 or 18.4 of Article 18 (Confidential Information, Nondisclosure and Publicity),] whether a claim is founded in tort or contract and even if [either Party] asserts or establishes a failure of the essential purpose of any limited remedy provided in this Agreement, under no circumstances shall [either Party] be liable for:

(i) incidental, special, consequential, punitive, exemplary or other indirect damages, including but not limited to, lost profits, or

(ii)

(1) except as specifically set forth in Section 13.3 of this Agreement, loss, damage or destruction of the Materials, or

(2) except as specifically set forth in Section 16.1 of this Agreement, the cost of cover or recall costs.

Any claims recoverable under this Section 13.2(a) are subject to Sections 13(b) and (c).

(b) Except for liability caused by Baxter's gross negligence or willful misconduct, [Baxter's breach of Article 17 (Intellectual Property) or Baxter's breach of Sections 18.1, 18.2, 18.3 or 18.4 of Article 18 (Confidential Information, Nondisclosure and Publicity),] and to the extent permitted under applicable laws: under no circumstances shall Baxter's aggregate liability under this Agreement, including but not limited to third party claims (except as provided in Section 14.2), exceed an amount equal to (a) the amounts paid by Baxter to Client pursuant to Section 4.2.2, if any, plus (b) the greater of:

(i) [the aggregate amount paid and/or amounts invoiced but not yet paid to Baxter by Client during the Term of this Agreement, or]

(ii) [one and one-half (1½) times the Production Price of the highest priced Batch of Product Produced hereunder (cumulatively, (a) and (b),] the **"Baxter Monetary Cap"**).

(c) [To the extent permitted under applicable laws, under no circumstances shall Client's aggregate liability to Baxter under this Agreement exceed an amount equal to the aggregate amount paid and/or amounts invoiced and not yet paid to Baxter by Client during the Term of this Agreement plus the amounts paid by Client to Baxter pursuant to Section 4.2.1, if any (the **"Client Monetary Cap"**), except for liability caused by Client's gross negligence or willful misconduct, Client's breach of Article 17 (Intellectual Property) or Client's breach of Sections 18.1, 18.2, 18.3 or 18.4 of Article 18 (Confidential Information, Nondisclosure and Publicity), and except to the extent recoverable under Article 14].

13.3. Risk of Loss. All Baxter supplied equipment and Baxter supplied Materials used by Baxter in the Production of Product (collectively, the **"Baxter Property"**) shall at all times remain the property of Baxter and Baxter assumes risk of loss for the Baxter Property until delivery of Product to a common carrier as specified under Section 6.1. Client assumes all risk of loss for Client supplied Materials, equipment owned by Client, and all Product (collectively, the **"Client Property"**); provided, however, [to the extent such] loss or damage is due to Baxter's [negligence or willful misconduct], Baxter shall, [to the extent of its negligence or willful misconduct,] reimburse Client for its actual costs for replacement of the loss or damage of Client Property, provided, however, that such costs do not exceed an amount equal to [one and one-half (1½) times the Production Price of the Batch of Product that was affected by such loss or damage].

13.4. Waiver of Claims. In connection with providing Process Services, each Party represents only that it will use commercially reasonable efforts in providing such information solely as it relates to Process Services studies, formulation, primary packaging and manufacturing process analysis. In connection with Baxter providing Process Services under this Agreement, Baxter represents only that it will use reasonable care in providing such Process Services, and Baxter makes no warranties or guarantees with respect to the results of any Process Services provided under this Agreement.

