EXHIBIT 10.8D  
EXECUTION COPY  
AGREEMENT  
This agreement (the “Agreement”) is made effective and entered into as of May 14th, 2007 (the “Effective Date”) by and between:  
Tercica, Inc., a company organized and existing under the laws of Delaware, USA, established and having its principal office at 0000 Xxxxxx Xxxxx Xxxxxxx, Xxxxx 000, Xxxxxxxx, XX 00000 XXX, (“COMPANY”) on the one part; and  
LONZA Hopkinton, Inc., a company organized and existing under the laws of Delaware, established and having its principal office at 00 Xxxxx Xxxxxx, Xxxxxxxxx, XX 00000 XXX, (“LONZA”) on the other part.  
The parties identified above hereinafter sometimes individually referred to as “Party” and collectively as “Parties”.  
1. LONZA is engaged in the contract process development and manufacture of biopharmaceutical products.  
2. COMPANY is interested in retaining LONZA as COMPANY’s contract manufacturer for the manufacture of recombinant human insulin-like growth factor-1 (“IGF-1”) in the form of formulated bulk IGF-1 drug substance (“DRUG SUBSTANCE”). The DRUG SUBSTANCE is used in the manufacture of COMPANY’s commercial drug product Increlex® (mecasermin [ \* ] infection) (“DRUG PRODUCT”).  
3. The Parties agree under this Agreement to (i) effect a technology transfer of COMPANY’s manufacturing process for the production of DRUG SUBSTANCE from LONZA’s facility in Baltimore, MD (the “Baltimore Site”) to LONZA’s facility in Hopkinton, MA (the “Hopkinton Site”) (such technology transfer activities, the “Technology Transfer”), which Technology Transfer shall begin as of the Effective Date; (ii) effect the primary terms and conditions, including without limitation the PRINCIPAL TERMS (as that term is defined in Paragraph 10 below), by which the Parties agree that LONZA shall perform the Technology Transfer and provide COMPANY with process development and manufacturing services for the production of DRUG SUBSTANCE at the Hopkinton Site, all as further described in this Agreement; and (iii) expeditiously negotiate in good faith and enter into a final and detailed agreement incorporating the terms and conditions of this Agreement, including without limitation the PRINCIPAL TERMS (as that term is defined in Paragraph 10 below), which agreement (the “Detailed Agreement”) may contain additional provisions that are appropriate for Technology Transfer, process development and manufacturing services for the manufacture of DRUG SUBSTANCE at the Hopkinton Site, provided that any such additional provisions are consistent with all terms and conditions of this Agreement.  
4. With respect to Technology Transfer activities and all other activities performed under this Agreement until the Detailed Agreement becomes effective, the Parties agree that such activities will be performed in accordance with the Standard Terms & Conditions (the “T & C”) included as Attachment A hereto. The T & C are hereby incorporated into this Agreement by reference.  
 [ \* ] = CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, HAS BEEN OMITTED AND FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.  
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 5. The Technology Transfer shall commence [ \* ], and the cGMP Conformance and Pre-Commercial Campaign (as that term is defined in Paragraph 10 below) shall commence [ \* ]. A more detailed schedule for Technology Transfer, process development and manufacture of DRUG SUBSTANCE in compliance with the regulatory requirements for current good manufacturing practices promulgated by the U.S. Food and Drug Administration (the “FDA”) under 21 C.F.R. Parts 210 and 211 (such regulatory requirements collectively, “cGMP”) is set forth in Attachment B hereto and is hereby agreed to by the Parties as a part of this Agreement and the Detailed Agreement. [ \* ]  
6. Under this Agreement, COMPANY makes a firm capacity reservation for LONZA’s process development and manufacturing capacity/personnel at the Hopkinton Site as follows:  
a. COMPANY and LONZA agree that, (i) within 14 days of the Effective Date of this Agreement, COMPANY will pay to LONZA a non-refundable capacity reservation fee in the amount of $1,300,000; (ii) with respect to the manufacture of engineering batches of DRUG SUBSTANCE, COMPANY will pay to LONZA a cGMP capacity reservation fee in the amount of $3,700,000 on or before January 4, 2008; and (iii) at least 6 months prior to commencement of the cGMP Conformance and Pre-Commercial Campaign (as that term is defined in Paragraph 10 below), COMPANY will pay to LONZA an amount equal to [ \* ] of total value of the total number of cGMP batches of DRUG SUBSTANCE to be manufactured in such cGMP Conformance and Pre-Commercial Campaign (the amounts set forth in items (i), (ii) and (iii) collectively, the “Reservation Fee”). The balance of the total value of the total number of cGMP batches manufactured in such cGMP Conformance and Pre-Commercial Campaign will be due and payable to LONZA by COMPANY upon the later of (i) [ \* ] or (ii) [ \* ]. The Reservation Fee will serve as a firm reservation, by LONZA, of sufficient process development and manufacturing capacity/personnel resources to produce DRUG SUBSTANCE at the Hopkinton Site for COMPANY in accordance with the estimated time periods identified herein.  
b. Pricing does not include [ \* ]  
c. The Reservation Fee is non-refundable, but upon entry into force of the Detailed Agreement, the Reservation Fee will be fully creditable toward costs of Technology Transfer and manufacture of engineering batches of DRUG SUBSTANCE.  
7. LONZA shall be entitled to compensation for all Technology Transfer, process development activities, and other work performed and expenses incurred by LONZA (A) within the scope of work detailed in Attachment B hereto; and (B) on or after the Effective Date through the date of termination of this Agreement or the Detailed Agreement, whichever is later, provided that in no event shall the total amount of such compensation exceed the amount of $5,000,000 (the sum of the amounts set forth in items (i) and (ii) of the first sentence in Paragraph 6a. above).  
Non-cGMP Activities:  
COMPANY shall not be required to pay any additional costs (other than as set forth in this Paragraph 7 and in Paragraph 6 above) for any Technology Transfer, process development activities, or other work performed and expenses incurred by LONZA, in each case (I) under this Agreement or the Detailed Agreement, except cGMP manufacturing activities for the production of DRUG SUBSTANCE at the Hopkinton Site by LONZA; (II) outside the scope of work detailed in Attachment B hereto; and (III) on or after the Effective Date through  
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 the date of termination of this Agreement or the Detailed Agreement, whichever is later, which activities are mutually agreed to in writing by LONZA and COMPANY or are required to meet obligations under any of the COMPANY’s regulatory authorizations or regulatory submissions worldwide; provided, however, that none of the foregoing shall include any activities which occur after FDA Approval.  
