HORIZON PHARMA PUBLIC LIMITED COMPANY
(Exact name of Registrant as specified in its charter)

Ireland
(State or other jurisdiction of incorporation or organization)

Connaught House, 1st Floor
1 Burlington Road, Dublin 4, D04 C5Y6, Ireland
(Address of principal executive offices)

011 353 1 772 2100
(Registrant’s telephone number, including area code)

Title of Each Class
Ordinary shares, nominal value $0.0001 per share

Name of Each Exchange on Which Registered
The NASDAQ Global Select Market

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.  Yes ☒ No ☐.

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act.  Yes ☐ No ☒.

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.  Yes ☒ No ☐.

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).  Yes ☒ No ☐.

Indicate by check mark whether disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of the registrant’s knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment.
Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of “large accelerated filer,” “accelerated filer,” “smaller reporting company,” and “emerging growth company” in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☒ Accelerated filer ☐
Non-accelerated filer ☐ (Do not check if a smaller reporting company) Smaller reporting company ☐
Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant is a shell company (as defined by Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

The aggregate market value of the registrant’s voting ordinary shares held by non-affiliates of the registrant, based upon the $34.74 per share closing sale price of the registrant’s ordinary shares on June 30, 2015 (the last business day of the registrant’s most recently completed second quarter), was approximately $4.7 billion. Solely for purposes of this calculation, the registrant’s directors and executive officers and holders of 10% or more of the registrant’s outstanding ordinary shares have been assumed to be affiliates and an aggregate of 21,858,502 shares of the registrant’s voting ordinary shares held by such persons on June 30, 2015 are not included in this calculation.

As of February 23, 2016, the registrant had outstanding 159,884,455 ordinary shares.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant’s definitive Proxy Statement for the registrant’s 2016 Annual Meeting of Shareholders are incorporated by reference into Part III of the registrant’s Annual Report on Form 10-K.
EXPLANATORY NOTE

Horizon Pharma Public Limited Company (the “Company”) is filing this Amendment No. 1 to Annual Report on Form 10-K/A (this “Amendment”) to amend the Company’s Annual Report on Form 10-K for the fiscal year ended December 31, 2015, as filed with the Securities and Exchange Commission (the “SEC”) on February 29, 2016 (the “10-K”). This Amendment is being filed solely to re-file revised redacted versions of Exhibits 2.4, 10.61, 10.62 and 10.68 to the 10-K, reflecting changes to the Company’s confidential treatment request with respect to certain portions of such exhibits. In addition, as required by Rule 12b-15 under the Securities Exchange Act of 1934, as amended, new certifications by the Company’s principal executive officer and principal financial officer are filed as exhibits to this Amendment.

No attempt has been made in this Amendment to modify or update the other disclosures presented in the 10-K. This Amendment does not reflect events occurring after the filing of the 10-K or modify or update those disclosures that may be affected by subsequent events. Accordingly, this Amendment should be read in conjunction with the 10-K and the registrant’s other filings with the SEC.
Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this Annual Report on Form 10-K/A to be signed on its behalf by the undersigned, thereunto duly authorized.

Horizon Pharma plc

By: /s/ Paul W. Hoelscher

Paul W. Hoelscher

Executive Vice President and Chief Financial Officer
(Principal Financial Officer)

Dated: May 26, 2017
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†† Schedules have been omitted pursuant to Item 601(b)(2) of Regulation S-K. Horizon Pharma Public Limited Company undertakes to furnish supplemental copies of any of the omitted schedules upon request by the Securities and Exchange Commission; provided, however, that Horizon Pharma Public Limited Company may request confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended, for any schedule so furnished.

** Confidential treatment has been requested with respect to certain portions of this exhibit. Omitted portions have been filed separately with the Securities and Exchange Commission.
AGREEMENT AND PLAN OF MERGER

by and among

HORIZON PHARMA USA, INC.,

HZNP LIMITED,

CRIOSTAIL LLC,

CREALTA HOLDINGS LLC,

GTCR FUND X/C LP

and

THE REPRESENTATIVE NAMED HEREIN

December 10, 2015
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***Confidential Treatment Requested***

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***Confidential Treatment Requested
THIS AGREEMENT AND PLAN OF MERGER (this “Agreement”), dated as of December 10, 2015, is made by and among Crealta Holdings LLC, a Delaware limited liability company (the “Company”), Horizon Pharma USA, Inc., a Delaware corporation (“[…***…]”), HZNP Limited, a private company limited by shares organized under the laws of Ireland (the “Purchaser,” and together with […***…], the “Purchasers”), Criostail LLC, a Delaware limited liability company and wholly owned subsidiary of the Purchaser (the “Merger Sub”), GTCR Fund X/C LP, a Delaware limited partnership […***…], and GTCR Fund X/B LP, a Delaware limited partnership, solely in its capacity as representative (the “Representative”) for […***…] and the Company’s Unitholders and Optionholders (all of whom are listed on the attached Sellers Schedule, collectively, the “Sellers”). Capitalized terms used and not otherwise defined herein have the meanings set forth in Article XI below.

WHEREAS, the Purchasers desire to acquire 100% of the membership interests of the Company through […***…] a reverse subsidiary merger transaction pursuant to which the Merger Sub will merge with and into the Company, with the Company surviving as a wholly owned subsidiary of the Purchaser […***…], on the terms and subject to the conditions set forth herein (the “Merger” and, together with the Stock Purchase, the “Transaction”);

WHEREAS, the respective boards of directors or managers (or the equivalent governing bodies) of the Purchasers, the Merger Sub, […***…] and the Company have approved this Agreement, the Merger and/or the Stock Purchase (as applicable) and the related transactions contemplated hereby, upon the terms and subject to the conditions set forth herein; and

WHEREAS, concurrent with the execution and delivery of this Agreement, as a material inducement to Purchasers’ and Merger Sub’s willingness to enter into this Agreement, each Seller listed on Schedule A has executed and delivered to the Purchaser a Joinder Agreement.

NOW, THEREFORE, in consideration of the mutual covenants contained herein and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto agree as follows:

ARTICLE I

THE MERGER AND THE STOCK PURCHASE

1.01 The Merger.

(a) Upon the terms and subject to the conditions set forth in this Agreement, at the Effective Time, the Merger Sub shall merge with and into the Company in accordance with the Delaware Limited Liability Company Act (as amended, “Delaware LLC Law”),
whereupon the separate existence of the Merger Sub shall cease and the Company shall be the surviving limited liability company (the “Surviving Company”) and a wholly owned subsidiary of the Purchaser [...***...].

(b) At the Closing, the Company and the Merger Sub shall cause a certificate of merger substantially in the form of Exhibit A hereto (the “Certificate of Merger”) to be executed, acknowledged and filed with the Secretary of State of the State of Delaware and shall make all other filings or recordings required by Delaware LLC Law in connection with the Merger. The Merger shall become effective at such time (the “Effective Time”) as the Certificate of Merger is duly filed with the Secretary of State of the State of Delaware in accordance with the Delaware LLC Law or at such later time as the Purchaser and the Company mutually agree and specify in the Certificate of Merger.

(c) From and after the Effective Time, the Surviving Company shall succeed to all the assets, rights, privileges, powers and franchises and be subject to all of the liabilities, restrictions, disabilities and duties of the Company and the Merger Sub, all as provided under Delaware LLC Law.

1.02 Conversion of Units.

At the Effective Time, by virtue of the Merger and without any action on the part of any party:

(a) Each Unit (and the membership interests represented thereby) issued and outstanding immediately prior to the Effective Time (other than (i) any Units (and the membership interests represented thereby) which are held by any wholly owned Subsidiary of the Company or in the treasury of the Company or by the Purchasers or the Merger Sub, all of which shall cease to be outstanding and be canceled for no consideration and none of which shall receive any payment with respect thereto, and (ii) any Units (and the membership interests represented thereby) which are held by [...***...], all of which shall be cancelled for no consideration and converted, without [...***...], all receiving any payment with respect thereto, into membership interests in the Surviving Company with a fair market value equal to the fair market value of such Units held by [...***...], as such membership interests are provided for by the Surviving Company LLC Agreement) and all rights in respect thereof shall, by virtue of the Merger and without any action on the part of the holder thereof, shall cease to exist and shall be converted into and represent solely the right to receive an amount in cash, without interest, equal to (A) the Allocable Portion of the Closing Merger Consideration attributable to such Unit less the portion of the Representative Holdback Amount attributable to such Unit, plus (B) any Additional Merger Consideration attributable to each such Unit (as set forth in the Closing Payment Schedule), plus (C) any Escrow Distribution attributable to such Unit (as set forth in the Closing Payment Schedule). No further transfer of any Units shall be made on the Unit Ownership Ledger after the Effective Time. If, after the Effective Time, a valid certificate previously representing any Units is presented to the Surviving Company, the Purchaser or the Paying Agent (in accordance with Section 1.04), such certificate shall be cancelled and shall be exchanged as provided in this Section 1.02.

***Confidential Treatment Requested
(b) Each membership interest of the Merger Sub (a “Merger Sub Interest”) issued and outstanding immediately prior to the Effective Time shall be converted into membership interests in the Surviving Company, as such common units are provided for by the Surviving Company LLC Agreement. As of the Effective Time, the Merger Sub Interests shall no longer be outstanding and shall automatically be canceled and shall cease to exist, and the holder or holders of such membership interests shall cease to have any rights with respect thereto, except the right to receive membership interests in the Surviving Company to be issued in consideration therefor as provided herein, without interest. As of the Effective Time, the Purchaser and […] shall be the holders of all the issued and outstanding units of the Surviving Company.

1.03 Merger Consideration.

(a) At least […] Business Days prior to the Closing Date, the Company shall prepare and deliver to the Purchaser a written statement, signed by the Company’s Chief Financial Officer (the “Pre-Closing Statement”), containing its good faith calculation of its estimate of (i) Closing Date Cash (the “Estimated Cash”), (ii) Closing Date Indebtedness (the “Estimated Indebtedness”), (iii) Net Working Capital (the “Estimated Net Working Capital Amount”), and (iv) Transaction Expenses (the “Estimated Transaction Expenses”). During the period beginning on the date of delivery of the Pre-Closing Statement by the Company until the Closing Date, as reasonably requested by the Purchaser, the Company shall consult with the Purchaser (including by giving the Purchaser an opportunity to provide comments to the Pre-Closing Statement), shall work in good faith to resolve any differences the Company and the Purchaser may have with respect to any of the amounts or calculations set forth in the Pre-Closing Statement, and the Company will make available to the Purchaser and its representatives the work papers and other books and records used in preparing the Pre-Closing Statement and afford the Purchaser and its representatives reasonable access to the relevant personnel and its external representatives of the Company to verify the accuracy of such amounts to the extent deemed reasonably necessary by the Purchaser.

(b) Prior to the Closing Date, the Company shall prepare and deliver to the Purchaser a spreadsheet (the “Closing Payment Schedule”), duly certified by the Chief Financial Officer of the Company setting forth:

(i) the calculation of the Closing Merger Consideration;

(ii) with respect to each holder of Units immediately prior to the Effective Time: (A) the name of such holder, (B) whether such holder is a current or former employee of the Company or any of its Subsidiaries, (C) the total number of Units held by such holder as of immediately prior to the Effective Time, with separate indication of the number of Allocated Units and the number of Unallocated Units (D) the portion of the Closing Merger Consideration that such holder is entitled to receive in respect of such Units pursuant to Section 1.02(a), with separate indication of the Closing Merger Consideration attributable to Allocated Units and Unallocated Units, (E) the portion of such holder’s proceeds referenced in the preceding clause (D) that are to be delivered by the Purchasers to the Representative to fund the Representative Holdback Amount under Section 1.08, with separate indication of the portion attributable to

***Confidential Treatment Requested

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Allocated Units and Unallocated Units, (F) such holder’s Residual Percentage, (G) whether any Taxes are required to be withheld from any portion of the consideration payable to such holder on account of the performance of services, and (H) if such holder held any Unallocated Units as of immediately prior to the Effective Time, (1) the Unallocated Unit Vesting Reporting Amount for such holder, (2) whether the Unallocated Unit Vesting Reporting Amount is properly reported on IRS Schedule K-1, IRS Form W-2, IRS Form 1099-MISC, or IRS Form 1042-S, and (3) if the Unallocated Unit Vesting Reporting Amount is not properly reported on IRS Schedule K-1, the Unallocated Unit Company Closing Payment Amount for such holder;

(iii) with respect to each holder of Options immediately prior to the Effective Time: (A) the name of such Optionholder, (B) whether such holder is an employee of the Company or any of its Subsidiaries, (C) the number of Units underlying such Option immediately prior to the Effective Time, (D) the portion of the Closing Merger Consideration that such holder is entitled to receive in respect of such Options pursuant to Section 1.05, (E) the portion of such holder’s proceeds referenced in the preceding clause (D) that are to be delivered by the Purchaser to the Representative to fund the Representative Holdback Amount under Section 1.08. (F) such holder’s Residual Percentage and (G) whether any Taxes are required to be withheld from any portion of the consideration payable to such holder in respect of such Options on account of the performance of services; and

(iv) […]***…]

(c) The calculations of Estimated Cash, Estimated Indebtedness, Estimated Net Working Capital and Estimated Transaction Expenses on the Pre-Closing Statement will be prepared and will be determined, on a consolidated basis, in accordance with the terms of Section 2.01 regarding the preparation of the Preliminary Statement.

(d) For purposes of this Agreement, the term “Closing Merger Consideration” means (i) $510,000,000 (the “Base Consideration”), minus (ii) the amount of the Estimated Indebtedness, plus (iii) the amount, if any, by which the Estimated Net Working Capital Amount exceeds the Target Net Working Capital Amount, minus (iv) the amount, if any, by which the Target Net Working Capital Amount exceeds the Estimated Net Working Capital Amount, minus (v) the amount of Estimated Cash, minus (vi) the Escrow Amount, minus (vii) the amount of the Estimated Transaction Expenses, plus (viii) the aggregate exercise price of the Options that are outstanding immediately prior to the Effective Time.

(e) For purposes of this Agreement, the term “Final Merger Consideration” means (i) the Base Consideration, minus (ii) the amount of Closing Date Indebtedness as finally determined pursuant to Article II, plus (iii) the amount, if any, by which the Net Working Capital as finally determined pursuant to Article II exceeds the Target Net Working Capital Amount, minus (iv) the amount, if any, by which the Target Net Working Capital Amount exceeds the Net ***Confidential Treatment Requested
Working Capital as finally determined pursuant to Article II, plus (v) the amount of Closing Date Cash as finally determined pursuant to Article II, minus (vi) the Escrow Amount, minus (vii) the amount of Transaction Expenses as finally determined pursuant to Article II, plus (viii) the aggregate exercise price of the Options that are outstanding immediately prior to the Effective Time.

1.04 Unit Exchange.

(a) The Purchaser shall cause a paying agent appointed by the Purchaser, and reasonably acceptable to the Representative (the “Paying Agent”), to effect the exchange of cash for the Units which are entitled to payment pursuant to Section 1.02. After the Effective Time, each Unitholder who has surrendered his, her or its Units (together with a certificate or certificates that immediately prior to the Effective Time represented such Units) pursuant to a duly executed and completed letter of transmittal, substantially in the form of Exhibit B attached hereto (each, a “Letter of Transmittal”), to the Paying Agent, shall be entitled to receive from the Paying Agent in exchange therefor the portion of the Closing Merger Consideration into which such Unitholder’s Units shall have been converted as a result of the Merger (less the portion of the Representative Holdback Amount attributable to such Units) as determined pursuant to Section 1.02 (it being agreed that any Unitholder that delivers a duly executed and completed Letter of Transmittal to the Paying Agent in accordance with this Section 1.04 at least [***] Business Days prior to the Closing shall be paid such consideration by the Paying Agent as promptly as reasonably practicable and, in any event, within [***] Business Days of the Closing) and thereafter, as, when and if any Additional Merger Consideration and/or Escrow Distribution is payable in accordance with the terms of this Agreement, such Unitholder shall be entitled to be paid the Additional Merger Consideration and/or Escrow Distribution into which such Unitholder’s Units shall have been converted as a result of the Merger as determined pursuant to Section 1.02. Notwithstanding the foregoing, the Closing Merger Consideration with respect to Unallocated Units (less the portion of the Representative Holdback Amount attributable to such Units) that is payable to holders who are not partners of the Company for U.S. federal income Tax purposes prior to the date of this Agreement shall be paid through the payroll system of the Surviving Company and/or its Subsidiaries in accordance with Section 3.02(d), until so surrendered and exchanged, each Unit shall represent solely the right to receive the Allocable Portion of the Closing Merger Consideration attributable to such Unit (less the portion of the Representative Holdback Amount attributable to such Unit), and any Additional Merger Consideration and/or Escrow Distribution into which it was converted pursuant to Section 1.02. Notwithstanding the foregoing, if any certificate representing such Units shall have been lost, stolen or destroyed, then, upon the making of an affidavit of such fact by the Person claiming such certificate to be lost, stolen or destroyed (which may include an indemnity or bond in customary form), the Paying Agent and/or the Surviving Company, as applicable, shall issue, in exchange for such lost, stolen or destroyed certificate, the Allocable Portion of the Closing Merger Consideration (less the applicable portion of the Representative Holdback Amount) and any Additional Merger Consideration and/or Escrow Distribution to be paid in respect of the Units represented by such certificate, as contemplated by this Article I.

(b) Any amount remaining with the Paying Agent after the [***] anniversary of the Closing Date may, at the Purchaser’s request, be remitted to the Surviving Company and thereafter any Unitholder shall direct any claims for payment hereunder to the

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Surviving Company as a general creditor thereof. Any such amounts remaining unclaimed by any Unitholder immediately prior to such time when such amounts would otherwise escheat to or become the property of any Governmental Entity, shall, to the extent permitted by applicable Laws, become the property of the Purchaser, free and clear of all claims or interest of any Person previously entitled thereto. Notwithstanding anything to the contrary in this Section 1.04, none of the Paying Agent, the Purchaser, the Surviving Company or any party hereto shall be liable for any amount properly paid to a public official in compliance with any applicable abandoned property, escheat or similar Law.

1.05 Options. The Company shall, as of the Effective Time, cause all Options, whether or not then vested or exercisable, to be canceled and extinguished, no longer be outstanding and cease to represent the right to acquire Units, and in consideration therefor, the Optionholders shall be entitled to receive with respect to each Option: (i) reasonably promptly following the Effective Time an amount in cash, without interest and subject to withholding pursuant to Section 3.03 below, equal to the product of (A) the excess, if any, of the Allocable Portion of the Closing Merger Consideration attributable to each Unit that is subject to such Option over the exercise price per Unit payable upon exercise of such Option, multiplied by (B) the number of Units that would be issued upon exercise of such Option if such holder had exercised such Option in full immediately prior to the Effective Time (the “Closing Option Consideration”), plus (ii) any Additional Merger Consideration attributable to the Common Units underlying such Option to the extent payable in accordance with the terms of this Agreement (as set forth in the Closing Payment Schedule), plus (iii) any Escrow Distribution attributable to the Common Units underlying such Option to the extent payable in accordance with the terms of this Agreement (as set forth in the Closing Payment Schedule).

1.06 Organizational Documents of the Surviving Company.

(a) At the Effective Time and without any further action on the part of the Company or the Merger Sub, the certificate of formation of the Company, as in effect immediately prior to the Effective Time, shall be the certificate of formation of the Surviving Company as of the Effective Time, until duly amended in accordance with applicable Law.

(b) At the Effective Time and without any further action on the part of the Company or the Merger Sub, the limited liability company agreement of the Company, as in effect immediately prior to the Effective Time, shall be amended and restated to read in its entirety as provided by Exhibit C and, commencing as of the Effective Time, shall be the limited liability company agreement of the Surviving Company (the “Surviving Company LLC Agreement”), until thereafter amended as provided therein and by applicable Law.

1.07 Directors and Officers of the Surviving Company.

(a) At the Effective Time, the Company’s board of managers shall resign and the managers of the Merger Sub immediately prior to the Effective Time shall become the managers of the Surviving Company and shall hold office subject to the applicable provisions of the Surviving Company LLC Agreement.
At the Effective Time, the officers of the Merger Sub immediately prior to the Effective Time shall be the officers of the Surviving Company and shall hold office subject to the applicable provisions of the Surviving Company LLC Agreement.

1.08 Representative Holdback. A portion of the proceeds otherwise to be received by the Sellers pursuant to Article I in an aggregate amount equal to $[...***...] (such initial deposit, as it may be decreased at any time in accordance with this Agreement, the “Representative Holdback Amount”) shall be delivered by the Purchasers to the Representative at the Closing, on behalf of the Sellers, by wire transfer of immediately available funds to a segregated account designated by the Representative (which account shall be used only to hold the Representative Holdback Amount and to pay any payments, fees, costs and expenses of the Representative payable by the Representative pursuant to the terms of this Agreement). The portion of the Representative Holdback Amount delivered to, and held by, the Representative on behalf of each such Seller shall be determined pro rata based upon each Seller’s Residual Percentage. The Representative is entitled to pay on behalf of the Sellers, and to the extent paid by the Representative from its own funds, obtain reimbursement for, any reasonable out-of-pocket fees, costs and expenses incurred by the Representative in the performance of its duties hereunder (“Representative Expenses”) from the Representative Holdback Amount, and the Representative shall not use any portion of the Representative Holdback Amount for any other purpose. For all purposes of this Agreement, any and all amounts paid by the Purchasers to the Representative pursuant to this Section 1.08 or otherwise in respect of the Representative Holdback Amount shall be deemed to have been paid to the Sellers and in no event shall the Purchasers or any of their Affiliates have any further obligation or Liability to any Seller in respect thereof. For the avoidance of doubt, any amounts paid by the Purchasers to the Representative in respect of the Representative Holdback Amount shall be treated for Tax purposes as having been received and voluntarily set aside by the Sellers at the time of payment by the Purchasers, and any Tax withholding with respect to such deemed contribution by any Seller shall be satisfied from such Seller’s share of other funds payable to such Seller at such time and shall not reduce the Representative Holdback Amount.

1.09 No Dissenter’s Rights or Appraisal Rights. No holder of Units or Options shall be entitled to any “dissenter’s rights,” “appraisal rights” or any similar remedies under Delaware LLC Law or any other applicable Law. Following the Effective Time, each holder of any Units and/or Options shall be entitled only to the right to receive the appropriate portion of the Closing Merger Consideration, the Additional Merger Consideration (if any) and the Escrow Distribution (if any) payable in respect of such Units and/or Options, as applicable, pursuant to the terms and conditions of this Agreement.

1.10 Stock Purchase.

(a) Sale and Purchase of Shares. At the Closing, upon the terms and subject to the conditions set forth in this Agreement, […] agrees to sell, assign, transfer and deliver to […] free and clear of any Liens (other than those imposed by federal or state securities laws), and […] agrees that it shall purchase and accept delivery from […] of the Shares, free and clear of any Liens (other than those imposed by federal or state securities laws).
Consideration. At the Closing, […] shall cause the Paying Agent to deliver to […] as consideration for the Shares, an aggregate amount equal to the Allocable Portion of the Closing Merger Consideration attributable to the Units […] (assuming for purposes of calculating such amount that such Units are outstanding at the Effective Time). Additionally, to the extent the Sellers are entitled to receive any Additional Merger Consideration and/or Escrow Distribution, then […] shall be entitled to receive, as consideration for the Shares, […] Residual Percentage of such Additional Merger Consideration and/or Escrow Distribution in accordance with the terms of this Agreement.

ARTICLE II

MERGER CONSIDERATION ADJUSTMENT

2.01 Final Closing Balance Sheet Calculation. As promptly as possible, but in any event within […] days after the Closing Date, the Purchasers will deliver to the Representative unaudited consolidated balance sheets of […] and of the Company and its Subsidiaries as of immediately prior to the Closing (the “Closing Balance Sheets”) and a statement showing the calculation of Closing Date Cash, Closing Date Indebtedness and Net Working Capital derived from the Closing Balance Sheets and the Transaction Expenses (together with the Closing Balance Sheets, the “Preliminary Statement”). The calculation of Net Working Capital in the Preliminary Statement shall be prepared in accordance with (i) GAAP, and shall not include any changes in assets or liabilities as a result of purchase accounting adjustments or other changes arising from or resulting as a consequence of the transactions contemplated hereby and (ii) to the extent not inconsistent with clause (i), the accounting methods, policies, categorizations, definitions, principles, assets recognition bases, practices, techniques and procedures (including in respect of management’s exercise of judgment) adopted in connection with the latest balance sheet included in the Audited Financial Statements. The parties agree that the purpose of preparing the Closing Balance Sheets and determining Closing Date Cash, Closing Date Indebtedness and Net Working Capital and the related purchase price adjustment contemplated by this Section 2.01 is to (A) measure the amount of Closing Date Cash and Closing Date Indebtedness and (B) measure changes in Net Working Capital against the Target Net Working Capital Amount, and such processes are not intended to permit the introduction of different judgments, accounting methods, policies, principles, practices, procedures, classifications or estimation methodologies for the purpose of preparing the Closing Balance Sheets or determining Closing Date Cash, Closing Date Indebtedness or Net Working Capital; provided, in each case, that the judgments, accounting methods, policies, principles, practices, procedures, classifications and estimation methodologies used in preparing the Preliminary Statement and determining Estimated Cash, Estimated Indebtedness and Estimated Net Working Capital were consistent with the requirements set forth in clauses “(i)” and “(ii)” above. The Representative and its accountants and other representatives shall be permitted reasonable access during normal business hours upon reasonable advance notice to review […] or any work papers related to the preparation of the Preliminary Statement and the adjustments contemplated hereby; provided, that such access does not unreasonably interfere with the business operations of the Purchasers, the Surviving Company or any of their respective Affiliates and that the Persons

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provided such access shall treat any confidential or proprietary information of [...***...] the Surviving Company or any of their respective Subsidiaries received in connection therewith as confidential and shall not disclose such information to any third party. The Representative and its accountants and other representatives may make reasonable inquiries of the Purchasers, the Surviving Company and their respective accountants regarding questions or disagreements, and the Purchasers shall use their, and shall cause the Surviving Company and its Subsidiaries to use their, commercially reasonable efforts to cause any such accountants to reasonably cooperate with and respond to such inquiries. If the Representative objects in good faith to any item on the Preliminary Statement, the Representative shall deliver to the Purchasers a statement setting forth its objections thereto (an "Objections Statement"). If an Objections Statement is not delivered to the Purchaser within [...***...] days after delivery of the Preliminary Statement to the Representative, the Preliminary Statement shall be final, binding and non-appealable by the parties hereto. The Objections Statement must set forth in reasonable detail (A) any item on the Preliminary Statement which the Representative reasonably believes has not been prepared in accordance with the terms of this Agreement and the Representative’s determination of the amount of such item and (B) the Representative’s alternative calculation of the Closing Date Cash, the Closing Date Indebtedness, the Transaction Expenses and/or the Net Working Capital, as the case may be, together with all relevant supporting documentation. Any item or amount that the Representative does not dispute in the Objections Notice within such [...***...] day period shall be final, binding and conclusive for all purposes hereunder. If an Objections Statement is timely delivered, the Representative and the Purchasers shall negotiate in good faith to resolve any such objections set forth therein, but if they do not reach a final resolution within [...***...] days after the delivery of the Objections Statement, the Representative and the Purchaser shall submit such dispute to [...***...] (the “Accounting Firm”). Any further submissions to the Accounting Firm must be written and delivered to each party to the dispute. The Accounting Firm shall make a final determination of Closing Date Cash, Closing Date Indebtedness, Net Working Capital and Transaction Expenses, and the resulting Final Merger Consideration calculated with reference to such amounts to the extent such amounts are in dispute (and have been reflected on an Objections Statement), in accordance with the guidelines and procedures set forth in this Agreement and on Exhibit D. The parties will use commercially reasonable efforts to cooperate with the Accounting Firm during the term of its engagement. If an Objections Statement is delivered to the Accounting Firm for resolution, the determination of Closing Date Cash, Closing Date Indebtedness, Net Working Capital and/or Transaction Expenses, as the case may be, and the resulting Final Merger Consideration calculated with reference thereto, shall become final and binding on the parties on the date the Accounting Firm delivers its final resolution in writing to the parties.

