Exhibit 10.1
Form 8-K
Bio-Path Holdings, Inc.
File No. 000-53404

Drug Product Development and Clinical Supply Agreement

THIS AGREEMENT is effective as of the 24th day of June, 2008 ("Effective Date").

BY AND BETWEEN:

Bio-Path Holdings, Inc., a corporation organized and existing under the laws of the State of Utah, with its principal offices located at 3293 Harrison Blvd., Suite 230, Ogden, UT 84403 (hereinafter referred to as "CLIENT").

AND:

ALTHEA TECHNOLOGIES, INC., a Delaware corporation, with a place of business located at 11040 Roselle Street, San Diego, CA 92121 (hereinafter referred to as "ALTHEA");

WHEREAS CLIENT has formulations and/or know-how related to each Drug Product, as defined below;

WHEREAS ALTHEA has the expertise and the manufacturing facility suitable for the Production of Drug Product;

WHEREAS, CLIENT wishes to have ALTHEA Produce Drug Product and ALTHEA wishes to Produce Drug Product for CLIENT;

NOW, THEREFORE, in consideration of the premises and the undertakings, terms, conditions and covenants set forth below, the parties hereto agree as follows:

Article 1, DEFINITIONS.

1.1 **AFFILIATE** of a party hereto shall mean any entity that controls or is controlled by such party, or is under common control with such party. For purposes of this definition, an entity shall be deemed to control another entity if it owns or controls, directly or indirectly, at least fifty percent (50%) of the voting equity of another entity (or other comparable interest for an entity other than a corporation).

1.2 **ALTHEA SOPs** shall mean ALTHEA'S Standard Operating Procedures which shall be deemed reviewed and approved by CLIENT unless prior to manufacture of CLIENT's Drug Product CLIENT's representative audits ALTHEA's SOPS and has modifications deemed necessary for the manufacture of CLIENT's Drug Product.

1.3 **BATCH** shall mean a specific quantity of a Drug Product comprising a number of units mutually agreed upon between CLIENT and ALTHEA, 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.

1.4 **BULK DRUG SUBSTANCE** shall mean the active compound, as set forth in the Project Plan, to be supplied by CLIENT for use in Production of Drug Product.

1.5 **cGMP** shall mean current Good Manufacturing Practices as defined in the FDA rules and regulations, 21 CFR Parts 210-211.

1.6 **CANCELLATION FEES** shall mean the fees payable by CLIENT in the event that CLIENT cancels the Production of any Batch of Drug Product set forth in the Project Plan, except in the event of a default by ALTHEA as set forth in Section 3.3.

1.7 **COMPONENTS** shall mean all Components used by ALTHEA in Production of Drug Product under this Agreement. Components are listed in the Project Plan, such Components identified as Components supplied by CLIENT ("CLIENT Supplied Components") and Components supplied by ALTHEA ("ALTHEA Supplied Components").

1.8 **CONFIDENTIAL INFORMATION** shall mean all information and data provided by one party to the other party except any portion of such information and data which:

(i) is known to the recipient as evidenced by its written records before receipt thereof from the disclosing party;

(ii) is disclosed to the recipient by a third person who has the right to make such disclosure;

(iii) is or becomes part of the public domain through no fault of the recipient; or

(iv) the recipient can reasonably establish has been independently developed by recipient without use of the information disclosed by the disclosing party.

1.9 **DEVELOPMENT** shall mean studies conducted by ALTHEA to develop a process to Produce Drug Product, in accordance with the Specifications and cGMP. Development activities shall be identified in the Project Plan.

1.10 **DRUG PRODUCT** shall mean each pharmaceutical product set forth in a development & regulatory Plan, if applicable, and a Project Plan to be Produced by ALTHEA in bulk or finished dosage form for development and/or clinical use only.

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

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

1.13 **IND** shall mean an Investigational New Drug Application for Drug Product, as defined in the United States Food and Drug Administration (FDA) rules and regulations, 21 CFR.

1.14 **LABELING** shall mean all labels and other written, printed, or graphic matter upon: (i) Drug Product or any container, carton, or wrapper utilized with Drug Product or (ii) any written material accompanying Drug Product.

1.15 **MASTER BATCH RECORD (MBR)** shall mean the formal set of instructions for Production of Drug Product. The MBR shall be developed and maintained in ALTHEA's standard format by ALTHEA, using CLIENT's master formula and technical support.

1.16 **PRODUCTION or PRODUCE** shall mean the formulation, filling, packaging, inspection, labeling, and testing of Drug Product by ALTHEA.

1.17 **PRODUCT SPECIFICATION SHEET** shall mean a listing of the analytical testing and corresponding Specifications, to be performed on the Bulk Drug Substance and Drug Product in connection with the stability program.

1.18 **PROJECT PLAN** shall mean the document containing the parameters for Production of Drug Product which shall be developed by ALTHEA and agreed to in writing by CLIENT for each Drug Product under this Agreement. Prior to commencing Production of any Drug Product, ALTHEA shall deliver two (2) signed originals of the Project Plan to CLIENT. CLIENT shall sign both originals of the Project Plan and return one (1) fully executed original to ALTHEA. Each fully executed Project Plan shall be incorporated herein by reference and made a part of this Agreement. ALTHEA shall have no obligation for Production of a Drug Product until CLIENT has executed and returned the Project Plan for such Drug Product to ALTHEA.

1.19 **PURCHASE PRICE** shall mean the amount to be paid by CLIENT as specified in each Project Plan.