COMPANY shall pay for all Technology Transfer, process development activities, and other work performed and expenses incurred by LONZA (x) under this Agreement or the Detailed Agreement, except cGMP manufacturing activities for the production of DRUG SUBSTANCE at the Hopkinton Site by LONZA; (y) outside the scope of work detailed in Attachment B hereto; and (z) on or after the Effective Date through the date of termination of this Agreement or the Detailed Agreement, whichever is later, which activities are neither mutually agreed to by the Parties nor required to meet obligations under any of the COMPANY’s regulatory authorizations or regulatory submissions worldwide, on a time and materials basis at the following hourly rates: (A) for technology transfer activities, a rate of [ \* ] per hour; (B) for process development activities, a rate of [ \* ] per hour; and (C) for any other work activities, a rate of [ \* ] per hour (the “Project Rates”). An outline of the activities within the scope of work is set forth in Attachment B.  
cGMP Activities:  
Notwithstanding any other provision in this Paragraph 7, COMPANY shall pay for all cGMP manufacturing activities for the production of DRUG SUBSTANCE at the Hopkinton Site by LONZA according to the batch pricing schedule set forth under the “Pricing” heading in Paragraph 10 of this Agreement. An outline of the cGMP manufacturing activities is set forth in Attachment B.  
8. All services to be provided or work to be performed under this Agreement or the Detailed Agreement may be performed by LONZA or by any direct or indirect subsidiary of LONZA’s parent company.  
9. The information contained in this Agreement (including scope of work, estimated completion dates and deliverables) is based and conditioned on information supplied by and represented by COMPANY.  
10. The Parties hereby agree to the following specific terms and conditions (the “PRINCIPAL TERMS”), in keeping with which (and in keeping with all other terms and conditions of this Agreement) LONZA shall perform Technology Transfer, process development activities, manufacturing services, and production of DRUG SUBSTANCE at the Hopkinton Site during the Term (as that term is defined under the heading “License to LONZA” in this Paragraph 10 below):  
Manufacturing:  
 •   
The COMPANY’s manufacturing process for production of the DRUG SUBSTANCE will be transferred from the Baltimore Site to the Hopkinton Site.  
 •   
LONZA will establish COMPANY’s manufacturing process for the production of DRUG SUBSTANCE on a [ \* ] liter scale in compliance with cGMP and the Master Production Record (which term shall have the same definition as that of “Master Production Record” set forth in Section 1.43 of that certain Manufacturing Services Agreement  
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 between Cambrex Bio Science Baltimore, Inc. and Tercica Medica, Inc. of December 20, 2002, as amended, subject to any changes proposed by LONZA and agreed to by COMPANY as necessary for scale-up and/or improvement of the process to accommodate a [ \* ] liter fermentation batch size) at the Hopkinton Site (such process as established at the Hopkinton Site, the “Manufacturing Process”).  
 •   
LONZA will perform a manufacturing campaign using the Manufacturing Process to produce DRUG SUBSTANCE for conformance and pre-commercial purposes (the “cGMP Conformance and Pre-Commercial Campaign”) during the calendar years of [ \* ] and [ \* ], which cGMP Conformance and Pre-Commercial Campaign shall be a single campaign consisting of [ \* ] validation batches of DRUG SUBSTANCE and up to [ \* ] additional batches of DRUG SUBSTANCE.  
 •   
LONZA will establish the Manufacturing Process in time for LONZA to perform manufacturing campaigns throughout the calendar year [ \* ], during which period LONZA will produce DRUG SUBSTANCE for use in the manufacture of commercial DRUG PRODUCT.  
 •   
Upon the FDA’s approval (“FDA Approval”) of the Manufacturing Process for the production of DRUG SUBSTANCE for use in the manufacture of DRUG PRODUCT for commercial sale or clinical use (any such DRUG SUBSTANCE so produced after FDA approval and designated for the manufacture of DRUG PRODUCT for commercial sale or clinical use, the “COMMERCIAL DRUG SUBSTANCE”), COMPANY will have a minimum purchase requirement of [ \* ] batches of COMMERCIAL DRUG SUBSTANCE per year.  
 •   
Subject to the COMPANY RIGHTS (as defined below), the Parties agree that with respect to the purchase or supply of DRUG SUBSTANCE (including without limitation COMMERCIAL DRUG SUBSTANCE) this Agreement and the Detailed Agreement shall be construed as preventing or otherwise inhibiting COMPANY from (i) manufacturing any additional supply of DRUG SUBSTANCE (ii) having any additional supply of DRUG SUBSTANCE manufactured for COMPANY by one or more third parties and/or (iii) purchasing any additional supply of DRUG SUBSTANCE manufactured by one or more third parties.  
 •   
LONZA shall have no obligation to manufacture and supply more than (i) [ \* ] of DRUG SUBSTANCE in each of the first [ \* ] full calendar years of this Agreement and the Detailed Agreement and (ii) [ \* ] of DRUG SUBSTANCE in any of the calendar year thereafter (collectively, the “Maximum Delivery Obligation”). In the event that COMPANY shall notify (the “Excess Demand Notice”) LONZA of its requirements for a quantity of DRUG SUBSTANCE in excess of the Maximum Delivery Obligation (the “Excess Demand”), LONZA shall have a right of first refusal to elect to supply such Excess Demand (the “Excess Demand Option”). LONZA shall notify COMPANY in writing of whether or not it intends to exercise the Excess Demand Option within [ \* ] months of the date of receipt of the Excess Demand Notice (the “Notice Period”). In the event that LONZA exercises the Excess Demand Option, then LONZA shall be required to make  
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 available a second location for the manufacture of the DRUG SUBSTANCE, and the Parties shall promptly meet to discuss amending the Detailed Agreement to provide for same. In the event that LONZA determines not to exercise the Excess Demand Option or fails to provide COMPANY written notice of its intentions regarding same within the Notice Period, then COMPANY shall be free to exercise its rights, by itself or through one or more third parties, to (i) manufacture any additional supply of DRUG SUBSTANCE, (ii) have any additional supply of DRUG SUBSTANCE manufactured for COMPANY by one or more third parties and/or (iii) purchase any additional supply of DRUG SUBSTANCE manufactured by one or more third parties, in each case, solely in excess of the Maximum Delivery Obligation as set forth above (the “COMPANY RIGHTS”).  