Article 14, INDEMNIFICATION

14.1. Client Indemnification. Client shall indemnify, defend and hold harmless Baxter and its Affiliates and any of their respective directors, officers, governors, members, employees, subcontractors and agents (collectively, the **"Indemnified Parties"**) from and against any and all Losses to, and Claims in connection with pending or threatened litigation or other proceedings, which arise out of or relate to any one of the following:

(a) Client's transport, storage, promotion, labeling, marketing, distribution, use or sale of Product;

(b) Baxter's use of the BDS to Produce Product in accordance with the Agreement;

(c) Client's negligence or willful misconduct;

(d) Materials except to the extent Baxter suppliers of Baxter supplied Materials are contractually required to indemnify Baxter for such Materials;

(e) Client's breach of any covenant, representation or warranty contained in this Agreement;

(f) the use of BDS or the sale, marketing or distribution of Product by Client violates the patent, trademark, copyright or other proprietary rights of any third party, except if such violation is caused by Baxter's proprietary processes, products and equipment; or

(g) the use of BDS or Production of Product by Baxter in accordance with this Agreement violates the patent, trademark, copyright or other proprietary rights of any third party, except if such violation is caused by Baxter's proprietary processes, products and equipment,

Except [to the extent the] foregoing (a), (b), or (d) [is caused by the] negligence or willful misconduct of Baxter. Client's indemnity obligations in the case of each of the foregoing (a) through (g) are subject to Section 14.2.

[Client's liability under this Section 14.1 shall not be subject to the Client Monetary Cap.]

14.2. Baxter Indemnification. Baxter shall indemnify, defend and hold harmless Client and its Affiliates and any of their respective directors, officers, governors, members, employees, subcontractors and agents from and against any and all Losses and Claims in connection with pending or threatened litigation or other proceedings, [to the extent resulting from] Baxter's negligence or willful misconduct. Baxter's liability under this Section 14.2 shall be subject to the Baxter Monetary Cap, except to the extent the Loss or Claim results from Baxter's gross negligence or willful misconduct; in which case, Baxter's indemnity obligations shall not be subject to the Baxter Monetary Cap.

14.3. Indemnitee Obligations. Any Party seeking indemnification hereunder (a) shall give prompt written notice to the other Party (the **"Indemnifying Party"**) of any Claim for which indemnification is sought, (b) shall permit the Indemnifying Party to assume full responsibility to investigate, prepare for and defend against the Claim, (c) shall reasonably assist the Indemnifying Party, at the Indemnifying Party's request and reasonable expense, in the investigation of and preparation for the defense of such Claim, and (d) shall not compromise or settle such Claim without the Indemnifying Party's prior written consent.

Article 15, INSURANCE

15.1. Client Insurance. Client shall procure and maintain, during the Term of this Agreement and for a period one (1) year beyond the expiration date of Product, Commercial General Liability Insurance, including without limitation, Product Liability and Contractual Liability coverage (the **"Client Insurance"**). Client Insurance for Product Liability shall cover amounts not less than [$2,000,000 (two million dollars)] per occurrence and aggregate and shall be with an insurance carrier with an A.M. Best rating of A-VII or better. Client Insurance for Product Liability will also include umbrella liability coverage in the amount of [$4,000,000 (four

million dollars)] per occurrence and aggregate. Baxter shall be named as an additional insured on the Client Insurance and Client promptly shall deliver a certificate of Client Insurance and endorsement of additional insured to Baxter evidencing such coverage. If Client fails to furnish such certificates or endorsements, or if at any time during the Term of this Agreement Baxter is notified of the cancellation or lapse of Client Insurance, and Client fails to rectify the same within [ten (10) calendar days] after notice from Baxter, in addition to all other remedies available to Baxter hereunder, Baxter, at its option, may (i) cease all work in process and refuse further Process Services and/or Production until Client re-establishes that Client is in compliance with Client Insurance requirements and/or (ii) terminate this Agreement.

15.2. Baxter Insurance. Baxter is, and will during the Term of this Agreement remain, self-insured for the type of liability that could arise under this Agreement in amounts no less than the coverage amounts set forth above for Client Insurance.