2.02 Post-Closing Adjustment Payment. If the Final Merger Consideration is greater than the Closing Merger Consideration, (a) the Representative shall deliver to the Purchasers an updated Closing Payment Schedule (which need not be certified by an officer of the Company) setting forth the portion of such excess amount payable to each Seller and (b) the Purchasers shall promptly (but in any event within [...***...] Business Days after the final determination of the Final Merger Consideration and receipt of the updated Closing Payment Schedule) pay, or cause to be paid, to the Paying Agent (for further payment to the Sellers other than Optionholders) and the Surviving Company (for further payment to the Optionholders in accordance with Section 3.02(k)), on a pro rata basis according to each Seller’s Residual Percentage, the amount of such excess in accordance with the Closing Payment Schedule, by

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wire transfer of immediately available funds to the account or accounts designated by the Paying Agent and the Surviving Company. If the Final Merger Consideration is less than the Closing Merger Consideration, the Representative shall promptly (but in any event within [...***...]] Business Days after the final determination of the Final Merger Consideration) pay on behalf of the Sellers (on a pro rata basis according to each Seller’s Residual Percentage) to the Purchasers the absolute value of such difference by wire transfer of immediately available funds to one or more accounts designated in writing by the Purchasers.

ARTICLE III

THE CLOSING

3.01 The Closing. The closing of the transactions contemplated by this Agreement (the “Closing”) shall take place at the offices of Kirkland & Ellis LLP located at 300 North LaSalle Street, Chicago, Illinois, 60654 at 10:00 a.m. local time on the [...***... ] Business Day following full satisfaction or due waiver of all of the closing conditions set forth in Article IV hereof (other than those to be satisfied at the Closing itself) or on such other date as is mutually agreeable to the Purchaser and the Representative. The date of the Closing is referred to herein as the “Closing Date.”

3.02 The Closing Transactions. Subject to the terms and conditions set forth in this Agreement, the parties hereto shall consummate the following transactions on the Closing Date:

(a) the Company and the Merger Sub shall cause the Certificate of Merger to be executed, acknowledged and filed with the Secretary of State of the State of Delaware;

(b) the Purchasers shall deposit with the Paying Agent, for prompt distribution by the Paying Agent in accordance with Section 1.04 and Section 1.10, an amount equal to (i) the Closing Merger Consideration, less (ii) the aggregate Closing Option Consideration (excluding the portion of the Representative Holdback Amount attributable to Options), less (iii) the Representative Holdback Amount, less (iv) the aggregate exercise price of the Options that are outstanding immediately prior to the Effective Time, less (v) the aggregate Unallocated Unit Company Closing Payment Amount;

(c) the Purchasers shall repay, or cause to be repaid, on behalf of the Company and its Subsidiaries, all amounts necessary to discharge fully the then outstanding balance of all of the Estimated Indebtedness set forth in the Pre-Closing Statement and which are set forth on the Indebtedness Schedule, by wire transfer of immediately available funds to the account(s) designated by the holders of such Estimated Indebtedness in the applicable Payoff Letter;

(d) subject to Section 3.03, the Purchasers shall deliver or cause the Surviving Company to deliver to each holder of Unallocated Units who is not a partner of the Company for U.S. federal income Tax purposes prior to the date of this Agreement, as soon as practicable (but in any event within two payroll periods following the Effective Time), the Allocable Portion of the Closing Merger Consideration attributable to such Unallocated Units less the portion of the

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Representative Holdback Amount attributable to such Unallocated Units (such amount being referred to as the “Unallocated Unit Company Closing Payment Amount”), which amount shall be paid through the payroll system of the Surviving Company and/or its Subsidiaries, subject to withholding pursuant to Section 3.03 below in respect of the entire Unallocated Unit Vesting Reporting Amount for such Unallocated Units;

(e) in accordance with Section 1.08, the Purchasers shall deliver the Representative Holdback Amount to the Representative (on behalf of the Sellers) by wire transfer of immediately available funds;

(f) the Purchasers shall deposit the Escrow Amount in a segregated account (the “Escrow Account”) maintained by the Escrow Agent in accordance with the Escrow Agreement;

(g) the Purchasers, the Merger Sub, the Company and the Representative shall make such other deliveries as are required by Article IV hereof;

(h) the Company shall deliver to the Purchaser and the Merger Sub written evidence of the termination of all agreements set forth on the Terminated Affiliated Transactions Schedule, which terminations shall be effective on or prior to the Closing Date;

(i) the Purchasers shall pay, or cause to be paid, on behalf of […] the Company and its Subsidiaries, the Sellers and the Representative (or any of their respective Affiliates), the Estimated Transaction Expenses set forth in the Pre-Closing Statement by wire transfer of immediately available funds to the account(s) designated in the Pre-Closing Statement;

(j) the […] the prepaid insurance policy (i.e., “tail coverage”) referenced in Section 8.03(b) (the “Tail D&O Policy”);

(k) subject to Section 3.03, the Purchasers shall deliver or cause the Surviving Company to deliver to each Optionholder, as soon as practicable (but in any event within […] following the Effective Time), such holder’s Closing Option Consideration (as determined in accordance with Section 1.05), less such Optionholder’s portion of the Representative Holdback Amount, by wire transfer of immediately available funds (or by such other method as is directed by the Representative) to the account(s) designated by the Representative; provided, that if an Optionholder is a present or former employee of the Surviving Company or any of its Subsidiaries for U.S. federal income Tax purposes, the Purchaser shall cause the Surviving Company to make such payment to such Optionholder through the payroll system of the Surviving Company and its Subsidiaries, subject to withholding pursuant to Section 3.03 below; and

(l) […] shall deliver to […] stock certificates representing all of the Shares, which certificates shall be endorsed to […] or accompanied by stock powers executed in blank.
3.03 Required Withholding. The Purchaser, the Surviving Company, the Paying Agent, and the Escrow Agent, as applicable, shall be permitted to deduct and withhold from any consideration payable or otherwise deliverable pursuant to this Agreement to any holder or former holder of Units, Options or Shares such amounts as may be required to be deducted or withheld therefrom under the Code or under any applicable provision of federal, state, local or foreign Tax law (including, for avoidance of doubt, as a result of the vesting of any Incentive Units for which elections under Section 83(b) of the Code were not made), taking into account any applicable exemption under such law. To the extent such amounts are so deducted or withheld and paid to the appropriate taxing authority, the amount of such consideration shall be treated for all purposes under this Agreement as having been paid to the Person to whom such consideration would otherwise have been paid.

ARTICLE IV

CONDITIONS TO CLOSING

4.01 Conditions to the Purchasers’ and the Merger Sub’s Obligations. The obligations of the Purchasers and the Merger Sub to consummate the transactions contemplated by this Agreement are subject to the satisfaction (or waiver by the Purchasers and the Merger Sub in writing) of the following conditions at or prior to the Closing:

(a) (i) The Fundamental Representations set forth in Article V (A) other than those Fundamental Representations that address matters as of particular dates, shall be true and correct […***…] as of the Closing Date as though then made and as though the Closing Date was substituted for the date of this Agreement throughout such representations and warranties, and (B) that address matters as of particular dates shall be true and correct […***…] as of such dates and (ii) the other representations and warranties set forth in Article V (A) other than those representations and warranties that address matters as of particular dates, shall be true and correct as of the Closing Date as though then made and as though the Closing Date was substituted for the date of this Agreement throughout such representations and warranties (without giving effect to materiality, Material Adverse Effect or similar phrases in the representations and warranties), and (B) that address matters as of particular dates shall be true and correct as of such dates (without regard to materiality, Material Adverse Effect or similar phrases in the representations and warranties), except […***…];

(b) Each of member of the Company Group and […***…] shall have performed in all material respects the covenants and agreements that are required to be performed by it under this Agreement at or prior to the Closing;

(c) The applicable waiting periods, if any, under the HSR Act shall have expired or been terminated (the “HSR Condition”);

(d) No Proceeding by any Governmental Entity shall have been instituted or threatened (and not subsequently settled, dismissed or otherwise terminated) which is […***…]
(e) No temporary restraining order, preliminary or permanent injunction or other order issued by any court of competent jurisdiction or other legal or regulatory restraint or prohibition preventing the consummation of the Merger or the material portions of the transactions contemplated by this Agreement, declaring unlawful the Merger or any of the transactions contemplated by this Agreement or causing such transactions to be rescinded shall be in effect;

(f) The Escrow Agent and the Representative shall have executed and delivered to the Purchaser the escrow agreement by and among the Purchaser, the Representative and the Escrow Agent, substantially in the form attached hereto as Exhibit E (the “Escrow Agreement”);

(g) Since the date of this Agreement, there shall not have been a Material Adverse Effect;

(h) [...] shall have delivered to [...] a certification dated as of the Closing Date, sworn under penalty of perjury, and in form and substance required under Treasury Regulation §1.1445-2(b)(2), stating that [...] is not a “foreign person” as defined in Code §1445; provided, however, that in the case of a failure to deliver such certification, the Purchasers’ and the Merger Sub’s sole remedy shall be to withhold on payments hereunder to the extent required by Code §1445 and the Treasury Regulations promulgated thereunder; and

(i) The Company shall have delivered to the Purchasers and the Merger Sub each of the following:

   (i) a certificate of the Company, signed by the Company’s Chief Executive Officer or Chief Financial Officer, dated as of the Closing Date, stating that the preconditions specified in Sections 4.01(a), 4.01(b), and 4.01(g) have been satisfied;

   (ii) a certification dated as of the Closing Date, executed by the requisite “Managers” required to bind the Company under the Company LLC Agreement, sworn under penalty of perjury, and in form and substance required under Treasury Regulation §1.1445-11T(d)(2), stating that (A) 50% or more of the value of the gross assets of the Company does not consist of “United States real property interests” (within the meaning of Code §897(c) and the Treasury regulations thereunder), and (B) 90% or more of the value of the gross assets of the Company does not consist of United States real property interests plus cash or cash equivalents (within the meaning of Treasury Regulation §1.1445-11T(d)(1)); provided, that in the case of a failure to deliver such certification, the Purchasers’ and the Merger Sub’s sole remedy shall be to withhold on payments hereunder to the extent required by Code §1445 and the Treasury Regulations promulgated thereunder;

   (iii) certified copies of resolutions duly adopted by the Company’s board of managers and [...] general partner authorizing the execution, delivery and performance of this Agreement and the other agreements contemplated hereby, and the consummation of all transactions contemplated hereby and thereby; and

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If the Closing occurs, all closing conditions set forth in this Section 4.01 which have not been fully satisfied as of the Closing shall be deemed to have been waived by the Purchaser and the Merger Sub.

4.02 Conditions to the Company’s Obligations. The obligation of the Company to consummate the transactions contemplated by this Agreement is subject to the satisfaction of the following conditions as of the Closing Date:

(a) The representations and warranties set forth in Article VI of this Agreement shall be true and correct in all material respects as of the Closing Date as though then made and as though the Closing Date was substituted for the date of this Agreement throughout such representations and warranties (without giving effect to materiality or similar phrases in the representations and warranties);

(b) The Purchasers and the Merger Sub shall have performed in all material respects the covenants and agreements that are required to be performed by them under this Agreement at or prior to the Closing;

(c) The HSR Condition;

(d) The Escrow Agent and the Purchasers shall have executed and delivered to the Representative the Escrow Agreement;

(e) No Proceeding by any Governmental Entity shall have been instituted or threatened (and not subsequently settled, dismissed or otherwise terminated) which is [...***…]

(f) No temporary restraining order, preliminary or permanent injunction or other order issued by any court of competent jurisdiction or other legal or regulatory restraint or prohibition preventing the consummation of the Merger or the material portions of the transactions contemplated by this Agreement, declaring unlawful the Merger or any of the transactions contemplated by this Agreement or causing such transactions to be rescinded shall be in effect; and

(g) The Purchasers and the Merger Sub shall have delivered to the Representative:

(i) a certificate of the Purchasers and the Merger Sub, dated as of the Closing Date, stating that the preconditions specified in Sections 4.02(a) and 4.02(b) have been satisfied; and

(ii) certified copies of the resolutions duly adopted by the Purchaser’s and [...***…] board of directors (or its equivalent governing body) and the Merger Sub’s board of managers (or its equivalent governing body) authorizing the execution, delivery and performance of this Agreement.
If the Closing occurs, all closing conditions set forth in this Section 4.02 which have not been fully satisfied as of the Closing shall be deemed to have been waived by the Company.

4.03 Frustration of Conditions. None of the Company, the Purchasers or the Merger Sub may rely on the failure of any condition set forth in Section 4.01 or 4.02, as applicable, to be satisfied if such failure was caused by such party’s failure to use, as required by this Agreement, its commercially reasonable efforts to consummate the Merger and consummate the transactions contemplated hereby as expeditiously as practicable.

ARTICLE V

REPRESENTATIONS AND WARRANTIES OF THE COMPANY

The Company represents and warrants to the Purchasers and the Merger Sub, except as set forth in the schedules accompanying this Agreement (each, a “Schedule” and, collectively, the “Disclosure Schedules”), as follows; provided, any disclosure set forth in any Schedule shall be considered to have been set forth in each other Schedule and shall be deemed to modify the representations and warranties in this Article V, in each case, if the relevance of the disclosure set forth in such Schedule to another Schedule or any representation or warranty that is not expressly qualified by such Schedule is reasonably apparent on the face of such disclosure:

5.01 Organization and Organizational Power. The Company is a limited liability company duly organized, validly existing and in good standing under the laws of the State of Delaware, and the Company has all requisite limited liability company power and authority and all authorizations, licenses and permits necessary to own and operate its properties and to carry on its businesses as now conducted, except where the failure to hold such authorizations, licenses and permits would not have a Material Adverse Effect. The Company is qualified to do business in every jurisdiction in which its ownership of property or the conduct of business as now conducted requires it to qualify, except where the failure to be so qualified would not have a Material Adverse Effect. The Company has heretofore made available to the Purchaser complete and correct copies of its Governing Documents (including the Company LLC Agreement) as in effect through and including the date hereof. The Company is not in material default under or in material violation of any provision of its Governing Documents. The Company is not a party to, or bound by, any Contract (including any Organizational Document) that entitles any Unitholder or other holder of equity interests in the Company to any “dissenter’s rights,” “appraisal rights” or any similar remedies under Delaware LLC Law or any other applicable Law.

5.02 Subsidiaries. Neither the Company nor any of its Subsidiaries owns or holds the right to acquire any stock, partnership interest or joint venture interest or other equity ownership interest in any other Person, other than as set forth on the Subsidiaries Schedule. Each of the Subsidiaries listed on the Subsidiaries Schedule (each, a “Company Subsidiary”) is duly organized, validly existing and in good standing under the laws of the jurisdiction of its incorporation or organization, has all requisite power and authority and all authorizations, licenses and permits necessary to own its properties and to carry on its businesses as now conducted and is qualified to do business in every jurisdiction in which its ownership of property
or the conduct of its businesses as now conducted requires it to qualify, except where the failure to hold such authorizations, licenses and permits or to be so qualified would not have a Material Adverse Effect. The Subsidiaries Schedule sets forth, with respect to each Company Subsidiary, such Subsidiary’s jurisdiction of incorporation or organization, the names of such Subsidiary’s beneficial owners, and the number of outstanding shares of capital stock (or equity interests of entities other than corporations) held by such Subsidiary’s beneficial owners. All of the outstanding shares of capital stock of, or other equity interests in, the Company Subsidiaries (a) have been validly issued and are fully paid and non-assessable and (b) are free and clear of any and all Liens other than Permitted Liens. All of the outstanding shares of capital stock (or equity interests of entities other than corporations) of each of the Company Subsidiaries are beneficially owned, directly or indirectly, by the Company. There are no outstanding warrants, securities convertible into or exchangeable for shares of capital stock (or equity interests of entities other than corporations) of any Company Subsidiary or any other commitments for the issuance or sale of any shares of capital stock (or equity interests of entities other than corporations) of any Company Subsidiary. The Company has heretofore made available to the Purchaser complete and correct copies of the Organizational Documents for each of the Company Subsidiaries as in effect through (and including) the date hereof. None of the Company Subsidiaries is in material default under or in material violation of any provision of its Organizational Documents.

5.03 Authorization; No Breach; Valid and Binding Agreement.

(a) The execution, delivery and performance of this Agreement, and the Transaction Agreements to which it is a party, by the Company and the consummation of the transactions contemplated hereby and thereby have been duly and validly authorized by all requisite limited liability company action, and no other limited liability company proceedings on its part are necessary to authorize the execution, delivery or performance of this Agreement.

(b) Except as set forth on the attached Authorization Schedule, the execution, delivery and performance of this Agreement by the Company and/or […] does not and the consummation of the transactions contemplated hereby will not conflict with or result in any material breach of, constitute a material default under, result in a material violation of, result in the creation of any material Lien upon any material assets of any member of the Company Group under, or require any material authorization, consent, approval, exemption or other action by or notice to any court or other Governmental Entity under, (i) the provisions of the certificates or articles of formation or incorporation or bylaws or other Organization Documents of any member of the Company Group, (ii) any Material Contract, including any material indenture, mortgage, lease, loan agreement or other agreement or instrument to which any member of the Company Group is bound (or give any Person the right to: (A) declare a default or exercise any remedy under any Material Contract; (B) accelerate the maturity or performance of any Material Contract; or (C) cancel, terminate or modify any right, benefit, obligation or other term of any Material Contract), or (iii) any order or decree by any Governmental Entity, or any Law, to which any member of the Company Group is subject.

(c) Assuming that this Agreement is a valid and binding obligation of the Purchaser and the Merger Sub, this Agreement constitutes a valid and binding obligation of the Company, enforceable in accordance with its terms, except as enforceability may be limited by

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bankruptcy laws, other similar laws affecting creditors’ rights and general principles of equity affecting the availability of specific performance and other equitable remedies.

(d) The adoption of this Agreement and approval of the Merger requires the affirmative vote (the “Required Member Vote”) of the holders of a majority of the Capital Units (as such term is defined in the Company LLC Agreement) outstanding on the applicable record date. The Required Member Vote is the only vote of the Company’s equityholders required under applicable Law, Delaware Law, the Company’s Organizational Documents and all Contracts to which the Company or any Company Subsidiary is a party to legally adopt this Agreement and approve the Merger.

5.04 Capitalization. As of the date hereof, the Capitalization Schedule accurately sets forth (a) the number of Units that are issued and outstanding, and (b) the number of issued options to acquire Units which are exercisable (or will become exercisable as a result of the transactions contemplated hereby (whether pursuant to the terms of such options or at the election of the Company’s board of managers)), as of immediately prior to the Effective Time. All such Units and Options are owned of record by the Unitholders and Optionholders in the amounts set forth on the Capitalization Schedule, and all of the outstanding Units have been duly authorized and were issued in compliance with all applicable Laws and the Company’s Organizational Documents. Except as set forth on the Capitalization Schedule, the Company does not have any other limited liability company interests, equity securities or securities containing any equity features authorized, issued or outstanding, and there are no agreements, options, warrants, profits interests, equity appreciation, phantom equity, calls, puts, rights to subscribe, conversion rights or other rights or arrangements outstanding which provide for the sale or issuance of any of the foregoing by the Company or its Subsidiaries. Except as set forth on the Capitalization Schedule, there are no agreements or other obligations (contingent or otherwise) which require the Company or its Subsidiaries to repurchase or otherwise acquire any of their respective limited liability company interests or other equity securities that would survive the Closing. There are no voting trusts, proxies or any other agreements or understandings with respect to the voting of the Units. The Company is not subject to any obligation (contingent or otherwise) to repurchase or otherwise acquire or retire any Units.

5.05 Financial Statements and Related Matters.

(a) Part A of the Financial Statements Schedule attached hereto consists of: (i) the Company’s unaudited consolidated balance sheet as of September 30, 2015 (the “Latest Balance Sheet”) and the related unaudited consolidated statement of income and cash flows for the nine-month period then ended (the “Latest Statement of Income and Cash Flows” and together with the Latest Balance Sheet, the “Unaudited Financial Statements”) and (ii) the Company’s audited consolidated balance sheet as of December 31, 2014, and the related audited consolidated statements of income, cash flows and members’ equity for the twelve-month period then ended (the “Audited Financial Statements” and together with the Unaudited Financial Statements, the “Financial Statements”). Except as set forth on the attached Financial Statements Schedule, the Financial Statements have been prepared in accordance with GAAP (subject in the case of the Unaudited Financial Statements to the absence of footnote disclosures and normal and customary year-end adjustments none of which are material in amount), consistently applied throughout the periods indicated therein, and present fairly in all material respects the financial
condition, results of operations and cash flows of the Company and its Subsidiaries (taken as a whole) as of the times and for the periods referred to therein. Neither the Company nor any of its Subsidiaries has any Liabilities or obligations that, if known, would be required by GAAP to be reflected or reserved against in a consolidated balance sheet, other than Liabilities and obligations (x) included or disclosed on the face of the Financial Statements, (y) incurred in the Ordinary Course of Business since the date of the Latest Balance Sheet or (z) incurred directly in connection with this Agreement or the transactions contemplated hereby.

(b) The Company maintains a system of internal accounting controls which are sufficient, in all material respects, to provide reasonable assurance that (i) transactions are executed by the members of the Company Group with management’s authorizations, (ii) transactions are recorded by the members of the Company Group as necessary to permit preparation of financial statements and to maintain accountability for assets, (iii) access to assets of the Company Group is permitted only in accordance with management’s authorization and (iv) the recorded accountability for assets of the Company Group is compared with existing assets of the Company Group at reasonable intervals and appropriate action is taken with respect to any differences.

(c) The Company has made available to the Purchaser a correct and complete aging schedule with respect to the billed accounts receivable of the Company and its Subsidiaries as of the date of the Latest Balance Sheet indicating a range of days elapsed since invoice. All of the accounts receivable, subject to the reserves which are reflected in the net amount set forth on the face of the Latest Balance Sheet, whether billed or unbilled, of the Company and its Subsidiaries arose in the Ordinary Course of Business, are carried at values determined in accordance with GAAP consistently applied, do not represent obligations for goods sold on consignment, on approval or on a sale-or-return basis and are not subject to any other repurchase or return arrangement. No Person has any Lien (other than Permitted Liens) on any accounts receivable of the Company or any Company Subsidiary and no request or agreement for deduction or discount has been made with respect to any accounts receivable of the Company or any Company Subsidiary.

(d) As of […***…], (i) the Company Group owns at least […***…] vials of KRYSTEXXA and […***…] units of MIGERGOT, in each case, packaged for commercial sale in the United States, and (ii) no vials of KRYSTEXXA have been packaged by or on behalf of the Company Group for commercial sale outside of the United States. As of […***…], the Company Group owns at least […***…] kilograms of […***…]. All existing inventories of the Company Group are useable or saleable in the Ordinary Course of Business and, as of the date of this Agreement, the oldest inventory of the Company Group has a remaining shelf life of at least […***…]. All inventories of the Company Group have been manufactured in accordance with Good Manufacturing Practices and are of good and marketable quality. The inventory levels maintained by the Company Group, subject to the inventory reserves set forth on the face of the Latest Balance Sheet, (A) are not excessive in light of the normal operating requirements of the Company Group, and (B) are adequate for the conduct of the operations of the Company Group in the Ordinary Course of Business.

5.06 Absence of Certain Developments.

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(a) Since [...***...], there has not been any Material Adverse Effect. Except as set forth on the Developments Schedule or except as expressly contemplated by this Agreement, since [...***...] to the date hereof, the Company and its Subsidiaries have conducted their business in the Ordinary Course of Business, and neither the Company nor its Subsidiaries has: effected any recapitalization, reclassification, merger, consolidation, equity dividend, equity split or like change in its capitalization or declared, accrued, set aside or paid any dividend or made any other distribution in respect of any equity securities;

(b) transferred, issued, sold, pledged, encumbered, disposed or delivered any units or shares of its or its Subsidiaries’ equity securities or issued or sold any securities convertible into, or options with respect to, or warrants to purchase or rights to subscribe for, any units or shares of its or its Subsidiaries’ equity securities, except for issuances of Units upon exercise of outstanding Options or as otherwise expressly contemplated by this Agreement;

(c) amended its or its Subsidiaries’ certificate or articles of formation or incorporation, operating agreement or bylaws or other Organizational Documents;

(d) sold, assigned or transferred any material portion of its assets, properties or rights, except in the Ordinary Course of Business or pursuant to any agreement set forth on the Contracts Schedule;

(e) (i) materially amended, terminated or accelerated, or exercised or waived any material rights under, any contract required to be disclosed on the Contracts Schedule (or any contract that would be required to be disclosed on the Contracts Schedule, but for the amendment, termination, acceleration, or exercise or waiver of any rights thereunder), or (ii) entered into any contract required to be disclosed on the Contracts Schedule, in each case other than in the Ordinary Course of Business;

(f) made any loans or incurred or guaranteed any Indebtedness;

(g) made any capital expenditures in excess of $[…***...] individually or $[…***...] in the aggregate or commitments therefor;

(h) granted any material Lien (other than Permitted Liens) on any of its material assets or material properties, including the Leased Real Property;

(i) (i) materially increased the compensation or fringe benefits (including vacation or paid-time-off entitlement) of any present or former director, officer, employee, consultant or independent contractor of the Company or any of its Subsidiaries, other than compensation raises to employees who are not officers or directors of the Company or any Company Subsidiary, consultants and independent contractors which are made in the Ordinary Course of Business and did not exceed […***...]% with respect to any such Person, (ii) granted any severance or termination pay to any present or former director, officer, employee, consultant or independent contractor of the Company or any of its Subsidiaries, (iii) granted any equity or equity-based awards or (iv) forgiven or discharged in whole or in part any outstanding material loans or advances to any present or former director, officer, employee, consultant or independent contractor of the Company or any of its Subsidiaries;

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commenced any legal Proceeding or settled, compromised or waived any material right in respect of any material litigation or other legal Proceeding;

(k) materially accelerated the collection of accounts receivable, materially delayed the purchase of supplies, materially delayed normal capital expenditures, repairs or maintenance, or materially delayed payment of accounts payable or accrued expenses; or

(l) committed or agreed to any of the foregoing.