Technology Transfer and Engineering:  
 •   
In connection with the transfer of the required technology from the Baltimore Site to the Hopkinton Site and the production of engineering batches of DRUG SUBSTANCE, COMPANY will pay to LONZA the Reservation Fee as set forth in Paragraph 6 above.  
 •   
LONZA will initiate construction and purchasing of equipment upon execution of this Agreement.  
 •   
Lonza will produce up to [ \* ] engineering batches of DRUG SUBSTANCE as outlined in the Attachment B to this Agreement. If sufficient data are gathered from [ \* ] engineering batches of DRUG SUBSTANCE, LONZA shall not produce [ \* ] engineering batch of DRUG SUBSTANCE, shall commence the cGMP Conformance and Pre-Commercial Campaign, and COMPANY shall receive a credit in the amount of [ \* ] to be applied against the Reimbursement Amount.  
 •   
In connection with the initiation of construction and purchasing of equipment and all spare parts, as well as assay validation and cleaning validation work, LONZA will bear upfront costs of $6,600,000 (the “Construction Costs”); provided, however, that should COMPANY fail to purchase at least [ \* ] batches of COMMERCIAL DRUG SUBSTANCE for any or no reason during the term of this Agreement or the Detailed Agreement, whichever is longer, COMPANY would reimburse LONZA for such costs by making a payment to LONZA in the amount of y, where y (the “Reimbursement Amount”) is calculated according to the following equation:  
[ \* ]  
where x represents the number of batches of validation batches and COMMERCIAL DRUG SUBSTANCE for which LONZA received payment in full.  
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 Pricing:  
 •   
Validation or Mixed Validation / Commercial Campaign  
 •   
Any manufacturing campaign in which LONZA uses the Manufacturing Process for the production of only [ \* ] consecutive validation batches of DRUG SUBSTANCE will cost [ \* ] per batch.  
 •   
Any manufacturing campaign in which LONZA uses the Manufacturing Process for the production of [ \* ] consecutive validation batches of DRUG SUBSTANCE and [ \* ] consecutive batches of COMMERCIAL DRUG SUBSTANCE will cost [ \* ] per batch; provided, that all [ \* ] batches shall be consecutively manufactured.  
 •   
Any manufacturing campaign in which LONZA uses the Manufacturing Process for the production of [ \* ] consecutive validation batches of DRUG SUBSTANCE and [ \* ] consecutive batches of COMMERCIAL DRUG SUBSTANCE will cost [ \* ] per batch; provided that all [ \* ] batches shall be consecutively manufactured.  
 •   
Commercial Campaign (each a “Batch Pricing Tier”)  
 •   
Any manufacturing campaign in which LONZA uses the Manufacturing Process for the production of [ \* ] consecutive batches of COMMERCIAL DRUG SUBSTANCE will cost [ \* ] per batch;  
 •   
Any manufacturing campaign in which LONZA uses the Manufacturing Process for the production of [ \* ] consecutive batches of COMMERCIAL DRUG SUBSTANCE will cost [ \* ] per batch;  
 •   
Any manufacturing campaign in which LONZA uses the Manufacturing Process for the production of [ \* ] consecutive batches of COMMERCIAL DRUG SUBSTANCE will cost [ \* ] per batch;  
 •   
Any manufacturing campaign in which LONZA uses the Manufacturing Process for the production of [ \* ] consecutive batches of COMMERCIAL DRUG SUBSTANCE will cost [ \* ] per batch; and  
 •   
Any manufacturing campaign in which LONZA uses the Manufacturing Process for the production of [ \* ] consecutive batches of COMMERCIAL DRUG SUBSTANCE will cost [ \* ] per batch.  
 •   
The pricing set forth above does not include cost of raw materials, consumables and disposables  
 •   
The Parties agree to switch to per gram pricing basis [ \* ]  
 •   
For first [ \* ] full calendar years of manufacturing in which LONZA uses the Manufacturing Process to produce COMMERCIAL DRUG SUBSTANCE, the pricing set forth above may increase at a rate of up [ \* ] annually. Thereafter, the then current pricing may increase at a rate of [ \* ] annually for the remainder of the term of the Detailed Agreement or this Agreement, whichever is longer.  
Forecasting:  
 •   
Prior to the first calendar quarter (the “Initial Quarter”) for which COMPANY wishes to establish a rolling supply of COMMERCIAL DRUG SUBSTANCE [ \* ], and thereafter before the first day of each subsequent calendar quarter, COMPANY shall provide LONZA with a rolling forecast of the quantities of, and the delivery dates for, COMMERCIAL DRUG SUBSTANCE that COMPANY shall require from LONZA for [ \* ] months commencing [ \* ] thereafter (each such forecast, [ \* ]), each such [ \* ] Forecast to be binding and non-binding as follows:  
 •   
For the first [ \* ] period in such [ \* ] Forecast, COMPANY shall be required to take delivery of or pay for [ \* ] of the quantity of COMMERCIAL DRUG SUBSTANCE forecasted for such [ \* ] month period (the [ \* ] Binding Quantity”).  
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 •   
For the [ \* ] period subsequent to the first [ \* ] period in such [ \* ] Forecast, COMPANY would be required to take delivery of or pay for [ \* ] of the quantity of COMMERCIAL DRUG SUBSTANCE forecasted for such [ \* ] month period (the “[ \* ] Binding Quantity”).  
 •   
For the last [ \* ] month period in such [ \* ] Forecast, the quantity of COMMERCIAL DRUG SUBSTANCE forecasted for such [ \* ] month period will be non-binding.  