15.3. No Limitation. Neither Party's liability will be limited to that which is recoverable by insurance.

Article 16, PRODUCT RECALLS

16.1. Recalls. In the event Client is required to recall any Product or elects to institute a voluntary recall, Client will be responsible for coordinating such recall. Client will promptly notify Baxter of such recall and provide Baxter with a copy of all documents relating to Production by Baxter of Product that is the subject of such recall, unless Client is claiming that such recall was caused by Baxter's negligence, in which case, Client will provide Baxter with a copy of all such documents. Baxter will cooperate with Client in connection with any recall, at Client's request and reasonable expense. Client will be responsible for all of the costs and expenses of such recall (including but not limited to costs associated with receiving and administering the recalled Product and notification of the recall to those persons whom Client deems appropriate); provided that Baxter will be responsible for all of the costs and expenses of such recall (including but not limited to costs associated with receiving and administering the recalled Product and notification of the recall to those persons whom Client deems appropriate) [to the extent due to the] negligence or willful misconduct of Baxter, with Baxter's payment not to exceed an amount equal to [one and one-half (1½) times the Production Price of the Batch of Product that was subject of the recall].

Article 17, INTELLECTUAL PROPERTY

17.1. Existing Intellectual Property. Except as the Parties may otherwise expressly agree in writing, each Party shall continue to own its existing patents, trademarks, copyrights, trade secrets and other intellectual property, without conferring any interests therein on the other Party. Without limiting the generality of the preceding sentence, Client shall retain all right, title and interest arising under the United States Patent Act, the United States Trademark Act, the United States Copyright Act and all other applicable laws, rules and regulations in and to all Products, BDS, labeling and trademarks associated therewith (collectively, **"Client's Intellectual Property"**). Neither Baxter nor any third party shall acquire any right, title or

interest in Client's Intellectual Property, express or implied, by virtue of this Agreement or otherwise, except to the extent expressly provided herein.

17.2. Inventions. For purposes of this Agreement, **"Invention"** shall mean information relating to or comprising any invention, innovation, improvement, development, discovery, computer program, device, trade secret, method, know-how, process, technique or the like, whether or not written or otherwise fixed in any form or medium, regardless of the media on which contained and whether or not patentable or copyrightable.

17.3. Ownership of Inventions. As between the Parties, ownership of Inventions shall be determined such that: (i) Client shall solely own all right, title and interest in and to any and all Inventions, whether conceived, reduced to practice, or created solely by Baxter Representatives, solely by Client Representatives or jointly by one or more Client Representative(s) together with one or more Baxter Representative(s), that materially incorporates Client BDS, Client's proprietary processes used in the Process Services, Product and/or Client Confidential Information, or uses of the foregoing, and any other Inventions that are conceived or created solely by Client Representatives that are not Baxter Inventions (**"Client Inventions"**), and (ii) Baxter shall solely own all right, title and interest in and to any and all Inventions whether conceived, reduced to practice, or created solely by Baxter Representatives, solely by Client Representatives or jointly by one or more Client Representative(s) together with one or more Baxter Representative(s), that materially incorporates Baxter proprietary processes used in the Process Services, Baxter pre-existing methodology in performing its services and/or Baxter Confidential Information, or uses of the foregoing and any other Inventions that are conceived or created solely by Baxter Representatives that are not Client Inventions (**"Baxter Inventions"**), and (iii) Client and Baxter shall jointly own all right, title and interest in and to any and all Inventions conceived, reduced to practice or created jointly by one or more Client Representative(s) together with one or more Baxter Representative(s) that are not Client Inventions or Baxter Inventions (**"Joint Inventions"**). Baxter shall promptly disclose in writing all such Inventions and Joint Inventions to Client in reasonable detail to evaluate potential patent claims. **"Representatives"** mean a Party's employees and/or their respective agents (i.e., employees or agents who would be or are properly named as co-inventors under the laws of the United States on any patent application claiming such inventions). Each Party shall have full rights to exploit its own Inventions and Joint Inventions for its own commercial purposes without any obligation to the other. The Parties shall share equally in the cost of mutually agreed patent filings with respect to all Joint Inventions. The decision to file for patent coverage on Joint Inventions shall be mutually agreed upon, and the Parties shall select a mutually acceptable patent counsel to file and prosecute patent applications based on such Joint Inventions.