5.07 Title to Properties.

(a) Except as set forth on the Liens Schedule, the Company or its Subsidiaries owns good and valid title to, or holds pursuant to valid and enforceable leases, all of the tangible personal property shown to be owned or leased by it on the Latest Balance Sheet […] or acquired after the date of the Latest Balance Sheet, free and clear of all Liens, except for Permitted Liens.

(b) The material machinery, equipment and other tangible assets owned or leased by the Company Group that are currently being used by or on behalf of the members of the Company Group in the conduct of the business of the Company Group (including in the manufacturing of the Company Products) (i) are in reasonably good operating condition and repair (normal wear and tear excepted), suitable for the uses intended therefore, and free from latent defects other than such defects as do not interfere with the intended use thereof in the conduct of normal operations, (ii) have been maintained in accordance with the normal practice of the Company Group and (iii) there is not currently any maintenance of any such assets that has been deferred by the Company Group. The attached Assets Schedule sets forth a complete and correct list of all material tangible assets of the Company Group (including all manufacturing equipment owned by the Company Group) that are not located on the Leased Real Property (which schedule includes the physical location of such assets). The Company or a Company Subsidiary has a right to promptly obtain possession of all material tangible assets owned by a member of the Company Group that are located at facilities controlled by third parties.

(c) The real property demised by the leases described on the attached Leased Real Property Schedule (the “Leased Real Property”) constitutes all of the real property leased by the Company and its Subsidiaries. The Leased Real Property leases are in full force and effect, and the Company or its Subsidiaries holds a valid and existing leasehold interest under each such lease, subject to proper authorization and execution of such lease by the other party and the application of any bankruptcy or creditor’s rights laws. The Company has delivered or made available to the Purchaser complete and accurate copies of each of the leases described on the Leased Real Property Schedule, and none of such leases have been modified in any material respect, except to the extent that such modifications are disclosed by the copies delivered or made available to the Purchaser and are described on the Leased Real Property Schedule. Neither the Company nor its Subsidiaries (i) is in default under any of such leases in any material respect, or (ii) has received notice of any default under any of such leases. To the Company’s knowledge, no landlord is in default with respect to any of such leases.

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None of the Company’s or its Subsidiaries’ possession and quiet enjoyment of the Leased Real Property has been disturbed and there are no disputes with respect to the Leased Real Property. No security deposit or portion thereof deposited with respect to such Leased Real Property has been applied in respect of a breach or default under such leases which has not been redeposited in full. None of the Company or its Subsidiaries owes any brokerage commissions or finder’s fees with respect to the Leased Real Property. None of the Company or any of its Subsidiaries has subleased, licensed or otherwise granted any Person the right to use or occupy such Leased Real Property or any portion thereof.

Neither […]***[…] the Company nor the Company’s Subsidiaries owns, or has ever owned, any real property.

5.08 Tax Matters.

(a) Except as set forth on the attached Taxes Schedule: Each member of the Company Group has filed all income and other material Tax Returns that it was required to file under applicable Law, and all such Tax Returns were correct and complete in all material respects. All Taxes due and owing by each member of the Company Group (whether or not shown to be due on any Tax Return) have been paid. Each member of the Company Group has properly reported and/or withheld and paid over to the appropriate taxing authority all amounts required to have been reported and/or withheld and paid in connection with any amounts paid or owing to any employee, independent contractor, creditor, member, stockholder, Affiliate or other third party. No member of the Company Group has waived any statute of limitations beyond the date hereof with respect to any Taxes or agreed to any extension of time with respect to any Tax assessment or deficiency that has not yet been either paid or resolved.

(b) No audits or administrative or judicial proceedings are pending or being conducted with respect to any Taxes or Tax Return of any member of the Company Group, nor has any member of the Company Group received any written notice from a taxing authority that it intends to conduct such an audit or investigation which audit or investigation has not yet commenced. All deficiencies asserted or assessments made as a result of any past examinations by any taxing authority of the Tax Returns of, or including, any member of the Company Group have been fully paid. No claim has been made in writing by any Tax authority in a jurisdiction where a member of the Company Group has not filed a Tax Return that such member of the Company Group is or may be subject to Tax by that jurisdiction.

(c) The unpaid Taxes of the Company and its Subsidiaries (i) did not, as of the date of the Latest Balance Sheet, exceed the reserve for Tax Liability (rather than any reserve for deferred Taxes established to reflect timing differences between book and Tax income) set forth on the face of the Latest Balance Sheet (rather than any notes thereto), and (ii) do not exceed that reserve as adjusted for the passage of time through the Closing Date in accordance with the past custom and practice of the Company and its Subsidiaries in filing their Tax Returns. The unpaid Taxes of […]***[…] (A) did not, as of the date of the balance sheet included in […]***[…] Balance Sheet Schedule, exceed the reserve for Tax Liability (rather than any reserve for deferred Taxes established to reflect timing differences between book and Tax income) set forth on the face of such balance sheet (rather than any notes thereto), and (B) do not exceed that reserve as adjusted for the passage of time through the Closing Date.

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in accordance with the past custom and practice of […***…] in filing its Tax Returns. Since the earlier of (x) the date of the Latest Balance Sheet and (y) the date of […***…] Balance Sheet Schedule, no member of the Company Group has incurred any Liability for Taxes outside the Ordinary Course of Business.

(d) No member of the Company Group has distributed stock of another Person, or has had its stock distributed by another Person, in a transaction that was purported or intended to be governed in whole or in part by Code §355 or §361.

(e) No member of the Company Group is or has been a party to any “listed transaction” as defined in Code §6707A and Treasury Regulation §1.6011-4.

(f) No member of the Company Group has applied for or received any private letter ruling from the Internal Revenue Service (or any comparable Tax ruling from any other Governmental Entity).

(g) […***…] has not been a “United States real property holding corporation” within the meaning of Code §897(c)(2) during the applicable period specified in Code §897(c)(1)(A)(ii). As of the Closing Date, within the meaning of Treasury Regulation §1.1445-11T(d), neither (i) 50% or more of the value of the gross assets of the Company consists of United States real property interests, nor (ii) 90% or more of the value of the gross assets of Company consists of U.S. real property interests plus cash or cash equivalents.

(h) There are no Liens as a result of any unpaid Taxes upon any of the assets of any member of the Company Group, other than Liens for Taxes not yet due and payable.

(i) The Company has made available to the Purchaser true, correct and complete copies of all U.S. federal, state, local and non-U.S. income and franchise Tax Returns, examination reports, and statements of deficiencies assessed against or agreed to by any member of the Company Group filed or received since […***…].

(j) Neither the Purchaser, any member of the Company Group, nor any of their Affiliates, will be required to include any item of income in, or exclude any item of deduction from, taxable income for any taxable period (or portion thereof) ending after the Closing Date as a result of any: (i) change in method of accounting by a member of the Company Group for a taxable period ending on or prior to the Closing Date, (ii) use of an improper method of accounting by a member of the Company Group for a taxable period ending on or prior to the Closing Date, (iii) “closing agreement” as described in Code §7121 (or any corresponding or similar provision of state, local or foreign income Tax law) executed by a member of the Company Group on or prior to the Closing Date; (iv) installment sale or open transaction disposition made by a member of the Company Group on or prior to the Closing Date; (v) prepaid amount received by a member of the Company Group on or prior to the Closing Date; or (vi) election under Code §108(i) by any member of the Company Group prior to the Closing.

(k) Except for […***…] interest in the Splitter LP, the Splitter LP’s interest in the Company, the Company’s interest in Crealta Pharmaceuticals LLC, and Crealta Pharmaceuticals LLC’s interest in Crealta Ireland Limited, no member of the Company Group directly or indirectly owns, and (never has directly or indirectly owned in any taxable period for

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which an applicable Tax statute of limitations has not expired), any equity interest in any corporation, partnership, limited liability company, trust or any other entity or arrangement that is treated as a “business entity” within the meaning of Treasury Regulation §301.7701-2.

(l) No member of the Company Group has (i) ever been a member of an affiliated group filing a consolidated, combined or unitary income Tax Return, (ii) ever been a party to any Tax sharing, indemnification or allocation agreement (other than this Agreement and any loan, lease or similar agreement entered into in the Ordinary Course of Business the primary purpose of which is not Taxes), or (iii) any Liability for the Taxes of any other Person (other than the Company or any of its Subsidiaries) under Treasury Regulations §1.1502-6 (or any similar provision of state, local or non-U.S. Law, including any arrangement for group or consortium relief or similar arrangement), as a transferee or successor, by contract, by operation of Law, or otherwise.

(m) For U.S. federal and applicable state income Tax purposes, (i) [...***...], (ii) the Splitter LP is and since its inception has been properly classified as a domestic partnership, and will be properly so classified until the Splitter LP Liquidation, under Treasury Regulations §§301.7701-2 and 301.7701-3, (iv) the Company is and since inception has been properly classified as a domestic partnership, and will properly be so classified through and until the Closing, under Treasury Regulations §§301.7701-2 and 301.7701-3, (iv) Crealta Pharmaceuticals LLC is and since [...***...], has been properly classified as an entity disregarded as separate from the Company, and will be properly so classified through the Closing, under Treasury Regulations §§301.7701-2 and 301.7701-3, and (v) Crealta Pharmaceuticals Ireland Limited is and since its inception has been properly classified as an entity disregarded as separate from the Company, and will properly be so classified through the Closing, under Treasury Regulations §§301.7701-2 and 301.7701-3.

(n) No member of the Company Group is subject to Tax in any country other than its country of incorporation, organization or formation by virtue of having employees, a permanent establishment or other place of business in that country. The Company has provided to the Purchaser all material documentation governing any applicable material Tax holidays or incentives that have current applicability to a member of the Company Group. All related party transactions involving members of the Company Group are at arm’s length and in material compliance with Code §482, the Treasury Regulations promulgated thereunder and any comparable provision of any other Tax Law.

(o) None of the Shares or Units is a “covered security” within the meaning of Code §6045(g). Except for Unallocated Units, no Share or Unit was issued in connection with the performance of services (i) for which no valid and timely Code §83(b) election was made and (ii) that does not satisfy the conditions of IRS Revenue Procedure 2001-43. The Company has provided the Purchaser with true, correct and complete copies of all election statements filed under Code §83(b) and received by [...***...] or the Company in accordance with Treasury Regulation §1.83-2(d). No Code §83(b) election was made for any of the Unallocated Units. No Optionholder is a partner of the Company for U.S. federal income Tax purposes.

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This Section 5.08 and Section 5.13 (to the extent it relates to Taxes) constitute the sole and exclusive representations and warranties of the Company in this Article V with respect to any Tax matters. None of the representations in Sections 5.08(a), 5.08(b), 5.08(c), 5.08(g), 5.08(h), 5.08(i) or 5.08(n) shall be deemed to apply to any Taxes that are not Indemnified Taxes, and, for the avoidance of doubt, no representation is made concerning the existence of any net operating loss, Tax basis or other Tax asset that any member of the Company Group may have in a taxable period beginning after the Closing Date.

5.09 Contracts and Commitments.

(a) Except for the Contracts set forth on Part A of the attached Contracts Schedule, and except for Contracts entered into by the Company or its Subsidiaries after the date hereof in accordance with Section 7.01, neither the Company nor any of its Subsidiaries is party to or bound by any (such Contracts required to be disclosed under Part A of the Contracts Schedule, the “Material Contracts”):

(i) collective bargaining agreement or any other Contract, program, policy or arrangement pursuant to which any of member of the Company Group is or may become obligated to make any bonus, severance or change in control payment or similar payment to a Company Employee (other than payments constituting base salary, incentive bonuses or commissions paid in the ordinary course of business) in excess of $[…***…] per annum;

(ii) equity purchase, option or similar plan;

(iii) (A) Contract or agreement for the employment of any officer, employee or other person on a full-time or consulting basis providing for or resulting in aggregate compensation in excess of $[…***…] per annum, or (B) any consulting or employment agreement with a health care provider entered into in the past […***…];

(iv) Contract, agreement or indenture relating to the borrowing of money or to mortgaging, pledging or otherwise placing a Lien, except for Permitted Liens, on any material portion of the assets of the Company and its Subsidiaries;

(v) Contract relating to indebtedness for borrowed money of any member of the Company Group, whether incurred, assumed, guaranteed or secured by any assets;

(vi) lease, Contract or agreement under which it is lessee of, or holds or operates any personal property owned by any other party, for which the annual rental exceeds $[…***…];

(vii) lease, Contract or agreement under which it is lessor of or permits any third party to hold or operate any property, real or personal;

(viii) Contract or group of related Contracts with the same party for the purchase of products or services which provided for payments by the Company or its

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Subsidiaries in excess of $[...***...]

during the trailing twelve-month period ending on the date of the Latest Balance Sheet
or which is reasonably expected as of the date hereof to be greater than $[...***...]
during any calendar year beginning on or after [...***...];

(ix) agreements or Contract relating to any completed or pending material business or product
acquisition by the Company or its Subsidiaries within the last [...***...];

(x) Contract that requires the Company or any Company Subsidiary to make any payments by way of
royalties, fees, or otherwise to any owner or licensor of, or other claimant to, any Intellectual Property;

(xi) material Contract, license or royalty agreement relating to the use by a third party of material
Intellectual Property owned by the Company or any Company Subsidiary (other than any nonexclusive licenses granted by
the Company in the Ordinary Course of Business);

(xii) any Contract that grants, assigns or otherwise transfers any material right, title or interest in or to
any Intellectual Property;

(xiii) Contract or agreement with any Affiliate;

(xiv) Contract or agreement that contains covenants or other agreements materially limiting the freedom
of the Company, any Company Subsidiary or any of their Affiliates to compete in any business, industry or geographic area
or with any other Person or requiring the Company or any of its Subsidiaries to exclusively sell, develop, supply, buy, lease
or distribute any products or other assets to or for any Person or which contain pricing protection or “most favored nation”
provisions or minimum purchase or minimum sale obligations or which prohibit the Company or any Company Subsidiary
from changing the price charged for any Company Product;

(xv) material Contract with minimum purchase commitments or “take or pay” contract terms;

(xvi) distribution, vendor, dealership, franchise or service Contract or agreement (excluding purchase
orders issued or received in the Ordinary Course of Business) relating to the distribution, marketing or sale of any Company
Products or services;

(xvii) warranty agreement with respect to products sold or services rendered by the Company, co-
promotion agreement or managed care contract;

(xviii) any Contract that is a settlement, conciliation or similar agreement pursuant to which the
Company or any Company Subsidiary will be required after the execution date of this Agreement (A) to conduct its business
in accordance with any material obligations or limitations from and after the execution of such Contract or (B) to pay
consideration in excess of $[...***...];

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(xix) Contract under which any member of the Company Group may receive or is required to make any
earn-out payments in the form of future milestones or otherwise;

(xx) Contract that provides for: (A) reimbursement of any current director or officer of a member of the
Company Group for, or advancement to any current director or officer of a member of the Company Group of, legal fees or
other expenses associated with any Proceeding or the defense thereof; or (B) indemnification of any current director or officer
of a member of the Company Group;

(xxii) Contract that (A) is with a supplier of material equipment, consumables, products, reagents, raw
materials or any component, or any services used in the Company Products, which supplier is the only source in the market
place or only supplier to the Company Group or (B) relates to any cell line used in the manufacture of any Company Product;

(xxii) Contract incorporating or relating to any material guaranty, warranty, sharing of liabilities or
indemnity (including any indemnity with respect to Intellectual Property) or similar obligation, other than Contracts entered
into in the Ordinary Course of Business; or

(xxiii) Contract with a Governmental Entity (including the OCS).

(b) Except as set forth on Part B of the Contracts Schedule, true and correct copies of all written Contracts,
agreements, settlements and instruments which are referred to on the Contracts Schedule have been made available to the Purchaser
and the Merger Sub, in each case together with all amendments, waivers or other changes thereto. The Contracts Schedule contains an
accurate and complete description of all material terms of all oral Contracts referred to therein.

(c) Neither the Company nor its Subsidiaries is in breach of, of default under, in any material respect, any
Contract, agreement, settlement or instrument listed on or required to be listed on Part A of the Contracts Schedule, to the knowledge
of the Company, no event or circumstance has occurred that, with notice or lapse of time or both, would constitute any event of default
under any such Contract and each such Contract, agreement, settlement or instrument is valid, binding, enforceable and in full force
and effect as it relates to the Company and its Subsidiaries and, to the Company’s knowledge, as it relates to the other parties thereto, in
each case except as enforceability may be limited by bankruptcy laws, other similar laws affecting creditors’ rights and general
principles of equity affecting the availability of specific performance and other equitable remedies. No event has occurred that with the
passage of time or the giving of notice or both would result in a material default, breach or event of noncompliance by the Company or
any of its Subsidiaries or, to the Company’s knowledge, any other party under any such contract, agreement, settlement or instrument
required to be listed on the Contracts Schedule. Except as set forth on the Contracts Schedule, with respect to each contract, agreement,
settlement or instrument required to be set forth on the Contracts Schedule: (i) neither the Company nor any of its Subsidiaries has
received written notice of the intention of any party to such contract, agreement, or instrument to decrease the rate of business, cancel,
terminate or
5.10 Intellectual Property.

(a) Part A of the Intellectual Property Schedule accurately identifies:

(i) in Part A(i) of the Intellectual Property Schedule: (A) each item of Registered IP in which any member of the Company Group has or purports to have an ownership interest of any nature (whether solely or jointly with another Person) (the “Company Registered IP”); (B) the jurisdiction in which such Company Registered IP has been registered or filed and the applicable registration or serial number; and (C) any other Person that has an ownership interest in such item of Company Registered IP and the nature of such ownership interest; and

(ii) each of the patents and patent applications included in the Company Registered IP that are owned solely or jointly by a member of the Company Group.

(b) The Company or a Company Subsidiary exclusively owns all right, title and interest to and in the Company IP (other than Intellectual Property licensed to the Company or Company Subsidiary or jointly owned with a third party as noted in Part A(i) of the Intellectual Property Schedule) free and clear of any Liens (other than Permitted Liens). Without limiting the generality of the foregoing:

(i) all application, registration, issuance, renewal and maintenance fees due for material Company Registered IP, including all Company Registered IP related to KRYSTEXXA® (pegloticase) or MIGERGOT® (ergotamine tartrate and caffeine suppositories), having a final due date on or before the date of this Agreement have been paid in full and are current;

(ii) no Company Employee, to the knowledge of the Company, has any claim, right (whether or not currently exercisable) or interest to or in any Company Owned IP and each Company Employee who is or was involved in the creation or development of any Intellectual Property for or on behalf of the Company or any Company Subsidiary has signed a valid, enforceable (A) agreement containing an assignment of all rights in and to such Intellectual Property to the Company or such Company Subsidiary (without further payment being owed to any such Company Employee and without any restrictions or obligations in the Company’s or such Company Subsidiary’s ownership and use thereof), or where such assignment is not permitted under applicable Law, an exclusive license of such Intellectual Property, which license is described in Part B(ii) of the Intellectual Property Schedule, and (B) confidentiality provisions protecting the Company Owned IP and Selected Licensed IP, which in each
case, to the knowledge of the Company, have not been materially breached by such Company Employee;

(iii) the Company and each Company Subsidiary has taken, in the exercise of its and their reasonable business judgment, all reasonable steps to maintain the confidentiality of all Company IP and otherwise protect, maintain and enforce all Company Owned IP and Selected Licensed IP (to the extent the Company or any Company Subsidiary has the right to maintain and enforce Selected Licensed IP), including to protect and enforce its rights in all proprietary information held by the Company or any Company Subsidiary, or purported to be held by the Company or any Company Subsidiary, as a trade secret;

(iv) none of the Company or any Company Subsidiary is now or has ever been a member or promoter of, or a contributor to, any industry standards body or any similar organization that could reasonably be expected to require or obligate the Company or any Company Subsidiary to grant or offer to any other Person any license or right to any Company IP;

(v) no funding, facilities or personnel of any Governmental Entity or any university, college, research institute or other educational institution is being used, or, to the knowledge of the Company, has been used, directly or indirectly, to create, in whole or in part, any Intellectual Property owned or purported to be owned by the Company or any Company Subsidiary, except for any such funding or use of facilities or personnel that does not result in such Governmental Entity or institution obtaining from the Company or any Company Subsidiary ownership or royalty rights or any other similar right, title or interest (including any “march in” rights) in or to such Intellectual Property (including any claim or option to any of the foregoing); and

(vi) To the knowledge of the Company, the Company and its Subsidiaries own or otherwise have the right, through ownership, license or otherwise, to all Intellectual Property (including all manufacturing and other know-how used in the manufacturing and packaging of KRYS TEXXA® (pegloticase)) necessary to conduct the business of the Company Group as conducted as of the date of this Agreement.

(c) All Company Owned IP and Selected Licensed IP that is material to the business of any of the Company Group is subsisting, has not expired, lapsed or been abandoned or cancelled, and to the Company’s knowledge, is valid and enforceable.

(d) Neither the execution, delivery or performance of this Agreement nor the consummation of any of the transactions contemplated hereby will, or would reasonably be expected to, with or without notice or the lapse of time, result in or give any other Person the right or option to cause, create, impose or declare: (A) a loss of, or Lien on, any Company Owned IP or Selected Licensed IP, in each case, that is material to the business of the Company and its Subsidiaries; or (B) the grant, assignment or transfer to any other Person of any license or other right or interest under, to or in any of the Company Owned IP or Selected Licensed IP.
To the knowledge of the Company, no Person has infringed, misappropriated or otherwise violated, and no Person is infringing, misappropriating or otherwise violating, any Company Owned IP or Selected Licensed IP. Part E of the Intellectual Property Schedule: (i) accurately identifies (and the Company has made available to the Purchaser an accurate and complete copy of) each letter or other written or electronic communication or correspondence that has been sent or otherwise delivered by or to any member of the Company Group or any Representative of the Company Group between [...] and the date of this Agreement regarding any alleged or suspected infringement or misappropriation of any Company Owned IP or Selected Licensed IP; and (ii) provides a brief description of the current status of the matter referred to in such letter, communication or correspondence.

The conduct of the business of the Company Group as conducted since [...] and including, without limitation, the development, manufacture, use, import, export, offer for sale, sale or other commercialization of any of the Company Products, does not and has not infringed (directly, contributorily, by inducement or otherwise), misappropriated or otherwise violated any Intellectual Property of any other Person. Part F of the Intellectual Property Schedule: (i) accurately identifies (and the Company has made available to the Purchaser an accurate and complete copy of) each letter or other written or electronic communication or correspondence that has been sent or otherwise delivered by or to any member of the Company Group or, to the knowledge of the Company, any Company Representative, between [...] and the date of this Agreement regarding any alleged or suspected infringement or misappropriation of any Intellectual Property of any other Person by any member of the Company Group or any of the Company Products; and (ii) provides a brief description of the current status of the matter referred to in such letter, communication or correspondence.

No infringement, misappropriation or similar claim or Proceeding involving infringement or misappropriation of any Intellectual Property is pending and served or, to the knowledge of the Company, pending and not served or threatened against any member of the Company Group or against any other Person who is, or has asserted or would reasonably be expected to assert that it is, entitled to be indemnified, defended, held harmless or reimbursed by the Company or any Company Subsidiary with respect to such claim or Proceeding (including any claim or Proceeding that has been settled, dismissed or otherwise concluded).

Part H of the Intellectual Property Schedule sets forth a true and correct list of all grants, benefits, incentives, subsidies and/or other awards received by any member of the Company Group or any other grants, benefits, incentives, subsidies and/or other awards received by third parties for which any member of the Company Group is Liable, in each case, from the OCS (each, an “OCS Grant”), including: (i) the month and year of such grant, (ii) the recipient of such grant, (iii) the amount of such grant, (iv) the aggregate amount of principal and interest outstanding under such grant, and (v) any non-monetary obligations undertaken or owed by any member of the Company Group with respect to such grant. [...]
5.11 Litigation. Except as set forth on the attached Litigation Schedule, as of the date hereof, there are no material suits or material Proceedings pending or, to the Company's knowledge, threatened in writing that involve the Company or its Subsidiaries (or any of the assets owned, leased or used by any of the Company or its Subsidiaries), at law or in equity, or before or by any Governmental Entity and neither the Company nor its Subsidiaries, or any assets of the Company or its Subsidiaries, is subject to any outstanding judgment, injunction, writ, order or decree of any court or other Governmental Entity.

5.12 Governmental Consents, etc. Except for the applicable requirements of the Hart-Scott-Rodino Antitrust Improvements Act of 1976 (the “HSR Act”), no material permit, consent, approval or authorization of, or declaration or notice to or filing with, any Governmental Entity is or will be required in connection with any of the execution, delivery or performance of this Agreement by the Company or the consummation of any transaction contemplated hereby and neither the execution, delivery or performance of this Agreement by the Company nor the consummation of any transaction contemplated hereby will give any Governmental Entity the right to revoke, withdraw, suspend, cancel, terminate or modify, any Governmental Authorization that is held by any of the Company or its Subsidiaries.

5.13 Employee Benefit Plans.

(a) Part A of the attached Employee Benefits Schedule sets forth an accurate and complete list of all the Company Employee Plans and Company Employee Agreements.

(b) With respect to each Company Employee Plan and Company Employee Agreement, the Company has made available to the Purchaser correct and complete copies of, as applicable: (i) the plan document, amendments thereto, communications promising benefits materially greater than those set forth in the aforementioned plan document and amendments.
thereto, trust agreements, and other funding vehicles; (ii) the most recent Annual Report (Form 5500 Series) and accompanying schedules and financial statements, if any; (iii) the current summary plan description and any material modifications thereto, if any (if required to be furnished under ERISA); (iv) the most recent determination or opinion letter from the IRS, if any with respect to each Company Employee Plan intended to be qualified under Section 401(a) of the Code; (v) all material correspondence, if any, to or from any Governmental Entity since […] relating to any Company Employee Plan; and (vi) all discrimination tests, if any, required under the Code for each Company Employee Plan intended to be qualified under Section 401(a) of the Code for the most recent plan year.

(c) Each of the Company Employee Plans that is intended to be qualified under Section 401(a) of the Internal Revenue Code of 1986, as amended (the “Code”), has received a favorable determination or prototype opinion letter from the Internal Revenue Service, and nothing has occurred since the date of such letter that would reasonably be expected to adversely affect the qualified status of such Plan. Except as has not had and would not reasonably be expected to result in a Material Adverse Effect, the Company Employee Plans comply in form and in operation with their terms and with the requirements of the Code and ERISA and other applicable Laws. To the Company’s knowledge, each member of the Company Group has substantially performed all material obligations required to have been performed by them under, and are not in default or violation of, and have no knowledge of any default or violation by any other party to, the material terms of any Company Employee Plan.