1.20 **REGULATORY AUTHORITY** shall mean those agencies or authorities responsible for regulation of Drug Product in the United States and overseas. ALTHEA shall have no obligation to Produce Drug Product in compliance with the requirements of a Regulatory Authority not specified in the applicable Project Plan.

1.21 **RELEASED EXECUTED BATCH RECORD** shall mean the completed batch record and associated deviation reports, investigation reports, and Certificates of Analysis created for each Batch of Drug Product.

1.22 **SPECIFICATIONS** shall mean those specifications set forth in Product Specification Sheet and the Master Batch Record for Drug Product, and to the extent that ALTHEA is required to test the Bulk Drug Substance, for the Bulk Drug Substance.

Article 2, DEVELOPMENT AND PRODUCTION OF DRUG PRODUCT.

2.1 **Initiation:** Upon execution of this Agreement and the corresponding Project Plan for each Drug Product, ALTHEA shall commence Development of such Drug Product pursuant to the timeline set forth in the Project Plan. Upon execution of this Agreement and the corresponding Project Plan for each Drug Product, ALTHEA shall commence Production of such Drug Product pursuant to the Project Plan. ALTHEA shall diligently perform the work necessary to complete the Development and Production of such Drug Product in accordance with the Project Plan.

2.2 **Documentation:** The Master Batch Record shall be reviewed and approved by ALTHEA and by CLIENT prior to commencement of Production. Any material change to an approved Master Batch Record will be reviewed and approved by ALTHEA and by CLIENT prior to said change being implemented. Each Batch of Drug Product shall be Produced by using a copy of the Master Batch Record. Each copy of the Master Batch Record for such Batch of Drug 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. ALTHEA shall provide CLIENT with required supporting Development and Production documentation in a form reasonably suitable for CLIENT's submission to the FDA.

2.3 **Bulk Drug Substance and Components Supply:**

2.3.1 CLIENT Responsibilities: CLIENT, at its sole cost and expense (including, without limitation, shipping costs), shall supply to ALTHEA, in a timely manner, (a) all Bulk Drug Substance required to satisfy the terms of this Agreement and (b) all other CLIENT Supplied Components, all to be delivered to ALTHEA as set forth in the applicable Project Plan for Production of such Drug Product. Except as may specifically be set forth in the Project Plan, on receipt of the Bulk Drug Substance and CLIENT Supplied Components as set forth above, ALTHEA's sole obligation with respect to evaluation of the Bulk Drug Substance and CLIENT Supplied Components shall be to review the accompanying certificate of analysis to confirm that the Bulk Drug Substance and CLIENT Supplied Components (if applicable) conform with the Specifications and component specifications, respectively.

2.3.2 ALTHEA Responsibilities: ALTHEA, at its sole cost and expense (including, without limitation, shipping costs), shall supply, in a timely manner, all ALTHEA Supplied Components as set forth in the applicable Project Plan for Production of such Drug Product.

2.4 **Bulk Drug Substance and Component Delivery Delays**: ALTHEA shall have no responsibility for delays in delivery of Drug Product caused by delays in receipt of Bulk Drug Substance or CLIENT Supplied Components. Notwithstanding anything in this Agreement to the contrary, in the event that ALTHEA receives the Bulk Drug Substance for Production of Drug Product from CLIENT with less time than requested in the applicable Project Plan prior to the scheduled date of Production of such Drug Product, but within sufficient time to Produce such Drug Product on such scheduled date as determined by ALTHEA in its sole discretion, ALTHEA shall Produce such Drug Product as per the original schedule. Notwithstanding anything in this Agreement to the contrary, in the event that ALTHEA receives the Bulk Drug Substance for Production of Drug Product from CLIENT with less time than requested in the applicable Project Plan prior to the scheduled date of Production of such Drug Product, and without sufficient time to Produce such Drug Product on the scheduled date as determined by ALTHEA in its sole discretion, ALTHEA shall reschedule Production of such Drug Product and shall charge CLIENT the applicable Cancellation Fee, provided, however, in the event CLIENT has provided notice to ALTHEA a minimum of forty five (45) days prior to the date scheduled for Production that delivery of the Bulk Drug Substance to Althea will be delayed, Althea shall reschedule the date for Production based on the new date for delivery of the drug substance and no fees will be owed by CLIENT.

2.5 **Importer of Record:** In the event any material or equipment to be supplied by CLIENT, including without limitation CLIENT Supplied Components and Bulk Drug Substance, is imported into the United States for delivery to ALTHEA ("Imported Goods"), 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.

2.6 **Material Safety Data Sheet**: CLIENT shall provide ALTHEA a Material Safety Data Sheet for Bulk Drug Substance and for each Drug Product. ALTHEA shall immediately notify CLIENT of any unusual health or environmental occurrence relating to Drug Product, including, but not limited to any claim or complaint by any employee of ALTHEA or any of its Affiliates or third party that the operations of ALTHEA pursuant to this Agreement have resulted in any adverse health or safety effect on an employee or third party. ALTHEA agrees to advise CLIENT immediately of any safety or toxicity problems of which it becomes aware regarding the Drug Product.

2.7 **Vendor and Supplier Audit and Certification**: CLIENT shall certify and audit all Drug Product- related vendors and suppliers, or approve ALTHEA'S selection of vendors and suppliers by way of signing this agreement.

2.8 **ALTHEA Progress Reports**: ALTHEA shall provide CLIENT with at least monthly written Microsoft Project reports on the progress of the Development and Production of a Drug Product, comparing actual accomplishments to the objectives set forth in the applicable Project Plan..