 •   
The Parties agree that, (i) for any of the first [ \* ] calendar quarters in a [ \* ] Forecast, the quantity forecasted in such calendar quarter and the quantity forecasted for the same calendar quarter in the next consecutive [ \* ] Forecast shall not differ by greater than [ \* ] and (ii) for any of the second [ \* ] in a [ \* ] Forecast, the quantity forecasted in such calendar quarter and the quantity forecasted for the same calendar quarter in the next consecutive [ \* ] Forecast shall not differ by greater than [ \* ]; provided, however, that these limitations shall not apply where COMPANY increases its [ \* ] Forecast so as to reach the next Batch Pricing Tier (but not beyond the Batch Pricing Tier applicable for [ \* ] Batches).  
Term and Termination:  
 •   
The Detailed Agreement shall continue in full force and effect for an initial term of 8 years, subject to renewal for one or more additional terms of five (5) years each, provided that the Parties agree in writing to any such renewal no later than two (2) years prior to the expiration of the initial term or any renewal thereof.  
 •   
Either Party may terminate the Detailed Agreement for convenience upon three (3) years’ prior written notice.  
 •   
Notwithstanding any limitation set forth in Paragraph 7, in the event that COMPANY terminates the Detailed Agreement for convenience or LONZA terminates the Detailed Agreement for cause, COMPANY will pay to LONZA an amount equal to the Reimbursement Amount plus the product of (i) the [ \* ] of the then current [ \* ] Forecast plus [ \* ] of the [ \* ] of the then current [ \* ] Forecast (in each case, as of the date of COMPANY’s or LONZA’s notice of termination, as applicable), multiplied by (ii) the applicable per batch price set forth in this Paragraph 10 above.  
Representations, Warranties and other Provisions:  
 •   
The Parties agree that this Agreement does not address all matters upon which agreement must be reached in order for the Detailed Agreement to be in a form and substance satisfactory to LONZA and COMPANY. The Parties agree that the Detailed Agreement will include such terms and conditions as are customary in a transaction of this type, including but not limited to, representations, warranties, conditions, limitations, and covenants, provided that all such terms and conditions to be included in the Detailed Agreement shall be consistent with the PRINCIPAL TERMS and all other terms and conditions set forth in this Agreement.  
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 License to LONZA  
 •   
COMPANY hereby grants to LONZA, for the term of this Agreement as extended by any renewal thereof or the term of the Detailed Agreement as extended by any renewal thereof, whichever is longer (the “Term”), a royalty-free, paid-up, non-exclusive license under any and all patents, patent applications, trade secrets, know-how and all other intellectual property rights that are owned or controlled by COMPANY as of the Effective Date or during the Term (“COMPANY Intellectual Property”) necessary for LONZA to perform its obligations under this Agreement or the Detailed Agreement, for the sole and limited purpose of LONZA’s performance of its obligations under this Agreement or the Detailed Agreement, including without limitation LONZA’s manufacture of DRUG SUBSTANCE for COMPANY. Any COMPANY Intellectual Property received by or disclosed to LONZA shall be treated as Confidential Information of COMPANY and shall be subject to the obligations of confidentiality and restrictions on use set forth in Paragraph 13 below.  
License to COMPANY  
 •   
LONZA hereby grants to COMPANY an irrevocable, paid-up, royalty-free, non-exclusive license, with the right to grant and authorize sublicenses, under any and all patents, patent applications, trade secrets, know-how and all other intellectual property rights owned or controlled by LONZA as of the Effective Date or during the Term that LONZA incorporates into the Manufacturing Process or that is necessary to practice the Manufacturing Process (“LONZA Manufacturing IP”), for the sole and limited purpose of manufacturing, using and/or selling of DRUG SUBSTANCE, DRUG PRODUCT or any other product containing IGF-1. Upon COMPANY’s reasonable request from time to time, LONZA shall document and disclose to COMPANY or COMPANY’s designee all LONZA Manufacturing IP in accordance with the exercise of COMPANY’s rights under this paragraph. Any LONZA Manufacturing IP received by or disclosed to COMPANY shall be treated as Confidential Information of LONZA and shall be subject to the obligations of confidentiality and restrictions on use set forth in Paragraph 13 below. COMPANY shall include a provision in all agreements with third party contractors for the manufacture, use and/or sale of the DRUG SUBSTANCE, DRUG PRODUCT or any other product containing IGF-1 that clearly states that such third party contractor’s right to use LONZA Manufacturing IP and LONZA Confidential Information is exclusively limited to the sole purpose of manufacturing, using and/or selling DRUG SUBSTANCE, DRUG PRODUCT or any other product containing IGF-1.  
11. The Parties will commence negotiations on the Detailed Agreement as soon as possible upon execution of this Agreement by both Parties. Through good faith negotiation, the Parties intend to execute the Detailed Agreement on or about July 31, 2007. In the event that the Parties are unable to execute the Detailed Agreement by July 31,2007, despite good faith efforts by both Parties, the Parties shall agree to have the Uniform Commercial Code (as in effect in the State of New York) supply any omitted terms and conditions of the Detailed Agreement in a manner consistent with all of the terms of this Agreement.  
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 12. This Agreement shall be effective as of the Effective Date and will terminate upon the earlier of (i) entry into force of the Detailed Agreement, or (ii) either Party giving three (3) years’ prior written notice to the other Party, at any time or for any reason, provided that in no event may either Party effect the termination of (A) this Agreement for convenience in accordance with clause (ii) of this sentence, or (B) the Detailed Agreement for convenience in accordance with the provisions under the heading “Term and Termination” in Paragraph 10 above, on or before the fourth (4th) anniversary of the Effective Date. The terms and conditions of Paragraphs 10 (but only the text under the heading “License to COMPANY”), 12, and 13 of the Agreement, and the terms and conditions of Paragraphs 1, 3, 8, 9, 10, 12, 13, 14, 15 and 16 of the T&C (in Attachment A to this Agreement), shall survive any termination or expiration of this Agreement or the Detailed Agreement.  
13. Confidential Information.  
Scope of Confidential Information  
“Confidential Information” means all proprietary and confidential information furnished by one Party to the other Party, including without limitation, any and all trade secrets, know-how, designs, formulations, ingredients, samples, processes, machines, processing and control information, product performance data, manuals, supplier lists, customer lists, purchase and sale records, price and pricing information, marketing information and computer programs, whether developed by the disclosing Party or furnished to such Party by a third party.  
Non-Disclosure and Non-Use.  