(d) With respect to the Company Employee Plans, all material contributions and premium payments required by the terms of a Company Employee Plan or applicable Law to have been made prior to the date hereof have been made. To the knowledge of the Company, no “prohibited transaction,” within the meaning of Section 4975 of the Code or Sections 406 and 407 of ERISA, and not otherwise exempt under Section 408 of ERISA, has occurred with respect to any Company Employee Plan that would result in material Liability to the Company or its Subsidiaries. There are no actions, suits or claims pending, or to the knowledge of the Company threatened or reasonably anticipated (other than routine claims for benefits), against any Company Employee Plan or against the assets of any Company Employee Plan. To the knowledge of the Company, there are no audits, inquiries or Proceedings pending or threatened by the IRS, Department of Labor, or any other Governmental Entity with respect to any Company Employee Plan. Neither the Company nor any of its Subsidiaries has incurred any material penalty or tax with respect to any Company Employee Plan under Section 502(i) of ERISA or Sections 4975 through 4980 of the Code.

(e) No member of the Company Group or any Company Predecessor Entity has ever maintained, sponsored, participated in, or contributed to or had any liability (including on account of being considered a single employer under Section 414 of the Code with any other Person) with respect to (i) any “multiemployer plan” (as defined in Section 4001(a)(3) of ERISA), or (ii) any “pension plan” (as defined in Section 3(2) of ERISA) that is subject to Section 412 of the Code or Title IV of ERISA. No member of the Company Group or any Company Predecessor Entity has ever maintained, sponsored, participated in, or contributed to or had any liability with respect to (A) any Company Pension Plan in which equity interests of any member of the Company Group is or was held as a plan asset, or (B) any Foreign Plan.
(f) No Company Employee Plan provides life, health, medical or other welfare benefits to former employees or beneficiaries or dependents thereof, except for health continuation coverage as required by Section 4980B of the Code or Part 6 of Subtitle B of Title I of ERISA.

(g) To the knowledge of the Company, the Company and its Subsidiaries have, prior to the Effective Time, substantially complied with the health care continuation requirements of COBRA, the requirements of FMLA, the requirements of HIPAA, and any similar provisions of state law applicable to the Company Employees, except where any failure to comply has not had, nor reasonably could be expected to have, a Material Adverse Effect.

(h) Except as set forth on Part H of the Employee Benefits Schedule, the consummation of the transactions contemplated by this Agreement will not constitute an event under any Company Employee Plan, Company Employee Agreement (either alone or upon the occurrence of any additional or subsequent events), that will result (either alone or in connection with any other circumstance or event) in any payment (whether of severance pay or otherwise), acceleration, forgiveness of indebtedness, vesting, distribution, increase in benefits or obligation to fund benefits with respect to any Company Employee.

(i) No member of the Company Group is party to any Contract, arrangement or plan that has resulted or would result, separately or in the aggregate, in the payment of any “excess parachute payment” within the meaning of Code Section 280G (or any corresponding provision of state, local or foreign tax law) as a result of the transactions contemplated by this Agreement (including in combination with other events or circumstances). No amount payable to any Person in connection with the consummation of the transactions contemplated by this Agreement (including in combination with other events or circumstances) will be limited as to the deduction related thereto pursuant to Section 280G of the Code or subject to an excise tax under Section 4999 of the Code. No member of the Company Group is under an obligation to gross-up any payment due to any Person for excise taxes due pursuant to Section 4999 of the Code.

(j) Each Company Employee Plan, Company Employee Agreement, employment agreement, or other compensation arrangement of the Company that constitutes a “nonqualified deferred compensation plan” subject to Section 409A of the Code has been written, executed, and operated in compliance with Section 409A of the Code and the regulations thereunder. Neither the Company nor any Affiliate of the Company has any obligation to gross-up or otherwise reimburse any Person for any tax incurred by such Person pursuant to Section 409A of the Code.

(k) With respect to each Company Employee Plan that is a health plan subject to compliance with the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act of 2010, (collectively, the “2010 Health Care Law”), there will not be any material Liability or material excise Tax under Section 4980H of the Code triggered with respect to operation of such Company Employee Plan for time periods prior the Closing. The Company was not an Applicable Large Employer (as defined in the 2010 Health Care Law) during calendar year 2015.
Except as set forth on Part L of the Employee Benefits Schedule, each recipient of equity interests in the Company or any member of the Company Group issued in connection with the performance of services has made a valid and timely election in respect of such equity interests pursuant to Section 83(b) of the Code, and the Company has made available to the Purchaser true, correct and complete copies of all election statements under Section 83(b) of the Code, together with evidence of timely filing of such election statements with the appropriate IRS center.

Except as set forth on Part M of the Employee Benefits Schedule, with respect to each Senior Management Agreement, neither the Company nor any member of the Company Group has taken any action to cause the definition of “Severance Period” under such Senior Management Agreement to exceed […]***…].

5.14 Insurance. The attached Insurance Schedule lists each material insurance policy maintained by the Company and its Subsidiaries. Neither the Company nor its Subsidiaries is in material default with respect to its obligations under any such insurance policy and, to the Company’s knowledge, each such insurance policy is in full force and effect. Such insurance policies are in full force and effect, all premiums due and payable under such insurance policies have been paid on a timely basis, there is no material claim pending under any such insurance policy as to which coverage has been questioned, denied or disputed by the underwriters of such policy and, as of the date of this Agreement, the Company has no knowledge of any threatened termination of, or material premium increase with respect to, any of such policies.

5.15 Compliance with Laws. Except as otherwise set forth on the attached Compliance with Laws Schedule:

(a) Each member of the Company Group is, and since […]***…] has been in compliance in all material respects with all applicable Laws (including Healthcare Laws, any pricing agreements with, or pricing regulations of, any Governmental Entity (including under the 340B Drug Pricing Program), any Laws relating to occupational health and safety, and, in each case, the rules and regulations promulgated thereunder).

(b) There are, and since […]***…] there have been, no material investigations, Proceedings or disciplinary actions pending or threatened in writing against the Company or its Subsidiaries by a Governmental Entity alleging material noncompliance with any applicable Laws or Healthcare Law in federal, state, foreign, and other jurisdictions and there is no Proceeding, audit, or recoupment by or before any Governmental Entity alleging a violation of Healthcare Laws in federal, state, foreign or other jurisdictions by the Company or its Subsidiaries.

(c) All material approvals, filings, permits, approvals, accreditations, authorizations and licenses of Governmental Entities (collectively, “Permits”) required to conduct the business of the Company Group are in the possession of the Company or one of its Subsidiaries, are valid and in full force and effect and are being complied with in all material respects.

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The Company and its Subsidiaries have filed with the applicable regulatory authorities (including the FDA or any other Governmental Entity performing functions similar to those performed by the FDA) all material filings, declarations, listings, registrations, reports or submissions that are required to conduct the business of the Company Group as presently conducted and as presently planned to be conducted, including but not limited to adverse event reports. All such filings, declarations, listings, registrations, reports or submissions were in material compliance with applicable Laws when filed, and to the knowledge of the Company, no deficiencies have been asserted by any applicable Governmental Entity with respect to any such filings, declarations, listing, registrations, reports or submissions. All preclinical and clinical investigations sponsored by the Company and/or any of its Subsidiaries, including those in which any or all regulatory obligations have been transferred to a third party, are being, and since […] have been, conducted in material compliance with applicable Laws, rules, regulations and guidance documents, including Good Laboratory Practices and Good Clinical Practices requirements, and federal and state Laws, rules, regulations and guidance documents restricting the use and disclosure of individually identifiable health information.

Since […] there has been no false or misleading statement or material omission in any statement made to any Governmental Entity, including, but not limited to the FDA, by the Company or any of its Subsidiaries.

Neither the Company nor any of its Subsidiaries has been debarred or convicted of any crime or engaged in any conduct that did or could result in debarment under 21 U.S.C. § 335a or exclusion from federal healthcare programs under 42 U.S.C. § 1320a-7, and to the Company’s knowledge, neither the Company nor any of its Subsidiaries has engaged in any conduct that would reasonably be expected to result in debarment or exclusion from U.S. federal health care programs.

Since […] there has been no recall, detention, withdrawal, seizure or termination or suspension of manufacturing requested or threatened by any Governmental Entity relating to the products sold by the Company and/or its Subsidiaries. Since […] there have been no field notifications or adverse regulatory actions taken (or, to the knowledge of the Company, threatened) by any Governmental Entity with respect to any Company Products and none of the Company or any Company Subsidiary has, either voluntarily or at the request of any Governmental Entity, provided post-sale warnings, safety alerts, “dear doctor” letters or investigator notices regarding an alleged lack of safety, efficacy or regulatory compliance of any of its products.

None of the Company, any Company Subsidiary, or any Company Representative has committed an act, made a statement or failed to make a statement, that (in any such case) is prohibited under the FDA’s policy respecting “Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities,” set forth in 56 Fed. Reg. 46191 (September 10, 1991). To Company’s knowledge, neither the Company nor any Company Subsidiary has made any voluntary or involuntary self-disclosure to any Governmental Entity or representative thereof regarding any material non-compliance with any Laws.

***Confidential Treatment Requested
Each of the Company and the Company Subsidiaries is, and since […***…], have, conducted their export and related transactions in all material respects in accordance with (i) all applicable export, re-export, and anti-boycott Laws of the United States and United States economic sanctions Laws administered by the Office of Foreign Assets Control within the U.S. Department of Treasury and (ii) all other applicable import and export control Laws in any countries in which such Person conducts business.

No member of the Company Group is or ever was (i) a party to a Medicaid Drug Rebate Agreement or (ii) a participant in the Medicaid Drug Rebate Program […***…]. No member of the Company Group has any rebate Liability under the Medicaid Drug Rebate Program.

No member of the Company Group has ever directly sold any Company Products outside of the United States.

Notwithstanding the foregoing, no representations and warranties are being made under this Section 5.15 with respect to environmental matters, which are covered exclusively by Section 5.16.

5.16 Environmental Compliance. Except as set forth on the attached Environmental Schedule:

(a) The Company and its Subsidiaries are, and have been during the past […***…] years, in material compliance with all applicable Environmental Requirements.

(b) The Company and its Subsidiaries possess all material Permits, licenses and other authorizations required under Environmental Requirements for their operations and are in material compliance with all terms and conditions of such Permits, licenses and other authorizations.

(c) There are no material suits or Proceedings pending or, to the Company’s knowledge, threatened against the Company or any of its Subsidiaries, pursuant to Environmental Requirements.

(d) Neither the Company nor any of its Subsidiaries is subject to any material judgment, order or decree of any court or other Governmental Entity that is outstanding and was issued pursuant to Environmental Requirements.

(e) Neither the Company nor its Subsidiaries has received, within the three (3) year period prior to the date hereof, any currently unresolved written notice of material violations or material liabilities arising under Environmental Requirements, including any notice of any material investigatory, remedial or corrective obligation, relating to the Company, its Subsidiaries or their facilities and arising under Environmental Requirements.

(f) This Section 5.16 constitutes the sole and exclusive representations and warranties of the Company with respect to any environmental matters, including any arising under Environmental Requirements.

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5.17 **Affiliated Transactions.** Except as set forth on the attached **Affiliated Transactions Schedule**, to the Company’s knowledge, no officer, director or Affiliate of the Company or any individual in such officer’s or director’s immediate family is a party to any material agreement, contract, commitment or transaction with the Company or has any material interest in any material property used by the Company.

5.18 **Employees.**

(a) Part A of the attached **Employee Schedule** contains a list of all current employees of the Company Group, and consultants and independent contractors providing services to the Company Group, as of the date of this Agreement, and correctly reflects, in all material respects: (i) their start dates; (ii) their positions; (iii) their full-time, part-time, or temporary status, and for employees of the Company Group, their employer and classification status (e.g., exempt or nonexempt); (iv) their base salaries or base hourly wage or contract rate; (v) their target bonus rates or target commission rates; (vi) accrued but unused vacation time and/or paid time off; (vii) any other compensation payable to them (including compensation payable pursuant to any other bonus, deferred compensation or commission arrangements or other compensation, mandatory end-of-service and/or severance payments); (viii) any promises or commitments made to them with respect to changes or additions to their compensation or benefits; (ix) their visa status, if applicable, (x) each employee of the Company Group who is not fully available to perform work because of disability or other leave, together with the basis of such leave and the anticipated date of return to service, and (xi) any outstanding loans.

(b) Except as set forth on the **Employee Schedule**, the employment of all employees of the Company Group is terminable by the Company or the applicable Company Subsidiary at will, without payment of severance or other compensation or consideration, and without advance notice. The Company has made available to the Purchaser accurate and complete copies of all employee manuals and handbooks, disclosure materials, policy statements and other materials relating to the employment of the employees of the Company Group.

(c) To the knowledge of the Company, no current or former consultant or independent contractor of the Company Group could reasonably be deemed to be a misclassified employee.

(d) Except as set forth on Part D of the attached **Employee Schedule**, (a) neither the Company nor its Subsidiaries has experienced any labor strike, walkout, lockout, picketing or other material labor dispute within the past [...***...], (b) to the Company’s knowledge, no union organizing activities are presently underway or threatened with respect to employees of either the Company or its Subsidiaries and no such activities have occurred within the past three (3) years, and (c) neither the Company nor any of its Subsidiaries have any collective bargaining agreements or collective bargaining relationships with any labor organization. During the past [...***...], neither the Company nor any of its Subsidiaries has implemented any employee layoffs requiring notice under the federal Worker Adjustment and Retraining Notification Act of 1988 or any similar applicable Law (collectively, the “**WARN Act**”) without complying therewith in all material respects.

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No member of the Company Group has any Liability for any payment to any trust or other fund governed by or maintained by or on behalf of any Governmental Entity with respect to unemployment compensation benefits, social security or other benefits or obligations for any employee of the Company Group (other than routine payments to be made in the Ordinary Course of Business). No member of the Company Group has engaged in any unfair labor practice within the meaning of the National Labor Relations Act. There is no claim, pending, or the knowledge of the Company, threatened against any member of the Company Group by an employee of the Company Group in respect of any illness or injury, which is not fully covered by an insurance policy listed on the Insurance Schedule.

5.19 Certain Business Practices. Each of the Company and its Subsidiaries, and to the Company’s knowledge, the Company Representatives (a) has not used and is not using any funds for any unlawful contributions, unlawful gifts, unlawful entertainment or other unlawful expenses; (b) has not made any direct or indirect unlawful payments to any foreign or domestic Government Official; (c) has not violated and is not violating any Anti-Corruption Laws; (d) has not established or maintained, and is not maintaining, any unlawful or unrecorded fund of monies or other properties; (e) has not made, and is not making, any false or fictitious entries on its accounting books and records; (f) has not made, and is not making, any bribe, rebate, payoff, influence payment, kickback or other unlawful payment of any nature, and has not paid, and is not paying, any fee, commission or other payment that has not been properly recorded on its accounting books and records as required by the Anti-Corruption Laws; and (g) has not otherwise unlawfully given or received anything of value to or from a Government Official, an intermediary for payment to any individual including Government Officials, any political party or customer for the purpose of obtaining or retaining business.

5.20 Material Suppliers. The attached Suppliers Schedule sets forth the names of the ten suppliers to whom the Company Group paid the greatest sum of money in respect of services, products and/or materials provided to the Company Group during the year ended December 31, 2014 and during the nine-months ended September 30, 2015. To the knowledge of the Company, since […***…], no supplier listed on the Suppliers Schedule has notified any member of the Company Group that it is canceling, materially reducing or otherwise terminating its business with the Company Group or that it intends to cancel, reduce or otherwise terminate its relationship with the Company Group. Each manufacturer of a Company Product is obligated under the terms of a Material Contract, upon the termination of such manufacturing relationship, to assist the Company with the transition of the manufacturing of such Company Product to a third party selected by the Company, which obligation includes transferring to the Company or its designee (a) all equipment owned by the Company or any Company Subsidiary that is then in the possession of such manufacturer and (b) any know-how that is owned or controlled by such manufacturer and that is necessary for, or otherwise used in, the manufacturing of such Company Product and, as of the date of this Agreement, no member of the Company Group has received written notice, and, to the Company’s knowledge there are no facts or circumstances, indicating that such manufacturer does not intend to satisfy such obligations.

5.21 Brokerage. Except for fees and expenses of the Persons listed on the attached Brokerage Schedule, there are no claims for brokerage commissions, finders’ fees or similar compensation in connection with the transactions contemplated by this Agreement based

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5.22 [...***...].

(a) Capacity, Power and Authority; Absence of Conflicts. [...***...] possesses full right, capacity, power and authority to enter into and carry out the transactions contemplated by this Agreement. This Agreement has been duly executed and delivered by [...***...]. Assuming the due authorization, execution and delivery by each of the Company, the Purchaser and the Merger Sub of this Agreement and the other Transaction Documents to which they are a party, this Agreement constitutes, and upon their execution and delivery, the other Transaction Documents to which [...***...] is to become a party will constitute, valid and binding obligations of [...***...], enforceable in accordance with their respective terms, except as enforceability may be limited by bankruptcy laws, other similar laws affecting creditors’ rights and general principles of equity affecting the availability of specific performance and other equitable remedies. The execution, delivery and performance by [...***...] of the Transaction Documents to which it is a party do not, and the consummation of the transactions contemplated hereby and thereby will not, (i) conflict with or result in any breach of the terms, conditions or provisions of [...***...] certificate of incorporation or bylaws or other Organizational Documents, (ii) conflict with or violate any Law to which [...***...] is subject or (iii) constitute a breach or default under (with or without notice or lapse of time, or both), result in a violation of, result in the creation of any Lien upon any assets of [...***...] under, or require any authorization, consent, approval, exemption or other action by or notice or declaration to, or filing with, any court or other Governmental Entity or other Person under, the provisions of any indenture, mortgage, lease, loan agreement or other agreement, Contract or instrument to which [...***...] is a party or otherwise bound.

(b) Ownership of the Shares; No Other Equity Interests. [...***...]

5.23 [...***...]

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Consents and Approvals. Except for compliance with the HSR Act, no consent, approval or authorization of, or declaration, filing or registration with, any Governmental Entity is required to be made or obtained by [...***...] in connection with the consummation of the transactions contemplated by this Agreement. No consent, approval or authorization of, or notice to any counterparty to any contract to which [...***...] is bound must be made or obtained by [...***...] in connection with the consummation of the transactions contemplated by this Agreement.

5.2.4 No Other Representations or Warranties. Except for the representations and warranties contained in Article VI, each of the Company and the Representative (a) acknowledges that none of Parent, Merger Sub nor any other Person on behalf of Parent makes any other express or implied representation or warranty (i) with respect to Parent or any of its Affiliates, (ii) with respect to any other information provided to the Company or the Company Representatives or (iii) in connection with the transactions contemplated by this Agreement and (b) disclaims reliance on any information other than the representations and warranties expressly set forth in Article VI.

ARTICLE VI

REPRESENTATIONS AND WARRANTIES OF THE PURCHASERS AND THE MERGER SUB

The Purchasers and the Merger Sub represent and warrant to the Sellers, [...***...] and the Company that, except as set forth in the Disclosure Schedules; provided, any information set forth in any Schedule or incorporated in any Section of this Agreement shall be considered to have been set forth in each other Schedule and shall be deemed to modify the representations and warranties in this Article VI, in each case, if the relevance of the disclosure set forth in such Schedule is reasonably apparent on the face of such disclosure:

6.01 Organization and Organizational Power. The Purchaser is a private company limited by shares duly organized, validly existing and in good standing under the laws of Ireland, with full power and authority to enter into this Agreement and perform its obligations hereunder. [...***...] is a corporation duly organized, validly existing and in good standing under the laws of the State of Delaware, with full power and authority to enter into this...
Agreement and perform its obligations hereunder. The Merger Sub is a limited liability company duly organized, validly existing and in good standing under the laws of the State of Delaware, with full power and authority to enter into this Agreement and perform its obligations hereunder.

6.02 Authorization. The execution, delivery and performance by each of the Purchasers and the Merger Sub of this Agreement and the other Transaction Documents to which they are a party and the consummation of the transactions contemplated hereby and thereby, and the performance of their obligations hereunder and thereunder, have been duly and validly authorized by all requisite corporate or limited liability company action, as the case may be, and no other proceedings on their part are necessary to authorize the execution, delivery or performance of this Agreement and the other Transaction Documents or the consummation of the transactions contemplated hereby and thereby. The Purchasers and Merger Sub have duly executed and delivered this Agreement and, at or prior to the Closing, will have duly and validly executed and delivered each of the other Transaction Documents to which they are a party. Assuming the due authorization, execution and delivery by each of the Company, the Representative and […]***…] of this Agreement and the other Transaction Documents to which they are a party, this Agreement constitutes, and upon their execution and delivery, the other Transaction Documents to which the Purchasers or Merger Sub is to become a party, will constitute, valid and binding obligations of each of the Purchasers and the Merger Sub, enforceable in accordance with their respective terms, except as enforceability may be limited by bankruptcy laws, other similar laws affecting creditors’ rights and general principles of equity affecting the availability of specific performance and other equitable remedies. No vote of the holders of any class or series of capital stock of the Purchasers or the Merger Sub (other than the consent of the Purchaser which has been obtained) is required to adopt this Agreement and approve the transactions contemplated hereby.

6.03 No Violation. Neither the Purchasers nor the Merger Sub is subject to or obligated under its certificate or articles of incorporation or formation, its bylaws or its operating agreement (or similar organizational documents), any Law, or any material permit, agreement or instrument, or any license or franchise, or subject to any order, writ, injunction or decree of any Governmental Entity, which would be breached or violated in any material respect by the Purchasers’ or the Merger Sub’s execution, delivery or performance of this Agreement or the consummation of the transactions contemplated hereby.

6.04 Governmental Consents. Except for the applicable requirements of the HSR Act, no material permit, consent, approval or authorization of, or declaration to or filing with, any Governmental Entity or any other Person is required to be obtained by the Purchasers or the Merger Sub in connection with its execution, delivery and performance of this Agreement or the consummation of the transactions contemplated hereby.

6.05 Litigation. As of the date of this Agreement, there are no suits or proceedings pending or, to the Purchasers’ or the Merger Sub’s knowledge, threatened in writing against the Purchasers or the Merger Sub at law or in equity, or before or by any Governmental Entity, which challenges the validity of this Agreement or would adversely affect or restrict the Purchasers’ or the Merger Sub’s performance under this Agreement or their ability to consummate the transactions contemplated hereby. As of the date of this Agreement, neither the

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Purchasers nor the Merger Sub is subject to any outstanding judgment, order or decree of any court or other Governmental Entity that would adversely affect or restrict the Purchasers’ or the Merger Sub’s ability to consummate the transactions contemplated hereby.

6.06 Brokerage. Except for the Persons listed on the attached Purchaser Brokerage Schedule, no Person is entitled to any brokerage commissions, finders’ fees or similar compensation in connection with the transactions contemplated by this Agreement based on any arrangement or agreement made by or on behalf of the Purchasers or the Merger Sub.

6.07 Investment Representation. The Purchaser is acquiring the membership interests of the Company for its own account with the present intention of holding such securities for investment purposes and not with a view to, or for sale in connection with, any distribution of such securities in violation of any federal or state securities laws. The Purchaser is an “accredited investor” as defined in Regulation D promulgated by the Securities and Exchange Commission under the Securities Act of 1933, as amended (the “Securities Act”). The Purchaser acknowledges that the membership interests of the Company have not been registered under the Securities Act, or any state or foreign securities laws and that the membership interests of the Company may not be sold, transferred, offered for sale, pledged, hypothecated or otherwise disposed of unless such transfer, sale, assignment, pledge, hypothecation or other disposition is pursuant to the terms of an effective registration statement under the Securities Act, and the membership interests of the Company are registered under any applicable state or foreign securities laws or sold pursuant to an exemption from registration under the Securities Act, and any applicable state or foreign securities laws.

6.08 Availability of Funds. The Purchasers and the Merger Sub, in the aggregate, will have at the Closing sufficient cash to make payment of all amounts to be paid by them hereunder on and after the Closing Date.

6.09 The Merger Sub. The Merger Sub is a newly organized limited liability company, formed solely for the purpose of engaging in the transactions contemplated by this Agreement. Prior to the date hereof, the Merger Sub has not engaged in any business activities or conducted any operations other than in connection with the transactions contemplated by this Agreement. The Merger Sub is a wholly owned Subsidiary of the Purchaser.

6.10 No Other Representations or Warranties. Except for the representations and warranties contained in Article V, each of the Purchasers and the Merger Sub (a) acknowledges that none of the Company, […]***…], the Sellers nor any other Person on behalf of the Company makes any other express or implied representation or warranty (i) with respect to […]***…] or the Company or any of its Subsidiaries, (ii) with respect to any other information provided to the Purchasers or the Merger Sub or (iii) in connection with the transactions contemplated by this Agreement and (b) disclaims reliance on any information other than the representations and warranties expressly set forth in Article V. Except to the extent covered by the representations and warranties contained in Article V, neither the Company nor any other Person is making any representations or warranties with respect to any information, documents, projections, forecasts or other material made available to the Purchaser, the Merger Sub or its or their representatives in certain “data rooms” or management presentations or otherwise in expectation of the transactions contemplated by this Agreement.

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ARTICLE VII

COVENANTS OF THE COMPANY

7.01 Conduct of the Business

(a) From the date hereof until the Closing, each member of the Company Group shall, and shall cause each of its respective Subsidiaries to, conduct its business and the businesses of its Subsidiaries in the Ordinary Course of Business, except (i) if the Purchaser or the Merger Sub shall have consented in writing or (ii) as otherwise required or permitted by this Agreement; provided that, the foregoing notwithstanding, (x) no member of the Company Group may use available cash as of immediately prior to the Closing to repay any Indebtedness, other than Item 1 on the Indebtedness Schedule, pay any Transaction Expenses or otherwise make any cash distributions and (y) no action by the Company or its Subsidiaries with respect to matters specifically addressed by any other provision of this Section 7.01 shall be deemed a breach of this Section 7.01, unless such action would constitute a breach of one or more of such other provisions and (y) the Company and its Subsidiaries’ failure to take any action prohibited by Section 7.01(b) shall not be a breach of this Section 7.01.