2.9 **Delivery Terms:** ALTHEA shall ship all Drug Product to CLIENT or to CLIENT's designated consignee. All shipments shall be shipped FOB ALTHEA, by a common carrier designated by CLIENT, at CLIENT's expense; provided, however, ALTHEA shall be responsible for the loading of the Drug Product on departure and shall bear risk of loss and all costs of such loading. CLIENT shall procure, at its cost, insurance covering damage or loss of Drug Product during shipping. All shipping instructions of CLIENT shall be accompanied by the name and address of the recipient and the shipping date.

2.10 **Exporter of Record:** CLIENT shall be the exporter of record for any Product shipped out of the United States, as CLIENT remains the owner of the Product. CLIENT warrants that all shipments of Product exported from the United States will be made in compliance with all applicable United States export laws and regulations and all applicable import laws and regulations into the country of deportation.

CLIENT shall be responsible for obtaining and paying for any licenses or other governmental authorization(s) necessary for the exportation from the United States. CLIENT shall select and pay the freight forwarder who shall solely be CLIENT's agent. CLIENT and its freight forwarder shall be solely responsible for preparing and filing the Shipper's Export Declaration and any other documentation required for the export.

2.11 **Foreign Corrupt Practices Act**. CLIENT acknowledges that it is not the agent of ALTHEA 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 resale of the Product.

2.12 **Deposits and Payment for Drug Product and Development:** Promptly upon execution of each Project Plan, CLIENT shall pay to ALTHEA forty percent (40%) of the total fees of this agreement, and thereafter will be invoiced monthly based on the specific services completed during the month. The final invoice for the Drug Product will be issued upon the delivery of released Drug Product to CLIENT by ALTHEA CLIENT shall pay all invoices within thirty (30) days of the invoice date therefore. Any payment due under this Agreement not received within the times noted above shall bear interest at the lesser of (a) the maximum rate permitted by law, and (b) 1.5% per month on the outstanding balance compounded monthly.

2.13 **Default in Payment Obligations:** In addition to all other remedies available to ALTHEA in the event of a CLIENT default, if CLIENT fails to make payments as required hereunder, ALTHEA may take appropriate measures to assure prompt and full payment, including refusal to Produce any Drug Product until CLIENT's account is paid in full, modify the foregoing terms of payment, place the account on a letter of credit basis, require full or partial payment in advance, suspend deliveries of Drug Product until CLIENT provides assurance of performance reasonably satisfactory to ALTHEA, and/or take other reasonable means as ALTHEA may determine.

2.14 **Returns:** Drug Product returned by third parties is the responsibility of CLIENT.

Article 3, TERM AND TERMINATION.

3.1 **Term:** This Agreement shall commence on the date first above written and will continue until the Development and Production, as described in the Project Plan, have been completed, unless sooner terminated pursuant to Section 3.2 herein (the "Term").

3.2 **Termination:** This Agreement may be terminated at any time upon the occurrence of any of the following events:

3.2.1 **Termination for Breach:** Either party may terminate this Agreement upon the 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 (or such additional time not to exceed ninety (90) days reasonably necessary to cure such default provided the breaching party has commenced a cure within the thirty (30) day period and is diligently pursuing completion of such cure) 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 Drug Product that is subject to the breach.

3.2.2 **Termination for Financial Matters**: This Agreement may be terminated immediately by either party by giving the other party written notice thereof in the event such other party makes a general assignment for the benefit of its creditors, or proceedings of a case are commenced in any court of competent jurisdiction by or against such party seeking (a) such party's reorganization, liquidation, dissolution, arrangement or winding up, or the composition or readjustment of its debts, (b) the appointment of a receiver or trustee for or over such party's property, or

(c) similar relief in respect of such party under any law relating to bankruptcy, insolvency, reorganization, winding up or composition or adjustment of debt, and such proceedings shall continue undismissed, or an order with respect to the foregoing shall be entered and continue unstated, for a period of more than sixty (60) days.

3.2.3 **Termination by Client**: This Agreement may be terminated by CLIENT at any time by giving ALTHEA notice thereof and payment to ALTHEA of the Cancellation Fee set forth in Section 3.3.

3.3 **Payment on Termination:** In the event of the termination of this Agreement by ALTHEA pursuant to Section 3.2.1, CLIENT shall reimburse ALTHEA for (a) all Components ordered prior to termination and not cancelable at no cost to ALTHEA, (b) all work-in-process commenced by ALTHEA, and (c) all finished Drug Product. In the event of cancellation by CLIENT of the Production of any Batch set forth in a Project Plan or in the event of termination of this Agreement, except for termination in the event of a default by ALTHEA pursuant to Section 3.2.1, CLIENT shall pay the Cancellation Fees as hereinafter set forth: (i) CLIENT is subject to a 20% charge if the Batch is canceled less than nine (9) weeks from the scheduled fill date, (ii) a 30% charge if the Batch is canceled less than six (6) weeks from the scheduled fill date, and (iii) a 50% charge if the Batch is canceled less than three (3) weeks from the scheduled fill date. In addition, CLIENT must compensate ALTHEA for any materials ordered or testing completed. For purposes of the foregoing, one (1) week is equivalent to seven (7) days. Following expiration or termination, ALTHEA shall ship such materials to CLIENT at CLIENT's cost and per CLIENT's instructions. CLIENT shall make payment for all expenses described in Section 3.3 thirty (30) days from the invoice date. In the event of termination by CLIENT for a breach by ALTHEA pursuant to Section 3.2.1, CLIENT shall not owe any Cancellation Fees.