It is contemplated that in the course of the performance of this Agreement or the Detailed Agreement each Party may, from time to time, disclose its Confidential Information to the other Party. LONZA agrees that, except as expressly provided herein, it shall not disclose to any third party other than any affiliate, parent or subsidiary of LONZA, Confidential Information received from or disclosed to it by COMPANY, and it shall not use any such Confidential Information for any purpose other than to fulfill LONZA’s obligations hereunder. COMPANY agrees that, except as expressly provided herein, it shall not disclose to any third party other than any affiliate, parent or subsidiary of COMPANY, Confidential Information received from or disclosed to it by LONZA, and it shall not use any such Confidential Information for any purpose other than to fulfill COMPANY’s obligations hereunder.  
Exclusions.  
The obligations of confidentiality and restrictions on use set forth in this Paragraph 13 shall not apply to information that: (i) at the time of disclosure, is known publicly or thereafter becomes known publicly through no fault of the receiving Party, its affiliates or agents; (ii) becomes available to the receiving Party from a third party not legally prohibited from disclosing such information; (iii) was developed by the receiving Party independently of Confidential Information obtained from the disclosing Party as evidenced by written records; (iv) was already known to the receiving Party before the receipt of such information from the disclosing Party, as shown by the receiving Party’s prior written records; or (v) is released by the receiving Party with the prior written consent of the disclosing Party.  
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 Exceptions to Duty of Nondisclosure.  
Notwithstanding the above, nothing contained in this Agreement or the Detailed Agreement shall preclude Company or LONZA from utilizing or disclosing Confidential Information of the other Party as may be necessary in prosecuting patent rights, obtaining governmental marketing approvals, manufacturing DRUG SUBSTANCE pursuant to the terms and conditions of this Agreement or the Detailed Agreement, or complying with other governmental laws and regulations or court orders (provided that the Party compelled to disclose such information provides the disclosing Party with prompt advance notice of such requirement of disclosure and all reasonable cooperation in connection with any action that the disclosing Party may pursue to limit or avoid such requirement of disclosure and/or obtain confidential treatment of the information subject to such requirement, all to the extent permitted by law). LONZA shall be permitted to disclose COMPANY’s Confidential Information to third party developmental and analytical services providers in connection with performance of LONZA’s obligations hereunder, provided that such providers shall be subject to confidentiality agreements with provisions at least as protective as the terms and conditions set forth herein. COMPANY shall be permitted to disclose and use LONZA’s Confidential Information that solely consists of LONZA Manufacturing IP in accordance with the exercise of COMPANY’s rights under Paragraph 10 above, provided that any third party who receives such Confidential Information in connection with any such exercise of rights shall be subject to confidentiality agreements imposing obligations of confidentiality and restrictions on use at least as protective as the terms and conditions set forth herein. The obligations of the parties relating to Confidential Information shall expire ten (10) years after the termination or expiration of the Term.  
Government Disclosure for Purposes of Obtaining Regulatory Approval.  
Each Party may disclose Confidential Information of the other Party hereunder to the extent required by applicable law or regulation in connection with any submission to a regulatory authority relating to DRUG SUBSTANCE, DRUG PRODUCT or any other product containing IGF-1 manufactured by the Manufacturing Process, provided that if a Party is required by law and/or regulation to make any such disclosure of the other Party’s Confidential Information, the disclosing Party will give reasonable advance notice to the other Party of such disclosure requirement and will use good faith efforts to assist such other Party in securing a protective order or confidential treatment of such Confidential Information required to be disclosed, except where such notice is impractical, for example in the event of a medical emergency, in which case the disclosing Party shall give notice to the other Party as soon as is reasonably practical.  
Public Announcements and SEC Filings.  
Except as otherwise set forth in this Paragraph 11, neither Party shall make public the terms of this Agreement or the transactions contemplated herein, or make any public statement which includes the name of the other Party or any of its affiliates, or otherwise use the name of the other Party or any of its affiliates in any public statement or document without the prior written consent of the other Party. Any such public announcement proposed by a Party that names the other Party shall first be provided in draft form to the other Party. Each Party agrees that it shall cooperate fully and in a timely manner with the other with respect to all required disclosures to the Securities and Exchange Commission and any other governmental or regulatory agencies, including requests for confidential treatment of Confidential Information of either Party included in any such disclosure. Since the applicable securities laws require  
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 COMPANY to file this Agreement, COMPANY shall (a) provide to LONZA a copy of the redacted version COMPANY intends to file, (b) provide LONZA a reasonable opportunity to comment thereon, and (c) redact such additional information as requested by LONZA, unless disclosure thereof is required by law and compelled by the Securities and Exchange Commission.  
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EXECUTION COPY  
 IN WITNESS WHEREOF, the Parties have executed this Agreement by and through their duly authorized representatives.  
 TERCICA, INC. LONZA HOPKINTON, INC.  
By:   
/s/ Xxxxxx Xxxxxxxxx  
 By:   
/s/ Xxxxxxx Xxxxxxx  
 (Signature) (Signature)  
Print Name: Xxxxxx Xxxxxxxxx Print Name: Xxxxxxx Xxxxxxx  
Title: Senior Vice President Title: VP, U.S. Microbial Operations  
Date: 14-May-2007 Date: 14-May-07  
 [ \* ] = CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, HAS BEEN OMITTED AND FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.  
12.  
EXECUTION COPY  
 Attachment A  
STANDARD TERMS & CONDITIONS  
1. PRODUCT/INTELLECTUAL PROPERTY:  
COMPANY represents and warrants to LONZA that, to the best of its knowledge, (a) it has the requisite intellectual property rights related to the PRODUCT and (b) the work performed by LONZA under the Agreement will not infringe any valid and enforceable patent right or violate any trade secret right of a third party.  
2. PAYMENT:  
All payments to LONZA by COMPANY for work performed by LONZA under the Agreement shall be in United States currency and shall be by check, wire transfer, money order or other method of payment approved in writing by LONZA. Payment for materials and consumables (i.e. reimbursable costs) and payment for any other fee, cost or charge payable to LONZA by COMPANY under the Agreement shall be due and payable within [ \* ] days of COMPANY’s receipt of any invoice for the same sent by LONZA to COMPANY. Any fee, charge or other payment due to LONZA by COMPANY that is not paid within [ \* ] after it is due shall accrue interest, from the date when the same was due and payable, at the rate of [ \* ] per annum, payable on demand.  