17.4. Disclaimer. Except as otherwise expressly provided herein, nothing contained in this Agreement shall be construed or interpreted, either expressly or by implication, estoppel or otherwise, as: (i) a grant, transfer or other conveyance by either Party to the other of any right, title, license or other interest of any kind in any of its Inventions or other intellectual property, (ii) creating an obligation on the part of either Party to make any such grant, transfer or other conveyance or (iii) requiring either Party to participate with the other Party in any cooperative development program or project of any kind or to continue with any such program or project.

17.5. Rights in Intellectual Property. The Party owning any intellectual property shall have the worldwide right to control the drafting, filing, prosecution and maintenance of patents covering the Inventions relating to such intellectual property, including decisions about the countries in which to file patent applications. Patent costs associated with the patent activities described in this Section shall be borne by the sole owner. Each Party will cooperate with the other Party in the filing and prosecution of patent applications. Such cooperation will include, but not be limited to, furnishing supporting data and affidavits for the prosecution of patent applications and completing and signing forms needed for the prosecution, assignment and maintenance of patent applications and patents.

17.6. Confidentiality of Intellectual Property. Intellectual property shall be deemed to be the Confidential Information of the Party owning such intellectual property. The protection of each Party's Confidential Information is described in Article 18. Any disclosure of information by one Party to the other under the provisions of this Article 17 shall be treated as the disclosing Party's Confidential Information under this Agreement. It shall be the responsibility of the Party preparing a patent application to obtain the written permission of the other Party to use or disclose the other Party's Confidential Information in the patent application before the application is filed and for other disclosures made during the prosecution of the patent application.

17.7. Permitted Use. As between Baxter and Client, Client shall at all times own Client supplied Materials, Product, Client's Intellectual Property and Client Inventions. Baxter shall maintain any Client supplied Materials, Product, Client's Intellectual Property and Client Inventions under its control (except as contemplated in Section 6.2.4) and shall not transfer, nor permit the transfer of, any Client supplied Materials, Product, Client's Intellectual Property and/or Client Inventions to any third party not specifically authorized in advance and in writing by Client. Baxter and its Representatives shall not use the Client supplied Materials, Product, Client's Intellectual Property and/or Client Inventions for any purpose other than as expressly permitted in this Agreement.

Article 18, CONFIDENTIAL INFORMATION, NONDISCLOSURE AND PUBLICITY

18.1. Confidentiality. It is contemplated that in the course of the performance of this Agreement each Party may, from time to time, disclose Confidential Information to the other. Each Party agrees to take all reasonable steps to prevent disclosure of Confidential Information to third parties. No provision of this Agreement shall be construed so as to preclude disclosure of Confidential Information as may be reasonably necessary to secure from any governmental agency necessary approvals or licenses or, in the case of Client, to obtain patents with respect to the Product.

18.2. Prior Confidentiality Agreement.

18.2.1 This Agreement, by reference, incorporates the Confidential Disclosure Agreement between Client and Baxter effective April 7, 2014 (the **"Confidentiality Agreement"**), and is made a part hereof as though fully set forth herein and all terms and conditions set forth in the Confidentiality Agreement shall continue to govern any disclosure made under the Confidentiality Agreement and shall govern any disclosure made under this Agreement after the Effective Date of this Agreement. In the event of a conflict between this Agreement and the Confidentiality Agreement, this Agreement shall govern. "Confidential Information", as used in this Agreement, shall have the meaning defined in the Confidentiality Agreement, which is hereby amended to apply to information "relating to the Potential Business Arrangement and/or the performance of the Product Development And Clinical Supply Agreement between the Parties dated October 23, 2014." The Master Batch Records, Materials Specifications, Process Services, Products Specifications, Release Executed Batch Records and the data and results contained in the Executed Batch Records, are automatically deemed the Confidential Information of Client.