3.4 **Survival:** Termination, expiration, cancellation or abandonment of this Agreement through any means or for any reason, except as set forth in Section 12.1, 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. The provisions of Sections 3, 6, 9, 10, 11, 12, 13, 14, and 15 hereof shall survive expiration or termination of this Agreement.

Article 4, CERTIFICATES OF ANALYSIS AND MANUFACTURING COMPLIANCE.

4.1 **Certificates of Analysis:** At CLIENT's cost and expense, ALTHEA shall test, or cause to be tested by third parties**,** in accordance with the Specifications, each Batch of Drug Product Produced pursuant to this Agreement before delivery to CLIENT. A certificate of analysis for each Batch delivered shall set forth the items tested, Specifications, and test results. ALTHEA 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 control unit. ALTHEA shall send, or cause to be sent, such certificates to CLIENT prior to the shipment of Drug Product (unless Drug Product is shipped under quarantine). CLIENT shall test, or cause to be tested, for final release, each Batch of Drug Product as meeting the Specifications. As required by the FDA (see Section 5.2 below), CLIENT assumes full responsibility for final release of each Batch of Drug Product.

4.2 **Manufacturing Compliance:** ALTHEA shall advise CLIENT immediately if an authorized agent of any Regulatory Authority visits ALTHEA's manufacturing facility and makes an inquiry or inspection regarding ALTHEA's Production of Drug Product for CLIENT. ALTHEA will also forward to CLIENT any documents of findings of violations, including but not limited to FDA Form 483. Manufacturing deviations and investigations which occur during Production of Drug Product and which do not cause the Production to be non-compliant with cGMP, shall not be deemed to cause such Drug Product to be non-conforming as set forth in Section 5.1.

4.3 **Reserve Samples:** CLIENT shall be responsible for obtaining and maintaining sufficient quantities of Bulk Drug Substance and Drug Product reserve samples pursuant to cGMP.

4.4 **Annual Quality Review:** CLIENT shall be responsible for evaluating, at least annually, the quality standards of Drug Product to determine the need for changes in Specifications, manufacturing processes, and/or controlled documents. CLIENT shall supply ALTHEA a copy of the evaluation and recommendations, if any.

4.5 **Distribution Records:** ALTHEA shall maintain distribution records that contain all of the appropriate information as specified in cGMP.

4.6 **Customer Complaints:** CLIENT, as required by cGMP, shall maintain complaint files. All specific CLIENT Drug Product-related complaints received by ALTHEA shall be forwarded to CLIENT. CLIENT shall be responsible for the review of the complaint to determine the need for an investigation or the need to report to the FDA as required by cGMP. CLIENT shall send to ALTHEA all Drug Product performance or manufacturing-related complaints which require investigation. ALTHEA shall conduct an investigation for each Drug Product performance or manufacturing-related complaint and shall report findings and follow-up of each investigation to CLIENT. CLIENT shall make these complaint files available to ALTHEA in the event they are required during an FDA inspection.

4.7 **Audits:** CLIENT, upon prior written notice and during normal business hours, shall have the right to inspect, once annually for not more than two (2) days, ALTHEA batch records and the portions of ALTHEA's facility used for Production of Drug Product. If CLIENT chooses to audit ALTHEA more than one (1) time in a calendar year or for more than two (2) days, CLIENT agrees to reimburse ALTHEA for ALTHEA's reasonable expenses incurred in hosting the audit. All audited data will be treated as Confidential Information of ALTHEA and CLIENT shall not be permitted to remove or copy data without ALTHEA's prior consent.

4.8 **Regulatory Compliance:** Unless otherwise stated, ALTHEA is responsible for compliance with all Federal, State and local laws and regulations ("Regulations") as they apply generally to Production, quality and specifications of pharmaceutical products. CLIENT shall be responsible for compliance with all Regulations as they apply to all other aspects of the Production, use, and sale of Drug Product, which responsibility shall include, without limitation, all contact and communications with the FDA regarding the foregoing.

Article 5, ACCEPTANCE OF DRUG PRODUCT.

5.1 **Non-Conforming Drug Product**: Within fifteen (15) calendar days from the date of Production of any Batch pursuant to the Project Plan, ALTHEA shall promptly forward to CLIENT, or CLIENT's designee, samples of such Batch. Within thirty (30) calendar days after receipt by CLIENT of the samples or fifteen (15) calendar days after receipt by CLIENT of the Released Executed Batch Record, whichever is later, CLIENT shall determine whether Drug Product conforms to ALTHEA's Drug Product Specifications, Master Batch Record, ALTHEA's current SOPs, and the Project Plan (collectively the "Product Requirements").

5.1.1 If (a) any Batch of Drug Product conforms to the Product Requirements, or (b) CLIENT fails to notify ALTHEA within the applicable time period that any Batch of Drug Product does not conform to the Product Requirements, then CLIENT shall be deemed to have accepted the Drug Product and waived its right to revoke acceptance.

5.1.2 If CLIENT believes any Batch of Drug Product does not conform to the Product Requirements, it shall notify ALTHEA by telephone, including a detailed explanation of the non-conformity, and shall confirm such notice in writing via overnight delivery to ALTHEA. Upon receipt of such notice, ALTHEA will investigate such alleged non-conformity, and (i) if ALTHEA agrees such Drug Product 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 if such investigation or plan requires data from sources other than CLIENT or ALTHEA, or (ii) if ALTHEA disagrees with CLIENT's determination that the Batch of Drug Product is non-conforming, ALTHEA shall so notify CLIENT by telephone within the thirty (30) calendar day period and confirm such notice in writing by overnight delivery.