3. WARRANTY:  
LONZA makes no representation or warranty regarding the DRUG SUBSTANCE’s safety or effectiveness, or otherwise, except that LONZA shall perform activities under the Agreement in compliance with all applicable regulatory requirements, including without limitation cGMP requirements. COMPANY acknowledges and agrees that LONZA and/or LONZA’s personnel (i) have not participated in the invention or testing of the DRUG SUBSTANCE, and (ii) have not evaluated the DRUG SUBSTANCE’s safety or suitability for use in humans or others. Other than quality control testing of the DRUG SUBSTANCE by LONZA as part of the work performed by LONZA under the Agreement, LONZA shall not be in any way responsible for DRUG SUBSTANCE testing. Notwithstanding the foregoing, LONZA warrants to COMPANY that all DRUG SUBSTANCE manufactured by LONZA using the Manufacturing Process hereunder: (i) was manufactured and analyzed in conformance with the Master Production Record; (ii) was transferred to COMPANY with a Certificate of Compliance that is accurate and complete with respect to each batch of DRUG SUBSTANCE so manufactured; (iii) was manufactured in compliance with cGMP; (iv) was packaged in accordance with shipping specifications for such DRUG SUBSTANCE; and (vi) was transferred free and clear of any liens or encumbrances of any kind to the extent arising through or as a result of the acts or omissions of LONZA, its affiliates or their respective agents. LONZA hereby warrants that during the Term the Hopkinton Site will be maintained in accordance with cGMP and in such condition as will allow LONZA to manufacture DRUG SUBSTANCE in compliance with cGMP and in conformance with the Master Production Record.  
4. COMPANY SUPPLIED MATERIALS, CONSUMABLES AND EQUIPMENT:  
COMPANY shall be responsible to supply and/or pay for all materials and consumables (i.e reimbursable costs). All materials and consumables shall be invoiced to COMPANY by LONZA at the relevant Acquisition Cost. “Acquisition Cost” shall mean [ \* ] for any such materials, including, but not limited to, [ \* ], and also including (i) with respect to all ingredients, solvents and other components of the DRUG SUBSTANCE required to perform the Manufacturing Process (excluding bags, liners and other single use or regularly replaced materials that are required to perform the Manufacturing Process, non-sterile coverings or protective gear used by  
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 LONZA employees or agents in the course of performing the development and manufacturing services hereunder (including without limitation, gloves, coveralls, booties, eye xxxxxxx and the like) and Resins (as defined below)) (collectively, “Raw Materials”) all of which meet the applicable material specifications, [ \* ] and (ii) with respect to all chromatographic media intended to refine or purify the DRUG SUBSTANCE, as specified in the Master Production Record, all of which meet the applicable materials specifications (the “Resins”), [ \* ]..  
If additional equipment, other than what is supplied by LONZA, is needed to perform work under the Agreement, LONZA shall be responsible to supply and/or pay for the equipment.  
5. HAZARDOUS WASTE:  
LONZA shall provide COMPANY with prior written notice of any hazardous waste that may be generated by the work performed by LONZA under the Agreement, only if such waste cannot be disposed of through LONZA’s standard waste disposal system. LONZA shall make any necessary special arrangements for disposal of such hazardous waste and COMPANY shall be solely responsible for all costs associated therewith.  
6. TAXES:  
Any federal, state, county or municipal sales or use tax, excise, customs charges, duties or similar charge, or any other tax assessment (other than that assessed against income), license, fee or other charge lawfully assessed or charged on the manufacture, sale or transportation of DRUG SUBSTANCE or DRUG PRODUCT sold pursuant to the Agreement, and all government license filing fees and Prescription Drug User (PDUFA) annual establishment fees with respect to all DRUG SUBSTANCE or DRUG PRODUCT she be paid by COMPANY.  
7. LONZA PERSONNEL:  
COMPANY agrees not to solicit for employment (or for use as an independent contractor) LONZA employees during the term of the Agreement and for a period of one (1) year thereafter.  
8. DELIVERY OF PRODUCT SAMPLES, SHIPPING CHARGES:  
If the Agreement is terminated and the Detailed Agreement has not become effective at the time of such termination, LONZA shall ship to COMPANY (i) the DRUG SUBSTANCE, (ii) COMPANY supplied equipment and samples, (iii) or any other COMPANY owned items in accordance with the COMPANY’s packing and shipping instructions, as provided by COMPANY to LONZA, all by common carrier, unless otherwise specified by COMPANY. Delivery shall be F.O.B. Shipping Point (the LONZA facility). COMPANY shall provide its preferred carrier’s account number and shall pay for all shipping costs in connection with the delivery of each shipped item. LONZA’s responsibility ceases and COMPANY’s risk of loss arises, upon delivery of each shipped item to the common carrier or common carrier’s authorized agent.  
9. INDEMNIFICATION:  
(a) COMPANY shall indemnify, defend and hold LONZA, its affiliates, and their respective directors, officers, employees and agents harmless from and against all losses, damages, liabilities, settlements, penalties, fines, costs and expenses (including, without limitation, reasonable attorneys’ fees and expenses) (collectively, “Liabilities”) to the extent such Liabilities arise out of or result from any claim, lawsuit or other action or threat by a third party arising out of, resulting from or related to (i) the manufacture, use, handling, distribution, marketing or sale of the DRUG PRODUCT, the DRUG SUBSTANCE or any product containing IGF-1, in any form, (ii) any material breach of the representations, warranties and covenants made by COMPANY under this Agreement and the Detailed Agreement, (iii) COMPANY’s negligent acts or omissions or willful misconduct and/or (iv) any recall of the DRUG PRODUCT, DRUG  
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 SUBSTANCE or any product containing IGF-1, in any form, provided that the foregoing obligation of indemnification shall not apply to the extent any such Liability arises out of or results from any material breach of the representations warranties and covenants made by LONZA in this Agreement and the Detailed Agreement, or LONZA’s negligent acts or omissions or willful misconduct.  