(b) From the date hereof until the Closing, except (i) as set forth on the Conduct of Business Schedule attached hereto, (ii) as otherwise required or permitted by this Agreement or (iii) as consented to in writing by the Purchaser or the Merger Sub (which consent will not be unreasonably withheld, conditioned or delayed), the Company shall not and shall cause each of its Subsidiaries not to:

(A) except for issuances of Units upon exercise of Options outstanding as of the date of this Agreement, issue, sell, grant, pledge, promise or deliver any equity securities or other equity interests or any subscriptions, warrants, options or other agreements or rights of any kind whatsoever to purchase or otherwise receive or be issued any equity securities or other equity interests or any securities convertible into, or exercisable or exchangeable for, any equity securities or interests of the Company or any of the Company’s Subsidiaries;

(B) effect any recapitalization, reclassification, dividend, equity split or like change in its capitalization or establish a record date for, declare, accrue, set aside or pay any dividend, make or pay any dividend or other distribution (whether in cash, stock, property or otherwise) in respect of its or its Subsidiaries’ equity securities or form a Subsidiary;

(C) amend or otherwise modify its or its Subsidiaries’ certificate or articles of formation or incorporation or other Organizational Documents;

(D) make any redemption or purchase of or otherwise acquire, directly or indirectly, any of its or its Subsidiaries’ equity securities or other equity interests;

(E) sell, assign or transfer, or exclusively license, any material portion of its assets, except in the Ordinary Course of Business and pursuant to an agreement set forth on the Contracts Schedule.
(F) make any investment in excess of $[...***...] in, or any loan in excess of $[...***...] to, any other Person, except in the Ordinary Course of Business and pursuant to any agreement set forth on the Contracts Schedule;

(G) make any capital expenditures, capital additions or capital improvements in excess of $[...***...] individually or $[...***...] in the aggregate or commitments therefor, except for such capital expenditures or commitments therefor that are reflected in the Company’s or its Subsidiaries’ current budget, a copy of which was previously made available to the Purchaser;

(H) hire any new employees, or implement any employee layoffs other than terminations of non-executive officers for cause;

(I) make any loan to, or enter into any other material transaction with, any of its directors, officers, or employees outside the Ordinary Course of Business except pursuant to any agreement set forth on the Contracts Schedule or the Affiliated Transactions Schedule;

(J) incur or guarantee any indebtedness for borrowed money or make any pledge of any of its or its Subsidiaries equity interests or material assets or permit any of its material assets to become subject to any Liens, except for Permitted Liens;

(K) acquire or agree to acquire by merging with, or by purchasing a portion of the stock or assets of, or by any other manner, any business or any entity;

(L) make or change any election in respect of Taxes, change an annual Tax accounting period, adopt or change any accounting method in respect of Taxes, file any amended Tax Return, enter into any closing agreement with respect to Taxes, settle any claim or assessment in respect of Taxes, surrender or abandon any right to claim a refund of Taxes, or consent to any extension or waiver of the limitation period applicable to any material claim or assessment in respect of Taxes or take any similar action relating to the filing of any Tax Return or the payment of any Tax, if such election, change, adoption, amendment, agreement, settlement, surrender, consent or other action would have the effect of increasing the Tax Liability of the Purchaser, any member of the Company Group, or any of their Affiliates for any period ending after the Closing Date;

(M) waive, release, assign, compromise, commence, settle or agree to settle any Proceeding, other than waivers, releases, compromises or settlements in the Ordinary Course of Business that (i) involve only the payment of monetary damages not in excess of (x) $[...***...] individually or (y) $[...***...] in the aggregate and (ii) do not include the imposition of equitable relief on, or the admission of wrongdoing by, the Company or any of its Subsidiaries;

(N) other than in the Ordinary Course of Business (e.g., in connection with normal safety updates) make, or materially amend, any filings with the FDA, the European Medicines Agency or any other Governmental Entity performing functions similar to those performed by the FDA, the European Medicines Agency or such other regulatory authority;

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(O) enter into any Material Contract, amend or modify in any material respect any Material Contract or terminate any Material Contract or knowingly waive any material right under any Material Contract;

(P) adopt, establish, enter into, amend or terminate any Company Employee Plan or Company Employee Agreement or any plan, agreement, program, policy, trust, fund or other arrangement that would be a Company Employee Plan or Company Employee Agreement if it were in existence as of the date of this Agreement (except for amendments to be required to comply with applicable Law),

(Q) increase the compensation or fringe benefits (including severance, termination, retention and change of control compensation or benefits) of, or grant any bonus or other incentive compensation to, any current or former Company Employee or other individual service provider of the Company or any Company Subsidiary,

(R) grant any severance or termination pay to any Company Employee or other individual service provider of the Company or any Company Subsidiary; provided, that the Company or a Company Subsidiary may make severance or termination payments to employees in accordance with the terms of Contract between such employees and the Company or a Company Subsidiary in effect on the date of this Agreement;

(S) terminate, cancel, amend, waive, modify or fail to maintain, renew or comply with any material Permit;

(T) enter into or adopt any plan or agreement of complete or partial liquidation, restructuring, recapitalization or dissolution, or file a voluntary petition in bankruptcy or commence a voluntary legal procedure for reorganization, arrangement, adjustment, release or composition of indebtedness in bankruptcy or other similar Laws now or hereafter in effect;

(U) sell, either directly or indirectly, any Company Products outside of the United States;

(V) take any action, with respect to any Senior Management Agreement, to cause the definition of “Severance Period” under such Senior Management Agreement to exceed […***…]; or

(W) agree or commit to take any of the actions described in clauses (A) through (V) of this Section 7.02(b).

(c) From the date hereof until the Closing, except to the extent reasonably required to complete the Splitter LP Liquidation, (i) […] shall not (A) transfer, assign, sell, gift-over, hedge, pledge or otherwise dispose of (whether by sale, liquidation, dissolution, dividend or distribution), enter into any derivative arrangement with respect to, create or suffer to exist any Liens (other than Permitted Liens) on any of the Shares or any right or interest therein or consent to any of the foregoing or (B) directly or indirectly take or cause the taking of any other action that would be reasonably expected to restrict, limit or interfere with the performance of […] obligations under this Agreement, (ii) […]

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shall cause […***…] not to (A) conduct any business other than holding equity interests in the Splitter LP and the Units, (B) transfer, assign, sell, gift-over, hedge, pledge or otherwise dispose of (whether by sale, liquidation, dissolution, dividend or distribution), enter into any derivative arrangement with respect to, create or suffer to exist any Liens (other than Permitted Liens) on any of the equity interests in the Splitter LP […***…] or any right or interest therein or consent to any of the foregoing, (C) incur any Indebtedness or other Liabilities, (D) declare, accrue, set aside or pay any dividend or make any other distribution in respect of any equity securities, or (E) enter into or adopt any plan or agreement of complete or partial liquidation, reorganization, recapitalization or dissolution, or file a voluntary petition in bankruptcy or commence a voluntary legal proceeding for reorganization, arrangement, adjustment, release or composition of indebtedness in bankruptcy or other similar laws now or hereafter in effect, and (iii) […***…] shall cause the Splitter LP not to (A) conduct any business other than holding the Units, (B) transfer, assign, sell, gift-over, hedge, pledge or otherwise dispose of (whether by sale, liquidation, dissolution, dividend or distribution), enter into any derivative arrangement with respect to, create or suffer to exist any Liens on any of the Units held by Splitter LP or any right or interest therein or consent to any of the foregoing, (C) incur any Indebtedness or other Liabilities, or (D) declare, accrue, set aside or pay any dividend or make any other distribution in respect of any equity securities.

7.02 Access to Books and Records. Subject to Section 8.07, from the date hereof until the Closing Date, the Company shall provide the Purchasers and their authorized representatives (the “Purchaser’s Representatives”) with reasonable access during normal business hours and upon reasonable notice to the offices, properties, senior personnel, books and records of […***…], the Company and their respective Subsidiaries in order for the Purchasers to have the opportunity to make such investigation as it shall reasonably desire to make of the affairs of the Company Group; provided that, notwithstanding the foregoing, (a) such access does not unreasonably interfere with the normal operations of the Company or its Subsidiaries, (b) such access shall occur in such a manner as the Company reasonably determines to be appropriate to protect the confidentiality of the transactions contemplated by this Agreement and (c) nothing herein shall require the Company to provide access to, or to disclose any information to, the Purchasers if such access or disclosure would reasonably be likely to (i) cause significant competitive harm to the Company or its Subsidiaries if the transactions contemplated by this Agreement are not consummated, (ii) waive any legal privilege or (iii) be in violation of applicable Law (including the HSR Act and other anti-competition Laws) or the provisions of any agreement entered into prior to the date of this Agreement to which the Company or any of its Subsidiaries is a party. The Purchasers acknowledges that the Purchasers are and remain bound by the Confidentiality Agreement, between Horizon Pharma plc and Crealta Holdings LLC dated September 24, 2015 (the “Confidentiality Agreement”).

7.03 Regulatory Filings. As soon as practicable following the date hereof until the Closing, to the extent not previously completed, the Company shall make or cause to be made all filings and submissions required under the HSR Act and any other material Laws or regulations applicable to the Company and its Subsidiaries for the consummation of the transactions contemplated herein. Until the Closing, the Company shall coordinate and cooperate with the Purchasers in exchanging such information and providing such assistance as the Purchasers may reasonably request in connection with all of the foregoing.
7.04 **Conditions** The Company and the Representative shall use commercially reasonable efforts to cause the conditions set forth in Section 4.01 to be satisfied as soon as practicable following the date hereof and to consummate the transactions contemplated herein as soon as possible after the satisfaction of the conditions set forth in Article IV (other than those to be satisfied at the Closing itself); provided that none of the Company, […***…], the Representative nor the Sellers shall be required to expend any funds to obtain any consent from any Governmental Entity required under Section 4.01. The Company and the Representative shall deliver to the Purchasers, no later than […***…] Business Days prior to the Closing Date, an appropriate payoff letter, dated no more than […***…] Business Days prior to the Closing Date, from each holder of Closing Date Indebtedness, which are indicated on the Indebtedness Schedule, indicating the amounts payable to such Person to fully satisfy such Indebtedness as of the Closing Date and stating that upon payment of such amount that such holder shall release his, her or its Liens and other security interests in, and agree to execute and/or file Uniform Commercial Code Termination Statements and such other documents or endorsements reasonably necessary to release his, her or its Liens and other security interest in, the assets and properties of Company Group, and that all obligations with respect to the related Indebtedness shall be satisfied (subject to the survival of obligations, if any, that by the terms of the documentation governing such Indebtedness continue after full repayment and termination of such Indebtedness) (each, a “Payoff Letter”).

7.05 **Exclusive Dealing**

(a) During the period from the date of this Agreement through the Closing or the earlier termination of this Agreement pursuant to Section 10.01, the Company and […***…] shall not, and shall cause their respective Subsidiaries not to, and shall not authorize or instruct any Company Representative to (i) solicit, initiate, discuss or knowingly encourage or facilitate the submission of any Takeover Proposal by any Person, (ii) participate in any discussions or negotiations regarding, or furnish to any Person any non-public information with respect to, or take any other action intended or reasonably expected to facilitate the making of any inquiry or proposal to the Company or […***…] that constitutes, or is reasonably expected to lead to, any Takeover Proposal by any Person or (iii) enter into any agreement, arrangement, letter of intent, term sheet, understanding or Contract with any Person the terms of which require it to abandon or terminate the transactions contemplated hereby. Without limiting the foregoing, it is understood that any violation of the restrictions set forth in the preceding sentence by any Company Representative, acting on behalf of, and with the authorization of, any member of the Company Group, shall be deemed to be a breach of this Section 7.05(a) by the Company.

(b) Neither the board of managers of the Company or […***…] shall (i) withdraw or modify in a manner materially adverse to the Purchaser or Merger Sub, the approval or recommendation by such board of managers of this Agreement or the transaction contemplated hereby, or (ii) approve or recommend any Takeover Proposal.

(c) In addition to the obligations of the Company and […***…] set forth in paragraphs (a) and (b) of this Section 7.05, each of the Company and […***…] shall promptly (and in all events within […***…]) advise the Purchaser orally and in writing of any request by any Person to the Company or […***…] for nonpublic information that the
Company or [...***…] reasonably believes is likely to lead to a Takeover Proposal or of any Takeover Proposal submitted to the Company or [...***…], or any inquiry by any Person directed to the Company or [...***…] with respect to or which the Company or [...***…] reasonably believes is likely to lead to any Takeover Proposal and the material terms and conditions of such request or inquiry, and shall promptly provide the Purchaser with a true, correct and complete copy of any Takeover Proposal that is received by the Company or [...***…] (or on their behalf). The Company shall, promptly after the execution of this Agreement, request the return or destruction of any confidential information shared in connection with any terminated discussions or negotiations with respect to any Takeover Proposal. Each of the Company and [...***…] shall (and shall cause its Affiliates and its and their respective representatives to) immediately cease and cause to be terminated any existing discussions or negotiations with any Persons (other than Parent or an Affiliate of Parent) conducted heretofore with respect to any Takeover Proposal.

7.06 Notification. From the date hereof until the Closing Date, if the Company has knowledge of any variances from the representations and warranties contained in Article V that would cause the condition set forth in Section 4.01(a) not to be satisfied, the Company shall, as soon as practicable (but in any event at least [...*** …] Business Days prior to the Closing), disclose to the Purchaser in writing such variances. The Company’s satisfaction of its obligations in the foregoing sentence shall not relieve the Company of any of its other obligations under this Agreement.

7.07 Unitholder Consent. The Company shall, in accordance with the Company LLC Agreement and the applicable requirements of the Delaware LLC Law, obtain the written consents of Unitholders for the adoption of this Agreement and the approval of the Merger and the other transactions contemplated hereby (the “Member Written Consent”). The Company shall deliver to the Purchaser the Member Written Consent executed by Unitholders who collectively constitute the Required Member Vote no later than [...*** …] following the time of execution and delivery of this Agreement.

7.08 Company Equity Plan. As soon as reasonably practicable following the date of this Agreement the Company shall obtain any necessary determinations and/or resolutions of the board of managers of the Company or a committee thereof and shall take any other actions that may be necessary (under the Company Equity Plan and award agreements pursuant to which Options are outstanding or otherwise) (a) to deliver, prior to the Closing, all required notifications of the Merger and the other transactions contemplated by this Agreement to the holders of Options, (b) to cancel and extinguish the Options as contemplated in Section 1.05 of this Agreement, and (c) to terminate the Company Equity Plan immediately prior to the Effective Time.

7.09 Termination of Certain Agreements and Company 401(k) Plan. The Company shall take all such steps as may be necessary to terminate, effective as of or prior to the Closing, all of the agreements set forth on the Terminated Affiliated Transactions Schedule. If requested in writing by the Purchaser at least [...*** …] days prior to the Closing Date, the Company shall adopt or cause to be adopted written resolutions providing for the termination of the Company 401(k) Plan (a copy of which shall be provided reasonably in advance to the Purchaser for its review and the Company shall consider in good faith all comments received

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from the Purchaser on such resolutions prior to their adoption), with such termination effective as of no later than the date immediately preceding the Closing Date but contingent on the occurrence of the Closing.

7.10 Liquidation of Splitter LP. Prior to the Closing, (a) [...***...] shall cause (i) the Splitter LP to be dissolved, (ii) the general partner of the Splitter LP to liquidate and wind up the Splitter LP (including all Liabilities and obligations of the Splitter LP), in each case, in accordance with applicable Law and the terms of the Organizational Documents of the Splitter LP (collectively, the “Splitter LP Liquidation”) and (b) [...***...] shall provide to the Purchasers reasonable documentation evidencing the Splitter LP Liquidation in accordance with the terms of this Section 7.10.

ARTICLE VIII

COVENANTS OF THE PURCHASER

8.01 Access to Books and Records. From and after the Closing, for a period of [...***...], the Purchasers shall, and shall cause the Surviving Company to, provide the Representative and its authorized representatives with access, during normal business hours and upon reasonable notice, to (i) the books and records (for the purpose of examining and copying) of the Company and its Subsidiaries with respect to periods or occurrences prior to or on the Closing Date, but excluding where such books and records are subject to (a) a dispute between the parties or (b) attorney-client privilege or other privilege which would be impaired by such disclosure; provided, that the Persons provided such access shall treat any non-public information of the Company Group as confidential and shall not disclose such information to any third party, and (ii) employees of the Purchasers, the Surviving Company and their Affiliates for purposes of better understanding books and records. Unless otherwise consented to in writing by the Representative, the Purchasers shall, and shall cause the Surviving Company and its Subsidiaries to, for a period of [...***...], the Purchasers shall, and shall cause the Surviving Company and its Subsidiaries to, for a period of [...***...], following the Closing Date, retain and not otherwise dispose of the books and records of the Company and its Subsidiaries relating to periods prior to the Closing Date in a manner reasonably consistent with the practices of the Purchasers for similar books and records.

8.02 Notification. From the date hereof until the Closing Date, if the Purchasers become aware of any variances from the representations and warranties contained in Article VI that would cause the condition set forth in Section 4.02(a) not to be satisfied, the Purchasers shall, as soon as practicable, disclose to the Representative and the Company in writing such variances.

8.03 Director and Officer Liability and Indemnification.

(a) For a period of [...***...] after the Closing Date, the Purchasers shall not, and shall not permit the Surviving Company or its Subsidiaries to amend, repeal or otherwise modify any provision in [...***...], the Company’s or the Company Subsidiaries’ certificate of formation, certification of incorporation, articles of incorporation, operating agreement, bylaws, or equivalent governing documents relating to the exculpation or indemnification (including fee advancement) of any officers, managers and/or directors (unless

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required by Law), it being the intent of the parties that the officers, managers and directors of the Company and its Subsidiaries shall, subject to the terms, conditions and limitations thereof, continue to be entitled to such exculpation and indemnification (including fee advancement) to the full extent of the Law and the Purchasers shall cause […***…], the Surviving Company and its Subsidiaries to, honor and perform under all such indemnification obligations owed to any of the individuals who were officers, managers and/or directors of […***…], the Company or its Subsidiaries at or prior to the Closing Date under the terms, and subject to the conditions and limitations, of such governing documents.

(b) Prior to or at the Closing, the […***…] shall purchase (and pay in full all premiums on) an extended reporting period endorsement under the Company’s existing directors’ and officers’ liability insurance coverage for the individuals who were officers, managers and directors of the Company Group at or prior to the Closing Date that shall provide such officers, managers and directors with coverage for […***…] following the Effective Time of not less than the existing coverage (in amount and scope) and have other terms not materially less favorable to the insured Persons than the directors’ and officers’ liability insurance coverage presently maintained by the Company […***…]. After the Effective Time, the Purchasers and the Surviving Company shall maintain such policy in full force and effect, and continue to honor the obligations thereunder.

(c) If the Surviving Company, its Subsidiaries or any of their respective successors or assigns (i) is to consolidate with or merges into any other Person and will not be the continuing or surviving corporation or entity of such consolidation or merger or (ii) is to transfer all or substantially all of its properties and assets to any Person, then, and in each such case, proper provisions shall be made so that the successors and assigns of the Surviving Company and its Subsidiaries shall assume all of the obligations set forth in this Section 8.03. The provisions of this Section 8.03 are intended for the benefit of, and will be enforceable by, each current and former officer, manager, director or similar functionary of the Company or its Subsidiaries and his or her heirs and representatives, and are in addition to, and not in substitution for, any other rights to indemnification or contribution that any such person may have had by contract or otherwise.

(d) Notwithstanding anything herein to the contrary, if any claim, action, suit, proceeding or investigation (whether arising before, at or after the Closing Date) is made against any individuals who were officers, managers or directors of […***…], the Company and its Subsidiaries at or prior to the Closing Date or any other party covered by directors’ and officers’ liability insurance, on or prior to the […***…] anniversary of the Closing Date, the provisions of this Section 8.03 shall continue in effect until the final disposition of such claim, action, suit, proceeding or investigation.

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8.04 Employment and Benefit Arrangements.

(a) For at least [...] following the Closing Date, the Purchasers shall cause the Surviving Company to provide to the Covered Employees, for so long as such Covered Employees remain employees of the Purchasers, the Surviving Company or any Subsidiary thereof, with base salary and cash incentive compensation targets that are no less favorable than the base salary and cash incentive compensation targets provided to such employees prior to the Closing and either (i) maintain in effect on behalf of employees of the Company and its Subsidiaries all employment, severance, termination, retirement and other compensation and benefit plans, programs, arrangements, agreements and policies (other than any equity-based plans) of the Company or its Subsidiaries as in effect as of the date hereof (the “Company Plans”), or (ii) provide all employees of the Company and its Subsidiaries with such compensation and benefit plans, programs, arrangements, agreements and policies as are provided to similarly situated employees of the Purchasers and/or their Affiliates. If the Purchasers require termination of the Company 401(k) Plan pursuant to Section 7.09, the Purchasers shall permit the employees of the Surviving Company and its Subsidiaries who are participants in the Company 401(k) Plan to be eligible immediately following the Closing to participate in a 401(k) plan maintained by the Purchasers or their Affiliates (the “Purchaser’s 401(k) Plan”) and to make rollover contributions of their account balances from the Company 401(k) Plan that are “eligible rollover distributions” (as defined in Section 402(c)(4) of the Code) to the Purchaser’s 401(k) Plan, including rollovers of promissory notes evidencing any outstanding plan loans under the Company 401(k) Plan.

(b) Notwithstanding anything to the contrary in this Section 8.04, for fiscal year 2015, the Purchaser shall pay, or shall cause the Surviving Company to pay, in accordance with the terms of the Company’s annual bonus plan (except that any employee who is terminated without cause by the Purchaser, the Surviving Company or any of their respective Subsidiaries shall be deemed to have satisfied any continued employment requirement or other requirement that such employee be employed by the Surviving Company or any of its Subsidiaries at the time of the bonus payment) at such time as payment is made under the Purchaser’s annual bonus plan (but provided that such payment shall be made no later than March 15, 2016) bonuses to Company Employees in an aggregate amount that at a minimum equals the amount of the total bonus accrual for Company Employees reflected as current liabilities in the calculation of Net Working Capital (as finally determined under Article II).

(c) To the extent a Covered Employee remains an employee of the Purchasers, the Surviving Company or any Subsidiary thereof, and such Covered Employee is eligible to participate in such plans (or would be eligible to participate in such plans after giving effect to provision of such service credit) the Purchasers shall use commercially reasonable efforts to provide such Covered Employees with service credit for all purposes (other than for purposes of benefit accrual under a defined benefit pension plan) under any compensation or benefit plans, programs, arrangements, agreements and policies sponsored by the Purchasers or any of their Affiliates, except to the extent duplication of benefits would result. To the extent that the Purchasers modify any welfare benefit coverage or plan under which the Covered Employees participate, the Purchasers shall use commercially reasonable efforts to waive any applicable waiting periods, pre-existing conditions or actively-at-work requirements and shall give such Covered Employees credit under the new coverages or benefit plans for deductibles.

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co-insurance and out-of-pocket payments that have been paid during the year in which such welfare benefit coverage or plan modification occurs. The Purchaser shall be solely responsible for any obligations arising under Section 4980B of the Code with respect to all “M&A qualified beneficiaries” as defined in Treasury Regulation §54.4980B-9.

(d) Nothing in this Section 8.04 shall (i) be construed to limit the right of the Purchasers, the Company, or any of the Company Subsidiaries (including, following the Effective Time, the Surviving Company) to amend or terminate any Company Employee Plan or other benefit plan, to the extent such amendment or termination is permitted by the terms of the applicable plan and subject to compliance with the other provisions of this Section 8.04, or (ii) be construed as a guarantee of continued employment or to require the Purchasers, the Company, or any of the Company Subsidiaries (including, following the Effective Time, the Surviving Company) to retain the employment of any Covered Employee or any other particular Person for any fixed period of time following the Effective Time, which employment may be terminated at any time in accordance with applicable Law. Nothing in this Section 8.04 shall give any third party, including any Covered Employees, any right to enforce the provisions of this Section 8.04 as a third-party beneficiary.

8.05 Regulatory Filings.

(a) To the extent not previously completed, the Purchasers, the Company and their respective representatives shall (i) take all of the steps reasonably necessary, and proceed diligently and in good faith, using reasonable best efforts to, within [… ***…] Business Days after the date hereof, make or cause to be made all filings and submissions required under the HSR Act or any other applicable antitrust or noncompetition Laws or regulations (“Antitrust Laws”) or other Laws applicable for the consummation of the transactions contemplated herein, and (ii) provide such other information and communication to any Governmental Entity or other Persons as such Governmental Entity or other Persons may reasonably request in connection therewith.

(b) In connection with their obligations under Section 8.05(a), each of the Purchasers and the Company shall, to the extent permitted by applicable Law, (i) keep each other informed in all material respects and on a reasonably timely basis of any material communication received by such party from, or given by such party to, any Governmental Entity and of any material communication received or given in connection with any Proceeding by a private party, in each case with respect to this Agreement or the transactions contemplated hereby, (ii) notify each other of all documents filed with, submitted to or received from any Governmental Entity with respect to this Agreement or the transactions contemplated hereby, (iii) furnish each other with such information and assistance as the other may reasonably request in connection with their preparation of any such governmental filing or submission hereunder and (iv) reasonably cooperate with each other in connection with any investigation or other inquiry by or before any Governmental Entity relating to this Agreement or the transactions contemplated hereby, including any Action initiated by a private party. Subject to applicable laws relating to the exchange of information, each of the Purchasers and the Company (A) shall have the right to review in advance, and to the extent practicable each will consult with each other with respect to, all information that appears in any filing made with, or written materials submitted to, any Governmental Entity with respect
to this Agreement or the transactions contemplated hereby in connection with the HSR Clearance, and (B) shall give the other a reasonable opportunity to attend and participate in meetings and telephone conferences with any such government agency relating to the foregoing. To the extent permitted by applicable law, the Company will not, nor will it permit any of its representatives to make any material communications with, or proposals relating to, or enter into, any material understanding, undertaking or agreement with, any Governmental Entity relating to the transactions contemplated by this Agreement without the Purchaser’s prior review and approval.

(c) Notwithstanding the foregoing, neither the Purchasers nor any of their Affiliates shall be required to sell, divest or otherwise dispose of, hold separate, enter into any license or similar agreement with respect to, restrict the ownership or operation of, or agree to sell, divest or otherwise dispose of, hold separate, enter into any license or similar agreement with respect to, or restrict the ownership or operation of any assets or businesses of the Company, the Purchasers or any of their respective Affiliates, unless such action would not have a material adverse impact on the Purchasers, any of their Subsidiaries or Affiliates, the Company or its Subsidiaries.

(d) The […] shall be responsible for all filing fees under the HSR Act, other Antitrust Laws and all other Laws or regulations applicable to the […]. The […] shall cause the filings under the HSR Act to be considered for grant of “early termination.”

8.06 Conditions. The Purchasers and the Merger Sub shall use all commercially reasonable efforts to cause the conditions set forth in Section 4.02 to be satisfied as soon as practicable following the date hereof, to cause the Closing to occur as expeditiously as possible following the execution of this Agreement and to consummate the transactions contemplated herein as soon as reasonably possible after the satisfaction of the conditions set forth in Article IV (other than those to be satisfied at the Closing itself).

8.07 Contact with Customers and Suppliers. Prior to the Closing, the Purchasers and the Purchaser’s Representatives may only contact and communicate with the customers, service providers and suppliers of the Company and its Subsidiaries regarding the transactions contemplated hereby after prior consultation with and written approval of the Representative.