5.1.3 If the parties dispute whether Batch of Drug Product is conforming or non-conforming, samples of the Batch of Drug Product 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. CLIENT shall bear the costs of such laboratory or consultant, except as set forth in Section 5.2.

5.2 **Remedies for Non Conforming Product:** In the event ALTHEA agrees that the Batch of Drug Product is non-conforming solely as a result of the negligence or any other fault of ALTHEA or the laboratory determines that the shipment of Drug Product is non-conforming solely as a result of the negligence or any other fault of ALTHEA, then ALTHEA, at its option, shall either (i) at its expense, and subject to CLIENT, at its expense, supplying the replacement Bulk Drug Substance and upon payment for the non-conforming Drug Product by CLIENT, replace such non-conforming Drug Product within sixty (60) calendar days from receipt of replacement Bulk Drug Substance from CLIENT, or (ii) refund the Purchase Price of the non-conforming Drug Product.

5.3 **Non-conforming Bulk Drug Substance**: If Drug Product is rejected by CLIENT, and such Drug Product's failure to meet the Product Requirements is the result of non-conforming Bulk Drug Substance, then such non-conformity shall be deemed not to be non-conforming solely as a result of the negligence of ALTHEA.

Article 6, DRUG PRODUCT RECALLS.

6.1 **Drug Product Recalls:** In the event CLIENT shall be required to recall any Drug Product because such Drug Product may violate local, state or federal laws or regulations, the laws or regulations of any applicable foreign government or agency or the Drug Product Specifications, or in the event that CLIENT elects to institute a voluntary recall, CLIENT shall be responsible for coordinating such recall. CLIENT promptly shall notify ALTHEA if any Drug Product is the subject of a recall and provide ALTHEA with a copy of all documents relating to such recall. ALTHEA shall cooperate with CLIENT in connection with any recall, at CLIENT's expense. CLIENT shall be responsible for all of the costs and expenses of such recall.

Article 7, FORCE MAJEURE; FAILURE TO SUPPLY.

7.1 **Force Majeure Events:** Failure of either party to perform under this Agreement (except the obligation to make payments) shall not subject such party to any liability to the other if such failure is caused by acts of God, acts of terrorism, fire, explosion, flood, drought, war, riot, sabotage, embargo, strikes or other labor trouble, compliance with any order or regulation of any government entity, or by any cause beyond the reasonable control of the affected party, whether or not foreseeable, provided that written notice of such event is promptly given to the other party.

7.2 **Failure to Supply:** If ALTHEA fails to supply all or any material part of Drug Product ordered by CLIENT, CLIENT may require ALTHEA to supply the undelivered Drug Product or a lesser quantity at a future date agreed upon by ALTHEA and CLIENT. The provisions of this Section 7.2 shall be without prejudice to CLIENT's rights under Section 3.2 and remedies provided for thereunder.

Article 8, CHANGES IN PRODUCTION.

8.1 **Changes to Master Batch Records and Product Specifications**: ALTHEA agrees to inform CLIENT within fifteen (15) days of the result of any regulatory development or changes to Drug Product-specific SOPs that materially affect the Production of Drug Product. ALTHEA shall notify CLIENT of and require written approval from CLIENT for changes to Master Batch Records and Drug Product Specifications prior to the Production of subsequent Batches of Drug Product.

8.2 **Facility Changes**

8.2.1 **Product-Specific Changes**: If facility, equipment, process or system changes are required of ALTHEA as a result of requirements set forth by the FDA or any other Regulatory Authority, and such regulatory changes apply primarily to the Production and supply of one or more Drug Products, then CLIENT and ALTHEA will review such requirements and agree in writing to such regulatory changes, and CLIENT shall bear 100% of the reasonable costs thereof.

8.2.2 **General Changes:** If such regulatory changes apply generally to one or more Drug Products as well as to other products Produced by ALTHEA 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 Drug Products relative to the Production of such other products.

Article 9, CONFIDENTIALITY.

9.1 **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 to obtain patents with respect to the Drug Product.

9.2 **Prior Confidentiality Agreement**: This Agreement, by reference, incorporates the Confidentiality Agreement signed by CLIENT and ALTHEA on February 12th, 2008, and is made a part hereof as though fully set forth herein.

9.3 **Third Party Disclosure**: ALTHEA shall be permitted to disclose Drug Product information to third party developmental and analytical service providers in connection with performance of its obligations hereunder provided such providers shall be subject to confidentiality agreements. Either party may disclose Confidential Information of the disclosing party to those Affiliates, agents and consultants who need to know such information to accomplish the purposes of this Agreement (collectively, "Permitted Recipients"); provided such Permitted Recipients are bound to maintain such Confidential Information in confidence.

9.4 **Litigation and Governmental Disclosure**: Each party may disclose Confidential Information hereunder to the extent such disclosure is reasonably necessary for prosecuting or defending litigation, complying with applicable governmental regulations or conducting pre-clinical or clinical trials, provided that if a party is required by law or regulation to make any such disclosure of the other party's Confidential Information it will, except where impractical for necessary disclosures, for example in the event of a medical emergency, give reasonable advance notice to the other party of such disclosure requirement and will use good faith efforts to assist such other party to secure a protective order or confidential treatment of such Confidential Information required to be disclosed.