(b) COMPANY shall indemnify, defend and hold LONZA, its affiliates and their respective directors, officers, employees and agents harmless from and against all Liabilities to the extent such Liabilities arise out of, result from or are related to any claim by a third party that LONZA’s manufacture of the DRUG SUBSTANCE for COMPANY hereunder or under the Detailed Agreement, to the extent such manufacture of DRUG SUBSTANCE is in compliance with the Master Production Record and the Manufacturing Process, infringes the intellectual property rights of such third party.  
(c) Subject to and except to the extent of any indemnification from COMPANY pursuant to subclause (a) or (b) above, LONZA shall indemnify, defend and hold COMPANY, and its affiliates, and their respective directors, officers, employees and agents harmless from and against all Liabilities to the extent such Liabilities arise out of or result from (i) any material breach of the representations and warranties made by LONZA under this Agreement and the Detailed Agreement or any material breach of any of the covenants made by LONZA or (ii) LONZA’s negligent acts or omissions or willful misconduct. An indemnified Party (the “Indemnitee”) which intends to claim indemnification shall promptly notify the indemnifying Party (the “Indemnitor”) in writing of any claim, lawsuit or other action in respect of which the Indemnitee, its affiliates or any of their respective directors, officers, employees and agents intend to claim such indemnification. Any delay in the Indemnitee’s notification to the Indemnitor of the claim for which Indemnitee intends to seek indemnification hereunder shall not preclude the Indemnitor’s obligation of indemnification for such claim, except to the extent such delay results in substantial prejudice to the Indemnitor. The Indemnitee shall permit, and cause its affiliates and their respective directors, officers, employees and agents to permit, the Indemnitor, at its discretion, to settle any such claim lawsuit or other action and agrees to the complete control of such defense or settlement by the Indemnitor; provided, however, that in order for the Indemnitor to exercise such rights, such settlement does not adversely affect the Indemnitee’s rights under this Agreement, impose any obligations on the Indemnitee in addition to those set forth herein, or admit wrongdoing on the part of the Indemnified Party (an “Adverse Settlement”). No Adverse Settlement shall be settled without the prior written consent of the Indemnitee. The Indemnitee, its affiliates and their respective directors, officers, employees and agents shall provide all reasonable cooperation with the Indemnitor and its legal representatives in the investigation and defense of any claim, lawsuit or other action covered by this indemnification, all at the reasonable expense of the Indemnitor. The Indemnitee shall have the right, but not the obligation, to be represented by counsel of its own selection and expense.  
10. LIMITATION OF LIABILITY:  
COMPANY HEREBY AGREES THAT TO THE FULLEST EXTENT PERMITTED BY LAW, LONZA’S LIABILITY TO COMPANY FOR ANY AND ALL INJURIES, CLAIMS, LOSSES, EXPENSES, OR DAMAGES, WHATSOEVER, ARISING OUT OF ANY BREACH OF THE AGREEMENT OR THE DETAILED AGREEMENT, OR ANY CAUSE OF ACTION FOR BREACH OF THE AGREEMENT OR THE DETAILED AGREEMENT, SHALL NOT EXCEED (I) PRIOR TO FDA APPROVAL, THE TOTAL CHARGES PAID BY COMPANY TO LONZA UNDER THE AGREEMENT OR THE DETAILED AGREEMENT AND (II) FROM AND AFTER FDA APPROVAL, THE GREATER OF (A) THE TOTAL CHARGES PAID BY COMPANY TO LONZA DURING THE TWENTY-FOUR (24) MONTHS PRECEDING THE EVENT GIVING  
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 RISE TO LIABILITY OR (B) FIVE (5) MILLION DOLLARS (COLLECTIVELY, THE “DOLLAR CAP”). TO THE EXTENT THAT THIS CLAUSE CONFLICTS WITH ANY OTHER CLAUSE, THIS CLAUSE SHALL TAKE PRECEDENCE OVER SUCH CONFLICTING CLAUSE, EXCEPT TO THE EXTENT OTHERWISE PROVIDED IN THIS PARAGRAPH 10 BELOW. IF APPLICABLE LAW PREVENTS ENFORCEMENT OF THIS CLAUSE, THEN THIS CLAUSE SHALL BE DEEMED MODIFIED TO PROVIDE THE MAXIMUM PROTECTION TO LONZA AS IS ALLOWABLE UNDER APPLICABLE LAW. THE DOLLAR CAP SHALL NOT APPLY TO ANY LIABILITY ARISING FROM ANY OBLIGATION OF INDEMNIFICATION PROVIDED IN PARAGRAPH 9 ABOVE.  
IN NO EVENT SHALL EITHER PARTY BE LIABLE TO THE OTHER OR ANY OF ITS AFFILIATES FOR ANY CONSEQUENTIAL, INCIDENTAL, INDIRECT, SPECIAL, PUNITIVE OR EXEMPLARY DAMAGES (INCLUDING, WITHOUT LIMITATION, LOST PROFITS, BUSINESS OR GOODWILL) SUFFERED OR INCURRED BY SUCH OTHER PARTY OR ITS AFFILIATES IN CONNECTION WITH ANY BREACH OF THE AGREEMENT OR THE DETAILED AGREEMENT, EVEN IF ADVISED OF THE POSSIBILITY OF SUCH DAMAGES. THE FOREGOING LIMITATION SHALL NOT APPLY TO (I) ANY OBLIGATION OF INDEMNIFICATION PROVIDED IN PARAGRAPH 9 ABOVE; OR (II) ANY CAUSE OF ACTION ARISING FROM THE FAILURE OF LONZA TO MEET A DRUG SUBSTANCE MANUFACTURING COMMITMENT OR DELIVER A FIRM ORDER FOR MANUFACTURING AND SUPPLY OF DRUG SUBSTANCE WITHIN [ \* ] DAYS OF THE APPLICABLE DELIVERY DATE, WHERE SUCH FAILURE IS A RESULT OF LONZA’S GROSS NEGLIGENCE, WILLFUL MISCONDUCT OR INTENTIONAL BREACH OF THE AGREEMENT OR THE DETAILED AGREEMENT (SO LONG AS SUCH FAILURE IS NOT DUE TO A BREACH OF THE AGREEMENT OR DETAILED AGREEMENT BY COMPANY) (A “DELIVERY DELINQUENCY”). NOTWITHSTANDING THE FOREGOING, THE DOLLAR CAP SHALL CONTINUE TO APPLY IN THE EVENT OF A DELIVERY DELINQUENCY, EXCEPT TO THE EXTENT OTHERWISE PROVIDED IN THIS PARAGRAPH 10 BELOW.  