ARTICLE IX

ADDITIONAL COVENANTS

9.01 Disclosure Generally. All Disclosure Schedules and exhibits attached hereto are incorporated herein and expressly made a part of this Agreement as though completely set forth herein. Without modifying or limiting the introductory language to Article V or Article VI, all references to this Agreement herein or in any of the Disclosure Schedules or exhibits shall be deemed to refer to this entire Agreement, including all Disclosure Schedules and exhibits.
9.02 Provision Respecting Legal Representation. Each of the Purchasers, the Merger Sub, […***…], the Company and their respective Subsidiaries hereby agrees, on its own behalf and on behalf of its directors, equityholders, members, partners, officers, employees and Affiliates, that, in the event that a dispute arises after the Closing between the Purchasers, the Surviving Company and/or their respective Subsidiaries, on the one hand, and the Representative, the Sellers and/or their respective Affiliates, Kirkland & Ellis LLP (“K&E”) may represent the Representative, the Sellers or any of their respective directors, managers, equityholders, members, partners, officers, employees or Affiliates in such dispute even though the interests of such Persons may be directly adverse to the Purchasers, the Surviving Company or any of their respective Subsidiaries, and even though K&E may have represented the Company or any of the Company’s Subsidiaries in a matter substantially related to such dispute, or may be handling ongoing matters for the Purchasers, the Company or any of their respective Subsidiaries. The Purchasers and the Merger Sub further agree that, as to all communications among K&E, the Company, any of the Company’s Subsidiaries, the Representative, the Sellers and/or any of their respective Affiliates that relate in any way to the transactions contemplated by this Agreement, the attorney-client privilege and the expectation of client confidence belongs to the Representative (on behalf of the Sellers) and may be controlled by the Representative and shall not pass to or be claimed by the Purchasers, the Surviving Company or any of their respective Subsidiaries. Notwithstanding the foregoing, in the event that a dispute arises between the Purchasers, the Surviving Company or any of their respective Subsidiaries and a third party (other than a party to this Agreement or any of their respective Affiliates) after the Closing, the Surviving Company or any of the Surviving Company’s Subsidiaries may assert the attorney-client privilege to prevent disclosure of confidential communications by K&E to such third party; provided, however, that neither the Surviving Company nor any of the Surviving Company’s Subsidiaries may waive such privilege without the prior written consent of the Representative, on behalf of the Sellers.

9.03 Tax Matters.

(a) Responsibility for Filing Tax Returns.

(i) The Representative, on behalf of the Sellers, shall prepare or cause to be prepared and timely file or cause to be timely filed (with the cooperation of the Purchasers) any (i) partnership income Tax Returns for the Company or the Splitter LP and […] in each case, with respect to taxable periods ending on or before the Closing Date (“Seller Prepared Returns”), and timely remit or cause to be timely remitted any Taxes shown thereon to the appropriate Governmental Entity.

(ii) The Purchasers shall prepare or cause to be prepared and timely file or cause to be timely filed all Tax Returns for the Company and its Subsidiaries and […] that are not Seller Prepared Returns for all periods (or portions thereof) ending prior to or including the Closing Date (including extensions) is after the Closing Date (“Purchaser Prepared Returns”), and timely remit or cause to be timely remitted any Taxes shown thereon to the appropriate Governmental Entity. To the extent any Taxes shown as due on Purchaser Prepared Returns that are prepared in accordance with Section 9.03 are Indemnified Taxes (which excludes, for the ***Confidential Treatment Requested
avoidance of doubt, any such Taxes taken into account in the calculation of Net Working Capital or Transaction Expenses in the calculation of the Final Merger Consideration pursuant to Article II), the Purchasers and the Representative shall jointly direct the Escrow Agent to distribute cash from the Escrow Account in the amount of such Indemnified Taxes prior to the due date for payment of such Taxes.

(iii) Each Seller Prepared Return and Purchaser Prepared Return shall be prepared and timely filed in a manner consistent with applicable Law, Sections 9.03(e) and 9.03(g), and to the extent not inconsistent with the foregoing, past practice, provided in the case of Purchaser Prepared Returns that such past practice reflects at least a “more likely than not” position (if such position is available). At least [...***...] prior to the date on which each income or other material Tax Return described this Section 9.03(a) is required to be filed, the Representative shall submit such Seller Prepared Return to the Purchaser, and the Purchaser shall submit such Purchaser Prepared Return to the Representative, in each case for the other’s review and approval as provided in the third-to-last sentence of this Section 9.03(a)(iii). The Purchaser and the Representative shall consider in good faith any reasonable comments provided by the other. No Tax Return described in this Section 9.03(a) shall be filed without the written consent of the Purchaser or the Representative, as applicable, which consent may not be unreasonably withheld, conditioned or delayed. If the parties are unable to resolve any dispute arising under this Section 9.03(a) within [...***...] days for the final due date of filing an applicable Tax Return (including available automatic extensions), the parties shall submit the dispute to the Accounting Firm, which will promptly determine those matters in dispute (based on presentations from the parties and not based on its independent review) and will render a written report as to the disputed matters. The costs and expenses of the Accounting Firm will be [...***...].

(b) Amendment of Tax Returns. Without the prior written consent of the Representative (not to be unreasonably withheld, conditioned or delayed), the Purchasers will not (i) except for Tax Returns that are filed in accordance with Section 9.03(a), file or amend or permit the Surviving Company or any of its Subsidiaries or [...***...] to file or amend any Tax Return relating to a taxable period (or portion thereof) ending on or prior to the Closing Date (a “Pre-Closing Tax Period”), (ii) with respect to Tax Returns filed pursuant to Section 9.03(a), after the date such Tax Returns are filed pursuant to Section 9.03(a), amend or permit any of the Surviving Company or any of its Subsidiaries or [...***...] to amend any such Tax Return, (iii) extend or waive, or cause to be extended or waived, or permit the Surviving Company or any of its Subsidiaries or [...***...] to extend or waive, any statute of limitations or other period for the assessment of any Tax or deficiency related to a Pre-Closing Tax Period or (iv) make or change any election or change any method of accounting with respect to Taxes with retroactive effect to a Pre-Closing Tax Period for any of the Company or any of its Subsidiaries or [...***...].

(c) No Section 338 Election. None of the Purchasers, the Merger Sub, the Company or any of their Affiliates shall make any election under Code §338 (or any similar provision under state, local or foreign Law) with respect to the transactions contemplated by this Agreement.

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(d) **Transfer Taxes.** Any transfer, documentary, sales, use, registration and real property transfer or gains tax, stamp tax, excise tax, equity transfer tax, or other similar Tax imposed as a result of the transactions contemplated by this Agreement (collectively, “Transfer Taxes”), and any penalties or interest with respect to the Transfer Taxes, shall be [***]. The party responsible under applicable Law for submitting payment of Transfer Taxes to the applicable Tax authority shall timely file all necessary Tax Returns and other documentation with respect to all such Transfer Taxes. If required by applicable Law, the Purchasers, [***], the Surviving Company or any Company Subsidiary, or any or all of the Sellers shall join in the execution of any such Tax Returns and other documentation.

(e) **Determinations Concerning Pre-Closing Taxes.** In connection with the preparation of Tax Returns under Section 9.03(a), the determination of Net Working Capital, and the determination of Indemnified Taxes, the Purchasers and the Sellers agree that:

(i) In the case of any Straddle Period: (A) the amount of any Tax based on or measured by income, receipts, or payroll of a member of the Company Group attributable to a Pre-Closing Tax Period (A) shall be determined based on an interim closing of the books as of the close of business on the Closing Date (and in the case of any Taxes attributable to the ownership of any equity interest in any partnership or other “flowthrough” entity, as if the taxable period of such partnership or other “flowthrough” entity ended as of the end of the Closing Date), and (B) the amount of other Taxes of the members of the Company Group attributable to the Pre-Closing Tax Period shall be deemed to be the amount of such Tax for the entire taxable period multiplied by a fraction the numerator of which is the number of days in the taxable period through and including the Closing Date and the denominator of which is the number of days in such taxable period.

(ii) To the extent permitted by applicable Law, all Transaction Tax Deductions shall be treated as properly allocable to a Pre-Closing Tax Period ending on the Closing Date. The parties shall apply the safe harbor election set forth in IRS Revenue Procedure 2011-29 to determine the amount of any success-based fees that are deductible in a Pre-Closing Tax Period. The Purchasers and the Sellers agree to prepare all U.S. federal, state and local income Tax Returns with respect to [***], the Company and its Subsidiaries consistent with this Section 9.03(e)(ii), whether or not such Tax Return is described in Section 9.03(a).

(f) **Request for Tax Returns.** At the request of the Representative, the Purchasers shall deliver to the Representative copies of all Tax Returns relating to the tax periods (or portions thereof) ending on or prior to the Closing.

(g) **Tax Treatment.** The Purchasers, [***], the Company, the Surviving Company, any of its Subsidiaries, and the Sellers agree to report, act and file all Tax Returns in a manner consistent with the following U.S. federal income tax treatment (and unless otherwise required by applicable Law, none shall take any position inconsistent therewith in any Tax Claim):

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the transactions effected pursuant to this agreement shall be treated as the purchase of the Shares by
the Purchaser followed immediately thereafter by the purchase of all the membership interests of the Company [...***…] by
the Purchaser, and that all membership interests of the Company held by [...***…];

(ii) [...***…] shall have a Tax year that ends as of the end of the day on the Closing Date;

(iii) the Company (as a result of termination under Code §708(b)), shall have a Tax year that ends as of
the end of the day on the Closing Date, and shall file a valid and timely election under Code §754 (and any corresponding
provision of state Law) with respect to such Tax year; and

(iv) neither the Company nor the Splitter LP shall make the election described in Code §6241(g)(4), as
amended pursuant to the Bipartisan Budget Act of 2015, Pub. L. No. 114-74, §1101, in respect of any Tax Return relating to
a Pre-Closing Tax Period (including any amendments thereof).

(h) Cooperation on Tax Matters. The Purchasers and the Representative shall cooperate fully, as and to
the extent reasonably requested by the other party, in connection with the preparation and filing of any Tax Return and any audit, litigation
or other proceeding with respect to Tax Returns or Taxes of the Company and its Subsidiaries or [...***…]. Such cooperation shall
include the retention and (upon the other party’s request) the provision of records and information which are reasonably relevant to any
such Tax Return, audit, litigation or other proceeding or any tax planning, and making employees available on a mutually convenient
basis to provide additional information and explanation of any materials provided hereunder.

(i) Tax Contests.

(i) At its election, the Representative, on behalf of the Sellers, will have the responsibility for, and the
right to control, any audit, litigation or other proceeding with respect to Tax Returns or Taxes of any member of the Company
Group (each, a “Tax Claim”) that relates solely to one or more taxable periods ending on or prior to the Closing Date;
provided, however, that the Purchaser and the Surviving Company will have the right, directly or through its designated
representatives, to review in advance and comment upon all submissions made in the course of such Tax Claims (including
any administrative appeals thereof), and the Representative shall not dispose of any Tax Claim without the prior written
consent of the Purchaser, which consent shall not be unreasonably withheld, conditioned or delayed. The Purchaser shall, at
its own expense, be permitted to participate in any Tax Claim controlled by the Representative. Notwithstanding the
foregoing, if any limits on indemnification hereunder would materially limit the Purchaser Indemnified Parties’ recovery for
the expected potential Damages arising under a Tax Claim, the Purchaser shall be entitled to control of the Tax Claim with
counsel of its own choosing, provided that in all cases the Representative

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shall be permitted to elect to control any U.S. federal or state income tax audit of the Company for a taxable period ending on or prior to the Closing Date. For the avoidance of doubt, if the Representative does not elect to defend a Tax Claim to which it is entitled to assume control pursuant to this Section 9.03(i)(i), the reasonable third party out-of-pocket expenses incurred by the Purchaser in connection therewith shall constitute Damages.

(ii) With respect to all Tax Claims not described in Section 9.03(i)(i) above, the Purchaser and the Surviving Company will have the responsibility for, and the right to control such Tax Claims, but, in respect of obligations under Section 9.03, with respect to any Tax Claim that relates in whole or in part to a Pre-Closing Tax Period or could reasonably be expected to give rise to material Indemnified Taxes, the Representative, on behalf of the Sellers, shall have the right, directly or through its designated representatives, to review in advance and comment upon all submissions made in the course of such Tax Claims (including any administrative appeals thereof) to the extent related to Pre-Closing Tax Periods or Indemnified Taxes, and the Surviving Company shall not dispose of any Tax Claim to the extent it relates to Pre-Closing Tax Periods or Indemnified Taxes without the consent of the Representative, which consent shall not be unreasonably withheld, conditioned or delayed.

(j) No Intermediary Transaction Tax Shelter. Neither the Purchasers nor the Merger Sub nor their Affiliates shall take any action with respect to the Company or its Subsidiaries or [...] that would cause the transactions contemplated by this Agreement to constitute part of a transaction that is the same as, or substantially similar to, the “Intermediary Transaction Tax Shelter” described in Internal Revenue Service Notices 2001-16 and 2008-111.

(k) Purchase Price Allocation. Within [...] the [...] shall prepare and deliver to the [...] an allocation of the Final Merger Consideration (plus any assumed liabilities required to be taken into account) amongst the assets of the Company and its disregarded entity Subsidiaries (the “Purchase Price Allocation”) for the Purchasers’ review and approval. The Purchase Price Allocation shall be prepared in accordance with applicable Law, including in accordance with Code §1060, §751 and §755 and the Treasury Regulations promulgated thereunder (and any similar Law, as appropriate). Within [...] days after the Representative’s delivery of the Purchase Price Allocation, the Purchasers shall deliver to the Representative either a notice accepting the Purchase Price Allocation or a statement setting forth objections thereto and the basis for such objections. The Purchaser and the Representative shall use good faith efforts to resolve any such objections. If they are unable to mutually agree on the Purchase Price Allocation, they shall submit the dispute to the Accounting Firm, which will promptly determine those matters in dispute (based on presentations from the parties and not based on its independent review) and will render a written report as to the disputed matters. The costs and expenses of the Accounting Firm will be split evenly between the Purchaser and the Representative (on behalf of the Sellers). The parties agree to file all U.S. federal, state and local income tax returns in a manner consistent with the Purchase Price Allocation.

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ARTICLE X

TERMINATION

10.01   Termination. This Agreement may be terminated at any time prior to the Closing:

(a) by the mutual written consent of the Purchaser and the Representative (on behalf of the Company);

(b) by the Purchaser upon written notice to the other parties hereto, if there has been a violation or breach by any member of the Company Group or [...***...] of any covenant, representation or warranty contained in this Agreement, which violation or breach (i) would cause the conditions set forth in Section 4.01(a) or Section 4.01(b) to not then be satisfied and (ii) has not been waived by the Purchaser in writing or, if curable, cured by the Company within [...***...] days after receipt by the Company of written notice thereof from the Purchaser; provided, however, that the Purchaser may not so terminate if it has breached this Agreement so as to cause any conditions set forth in Section 4.02(a) or Section 4.02(b) not to be then satisfied;

(c) by the Representative (on behalf of the Company) upon written notice to the other parties hereto, if there has been a violation or breach by the Purchaser or Merger Sub of any covenant, representation or warranty contained in this Agreement, which violation or breach (i) would cause the conditions set forth in Section 4.02(a) or Section 4.02(b) to not then be satisfied and (ii) has not been waived by the Representative (on behalf of the Company) in writing or, if curable, cured by the Purchaser within [...***...] days after receipt by the Purchaser of written notice thereof from the Representative (on behalf of the Company); provided that the following violations or breaches shall not be subject to cure hereunder unless otherwise agreed to in writing by the Seller and shall be deemed breaches or violations that prevent the satisfaction of the conditions to the obligations of the Seller at the Closing: (i) a breach by the Purchaser of Section 3.02, (ii) the failure of the Closing to occur on the date specified in Section 3.01 or (iii) the failure to deliver the Closing Cash Consideration on the Closing Date as required hereunder; provided further that the Representative (on behalf of the Company) may not so terminate if any member of the Company Group or [...***...] has breached this Agreement so as to cause any conditions set forth in Section 4.01(a) or Section 4.01(b) not to be then satisfied;

(d) by the Purchaser or the Representative (on behalf of the Company) upon written notice to the other parties hereto, if the transactions contemplated hereby have not been consummated on or before [...***...] (such date, the “Outside Date”); provided that (i) the right to terminate this Agreement under this Section 10.01(d) shall not be available to any party whose failure to fulfill any obligation under this Agreement has been the primary cause of, or resulted in, the failure of the Closing of the transactions contemplated hereby to occur on or prior to such date, (ii) in the event that all of the conditions contained in Article IV (other than those conditions that by their terms or nature are to be satisfied at the Closing, but subject to such conditions being able to be satisfied at the Closing) are satisfied prior to the Outside Date but the HSR Condition is not satisfied at least [...***...] prior to the Outside Date, either the Purchaser or the Representative may elect, by notice to the other party at least [...***...] prior to the Outside Date, to extend the Outside Date to [...***...] (the “Extended Outside
Date”) and (iii) if the satisfaction, or waiver by the appropriate party, of all of the conditions contained in Article IV (other than those conditions that by their terms or nature are to be satisfied at the Closing, but subject to such conditions being able to be satisfied at the Closing) occurs […]**…** Business Days or less prior to the Outside Date or, as applicable, the Extended Outside Date, then neither the Purchaser nor the Representative (on behalf of the Company) shall be permitted to terminate this Agreement pursuant to this Section 10.01(d) until the […]**…** Business Day after the Outside Date or, as applicable, the Extended Outside Date; or

(e) by the Purchaser, if the Required Member Vote has not been obtained by the Company within […]**…** following the execution and delivery of this Agreement.

10.02 Effect of Termination. Any termination of this Agreement under Section 10.01 will be effective immediately upon the delivery of a valid written notice of the terminating party to the other parties hereto. In the event this Agreement is terminated by either the Purchaser or the Company as provided in Section 10.01, the provisions of this Agreement shall immediately become void and of no further force and effect (other than this Section 10.02, Article XI and Article XII and the Confidentiality Agreement), and there shall be no Liability on the part of the Purchaser, Merger Sub, Representative, the Company or the Sellers to one another, except for any willful breaches of this Agreement prior to the time of such termination.

ARTICLE XI

DEFINITIONS

11.01 Definitions. For purposes hereof, the following terms when used herein shall have the respective meanings set forth below:

“Additional Merger Consideration” means, as of any date of determination, without duplication, any consideration paid or payable to the Sellers pursuant to Section 2.02 pro rata in accordance with each Seller’s Residual Percentage.

“Affiliate” of any particular Person means any other Person controlling, controlled by or under common control with such particular Person, where “control” means the possession, directly or indirectly, of the power to direct the management and policies of a Person whether through the ownership of voting securities, contract or otherwise.

“Allocable Portion of the Closing Merger Consideration” means, with respect to any Unit outstanding immediately prior to the Effective Time (which for this purpose shall include all Units issuable upon exercise of all Options outstanding immediately prior to the Effective Time), an amount, rounded down to the nearest whole cent, equal to that portion, if any, of the Closing Merger Consideration that would be payable in respect of such Unit if the Company were liquidated immediately after the Closing and the Closing Merger Consideration was available for distribution to the Sellers in accordance with Section 4.1 of the Company LLC Agreement (assuming, for the avoidance of doubt, that all Incentive Units have vested and all Options have been exercised prior to such distribution).

“Allocated Units” means Units that are not Unallocated Units.

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“Business Day” means any day other than a Saturday, a Sunday or other day on which banks are required or authorized by Law to be closed in Chicago, Illinois or New York, New York.

“Closing Date Cash” means all cash and cash equivalents held by the Company, […] and/or their respective Subsidiaries as of immediately prior to the Closing.

“Closing Date Indebtedness” means all Indebtedness of the Company, […] and/or their respective Subsidiaries as of immediately prior to the Closing.

“COBRA” shall mean the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended.

“Company 401(k) Plan” means the Crealta Pharmaceuticals 401(k) Plan.

“Company Employee” means any current or former officer or other employee, or any individual who is a current or former independent contractor, consultant or director, of or to any member of the Company Group or any Company Predecessor Entity.

“Company Employee Agreement” shall mean each management, employment, severance, consulting, relocation, repatriation, expatriation, or other similar agreement, or contract between any member of the Company Group or any Company Predecessor Entity and any Company Employee.

“Company Employee Plan” means any employee benefit plan (as defined in Section 3(3) of ERISA) and each other material program, policy, practice, contract, agreement, commitment or other arrangement providing or promising benefits to any Company Employee or any beneficiary or dependent thereof that is sponsored or maintained by any member of the Company Group or any Company Predecessor Entity or to which any member of the Company Group or any Company Predecessor Entity contributes or is obligated to contribute or has or may have any material Liability, whether or not written, funded or unfunded including without limitation any employee welfare benefit plan within the meaning of Section 3(1) of ERISA, any employee pension benefit plan within the meaning of Section 3(2) of ERISA (whether or not such plan is subject to ERISA) and any material compensation, bonus, incentive, deferred compensation, vacation, stock purchase, stock option, equity or similar award, severance, termination pay, employment, performance award, change of control or material fringe benefit plan, program or policy, except such definition shall not include any Company Employee Agreement.

“Company Equity Plan” means the Crealta Holdings LLC 2014 Non-Qualified Unit Option Plan.

“Company Group” means […] and/or their respective Subsidiaries.

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“Company IP” means: (i) all Intellectual Property relating to the Company Products in which the Company or any Company Subsidiary has an ownership interest; and (ii) all other Intellectual Property with respect to which the Company or any Company Subsidiary has (or purports to have) an ownership interest or an exclusive license or similar exclusive right.

“Company LLC Agreement” means the Amended and Restated Limited Liability Company Agreement of the Company, dated as of August 2, 2013 (as amended).

“Company Owned IP” means the Company IP that is owned (or purported to be owned) by the Company or any Company Subsidiary.

“Company Pension Plan” shall mean each Company Employee Plan that is an “employee pension benefit plan,” within the meaning of Section 3(2) of ERISA.

“Company Predecessor Entity” means any company or entity to which the Company or any Company Subsidiary is a successor.

“Company Products” means all products that have been since [...***...], are currently or are currently scheduled to be marketed, sold, licensed or provided by the Company or any of its Subsidiaries, including KRYSTEXXA® (pegloticase), MIGERGOT® (ergotamine tartrate and caffeine suppositories) and MELOXICAM ZYDIS (i.e., any formulation of MELOXICAM that incorporates, is manufactured with or otherwise uses Zydis® Fast Dissolving Dosage Form).

“Company Representative” means with respect to any member of the Company Group, the directors, officers, other employees, agents, attorneys, accountants, investment bankers, and other advisors and representatives of such member of the Company Group.

“Contract” means any written, oral or other agreement, contract, subcontract, lease, understanding, arrangement, instrument, note, option, warranty, purchase order, license, sublicense, insurance policy, benefit plan or legally binding commitment.

“Covered Employees” shall mean employees who are employed by any member of the Company Group at the Effective Time.

“Damages” shall mean losses, costs, damages and expenses, including reasonable out-of-pocket attorneys’ fees and expenses and reasonable fees and expenses of other professionals and experts that have been incurred or properly paid by an Indemnified Party.

“Environmental Requirements” means any Law, any judicial and administrative order or determination concerning (a) pollution or the protection, preservation or restoration of the environment (including all those relating to the generation, handling, transportation, treatment, storage, disposal, distribution, labeling, discharge, release, threatened release, control, or cleanup of any hazardous materials, hazardous substances or hazardous wastes, or petroleum); (b) the exposure to, or the use, storage, recycling, treatment, generation, transportation, processing, handling, labeling, production, release or disposal of, any Hazardous Substances; or (c) public health and safety issues (including occupational safety and health) solely with respect...
to exposure to Hazardous Substances; in each case of (a) through (c) as enacted as of or prior to the Closing Date.


“Escrow Agent” means Citibank, N.A.

“Escrow Amount” means $[…***…].

“Escrow Distribution” means each distribution of the Escrow Funds to the Paying Agent and the Surviving Company pursuant to Section 12.06.

“Escrow Period” means the period beginning on […] and ending at 11:59 pm Central Time on the date that is […]….

“Executive Employee” means each of […]….

“FDA” means the United States Food and Drug Administration.

“FMLA” shall mean the Family Medical Leave Act of 1993, as amended.

“Foreign Plan” shall mean any plan, program, policy, practice, agreement or other arrangement mandated by a government other than the United States, any Company Employee Plan maintained or contributed to by the Company or any member of the Company Group that is not subject to United States law, and any Company Employee Plan that covers or has covered employees whose services are performed primarily outside of the United States.

“Fundamental Representations” means the representations and warranties set forth in […]….

“GAAP” means United States generally accepted accounting principles.

“Government Official” means (i) any officer or employee of any Governmental Entity, (ii) any Person acting in an official capacity on behalf of a Governmental Entity, (iii) any officer or employee of a Person that is majority or wholly owned by a Governmental Entity, (iv) any officer or employee of a public international organization, such as the World Bank or the United Nations or (v) any officer or employee of a political party or any Person acting in an official capacity on behalf of a political party, in each case, acting in his or her official capacity.

“Governmental Entity” means any federal, national, state, foreign, provincial, local or other government or any governmental, regulatory, administrative or self-regulatory authority, agency, bureau, board, commission, court, judicial or arbitral body, department,
political subdivision, tribunal or other instrumentality thereof, including any multinational authority having governmental or quasi-
governmental powers, or any other industry self-regulatory authority or arbitral body.

“Hazardous Substances” means shall mean any substance for which exposure is regulated by any Governmental
Entity or any Law due to its dangerous or deleterious properties or characteristics, including any toxic waste, pollutant, contaminant,
hazardous substance, toxic substance, hazardous waste, special waste, petroleum or any derivative or by-product thereof, radon,
radioactive material, asbestos, or asbestos containing material, urea formaldehyde foam insulation, lead, toxic mold, mold spores and
mycotoxins or polychlorinated biphenyls.

“Healthcare Laws” means (i) the Federal Food, Drug and Cosmetic Act and the regulations promulgated
thereunder, (ii) the Public Health Service Act (42 U.S.C. §201 et seq.), and the regulations promulgated thereunder, (iii) all federal and
state fraud and abuse laws, including the Federal Anti-Kickback Statute (42 U.S.C. §1320a-7(b)(b)), the civil False Claims Act (31
U.S.C. §3729 et seq.), the administrative False Claims Law (42 U.S.C. §1320a-7(b)(a)), the Anti-Inducement Law (42 U.S.C. §1320a-
7a(a)(5)), the exclusion laws (42 U.S.C. §1320a-7), and the regulations promulgated pursuant to such statutes, (iv) HIPAA, (v) the
the Social Security Act and the regulations promulgated thereunder, and (vii) all applicable laws, rules and regulations, ordinances,
judgments, decrees, orders, writs and injunctions administered by the FDA and other Governmental Entities that regulate the design,
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those who have been excluded from government health care programs, quality, safety, privacy, security, licensure, accreditation or any
other aspect of providing health care services.

“HIPAA” shall mean the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. §1320d et seq.),
as amended by the Health Information, Technology for Economic and Clinical Health Act of 2009, the regulations promulgated
thereunder and comparable state Laws.

“Incentive Unit” means any Unit that is or was subject to vesting.

“Indebtedness” means, as of any particular time, without duplication, (a) all obligations (including all obligations in
respect of principal, accrued interest, penalties, fees and premiums (prepayment, redemption or otherwise)) of the Company, […]***…
and/or their respective Subsidiaries (i) for borrowed money, (ii) in respect of capitalized leases (as determined in accordance with
GAAP), (iii) evidenced by notes, bonds, debentures, mortgages, indentures or similar contracts, instruments or agreements, (iv) in
respect of letters of credit and bankers’ acceptances, in each case, to the extent drawn or funded, (v) for break fees or other breakage
costs for contracts or agreements relating to interest rate or currency protection, swap agreements, collar agreements or other hedging
arrangement, (vi) pursuant to any surety bond, performance bond or other guarantee of contractual obligations, to the extent a claim has been

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made against such bond obligation or guarantee as of such time, [...***…].