18.2.2 All obligations of confidentiality and non-use imposed upon the Parties under this Agreement (including the Confidentiality Agreement), including without limitation the period of confidentiality and non-use as set forth in the Confidentiality Agreement which is hereby amended by this Section 18.2.2, shall expire five (5) years after the expiration or earlier termination of this Agreement; provided that such obligations shall continue indefinitely as to the Executed Batch Records, Master Batch Records, Materials Specifications, Process Services, Products Specifications, and Release Executed Batch Records, until falling within an exception in section 2 of the Confidentiality Agreement.

18.2.3 Section 3 of the Confidentiality Agreement is hereby amended by this Section 18.2.3 to include use and disclosure as reasonably required for the performance of this Agreement.

18.2.4 The Disclosure Term is hereby amended by this Section 18.2.4 (i) to continue for the longer of the Disclosure Term in the Confidentiality Agreement or until the date of the expiration or termination of this Agreement, and (ii) to provide that neither Party may terminate or cancel the Confidentiality Agreement except co-terminus with the expiration or termination of this Agreement.

18.3. Third Party Disclosure. Baxter will be permitted to disclose Product information to third party developmental and analytical services providers that are Qualified Subcontractors in connection with performance of its obligations hereunder provided such providers shall be subject to confidentiality agreements.

18.4. Limitation of Disclosure. The Parties agree that, except as otherwise may be required by applicable laws, regulations, rules or orders, including without limitation the rules and regulations promulgated by the United States Securities and Exchange Commission (the **"SEC"**), and except as may be authorized in the Confidentiality Agreement and unless otherwise

agreed in this Agreement, no information concerning this Agreement and the transactions contemplated herein shall be made public by either Party without the prior written consent of the other.

18.5. Publicity and SEC Filings. The Parties agree that the public announcement of the execution of this Agreement shall only be by one or more press releases mutually agreed to by the Parties. The failure of a Party to return a draft of a press release with its proposed amendments or modifications to such press release to the other Party within five (5) business days of the Party's receipt of the press release shall be deemed as approval of such press release. Each Party agrees that it shall cooperate fully and in a timely manner with the other with respect to all disclosures to the SEC or any other governmental or regulatory agencies, including providing written notice to the other Party and sufficient time to review and request confidential treatment of Confidential Information of such other Party included in any such disclosure. Each Party may communicate information to its investors to the extent made public by the other Party.

18.6. Reference List. Neither Party shall be entitled to put the other Party's name on a reference list without the other Party's prior written approval.

Article 19, FORCE MAJEURE

19.1. Any delay in the performance of any of the duties or obligations of either Party hereto (except the payment of money) caused by an event outside the affected Party's reasonable control shall not be considered a breach of this Agreement, and unless provided to the contrary herein, the time required for performance shall be extended for a period equal to the period of such delay. Such events shall include without limitation, acts of God; acts of public enemies; insurrections; riots; terrorist actions; injunctions; embargoes; labor disputes, including strikes, lockouts, job actions, or boycotts; fires; explosions; floods; shortages of Materials or energy due to a supplier's event of force majeure; delays in the delivery of Materials or energy due to a supplier's event of force majeure; acts or orders of any government or agency thereof or other unforeseeable causes beyond the reasonable control and without the fault or negligence of the Party so affected. The Party so affected shall give prompt notice to the other Party of such cause and a good faith estimate of the continuing effect of the force majeure condition and duration of the affected Party's nonperformance, and shall take whatever reasonable steps are appropriate to relieve the effect of such causes as rapidly as possible. If the period of nonperformance by Baxter because of Baxter force majeure conditions exceeds one hundred twenty (120) calendar days, Client may terminate this Agreement or any Batch by written notice to Baxter without liability or penalty including without limitation without payment of any Reschedule Fees. If the period of nonperformance by Client because of Client force majeure conditions exceeds one hundred twenty (120) calendar days, Baxter may terminate this Agreement by written notice to Client.