9.5 **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, and except as may be authorized in Section 9.4, 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.

9.6 **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) days of such party's receipt of such press release shall be deemed as such party's approval of such press release as received by such party. Each party agrees that it shall cooperate fully and in a timely manner with the other with respect to all 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.

9.7 **Duration of Confidentiality**: All obligations of confidentiality and non-use imposed upon the parties under this Agreement shall expire ten (10) years after the expiration or earlier termination of this Agreement; provided, however, that Confidential Information which constitutes the trade secrets of a party shall be kept confidential indefinitely, subject to the limitations set forth in Sections 9.4 through 9.5.

Article 10, INVENTIONS.

10.1 **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 Drug Products, Bulk Drug Substance, Labeling and trademarks associated therewith (collectively, "CLIENT's Intellectual Property"). Neither ALTHEA nor any third party shall acquire any right, title or interest in CLIENT's Intellectual Property by virtue of this Agreement or otherwise, except to the extent expressly provided herein.

10.2 **Individually Owned Inventions:** Except as the parties may otherwise agree in writing, all Inventions (as defined herein) which are conceived, reduced to practice, or created by a party in the course of performing its obligations under this Agreement shall be solely owned and subject to use and exploitation by the inventing party without a duty to account to the other party, provided, however, any Inventions or changes to CLIENT's Drug Product formulation shall be owned solely by CLIENT. For purposes of this Agreement, "Invention" shall mean information relating to any 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.

10.3 **Jointly Owned Inventions:** All Inventions which are conceived, reduced to practice, or created jointly by the parties 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) in the course of the performance of this Agreement shall be owned jointly by the parties. Each party shall have full rights to exploit such 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 such jointly owned Inventions. The decision to file for patent coverage on jointly owned 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.

10.4 **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.

10.5 **Rights in IP**: The party owning any IP shall have the world wide right to control the drafting, filing, prosecution and maintenance of patents covering the Inventions relating to such IP, 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.

10.6 **Confidentiality of IP**: IP shall be deemed to be the Confidential Information of the party owning such IP. The protection of each party's Confidential Information is described in Article 9. Any disclosure of information by one party to the other under the provisions of this Section 10 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.

Article 11, REPRESENTATIONS AND WARRANTIES.

11.1 **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; and (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.

11.2 **ALTHEA Warranty**: ALTHEA represents and warrants that Drug Product shall be Produced in accordance with cGMP and the Drug Product Specifications at the time of release. ALTHEA represents and warrants that it has obtained (or will obtain prior to Producing Drug Product), and will remain in compliance with during the term of this Agreement, all permits, licenses and other authorizations (the "Permits") which are required under federal, state and local laws, rules and regulations applicable to the Production only of Drug Product as specified in the Project Plan; provided, however, ALTHEA shall have no obligation to obtain Permits relating to the sale, marketing, distribution or use of Bulk Drug Substance or Drug Product or with respect to the Labeling of Drug Product. ALTHEA makes no representation or warranty with respect to the sale, marketing, distribution or use of the Bulk Drug Substance or as to printed materials supplied by CLIENT or its consignee. At the time of release, of the Drug Product, ALTHEA represents and warrants that such Drug Product shall be free from defects in design and workmanship.

11.3 **Disclaimer of Warranties**: Except for those warranties set forth in Sections 11.1 and 11.2 of this Agreement, ALTHEA makes no warranties, written, oral, express or implied, with respect to Drug Product or the Development and Production of Drug Product. 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 ALTHEA. NO WARRANTIES OF ALTHEA MAY BE CHANGED BY ANY REPRESENTATIVES OF ALTHEA. CLIENT accepts Drug Product subject to the terms hereof.

11.4 **CLIENT Warranties**: CLIENT warrants that (a) it has the right to give ALTHEA any information provided by CLIENT hereunder, and that ALTHEA has the right to use such information for the Production of Drug Product, and (b) CLIENT has no knowledge of any (i) patents or other intellectual rights that would be infringed by ALTHEA's Production of Drug Product under this Agreement, or (ii) proprietary rights of third parties which would be violated by ALTHEA's performance hereunder. CLIENT further warrants that the Bulk Drug Substance provided to ALTHEA hereunder (1) conforms to the Bulk Drug Substance Specifications and (2) is not adulterated or misbranded within the meaning of the FD&C Act.

Article 12, LIMITATION OF LIABILITY AND WAIVER OF SUBROGATION.

12.1 **Limitation of Liability**: CLIENT's sole and exclusive remedy for breach of this Agreement is limited to those remedies set forth in Article 5 and at ALTHEA's decision, in ALTHEA's sole discretion, to either replace the non-conforming Drug Product or reimburse CLIENT for the Purchase Price for the non-conforming Drug Product. Under no circumstances shall ALTHEA be liable for loss of use or profits or other collateral, special, consequential or other damages, losses, or expenses, including but not limited to the cost of cover or the cost of a recall in connection with, or by reason of the Production and delivery of Drug Product under this Agreement whether such claims are founded in tort or contract. The foregoing constitutes the sole and exclusive remedy of CLIENT and the sole and exclusive liability of ALTHEA. All claims by CLIENT for breach or default under this Agreement shall be brought within one (1) year after the cause of action accrued or shall be deemed waived.