“Indemnified Taxes” means (i) all Taxes (or the non-payment thereof) of any member of the Company Group for all Pre-Closing Tax Periods (calculated in accordance with Section 9.03(e)), (ii) all Taxes of any member of an affiliated, consolidated, combined or unitary group of which any member of the Company Group (or any predecessor thereof) is or was a member on or prior to the Closing Date, including pursuant to Treasury Regulation Section 1.1502-6 or any analogous or similar state, local, or non-U.S. Law or regulation, (iii) any and all Taxes of any Person imposed on a member of the Company Group as a transferee or successor, by contract or pursuant to any applicable Law, which Taxes relate to an event or transaction occurring before the Closing, (iv) any Transfer Taxes that are the responsibility of the Sellers under Section 9.03(d), (v) all Transaction Payroll Taxes, and (vi) any Taxes attributable to inaccuracies in the certifications delivered pursuant to Sections 4.01(h) or 4.01(i)(ii); [...***…].

“Intellectual Property” means any or all of the following: (i) copyrights and registrations and applications for registration thereof; (ii) trade names, trademarks, service marks, trade dress, domain names, URLs, logos and other source identifiers, and registrations and applications for registration thereof, together with the goodwill symbolized by any of the foregoing; (iii) patents and applications therefor and all reissues, divisions, renewals, extensions, provisionals, continuations and continuations-in-part thereof; (iv) internet uniform resource locators and domain names; (v) statutory invention registrations, invention disclosures, inventions, know-how, trade secrets, software, formulae, methods, processes, protocols, specifications, techniques, and other forms of technology (whether or not embodied in any tangible form and including all tangible embodiments of the foregoing, such as laboratory notebooks, samples, studies and summaries) and other proprietary information, and (vi) all rights under, in or to any of the foregoing that may exist or be created under the laws of any jurisdiction in the world.

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“IRS” shall mean the United States Internal Revenue Service.

“Law” means any law, rule, regulation, judgment, injunction, order, ordinance, statute, ruling or decree issued, enacted, adopted, promulgated, implemented or otherwise put into effect by or under the authority of any court or other Governmental Entity.

“Liability” means any liability, debt, obligation, deficiency, penalty, assessment, fine, claim or other loss, fee, cost or expense of any kind or nature whatsoever, whether asserted or unasserted, absolute or contingent, known or unknown, accrued or unaccrued, liquidated or unliquidated, and whether due or to become due and regardless of when asserted.

“Liens” means any encumbrance, hypothecation, lien, deed of trust, mortgage, easement, encroachment, pledge, restriction, security interest, option, title retention or other security arrangement, or any other charge or claim of a similar nature in or on any asset, property or property interest.

“Material Adverse Effect” means any change, effect, event, occurrence or development that, individually or in the aggregate, has, or would reasonably be expected to have, a materially adverse effect on (a) the assets, properties, results of operations, business or financial condition of […***…], the Company and their respective Subsidiaries taken as a whole or (b) the ability of […***…] or the Company to consummate the transactions contemplated by this Agreement; provided, however, that with respect to the foregoing clause (a), none of the following shall be deemed in themselves, either alone or in combination, to constitute, and none of the following shall be taken into account in determining whether there has been or will be, a Material Adverse Effect: any change, effect, event, occurrence or development attributable to (i) the announcement or execution of this Agreement, (ii) conditions generally affecting the industries in which the Company and its Subsidiaries participate, the U.S. economy as a whole or the capital markets in general (including currency fluctuation) or the markets in which the Company and its Subsidiaries operate; (iii) any change in applicable Laws, (iv) actions specifically required to be taken under applicable Laws, this Agreement by the Company or any Subsidiary thereof (excluding any covenants relating to the operation of the Company and its Subsidiaries in the Ordinary Course of Business); (v) any change in GAAP or other accounting requirements or principles or the interpretation thereof; (vi) the failure of the Company or its Subsidiaries to meet or achieve the results set forth in any projection or forecast (provided, that this clause (vi) shall not prevent a determination that any change or effect underlying such failure to meet projections or forecasts has resulted in a Material Adverse Effect (to the extent such change or effect is not otherwise excluded from this definition of Material Adverse Effect)); or (vii) the commencement, continuation or escalation of a war, material armed hostilities or other material international or national calamity or act of terrorism; provided that, in the case of clauses (ii), (iii), (v) and (vii) above, if such change, effect, event, occurrence or development disproportionately affects the Company and its Subsidiaries as compared to other Persons or businesses that operate in the industry in which the Company and its Subsidiaries operate, then such change, effect, event, occurrence or development may be taken into account in determining whether a Material Adverse Effect has or will occur.

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“Net Working Capital” means (i) current assets [...] of the Company, [...] and/or their respective Subsidiaries as of immediately prior to the Closing, minus (ii) current liabilities [...] of the Company, [...] and/or their respective Subsidiaries as of immediately prior to the Closing.

“OCS” means the Office of the Chief Scientist of Israeli Ministry of the Economy.

“Optionholder” means a holder of Options.

“Options” means options to acquire the Company’s Common Units.

“Ordinary Course of Business” means the ordinary course of business, including with regard to nature, frequency and magnitude, and otherwise consistent with past practice.

“Organizational Documents” means with respect to any particular entity, (i) if a corporation, the articles or certificate of incorporation and the bylaws (or similar organizational documents for any entity organized or existing in any non-U.S. jurisdiction), (ii) if a limited partnership, the limited partnership agreement and the articles or certificate of limited partnership (or similar organizational documents for any entity organized or existing in any non-U.S. jurisdiction), (iii) if a limited liability company, the articles of organization or certificate of formation and the limited liability company agreement or operating agreement (or similar organizational documents for any entity organized or existing in any non-U.S. jurisdiction), (iv) if any other type of entity (including any non-U.S. entity), the formation or organizational documents and the governing documents, (v) all equityholders’ agreements, voting agreements, voting trust agreements, joint venture agreements, or registration rights agreements, and (vi) any amendment or supplement to any of the foregoing.

“Permitted Liens” means (i) statutory Liens for current Taxes or other governmental charges not yet due and payable or the amount or validity of which is being contested in good faith by appropriate proceedings by the Company and/or its Subsidiaries and for which adequate accruals or reserves have been established on the Latest Balance Sheet in accordance with GAAP; (ii) mechanics’, carriers’, workers’, repairers’ and similar statutory Liens arising or incurred in the Ordinary Course of Business which are not yet due and payable or the amount or validity of which is being contested in good faith by appropriate proceedings by the Company and/or its Subsidiaries and for which adequate accruals or reserves have been established on the Latest Balance Sheet in accordance with GAAP; (iii) zoning, entitlement, building and other land use regulations imposed by governmental agencies having jurisdiction over the Leased Real Property which are not violated by the current use and operation of the Leased Real Property, as applicable, and which do not adversely affect, impair or interfere with the current use, occupancy or operation of such Leased Real Property; (iv) covenants, conditions, restrictions, easements and other similar matters of record affecting title to the Leased Real Property which do not materially affect, impair or interfere with the occupancy or use of the Leased Real Property, as applicable for the purposes for which it is currently used in connection with the Company’s and its Subsidiaries’ businesses; (v) title to any portion of the Leased Real Property lying within the right of way or boundary of any public road or private road which, individually or in the aggregate, do not materially adversely affect the value or the continued use

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of such Leased Real Property; (vi) Liens on goods in transit incurred pursuant to documentary letters of credit set forth on the Contracts Schedule; and (vii) Liens set forth on the Permitted Liens Schedule.

“Person” means an individual, a partnership, a corporation, a limited liability company, an association, a joint stock company, a trust, a joint venture, an unincorporated organization or a Governmental Entity or any department, agency or political subdivision thereof.

“Proceeding” means any action, suit, charge, complaint, litigation, arbitration, proceeding (including any civil, criminal, administrative, investigative or appellate proceeding), hearing, inquiry, audit, examination or investigation commenced, brought, conducted or heard by or before, or otherwise involving, any court or other Governmental Entity or any arbitrator or arbitration panel.

“Registered IP” means all Intellectual Property that is registered, filed or issued with, by or under the authority of any Governmental Entity, including all patents, registered copyrights and registered trademarks and all applications for any of the foregoing.

“Residual Percentage” means the percentage set forth next to each Seller’s name on the Closing Payment Schedule.

“Selected Licensed IP” means all Company IP, other than Company Owned IP, relating to KRYS TEXXA® (pegloticase).

“Senior Management Agreement” shall have the meaning ascribed to such term in the Disclosure Schedules.

“Splitter LP” means GTCR/Crealta Splitter LP, a Delaware limited partnership.

“Straddle Period” means any taxable period that includes (but does not end on) the Closing Date.

“Subsidiary” means, with respect to any Person, any corporation of which a majority of the total voting power of shares of stock entitled (without regard to the occurrence of any contingency) to vote in the election of directors, managers or trustees thereof is at the time owned or controlled, directly or indirectly, by such Person or one or more of the other Subsidiaries of such Person or a combination thereof, or any partnership, limited liability company, association or other business entity of which a majority of the partnership, limited liability company or other similar ownership interest is at the time owned or controlled, directly or indirectly, by such Person or one or more Subsidiaries of such Person or a combination thereof. For purposes of this definition, a Person is deemed to have a majority ownership interest in a partnership, limited liability company, association or other business entity if such Person is allocated a majority of the gains or losses of such partnership, limited liability company, association or other business entity or is or controls the managing director or general partner of such partnership, limited liability company, association or other business entity.

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“Takeover Proposal” means any proposal or offer from any Person (other than the Purchasers or their Affiliates or their respective representatives) for any acquisition by such Person (whether by merger, recapitalization, consolidation, arrangement, amalgamation, purchase of capital stock or other equity securities, purchase of assets, takeover bid or otherwise) of (a) all or a substantial amount of assets of any member of the Company Group (other than an acquisition of assets of the Company Group in the Ordinary Course of Business or as permitted under the terms of this Agreement) or (b) more than a [...] interest in the total voting securities of the Company or [...] or any tender offer or exchange offer that if consummated would result in any Person beneficially owning [...] or more of any class of equity securities of the Company or [...] or any merger, consolidation, or business combination of the Company or [...] with any unaffiliated third party, other than the transactions contemplated by this Agreement.

“Target Net Working Capital Amount” means $. [...]

“Tax” or “Taxes” means any federal, state, local, or non-U.S. income, gross receipts, license, payroll, employment, excise, severance, stamp, occupation, premium, windfall profits, environmental (including taxes under Code §59A), customs duties, capital stock, franchise, profits, withholding, social security (or similar), unemployment, disability, real property, personal property, escheat, sales, use, transfer, registration, value added, alternative or add-on minimum, estimated, or other tax of any kind whatsoever, including any interest, penalty, or addition thereto, whether disputed or not.

“Tax Representations” means the representations and warranties set forth in Section 5.08 (Tax Matters).

“Tax Returns” means any return, declaration, statement, election, report, claim for refund, information return or other document (including schedules or any related or supporting information) filed or required to be filed with any Governmental Entity charged with the determination, assessment or collection of any Tax (or provided to a third party pursuant to applicable Tax Laws, such as withholding Tax certificates).

“Transaction Documents” mean this Agreement, the Escrow Agreement and all other agreements, instruments and certificates expressly contemplated by this Agreement to be executed and delivered by any party in connection with the consummation of the transactions contemplated by this Agreement.

“Transaction Expenses” shall mean, [...], (a) all fees, costs and expenses accrued, incurred or otherwise payable by [...], the Company, any Subsidiary thereof and/or the Representative (and/or any of their respective Affiliates) at or prior to the Closing in connection with the transactions contemplated by this Agreement and the other Transaction Documents, including any of the foregoing that are payable in connection with the negotiation, documentation and execution of this Agreement and the other Transaction Documents or the consummation of the transactions contemplated hereby or thereby (including any of the foregoing payable to counsel, investment bankers or other representatives or advisors of [...], the Company, any Subsidiary thereof and/or the Representative (and/or any of their respective Affiliates), in each case to the ***Confidential Treatment Requested
extent unpaid as of the Closing), (b) any commission, severance, bonus, or other similar payment or benefit of any kind payable by any member of the Company Group contingent solely upon the consummation of the Merger (including the employer portion of any payroll or employment Taxes incurred or accrued with respect to such payments), and (c) any costs, expenses, fees or other payments owed or payable by any member of the Company Group in connection with the termination or settlement of any Affiliated Agreements in accordance with Section 7.09; [...***...].

“Transaction Payroll Taxes” means the employer portion of any payroll or employment Taxes incurred or accrued with respect to any accelerated vesting of Incentive Units, option exercises, option cash-outs, bonuses, or other compensatory payments made in connection with the transactions contemplated by this Agreement on or about or prior to the Closing Date.

“Transaction Tax Deductions” means any income Tax deductions that [...***...] deductible by [...***...], the Company or its Subsidiaries on or prior to the Closing Date and result from or are attributable to expenses, fees or payments of or by the Sellers, [...***...], the Company or its Subsidiaries in connection with the transactions contemplated by this Agreement, including all such amounts that are (i) included in Net Working Capital, Indebtedness or Transaction Expenses (including Transaction Payroll Taxes), (ii) Closing Option Consideration and any other compensatory amounts payable pursuant to the transactions contemplated by this Agreement, or (iii) deferred financing fees; provided that, to the extent applicable, the parties agree to apply and make the safe harbor election set forth in IRS Revenue Procedure 2011-29 to determine the amount of deductions attributable to the payment of any success based fees within the scope of such revenue procedure. Any dispute regarding whether [...***...] is met shall be referred to the Accounting Firm for final resolution.

“Unallocated Unit Vesting Reporting Amount” shall mean the amount to be reported by the Company or its applicable Subsidiary in respect of the vesting of a Unitholder’s Unallocated Units at Closing, which amount shall be equal to the sum of (i) the portion of the Closing Merger Consideration that the Unitholder is entitled to receive (treating, for the avoidance of doubt, the Representative Holdback as if it were paid to the Sellers on the Closing Date), and (ii) the portion of the Escrow Amount that such Unitholder would be entitled to receive if the Escrow Amount were paid to the Sellers on the Closing Date, in each case determined before taking into account any withholding Taxes.

“Unallocated Units” means Units granted pursuant to Items 1 or 2 on the Conduct of Business Schedule.

“Unitholder” means a holder of Units.

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“Units” means the Company’s Common Units.

11.02 Other Definitional Provisions.

(a) Accounting Terms. Accounting terms which are not otherwise defined in this Agreement have the meanings given to them under GAAP. To the extent that the definition of an accounting term defined in this Agreement is inconsistent with the meaning of such term under GAAP, the definition set forth in this Agreement will control.

(b) Successor Laws. Any reference to any particular Code section or any Law will be interpreted to include any revision of or successor to that section regardless of how it is numbered or classified.

11.03 Index of Defined Terms.

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ARTICLE XII

MISCELLANEOUS

12.01 Survival of Representations, Warranties, Covenants and Agreements. The representations and warranties of the Company contained in Article V of this Agreement or in any certificate delivered to Parent or Merger Sub by or on behalf of the Company in connection herewith and the covenants and agreements contained in this Agreement that are to be performed by the Company prior to Closing (the “Pre-Closing Covenants”) shall survive until the termination of […***…]; provided, that (a) the Tax Representations shall survive until the date that is […***…] days after the applicable statute of limitations for the subject matter of such representations and warranties expires and (b) the Fundamental Representations shall survive until 11:59 p.m. Pacific Time on the date that is […***…] following the Closing Date; provided, further, that any claim that is properly asserted in writing pursuant to this Article XII prior to the expiration of the survival period applicable to such representation or warranty set forth above shall survive until such claim is finally resolved and satisfied. Except for Section 6.10, the representations and warranties of the Purchasers and Merger Sub contained in this Agreement or in any certificate delivered pursuant to this Agreement shall terminate […***…]. All covenants and other agreements contained in this Agreement other than the Pre-Closing Covenants shall survive […***…] in accordance with their respective terms. It is the express intent of the parties hereto that, if the applicable survival period for an item as contemplated by this Section 12.01 is shorter or longer than the statute of limitations that would otherwise have been applicable to such item, then, by contract, the applicable statute of limitations with respect to such item shall be reduced or extended, as applicable, to the shortened or extended survival period contemplated hereby, as the case may be. The parties hereto acknowledge that the time periods set forth in this Section 12.01 for the assertion of claims under this Agreement are the result of arms’-length negotiation among the parties and that they intend for the time periods to be enforced as agreed by the parties.

12.02 Indemnification by the Sellers. Subject to the other provisions of this Article XII and the Escrow Agreement, following the Closing, each Seller shall, severally and not jointly, in accordance with such Seller’s Residual Percentage, indemnify the Purchasers and the Surviving Company, their respective Affiliates, and each of their respective officers, directors, employees, stockholders, agents, other representatives, successors and permitted assigns (each a “Purchaser Indemnified Party”) in respect of, and hold them harmless against, any Damages suffered, incurred or sustained by any Purchaser Indemnified Party resulting from or arising out of:

(a) any inaccuracy in or breach, as of the date of this Agreement and/or as of the Effective Time (as if such representation or warranty had been made as of the Effective Time), of any representation or warranty made by the Company in Article V of this Agreement or in any certificate delivered to Parent or Merger Sub by or on behalf of the Company in connection herewith;
(b) any breach or nonfulfillment by any member of the Company Group, [...] or the Representative of any of their respective covenants, obligations or agreements contained in this Agreement;

(c) regardless of the disclosure of any matter set forth in the Disclosure Schedules, the allocation or misallocation of the Closing Merger Consideration, the Additional Merger Consideration and/or Escrow Distributions amongst the Sellers, including as a result of any inaccuracy or error in the Closing Payment Schedule;

(d) any claim by a current or former holder of Units, Options or Shares or any other Person, seeking to assert, or based upon: (i) ownership or rights to ownership of any shares of capital stock, membership interests or other equity securities of any member of the Company Group, including any claims for breaches of fiduciary duties owed to such Person in such capacity; or (ii) any rights of a stockholder or other equity holder (other than in the case of clauses “(i)” and “(ii)” claims based on the rights of any such Person to receive a portion of the payments contemplated to be made to such Person hereby as and to the extent set forth herein), including any option, preemptive rights or rights to notice or to vote;

(e) any Closing Date Indebtedness or Transaction Expenses in each case, to the extent not taken into account in the calculation of the Final Merger Consideration in accordance with Article II;

(f) regardless of the disclosure of any matter set forth in the Disclosure Schedules, any Indemnified Taxes; and/or

(g) the Splitter LP Liquidation.

12.03 Indemnification Limitations

(a) Except in the case of fraud and claims under Section 9.03, (i) this Article XII shall be the exclusive means for any Purchaser Indemnified Party to collect any Damages for which it is entitled to indemnification under this Agreement and (ii) the Purchaser Indemnified Parties’ sole and exclusive source of recovery for indemnification claims under Section 12.02(a) [...] provided, that in no event shall any Seller’s aggregate Liability to the Purchaser Indemnified Parties for indemnification claims pursuant to this Article XII and Section 9.03 exceed [...] The parties acknowledge that there shall not be any duplicative recovery for any Damages arising from the same facts and circumstances.

(b) Notwithstanding anything to the contrary contained in this Agreement, no Purchaser Indemnified Party shall be entitled to recover any Damages related to any particular claim for indemnification under Section 12.02(a), unless and until the amount of such Damage

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for which it would otherwise be entitled to indemnification under Section 12.02(a) exceeds [...] (the “Per Claim Deductible”) (it being understood and agreed that (i) any claim for an amount of less than the Per Claim Deductible shall be disregarded in determining whether the Indemnity Deductible has been exceeded and (ii) any Damage or Damages resulting from any single claim or series of related claims arising out of or resulting from the same facts, events, or circumstances shall be deemed to be one and the same claim for these purposes and shall be aggregated in determining whether the Per Claim Deductible was exceeded); provided, that the Per Claim Deductible shall not apply to (i) any claims for fraud or (ii) any Damages related to the inaccuracy in or breach of any of the Fundamental Representations or the Tax Representations.

(c) Notwithstanding anything to the contrary contained in this Agreement, no Purchaser Indemnified Party shall be entitled to recover any Damages under Section 12.02(a) unless and until the aggregate Damages in excess of the Per Claim Deductible for which they would otherwise be entitled to indemnification under Section 12.02(a) exceed [...] (the “Indemnity Deductible”) (at which point the Purchaser Indemnified Parties shall become entitled to be indemnified only for such Damages in excess of the Indemnity Deductible); provided, that the Indemnity Deductible shall not apply to (i) any claims for fraud or (ii) any Damages related to the inaccuracy in or breach of any of the Fundamental Representations or the Tax Representations.

(d) For purposes of Section 12.02(a), a breach shall be determined without regard to any qualification based on materiality, Material Adverse Effect or similar qualifier contained in such representation or warranty (or in any defined term contained in such representation or warranty other than the first sentence of Section 5.06 and the definition of “Material Adverse Effect” in Article XI. Additionally, a Purchaser Indemnified Party’s entitlement to indemnification pursuant to this Agreement will not be affected by any examination made for or on behalf of any of such parties or the knowledge of any of their respective officers, directors, Affiliates, employees, agents or representatives.

(e) No Seller shall be liable to any Purchaser Indemnified Party for any Damages to the extent such Damages constitute punitive damages, except to the extent such punitive damages are sought or obtained by a third party.

(f) The amount of any Damages that are subject to indemnification under this Article XII shall be calculated net of the amount of any insurance proceeds, contribution, indemnification payments or similar payments or reimbursements actually received by the Purchaser Indemnified Parties in respect of such Damages (net of any costs or expenses incurred in obtaining such insurance, indemnification or reimbursement, including any increases in insurance premiums or retro-premium adjustments resulting from such recovery), provided, that nothing in this Section 12.03(f) shall be construed as or give rise to an obligation to seek any such insurance, indemnification or reimbursement. No Purchaser Indemnified Party shall have any right of indemnification hereunder with respect to any Damages or alleged Damages to the extent that the Damage or alleged Damage is included in the calculation of Net Working Capital or deducted as Indebtedness or Transaction Expenses in the determination of Final Merger Consideration.

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(g) All indemnification payments made to the Purchasers from the Escrow Account shall be treated by the parties as an adjustment to the proceeds received by the Sellers pursuant to Article I of this Agreement.

(h) Notwithstanding anything to the contrary contained in this Agreement, the Purchaser Indemnified Parties shall not be entitled to any indemnification for Taxes attributable to transactions occurring on the Closing Date after the Closing outside the Ordinary Course of Business (other than as explicitly contemplated by this Agreement) or transactions that occur or are deemed to occur at or immediately prior to or immediately following the Closing that are solely attributable to Purchaser’s financing of the transactions contemplated by this Agreement.

12.04 Indemnification Claims Procedure.

(a) If a Purchaser Indemnified Party determines in good faith that such Purchaser Indemnified Party has a bona fide claim for indemnification pursuant to this Article XII, then the Purchaser (on behalf of any Purchaser Indemnified Party) shall deliver to the Representative a written notice (a “Claim Notice”) (i) stating that a Purchaser Indemnified Party has a claim for indemnification pursuant to this Article XII, (ii) to the extent possible, providing a good faith non-binding, preliminary estimate of the amount of indemnifiable Damages such Purchaser Indemnified Party claims to have incurred or suffered or could reasonably be expected to incur or suffer (the “Estimated Claim Amount”); and (iii) specifying in reasonable detail (based upon the information then possessed by such Purchaser Indemnified Party) the material facts known to the Purchaser Indemnified Party giving rise to such claim. Subject to this Article XII, no delay in providing such a Claim Notice shall affect a Purchaser Indemnified Party’s rights hereunder, unless (and then only to the extent that) the Sellers are actually and materially prejudiced by such delay. At the time of delivery of any Claim Notice, the Purchaser shall deliver a duplicate copy of such Claim Notice to the Escrow Agent (on behalf of the applicable Purchaser Indemnified Party).

(b) If the Representative in good faith objects to any claim made in a Claim Notice, then the Representative shall deliver a written notice (a “Claim Dispute Notice”) to the Purchaser and the Escrow Agent during the [...***...] calendar day period commencing upon receipt by the Representative of the Claim Notice. The Claim Dispute Notice shall set forth in reasonable detail the principal basis for the dispute of any claim made in the relevant Claim Notice. If no Claim Dispute Notice is delivered prior to the expiration of such [...***...] calendar day period, then (i) each claim for indemnification set forth in such Claim Notice shall be deemed to have been conclusively determined in favor of the Purchaser Indemnified Party for purposes of this Article XII on the terms set forth in the Claim Notice and (ii) as applicable, if any funds remain in the Escrow Account, then the Purchaser may, in its sole and absolute discretion, direct the Escrow Agent to deliver cash from the Escrow Account to the Purchaser in accordance with this Section 12.04, or as otherwise required pursuant to this Article XII, the Sellers shall make payment to the Purchaser Indemnified Party in respect of the Damages set forth in such Claim Notice.

(c) Following delivery of a Claim Dispute Notice, the Purchaser and the Representative shall attempt in good faith to resolve any such objections raised in such Claim Dispute Notice. If the Purchaser and the Representative agree to a resolution of such objection,
then (i) a memorandum setting forth the matters conclusively determined by the Purchaser and the Representative shall be prepared and signed by both parties and (ii) as applicable, if such memorandum calls for a payment to a Purchaser Indemnified Party and any funds remain in the Escrow Account, the Purchaser may, in its sole and absolute discretion, direct the Escrow Agent to act in accordance with such memorandum and distribute cash from the Escrow Account in accordance therewith, or as otherwise required pursuant to this Article XII, the Sellers shall make payment to the Purchaser Indemnified Party in accordance with such memorandum.

(d) If no such resolution can be reached during the […] calendar day period following receipt of a given Claim Dispute Notice, then upon the expiration of such […] calendar day period, either the Purchaser or the Representative may bring suit to resolve the objection in accordance with Sections 12.14 and 12.18. The decision of the trial court as to the validity and amount of any claim in such Claim Notice shall be non-appealable, binding and conclusive upon the Purchaser and the Sellers. As applicable, if such decision calls for a payment to a Purchaser Indemnified Party and any funds remain in the Escrow Account, the Purchaser may, in its sole and absolute discretion, direct the Escrow Agent to act in accordance with such decision and distribute cash from the Escrow Account in accordance therewith, or as otherwise required pursuant to this Article XII, the Sellers shall make payment to the Purchaser Indemnified Party in accordance with such decision. Judgment upon any award rendered by the trial court may be entered in any court having competent jurisdiction.