Article 20, NOTICES

20.1. All notices hereunder shall be delivered by facsimile (confirmed by overnight delivery), or by overnight delivery with a reputable overnight delivery service, to the following address of the respective Parties:

If to Baxter:

Baxter Pharmaceutical Solutions LLC
927 South Curry Pike
Bloomington, Indiana 47403
Attn: Contract Management

Fax No. (812) 332-3079
Telephone No. (812) 333-0887

With a copy to:

Baxter Healthcare Corporation
One Baxter Parkway
Deerfield, Illinois 60015-4633
Attn: General Counsel

Fax No. (224) 948-2450
Telephone No. (224) 948-3440

If to Client:

Genocea Biosciences, Inc.
Cambridge Discovery Park
100 Acorn Park Drive, 5th floor
Cambridge, MA 02140
Attn: President

Fax No. (617) 876-8192
Telephone No. (617) 876-8191

With a copy to:

B. Jean Weidemier, Esq.
Cambridge Licensing Law, LLC
470 Atlantic Avenue, 4th Floor
Boston, MA 02210
Attn: B. Jean Weidemier, Esq.

Fax No. (617) 395-8815
Telephone No. (617) 395-1239

Notices shall be effective on the day following the date of transmission if sent by facsimile, and on the second business day following the date of delivery to the overnight delivery service if sent by overnight delivery. A Party may change its address listed above by notice to the other Party given in accordance with this Section.

Article 21, APPLICABLE LAW

21.1. This Agreement is being delivered and executed in the State of New York. In any action brought regarding the validity, construction and enforcement of this Agreement, it shall be governed in all respects by the laws of the State of New York, without regard to the principles of conflicts of laws. The courts of the State of New York shall have personal jurisdiction over the Parties hereto in all matters arising hereunder, and venue for such suit will be in a state or federal court for the City of New York, New York.

Article 22, ASSIGNMENT

22.1. Neither Party shall assign this Agreement or any part hereof or any interest herein to any third party (or in the case of Baxter use any subcontractor) without the prior written approval of the other Party. The Parties shall be entitled to assign this Agreement to one of its Affiliates without the other Party's prior approval; provided that such Party shall remain responsible for the performance of its obligations hereunder by such Affiliate. No consent shall be required in the case of a transfer to a wholly-owned subsidiary or transaction involving the merger, consolidation, corporate reorganization or sale of all or substantially all of the assets or portion of the business of the Party seeking such assignment or transfer and such transaction relates to the business covered by this Agreement and the resulting entity assumes all of the obligations under this Agreement. No assignment shall be valid unless the permitted assignee(s) assumes all obligations of its assignor under this Agreement. No assignment shall relieve any Party of responsibility for the performance of its obligations hereunder prior to the effective date of assignment.

Article 23, TAXES

23.1. Client shall pay all national, state, municipal or other sales, use, excise, import, property, value added, or other similar taxes, assessments or tariffs assessed upon or levied against the sale of Product to Client pursuant to this Agreement or the sale or distribution of Product by Client (or at Client's sole expense, defend against the imposition of such taxes and expenses). Baxter shall notify Client of any such taxes that any governmental authority is seeking to collect from Baxter, and Client may assume the defense thereof in Baxter's name, if necessary, and Baxter agrees to fully cooperate in such defense to the extent of the capacity of Baxter, at Client's expense. Baxter shall pay all national, state, municipal or other taxes on the income resulting from the sale by Baxter of the services provided to Client under this Agreement, including but not limited to, gross income, adjusted gross income, supplemental net income, gross receipts, excess profit taxes, or other similar taxes.

Article 24, SUCCESSORS AND ASSIGNS

24.1. This Agreement shall be binding upon and shall inure to the benefit of the Parties hereto, their successors and permitted assigns.