12.2 **Waiver of Subrogation**: All ALTHEA Supplied Components and equipment used by ALTHEA in the Production of Drug Product (collectively, "ALTHEA Property") shall at all times remain the property of ALTHEA and ALTHEA assumes risk of loss for such property until delivery of Drug Product to a common carrier as specified under Section 2.10. ALTHEA hereby waives any and all rights of recovery against CLIENT and its Affiliates, and against any of their respective directors, officers, employees, agents or representatives, for any loss or damage to ALTHEA Property to the extent the loss of damage is covered or could be covered by insurance (whether or not such insurance is described in this Agreement). CLIENT assumes all risk of loss for all CLIENT Supplied Components, all Bulk Drug Substance supplied by CLIENT, and all Drug Product (collectively, "CLIENT Property"). CLIENT hereby waives any and all rights of recovery against ALTHEA and its Affiliates, and against any of their respective directors, officers, employees, agents or representatives, for any loss or damage to the CLIENT Property to the extent the loss of damage is covered or could be covered by insurance (whether or not such insurance is described in this Agreement).

12.3 **Waiver of Claims:** In connection with providing Development services, ALTHEA represents only that it will use reasonable care in providing such information solely as it relates to development studies, formulation, primary packaging and manufacturing process development. ALTHEA makes no representation or warranty, and CLIENT expressly waives all claims against ALTHEA and its Affiliates, and any of their respective agents or employees, arising out of or in connection with any claims relating to the stability, efficacy, safety, or toxicity of Drug Product developed, formulated, packaged or manufactured in accordance with the Development services provided by ALTHEA.

Article 13, INDEMNIFICATION.

13.1 **CLIENT Indemnification**: CLIENT shall indemnify, defend and hold harmless ALTHEA and its Affiliates, and any of their respective directors, officers, employees, subcontractors and agents (collectively the "Indemnified Parties") from and against 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) arising out of or in connection with property damage or personal injury (including without limitation death) of third parties (collectively "Claims") including without limitation Claims allegedly resulting in whole or in part by the negligent acts or omission of the Indemnified Parties or for acts or omissions for which the Indemnified Parties otherwise would be strictly liable, in connection with (a) CLIENT's storage, promotion, labeling, marketing, distribution, use or sale of Bulk Drug Substance or Drug Product, (b) CLIENT's negligence or willful misconduct, (c) CLIENT's breach of this Agreement, or (d) any claim that the use, sale, Production, marketing or distribution of Bulk Drug Substance or Drug Product by ALTHEA or CLIENT violates the patent, trademark, copyright or other proprietary rights of any third party, except to the extent any of the foregoing (a) or (d) is caused solely by the negligence or willful misconduct of the Indemnified Parties or solely by the breach by ALTHEA of its obligations under this Agreement.

13.2 **ALTHEA Indemnification**: ALTHEA shall indemnify, defend and hold harmless CLIENT and its Affiliates and any of their respective directors, officers, employees, subcontractors and agents from and against any and all Claims resulting solely from the Indemnified Parties' negligence or willful misconduct or solely from the ALTHEA's breach of its obligations under this Agreement.

13.3 **Indemnitee Obligations**: A party (the "Indemnitee") which intends to claim indemnification under this Article 13 shall promptly notify the other party (the "Indemnitor") in writing of any action, claim or other matter in respect of which the Indemnitee or any of its Affiliates, or any of their respective directors, officers, employees, subcontractors, or agents, intend to claim such indemnification; provided, however, that failure to provide such notice within a reasonable period of time shall not relieve the Indemnitor of any of its obligations hereunder except to the extent the Indemnitor is prejudiced by such failure. The Indemnitee shall permit, and shall cause its Affiliates, and their respective directors, officers, employees, subcontractors and agents to permit, the Indemnitor, at its discretion, to settle any such action, claim or other matter, and the Indemnitee agrees to the complete control of such defense or settlement by the Indemnitor. Notwithstanding the foregoing, the Indemnitor shall not enter into any settlement that would adversely affect the Indemnitee's rights hereunder, or impose any obligations on the Indemnitee in addition to those set forth herein, in order for it to exercise such rights, without Indemnitee's prior written consent, which shall not be unreasonably withheld or delayed. No such action, claim or other matter shall be settled without the prior written consent of the Indemnitor, which shall not be unreasonably withheld or delayed. The Indemnitee, its Affiliates, and their respective directors, officers, employees, subcontractors and agents shall fully cooperate with the Indemnitor and its legal representatives in the investigation and defense of any action, claim or other matter covered by the indemnification obligations of this Article 13. The Indemnitee shall have the right, but not the obligation, to be represented in such defense by counsel of its own selection and at its own expense.

13.4 **Injunction**: In the event that the Production or sale of a Drug Product is enjoined due to alleged infringement by either party of the proprietary rights of a third party, such action shall be deemed a breach of this Agreement by CLIENT and subject to the terms of Article 3.

Article 14, INSURANCE.

14.1 **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 Drug Product, Commercial General Liability Insurance, including without limitation, Product Liability and Contractual Liability coverage (the "CLIENT Insurance"). The CLIENT Insurance shall cover amounts not less than one million dollars ($1,000,000) combined single limit and shall be with an insurance carrier reasonably acceptable to ALTHEA. ALTHEA 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 ALTHEA evidencing such coverage. If CLIENT fails to furnish such certificates or endorsements, or if at any time during the Term of this Agreement ALTHEA is notified of the cancellation or lapse of the CLIENT Insurance, and CLIENT fails to rectify the same within ten (10) calendar days after notice from ALTHEA, in addition to all other remedies available to ALTHEA hereunder, ALTHEA, at its option, may obtain the CLIENT Insurance and CLIENT promptly shall reimburse ALTHEA for the cost of the same. Any deductible and/or self insurance retention shall be the sole responsibility of CLIENT.