NOTWITHSTANDING ANY OTHER PROVISION IN THIS PARAGRAPH 10, IN THE EVENT OF ANY DELIVERY DELINQUENCY, COMPANY MAY ELECT TO PROVIDE LONZA WITH A NOTICE OF TERMINATION FOR CAUSE, WHICH NOTICE SHALL EFFECT A TERMINATION IN ACCORDANCE WITH AND PURSUANT TO THE PROVISIONS OF PARAGRAPH 12 OF THIS AGREEMENT; PROVIDED HOWEVER, (I) FOR THE DURATION OF THE PERIOD COMMENCING ON LONZA’S RECEIPT OF THE NOTICE OF TERMINATION FOR CAUSE IN ACCORDANCE WITH THIS SENTENCE UP UNTIL THE EFFECTIVE DATE OF TERMINATION PROVIDED IN PARAGRAPH 12 OF THIS AGREEMENT (THE “WINDING-UP PERIOD”), THIS AGREEMENT OR THE DETAILED AGREEMENT, AS APPLICABLE, SHALL REMAIN IN FULL FORCE AND EFFECT WITH RESPECT TO ALL RIGHTS AND OBLIGATIONS OF THE PARTIES THEREUNDER, INCLUDING WITHOUT LIMITATION LONZA’S OBLIGATIONS TO MANUFACTURE AND SUPPLY TO COMPANY COMMERCIAL DRUG SUBSTANCE, DRUG SUBSTANCE AND ANY OTHER PRODUCT CONTAINING IGF-1 UNDER THE TERMS AND CONDITIONS OF THE AGREEMENT OR THE DETAILED AGREEMENT, ANY BREACH OF WHICH OBLIGATIONS SHALL ENTITLE COMPANY TO INJUNCTIVE RELIEF FOR THE SPECIFIC PERFORMANCE OF THE SAME, WHICH RELIEF MAY AWARDED BY, OR IN CASE OF SUCH RELIEF AWARDED IN ANOTHER FORUM AN ORDER OF ENFORCEMENT MAY BE ISSUED BY, ANY COURT OF COMPETENT JURISDICTION, AND THE PARTIES HEREBY AGREE AND STIPULATE THAT THE INADEQUACY OF MONETARY DAMAGES AND THE BALANCE OF EQUITIES JUSTIFY THE GRANT OF ANY SUCH INJUNCTIVE RELIEF, WHICH RELIEF SHALL BE IN ADDITION TO ANY AND ALL OTHER REMEDIES TO WHICH  
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 COMPANY MAY BE ENTITLED AT LAW OR IN EQUITY; AND (II) LONZA SHALL BE LIABLE FOR ANY AND ALL COSTS INCURRED DURING THE WINDING-UP PERIOD IN CONNECTION WITH (A) TECHNOLOGY TRANSFER ACTIVITIES FOR THE TRANSFER TO THE FACILITY OF ANY THIRD PARTY MANUFACTURER DESIGNATED BY COMPANY (THE “THIRD PARTY MANUFACTURING SITE”), OF ANY AND ALL TECHNOLOGY INVOLVED IN THE MANUFACTURING PROCESS(ES) USED BY LONZA IN THE PRODUCTION OF DRUG SUBSTANCE, COMMERCIAL DRUG SUBSTANCE, AND/OR ANY OTHER PRODUCT CONTAINING IGF-1 FOR COMPANY (THE “MANUFACTURED PRODUCTS”) (B) PROCESS DEVELOPMENT ACTIVITIES FOR THE ESTABLISHMENT OF THE MANUFACTURING PROCESS(ES) DESCRIBED IN CLAUSE (A) OF THIS SENTENCE AT THE THIRD PARTY MANUFACTURING SITE, AND (C) PROCESS VALIDATION AND QUALIFICATION ACTIVITIES IN SUPPORT OF ANY AND ALL REGULATORY AUTHORIZATION(S) NECESSARY FOR THE THIRD PARTY MANUFACTURING SITE TO SERVE AS A REPLACEMENT FOR LONZA AS COMPANY’S SOURCE OF MANUFACTURING AND SUPPLY FOR THE MANUFACTURED PRODUCTS, BUT IN NO EVENT SHALL LONZA’S LIABILITY FOR COSTS PURSUANT TO CLAUSE (II) OF THIS SENTENCE EXCEED [ \* ] DOLLARS ($[ \* ]).  
11. SECURITY PROCEDURES:  
COMPANY personnel authorized to have access to the LONZA facility in connection with the work performed by LONZA under the Agreement shall abide by the security procedures established by LONZA. COMPANY shall be liable for any breaches of security by COMPANY personnel. All COMPANY personnel shall agree to abide by LONZA policies and standard operating procedures established by LONZA.  
12. RECORDS:  
LONZA will maintain accurate records for all work performed by LONZA under the Agreement. If process development work is performed under the Agreement, LONZA will maintain accurate records of such process development work (the ‘‘Development Records”). COMPANY shall own the Development Records developed for COMPANY.  
13. GOVERNING LAW:  
The Agreement and any suits, disputes, actions or other legal proceedings related to or arising out of the work performed by LONZA under the Agreement shall be governed by and construed in accordance with the internal laws of the State of New York, without giving effect to its conflicts of laws provisions.  
14. SEVERABILITY:  
Each provision shall be treated as a separate and independent clause, and the unenforceability of any one clause shall in no way impair the enforceability of any of the other clauses herein. If one or more of the provisions shall for any reason be held to be excessively broad as to scope, activity, subject or otherwise so as to be unenforceable at law, such provision or provisions shall be construed by the appropriate judicial body by limiting or reducing it or them so as to be enforceable to the maximum extent compatible with the applicable law as it shall then appear.  
15. TERMINATION:  
The work performed by LONZA under the Agreement can be terminated in accordance with the termination provisions stated in the body of the Agreement.  
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 16. DEFINITIONS:  
Capitalized terms not herein defined shall have the meanings ascribed to them in the Agreement.  
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18.  
EXECUTION COPY  
 Attachment B  
[\*]  
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19.