Article 25, ENTIRE AGREEMENT; INTERPRETATION

25.1. This Agreement, including the Project Plan and Quality Agreement and any other agreements specifically incorporated by reference ("Incorporated Agreements"), constitutes the entire agreement between the Parties concerning the subject matter hereof and supersedes all written or oral prior agreements or understandings with respect thereto. The headings used in this Agreement are for convenience only and are not part of this Agreement. The term "includ(ing)(e/es)" and correlatives means "includ(ing)(e/es) without limitation." The terms of this Agreement Articles 1 through 31 shall control in the event of a conflict between this Agreement Articles 1 through 31 and any of its Incorporated Agreements, unless expressly provided otherwise by reference to a specific section of this Agreement Articles 1 through 31.

Article 26, SEVERABILITY

26.1. If any term or provision of this Agreement shall for any reason be held invalid, illegal or unenforceable in any respect, such invalidity, illegality or unenforceability shall not affect any other term or provision hereof, and this Agreement shall be interpreted and construed as if such term or provision, to the extent the same shall have been held to be invalid, illegal or unenforceable, had never been contained herein.

Article 27, WAIVER AND MODIFICATION OF AGREEMENT

27.1. No waiver or modification of any of the terms of this Agreement shall be valid unless in writing and signed by authorized representatives of both Parties hereto. Failure by either Party to enforce any rights under this Agreement shall not be construed as a waiver of such rights nor shall a waiver by either Party in one or more instances be construed as constituting a continuing waiver or as a waiver in other instances.

Article 28, INDEPENDENT CONTRACTOR

28.1. Both Parties shall act as an independent contractor as to the other Party in Baxter's providing the services required hereunder and shall not be considered an agent of, or joint venturer with, the other Party.

Article 29, ATTORNEY'S FEES

29.1. The successful Party in any litigation or other dispute resolution proceeding to enforce the terms and conditions of this Agreement shall be entitled to recover from the other Party reasonable attorney's fees and related costs involved in connection with such litigation or dispute resolution proceeding.

Article 30, COUNTERPARTS

30.1. For convenience, this Agreement may be executed in counterparts with the same force and effect as if each of the signatories had executed the same Agreement.

Article 31, DISPUTE RESOLUTION

31.1. Prior to initiating litigation, the Parties shall make a good faith attempt to resolve any dispute internally by escalating it to higher levels of management, and if such higher levels of management are not able to resolve the matter within [sixty (60) days], either Party may, in its sole discretion initiate a nonbinding mediation process. Each Party hereby commits to attending at least one mediation session and participating in good faith in the mediation process for a period of [ninety (90) days] as described below. If a Party initiates a mediation process, the Parties shall engage in non-binding mediation for a period of at least [ninety (90) days] to attempt to resolve any and all disputes before a sole mediator (the "**Mediator**") selected from Conflict Prevention & Resolution, Inc. or its successor (**"CPR"**), or if CPR is no longer able to supply the Mediator, such Mediator shall be selected from the American Arbitration Association, with such mediation to be held in the neutral location determined by the Mediator. A representative of each Party with authority to resolve the dispute shall participate in the mediation. The Parties shall share the costs of the Mediator and mediation equally, except that each Party shall pay its own attorneys' fees and expenses. If the representatives of the Parties have not been able to resolve the dispute within such [ninety (90) day] period, the Parties shall have the right to pursue any other remedies legally available to resolve such dispute.

31.2. Notwithstanding anything to the contrary in this Agreement, each Party reserves the right to initiate court proceedings at any time to seek injunctive or other temporary relief.

[SIGNATURES ON THE FOLLOWING PAGE]

IN WITNESS WHEREOF, the Parties have caused this Agreement to be signed by their duly authorized representatives as of the Effective Date.

BAXTER PHARMACEUTICAL SOLUTIONS LLC	**GENOCEA BIOSCIENCES, INC.**
By: /s/ Marsha Prokop	By: /s/ William D. Clark
Name: Marsha Prokop	Name: William D. Clark
Title: Director, Contract Management	Title: CEO