14.2 **ALTHEA Insurance**: ALTHEA shall procure and maintain, during the Term of this Agreement and for a period of one (1) year beyond the expiration date of Drug Product, Commercial General Liability Insurance, including without limitation, Product Liability and Contractual Liability coverage (the "ALTHEA Insurance"). The ALTHEA Insurance shall cover amounts not less than one million dollars ($1,000,000) combined single limit. CLIENT shall be named as an additional insured on the ALTHEA Insurance.

Article 15, GENERAL PROVISIONS.

15.1 **Notices:** 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 CLIENT: Bio-Path Holdings, Inc.
12 Greenway Plaza, Suite 1100
Houston, TX 77046
Attn: Peter Nielsen
President and Chief Executive Officer

Telephone: (832) 971-6616
Facsimile: (713) 425-4999

If to ALTHEA: Althea Technologies, Inc.
11040 Roselle Street
San Diego, CA 92121
Attn: Alan Moore
Executive Vice President and Chief Business Officer

Telephone: (858) 882-0123
Facsimile: (858) 882-0133

For specific inquiries, the following ALTHEA responsible parties may be contacted directly:

Project Manager	Chris Duffy
Quality Control Manager	Niels King
Quality Assurance Manager	Elaine Sapinoso

Materials Manager Melissa Rosness

For specific inquiries, the following CLIENT responsible parties may be contacted directly:

Quality Assurance/Regulatory Director: Dai-Shan Wong

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.

15.2 **Entire Agreement; Amendment:** The parties hereto acknowledge that this Agreement sets forth the entire agreement and understanding of the parties and supercedes all prior written or oral agreements or understandings with respect to the subject matter hereof. No modification of any of the terms of this Agreement, or any amendments thereto, shall be deemed to be valid unless in writing and signed by an authorized agent or representative of both parties hereto. No course of dealing or usage of trade shall be used to modify the terms and conditions herein.

15.3 **Waiver:** None of the provisions of this Agreement shall be considered waived by any party hereto unless such waiver is agreed to, in writing, by authorized agents of both parties. The failure of a party to insist upon strict conformance to any of the terms and conditions hereof, or failure or delay to exercise any rights provided herein or by law shall not be deemed a waiver of any rights of any party hereto.

15.4 **Obligations to Third Parties:** Each party warrants and represents that this Agreement is not inconsistent with any contractual obligations, expressed or implied, undertaken with any third party.

15.5 **Assignment:** This Agreement shall be binding upon and inure to the benefit of the successors or permitted assigns of each of the parties and may not be assigned or transferred by either party without the prior written consent of the other, which consent will not be unreasonably withheld or delayed, except that no consent shall be required in the case of a transfer to a wholly-owned subsidiary or transaction involving the merger, consolidation or sale of substantially all of the assets 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 the obligations under this Agreement. ALTHEA may, without such consent, assign this Agreement to an Affiliate of ALTHEA, provided that the assignee assumes all obligations of ALTHEA under this Agreement. No assignment shall relieve any party of responsibility for the performance of its obligations hereunder.

15.6 **Successors and Assigns:** This Agreement shall be binding upon and shall inure to the benefit of the parties hereto, their successors and permitted assigns.

15.7 **Taxes:** 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 Drug Product to CLIENT pursuant to this Agreement or the sale or distribution of Drug Product by CLIENT (or at CLIENT's sole expense, defend against the imposition of such taxes and expenses). ALTHEA shall notify CLIENT of any such taxes that any governmental authority is seeking to collect from ALTHEA, and CLIENT may assume the defense thereof in ALTHEA's name, if necessary, and ALTHEA agrees to fully cooperate in such defense to the extent of the capacity of ALTHEA, at CLIENT's expense. ALTHEA shall pay all national, state, municipal or other taxes on the income resulting from the sale by ALTHEA of the Drug Product 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.

15.8 **Independent Contractor:** ALTHEA shall act as an independent contractor for CLIENT in providing the services required hereunder and shall not be considered an agent of, or joint venturer with, CLIENT. Unless otherwise provided herein to the contrary, ALTHEA shall furnish all expertise, labor, supervision, machining and equipment necessary for performance hereunder and shall obtain and maintain all building and other permits and licenses required by public authorities.

15.9 **Governing Law:** This Agreement is being delivered and executed in the State of California. 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 California, without regard to the principals of conflicts of laws. The courts of the State of California 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 San Francisco, California.

15.10 **Attorney's Fees:** 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.

15.11 **Severability:** In the event that any term or provision of this Agreement shall violate any applicable statute, ordinance, or rule of law in any jurisdiction in which it is used, or otherwise be unenforceable, such provision shall be ineffective to the extent of such violation without invalidating any other provision hereof.

15.11 **Headings, Interpretation:** The headings used in this Agreement are for convenience only and are not part of this Agreement.

IN WITNESS WHEREOF, the parties hereto have each caused this Drug Product Development and Clinical Supply Agreement to be executed by their duly-authorized representatives as of the Effective Date above written.

BIO-PATH HOLDINGS, INC.	**ALTHEA TECHNOLOGIES, INC.**
By: /s/ Peter H. Nielsen	By: /s/ W. Alan Moore
Name: Peter H. Nielsen	Name: W. Alan Moore
Title: CEO and President	Title: Executive Vice President and CBO