12.05 Third Party Claims. In the event of the assertion of any actual or possible Proceeding that has been or may be brought or asserted by a third party against a Purchaser Indemnified Party and that may be subject to indemnification pursuant to this Agreement (each, a “Third-Party Claim”), the Purchaser shall proceed with the defense of such Third-Party Claim on its own (and the costs and expenses incurred by the Purchaser in connection with the defense, settlement or resolution of such Third-Party Claim (including reasonable attorneys’ fees, other professionals’ and experts’ fees and court or arbitration costs) may be included in the Damages for which the Purchaser may seek indemnification pursuant to a claim made hereunder). Representative shall be entitled to participate in the defense of such action, lawsuit, proceeding, investigation or other claim giving rise to the Purchaser’s claim for indemnification under this Agreement at Representative’s expense, and at its option shall be entitled to assume the defense thereof with reputable counsel reasonably acceptable to the Purchaser; provided that Representative shall continue to be entitled to assert any limitation on any claims contained herein; and provided further that Representative shall not have the right to assume control of such defense if (i) the claim which Representative seeks to control (a) involves a claim that is reasonably likely to have a material adverse effect on the reputation, customer or supplier relations or future business prospects of the Purchasers, the Surviving Company or any of their respective Affiliates, (b) seeks equitable or injunctive relief, except where equitable or injunctive relief is incidental to a primary claim or claims for monetary damages and such claim is not reasonably likely to result in equitable or injunctive relief; (c) is brought by a Governmental Entity, (d) involves criminal allegations or (e) would reasonably be expected to result in greater liability to Purchaser Indemnified Parties than the Sellers, taking into account the Indemnity Deductible, the Escrow Amount and other limitations on indemnification herein or (ii) the Representative (or counsel selected by Representative) has failed or is failing to prosecute or defend such claim, and is provided written notice of such failure by the Purchaser Indemnified Party and such failure is not reasonably cured within […] Business Days of receipt of

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such notice. In the event that the Representative assumes the defense of any Third-Party Claim pursuant to the prior sentence, the Purchaser shall be entitled to participate in the defense of such Third Party Claim with separate counsel at the Purchaser’s expense. Neither the Purchaser nor Representative shall not have the right to settle, adjust or compromise such Third-Party Claim without the consent of the other party (which consent shall not be unreasonably withheld, conditioned or delayed), it being agreed that the other party shall consent to any settlement, adjustment or compromise of such Proceeding unless the settlement will result in injunctive or other equitable relief being imposed against the Sellers, on the one hand, or against the Purchaser or any member of the Company Group, on the other, as the case may be, or the settlement does not expressly and unconditionally release the Sellers, on the one hand, or the Purchaser or the Company Group, on the other, as applicable, from all liabilities and obligations with respect to such Third-Party Claim without prejudice, except for payments that would be required to be paid by Representative representing the Indemnity Deductible and/or the Per Claim Deductible. The Purchasers shall give the Representative prompt notice of the commencement of any such Third-Party Claim against a Purchaser Indemnified Party; provided, that any failure on the part of the Purchaser to so notify the Representative shall not limit any of the obligations of the Sellers pursuant to this Article XII (except and only to the extent such failure actually and materially prejudices the defense of such Third-Party Claim). For the avoidance of doubt, Tax Claims shall be subject to Section 9.03(i) rather than this Section 12.05.

12.06 Release of Escrow Amount.

(a) On the […] Business Day following the termination of the Escrow Period, the Escrow Agent shall release the then remaining Escrow Funds (to the extent such funds have not been utilized to pay the Purchaser Indemnified Parties for any indemnification claims under this Article XII) to (i) the Paying Agent for further distribution to the Sellers (other than the Optionholders in respect of Options) and (ii) the Surviving Company (or any successor thereto) for further distribution to the Optionholders in respect of the Options, in each case, in accordance with Section 1.04 and Section 1.05, as applicable; provided, that the Escrow Agent shall retain an amount (up to the total amount of the then remaining Escrow Funds) equal to the amount of any claims for indemnification asserted in good faith prior to the termination of the Escrow Period but which are not yet resolved (each such claim, an “Unresolved Claim”). The amount of the Escrow Funds retained for each Unresolved Claim shall be released (to the extent such funds are not utilized to indemnify any Purchaser Indemnified Party for such Unresolved Claim in accordance with the terms of this Agreement) by the Escrow Agent to the Paying Agent or the Surviving Company, as applicable, in accordance with the prior sentence upon the final and binding resolution of such Unresolved Claim in accordance with this Article XII and the Escrow Agreement.

(b) Notwithstanding anything herein to the contrary, at least […] Business Days prior to any Escrow Distribution to the Sellers, the Representative shall deliver to the Purchasers an updated Closing Payment Schedule (which need not be certified by an officer of the Company) setting forth the portion of such Escrow Distribution payable to each Seller.

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12.07 Representative.

(a) Authority. By the approval of this Agreement pursuant to the Delaware LLC Law, the Sellers hereby irrevocably constitute and appoint the Representative as the representative, agent, proxy, and attorney-in-fact for each of the Sellers for all purposes authorized under this Agreement, including the full power and authority on the Sellers’ behalf (i) to consummate the transactions contemplated herein; (ii) to pay such Seller’s expenses incurred in connection with the negotiation and performance of this Agreement (whether incurred on or after the date hereof), including by using funds from the Representative Holdback Amount; (iii) to disburse any funds received hereunder to such Seller and each other Seller; (iv) to endorse and deliver any certificates or instruments representing the Units and execute such further instruments of assignment as the Purchaser or the Merger Sub shall reasonably request; (v) to execute and deliver on behalf of such Seller any amendment or waiver hereto; (vi) (A) to dispute or refrain from disputing, or to deliver instructions, on behalf of such Seller relative to any amounts to be received by such Seller under any Transaction Document or any other agreement contemplated hereby or thereby, any claim made by the Purchaser under any Transaction Document or any other agreement contemplated hereby or thereby, (B) to negotiate and compromise, on behalf of such Seller, any dispute that may arise under, and exercise or refrain from exercising any remedies available under, the Transaction Documents or any other agreement contemplated hereby or thereby (including pursuant to Article XII of this Agreement), and (C) to execute, on behalf of such Seller, any settlement agreement, release or other document with respect to such dispute or remedy; (vii) to engage attorneys, accountants, agents or consultants on behalf of the Sellers in connection with the Transaction Documents or any other agreement contemplated hereby or thereby and paying any fees related thereto; (viii) to take all other actions to be taken by or on behalf of such Seller in connection herewith; (ix) to retain the Representative Holdback Amount and pay amounts therefrom in accordance with this Agreement; and (x) to do each and every act and exercise any and all rights which such Seller or the Sellers collectively are permitted or required to do or exercise under this Agreement or any other Transaction Document; provided, however, that, notwithstanding the foregoing, the Representative shall not have the authority to agree to any amendment of this Agreement or enter into any agreement or take any of the foregoing actions that would treat any Units differently than other Units. Each of the Sellers agrees that such agency and proxy are coupled with an interest, are therefore irrevocable without the consent of the Representative and shall survive the death, incapacity, bankruptcy, dissolution or liquidation of any Seller. If any Seller dies or becomes incapacitated, disabled or incompetent (such deceased, incapacitated, disabled or incompetent Seller being a “Former Seller”) and, as a result, the agency and power of attorney conferred by this Section 12.07 is revoked by operation of law, it shall not be a breach by such Former Seller under this Agreement if the heirs, beneficiaries, estate, administrator, executor, guardian, conservator or other legal representative of such Former Seller (each a “Successor Seller”) confirms the appointment of the Representative as agent and attorney-in-fact for such Successor Seller. All decisions and actions by the Representative (to the extent authorized by this Agreement) shall be binding upon all of the Sellers, and no Seller shall have the right to object, dissent, protest or otherwise contest the same.

(b) Authority; Indemnification. Each Seller agrees that the Purchasers, the Merger Sub and the Surviving Company shall be entitled to rely on any action taken by the Representative, on behalf of such Seller, pursuant to Section 12.07(a) above (an “Authorized…

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(c) **Exculpation.** The Representative shall not have by reason of this Agreement a fiduciary relationship in respect of any Seller, except in respect of amounts received on behalf of such Seller. The Representative shall not be liable to any Seller for any action taken or omitted by it or any agent employed by it hereunder or under any other document entered into in connection herewith, except that the Representative shall not be relieved of any Liability imposed by law for willful misconduct. The Representative shall not be liable to the Sellers for any apportionment or distribution of payments made by the Representative in good faith, and if any such apportionment or distribution is subsequently determined to have been made in error the sole recourse of any Seller to whom payment was due, but not made, shall be to recover from other Sellers any payment in excess of the amount to which they are determined to have been entitled. The Representative shall not be required to make any inquiry concerning either the performance or observance of any of the terms, provision or conditions of this Agreement. Neither the Representative nor any agent employed by it shall incur any Liability to any Seller by virtue of the failure or refusal of the Representative for any reason to consummate the transactions contemplated hereby or relating to the performance of its other duties hereunder, except for actions or omissions constituting fraud or bad faith.

(d) **Representative Holdback Amount.** The Representative will be entitled to obtain reimbursement from the Representative Holdback Amount for any payments, fees, costs and expenses of the Representative payable by the Representative pursuant to this Agreement and will distribute in its discretion any remaining portion of the Representative Holdback Amount to the Sellers on a pro rata basis according to each Seller’s Residual Percentage, it being understood and agreed that such distribution(s) shall be the responsibility of the Representative only and that neither the Purchaser nor the Surviving Company shall have any obligation to ensure that such distribution is, or distributions are, made.

12.08 **Press Releases and Communications.** Other than delivery of an information memorandum to the Sellers by the Company regarding the transactions contemplated by this Agreement (it being agreed that the Company shall give the Purchaser a reasonable opportunity to review and comment on such information memorandum and the Company shall give reasonable consideration to all reasonable additions, deletions or changes suggested thereto by the Purchaser), no press release or public announcement related to this Agreement or the transactions contemplated herein, shall be issued or made by any party hereto (or any Affiliate to a party hereto) without the joint approval of the Purchaser and the Representative, unless required by Law (in the reasonable advice of counsel), court order or by
12.09 **Expenses.** Except as otherwise expressly provided herein, the Company and the Representative, on the one hand, and the Purchasers and the Merger Sub, on the other hand, shall pay all of their own expenses (including attorneys’ and accountants’ fees and expenses) in connection with the negotiation of this Agreement, the performance of their obligations hereunder and the consummation of the transactions contemplated by this Agreement; provided that the Purchasers shall pay the Transaction Expenses on behalf of […] and the Company and its Subsidiaries as provided in Section 3.02(i).

12.10 **Knowledge Defined.** For purposes of this Agreement, (a) “the Company’s knowledge” and “knowledge of the Company” as used herein shall mean the actual knowledge, of each of […] and (b) “the Purchaser’s knowledge” as used herein shall mean the actual knowledge of […]

12.11 **Notices.** All notices, demands and other communications to be given or delivered under or by reason of the provisions of this Agreement shall be in writing and shall be deemed to have been given (a) when personally delivered, (b) when transmitted via facsimile device to the number set out below if the sender on the same day sends a confirming copy of such notice by a recognized overnight delivery service (charges prepaid), (c) the day following the day (except if not a Business Day then the next Business Day) on which the same has been delivered prepaid to a reputable national overnight air courier service or (d) the third Business Day following the day on which the same is sent by certified or registered mail, postage prepaid. Notices, demands and communications, in each case to the respective parties, shall be sent to the applicable address set forth below, unless another address has been previously specified in writing:

**Notices to the Merger Sub and, after the Closing, the Surviving Company:**

c/o Horizon Pharma, Inc.
520 Lake Cook Road, Suite 520
Deerfield, Illinois 60015
Attn: General Counsel
Facsimile No.: (847) 572-1631

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12.12 Assignment. This Agreement and all of the provisions hereof shall be binding upon and inure to the benefit of the parties hereto and their respective successors and permitted assigns, except that neither this Agreement nor any of the rights, interests or obligations hereunder may be assigned or delegated by the Purchaser or the Merger Sub without the prior written consent of the Company and the Representative; provided, however, without the prior written consent of the Company and the Representative, (i) the Purchaser may assign this Agreement or any of its rights or interests hereunder to any of its lenders as collateral security and (ii) the Purchaser may assign this Agreement or any of its rights, interests or obligations
hereunder to any of its Affiliates, or any successors by operation of Law, or to any Person in connection with a reorganization, merger, acquisition, consolidation, sale of assets or other similar transaction. No assignment of any obligations hereunder shall relieve the parties of any of their obligations pursuant to this Agreement.

12.13 Severability. Whenever possible, each provision of this Agreement shall be interpreted in such manner as to be effective and valid under applicable Law, but if any provision of this Agreement is held to be prohibited by or invalid under applicable Law, such provision shall be ineffective only to the extent of such prohibition or invalidity, without invalidating the remainder of such provision or the remaining provisions of this Agreement.

12.14 References. The table of contents and the section and other headings and subheadings contained in this Agreement and the Exhibits hereto are solely for the purpose of reference, are not part of the agreement of the parties hereto, and shall not in any way affect the meaning or interpretation of this Agreement or any Exhibit hereto. All references to days or months shall be deemed references to calendar days or months. All references to “$” shall be deemed references to United States dollars. Unless the context otherwise requires, any reference to a “Section,” “Exhibit,” “Disclosure Schedule” or “Schedule” shall be deemed to refer to a section of this Agreement, exhibit to this Agreement or a schedule to this Agreement, as applicable. Capitalized terms used in the Disclosure Schedules and not otherwise defined therein have the meanings given to them in this Agreement. The words “hereof,” “herein” and “hereunder” and words of similar import referring to this Agreement refer to this Agreement as a whole and not to any particular provision of this Agreement. The word “including” or any variation thereof means “including, without limitation” and shall not be construed to limit any general statement that it follows to the specific or similar items or matters immediately following it. Unless the context otherwise clearly indicates, each defined term used in this Agreement shall have a comparable meaning when used in its plural or singular form.

12.15 Construction. The language used in this Agreement shall be deemed to be the language chosen by the parties hereto to express their mutual intent, and no rule of strict construction shall be applied against any Person. The specification of any dollar amount or the inclusion of any item in the representations and warranties contained in this Agreement or the Disclosure Schedules attached hereto is not intended to imply that the amounts, or higher or lower amounts, or the items so included, or other items, are material or are or are not required to be disclosed, and no party shall use the fact of the setting of the amounts or the fact of the inclusion of any item in this Agreement or the Disclosure Schedules in any dispute or controversy between the parties as to whether any obligation, item or matter not described or included in this Agreement or Disclosure Schedules is material or are or are not required to be disclosed. The information contained in this Agreement and in the Disclosure Schedules and Exhibits hereto is disclosed solely for purposes of this Agreement, and no information contained herein or therein shall be deemed to be an admission by any party hereto to any third party of any matter whatsoever (including any violation of Law or breach of contract). For purposes of this Agreement, only those documents posted by the Company or a Person acting on its behalf to the online data room hosted on behalf of the Company and located at https://www.rrdvenue.com before 11:59 pm Chicago Time on the date that is one Business Day prior to the date of this Agreement shall be deemed hereunder to have been “delivered,” “furnished” or “made available” (or any phrase of similar import) to the Purchaser by the Company.
12.16 Amendment and Waiver. Any provision of this Agreement or the Disclosure Schedules (other than updates to the Sellers Schedule and the Capitalization Schedule to reflect (i) the distribution of Units by Splitter LP upon completion of the Splitter LP Liquidation and (ii) grants of Incentive Units as set forth in Items 1 and 2 on the Conduct of Business Schedule, which amendments may be done in writing delivered by the Company to the Purchasers prior to the Closing) or Exhibits hereto may be amended or waived only in a writing signed by the Purchasers, the Merger Sub, the Company and the Representative. No waiver of any provision hereunder or any breach or default thereof shall extend to or affect in any way any other provision or prior or subsequent breach or default.

12.17 Complete Agreement. This Agreement and the documents referred to herein (including the other Transaction Documents and the Confidentiality Agreement) contain the complete agreement between the parties hereto and supersede any prior understandings, agreements or representations by or between the parties, written or oral, which may have related to the subject matter hereof in any way.

12.18 Third-Party Beneficiaries. Section 8.03 shall be enforceable by the current and former officers, directors and similar functionaries of the Company and/or its Subsidiaries and his or her heirs and representatives. Except as otherwise expressly provided herein, nothing expressed or referred to in this Agreement will be construed to give any Person other than the parties to this Agreement any legal or equitable right, remedy, or claim under or with respect to this Agreement or any provision of this Agreement.

12.19 Waiver of Trial by Jury. EACH PARTY TO THIS AGREEMENT HEREBY WAIVES, TO THE FULLEST EXTENT PERMITTED BY LAW, ANY RIGHT TO TRIAL BY JURY OF ANY CLAIM, DEMAND, ACTION, OR CAUSE OF ACTION (A) ARISING UNDER THIS AGREEMENT OR THE OTHER TRANSACTION DOCUMENTS OR (B) IN ANY WAY CONNECTED WITH OR RELATED OR INCIDENTAL TO THE DEALINGS OF THE PARTIES HERETO IN RESPECT OF THIS AGREEMENT OR ANY OF THE TRANSACTIONS RELATED HERETO, IN EACH CASE WHETHER NOW EXISTING OR HEREAFTER ARISING, AND WHETHER IN CONTRACT, TORT, EQUITY, OR OTHERWISE. EACH PARTY TO THIS AGREEMENT HEREBY AGREES AND CONSENTS THAT ANY SUCH CLAIM, DEMAND, ACTION, OR CAUSE OF ACTION SHALL BE DECIDED BY COURT TRIAL WITHOUT A JURY, AND THAT THE PARTIES TO THIS AGREEMENT MAY FILE A COPY OF THIS AGREEMENT WITH ANY COURT AS WRITTEN EVIDENCE OF THE CONSENT OF THE PARTIES HERETO TO THE WAIVER OF THEIR RIGHT TO TRIAL BY JURY.

12.20 Purchaser and Merger Sub Deliveries. Each of the Purchasers and the Merger Sub agrees and acknowledges that, subject to Section 12.10, all documents or other items delivered or made available to the Purchasers’ authorized representatives shall be deemed to be delivered or made available, as the case may be, to the Purchaser and the Merger Sub for all purposes hereunder.

12.21 Delivery by Electronic Transmission. This Agreement and any signed agreement entered into in connection herewith or contemplated hereby, and any amendments hereto or thereto, to the extent signed and delivered by means of a facsimile machine or by .pdf,
.tif, .gif, .jpeg or similar attachment to electronic mail, shall be treated in all manner and respects as an original contract and shall be considered to have the same binding legal effects as if it were the original signed version thereof delivered in person. At the request of any party hereto or to any such contract, each other party hereto or thereto shall re-execute original forms thereof and deliver them to all other parties. No party hereto or to any such contract shall raise the use of a facsimile machine or by .pdf, .tif, .gif, .jpeg or similar attachment to electronic mail to deliver a signature or the fact that any signature or contract was transmitted or communicated through the use of facsimile machine or by .pdf, .tif, .gif, .jpeg or similar attachment to electronic mail as a defense to the formation of a contract and each such party forever waives any such defense.

12.22 Counterparts. This Agreement may be executed in multiple counterparts, any one of which need not contain the signature of more than one party, but all such counterparts taken together shall constitute one and the same instrument.

12.23 Governing Law. All issues and questions concerning the construction, validity, interpretation and enforceability of this Agreement and the Exhibits and Schedules hereto shall be governed by, and construed in accordance with, the laws of the State of Delaware, without giving effect to any choice of law or conflict of law rules or provisions (whether of the State of Delaware or any other jurisdiction) that would cause the application of the laws of any jurisdiction other than the State of Delaware.

12.24 Jurisdiction. Except as otherwise expressly provided in this Agreement, any suit, action or proceeding seeking to enforce any provision of, or based on any matter arising out of or in connection with, this Agreement or the transactions contemplated hereby may be brought in the United States District Court for the District of Delaware, the Delaware Court of Chancery of the State of Delaware or any other court of the State of Delaware, and each of the parties hereto hereby consents to the exclusive jurisdiction of such courts (and of the appropriate appellate courts therefrom) in any such suit, action or proceeding and irrevocably waives, to the fullest extent permitted by law, any objection which it may now or hereafter have to the laying of the venue of any such suit, action or proceeding in any such court or that any such suit, action or proceeding which is brought in any such court has been brought in an inconvenient forum. Process in any such suit, action or proceeding may be served on any party anywhere in the world, whether within or without the jurisdiction of any such court. Without limiting the foregoing, each party agrees that service of process on such party as provided in Section 12.11 shall be deemed effective service of process on such party.

12.25 Specific Performance. The parties hereto agree that irreparable damage would occur in the event that any of the provisions of this Agreement were not performed by the Purchasers, the Merger Sub, the Company or the Representative, as applicable, in accordance with their specific terms or were otherwise breached by the Purchasers, the Merger Sub, the Company or the Representative, as applicable. It is accordingly agreed that the parties shall be entitled to an injunction or injunctions to prevent breaches of this Agreement by any of the Purchasers, the Merger Sub, the Company or the Representative, as applicable, and to enforce specifically the terms and provisions hereof against the Purchasers, the Merger Sub, the Company or the Representative, as applicable, in any court having jurisdiction, this being in addition to any other remedy to which the parties hereto are entitled at law or in equity.
12.26 **Time is of the Essence.** The parties hereby expressly acknowledge and agree that time is of the essence for each and every provision of this Agreement.

* * * *

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IN WITNESS WHEREOF, the parties hereto have executed this Agreement and Plan of Merger on the date first
above written.

Company: CREALTA HOLDINGS LLC

By: /s/ Edward J. Fiorentino
   Name: Edward J. Fiorentino
   Title: Chairman and Chief Executive Officer

Signature Page to Agreement and Plan of Merger
IN WITNESS WHEREOF, the parties hereto have executed this Agreement and Plan of Merger on the date first above written.

Purchaser: HZNP LIMITED

By: /s/ Kevin Insley
   Name: Kevin Insley
   Title: Director

Merger Sub: CRIOSTAIL LLC

By: /s/ Timothy P. Walbert
   Name: Timothy P. Walbert
   Title: President and Chief Executive Officer

HORIZON PHARMA USA, INC.

By: /s/ Timothy P. Walbert
   Name: Timothy P. Walbert
   Title: President and Chief Executive Officer

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Signature Page to Agreement and Plan of Merger
GTCR FUND X/C LP

By: GTCR Partners X/A&C LP
Its: General Partner

By: GTCR Investment X LLC
Its: General Partner

By: /s/ Constantine S. Mihas
Name: Constantine S. Mihas
Title: Authorized Signatory

***Confidential Treatment Requested

Signature Page to Agreement and Plan of Merger (cont’d)
Representative: GTCR FUND X/B LP

By: GTCR Partners X/B LP
Its: General Partner

By: GTCR Investment X LLC
Its: General Partner

By: /s/ Constantine S. Mihas
Name: Constantine S. Mihas
Title: Authorized Signatory

Signature Page to Agreement and Plan of Merger (cont’d)
CERTIFICATE OF MERGER

OF

CRIOSTAIL LLC

(a Delaware limited liability company)

WITH AND INTO

CREALTA HOLDINGS LLC

(a Delaware limited liability company)

* * * * * * * * * *

In accordance with the provisions of Title 6, §18-209 of the Delaware Limited Liability Company Act

* * * * * * * * * *

Crealta Holdings LLC, duly organized and existing under and by virtue of the laws of the State of Delaware (the “Company”), desiring to merge Criostail LLC, a Delaware limited liability company (the “Merger Sub”), with and into itself, pursuant to the provisions of Title 6, §18-209 of the Delaware Limited Liability Company Act, DOES HEREBY CERTIFY as follows:

FIRST: The name and state of organization of the constituent limited liability companies of the merger (the “Merger”) are as follows:

<table>
<thead>
<tr>
<th>NAME</th>
<th>STATE OF ORGANIZATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Crealta Holdings LLC</td>
<td>Delaware</td>
</tr>
<tr>
<td>Criostail LLC</td>
<td>Delaware</td>
</tr>
</tbody>
</table>

SECOND: An Agreement and Plan of Merger (the “Merger Agreement”) has been approved, adopted, certified, executed and acknowledged by both of the limited liability companies.
THIRD: The name of the surviving limited liability company of the Merger is Crealta Holdings LLC (the “Surviving Company”).

FOURTH: An executed copy of the Merger Agreement is on file at the principal place of business of the Surviving Company, Crealta Holdings LLC, such address is 520 Lake Cook Road, Suite 520, Deerfield, IL 60015, and a copy of the Merger Agreement will be furnished by the Surviving Company, upon request and without cost, to any member of the limited liability companies or any person holding an interest in any other business entity which is to merge or consolidate.

FIFTH: The Merger shall be effective immediately upon filing.

* * * * *

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IN WITNESS WHEREOF, said limited liability company has caused this certificate to be signed by an authorized person this ___ day of ______, 2015.

Crealta Holdings LLC
a Delaware limited liability company

By:  /s/ ________________
Name: Edward J. Fiorentino
Its: Chief Executive Officer

Certificate of Merger
Letter of Transmittal
For Units of
Crealta Holdings LLC

Surrendered Pursuant to
the Merger of
Criostail LLC with and into Crealta Holdings LLC

The Paying Agent for the Merger is: Continental Stock Transfer & Trust Company

DELIVERY INSTRUCTIONS

By Mail, Hand or Overnight Courier
Continental Stock Transfer & Trust Co.
17 Battery Place- 8th Floor
New York, NY 10004
Attention: Corporate Actions

For information please email: reorg@continentalstock.com or call (917) 262-2378

THE INSTRUCTIONS ACCOMPANYING THIS LETTER OF TRANSMITTAL SHOULD BE READ CAREFULLY BEFORE THIS LETTER OF TRANSMITTAL IS COMPLETED.

DESCRIPTION OF UNITS SURRENDERED

Name and Address of Unitholder
(Please fill in, exactly as name appears on Unit Certificate(s))

Security Position(s) Surrendered (Attach additional signed list if necessary)

<table>
<thead>
<tr>
<th>Type of Unit(s) (e.g., Capital Units, Incentive Units)</th>
<th>Unit Certificate Number(s)</th>
<th>Check box if Lost/Displaced (See Instruction 10)</th>
<th>Number of Units Represented by Unit Certificate(s)</th>
</tr>
</thead>
<tbody>
<tr>
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</tbody>
</table>
DELIVERY OF THIS LETTER OF TRANSMITTAL OR ANY OTHER REQUIRED DOCUMENT TO AN ADDRESS OTHER THAN AS SET FORTH ABOVE DOES NOT CONSTITUTE A VALID DELIVERY.

### CHECK PAYMENT INSTRUCTIONS

If you wish to have the cash consideration to be paid to you in the Merger (as defined herein) in exchange for your Unit(s) sent by check, please complete the remainder of this Letter of Transmittal and provide mailing address instructions below.

<table>
<thead>
<tr>
<th>Address</th>
</tr>
</thead>
<tbody>
<tr>
<td>City, State, Zip</td>
</tr>
<tr>
<td>Country</td>
</tr>
</tbody>
</table>

### WIRE PAYMENT INSTRUCTIONS

If you wish to have the cash consideration to be paid to you in the Merger (as defined herein) in exchange for your Unit(s) sent by wire transfer, please complete the remainder of this Letter of Transmittal and provide wire instructions below or include such instructions herewith. For international wires, please provide the SWIFT code (BIC) in the ABA Number field, and the complete IBAN in the Account Number field, if available. A $50.00 wire transfer fee will be deducted from your payment.

<table>
<thead>
<tr>
<th>Bank Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bank Routing Number (ABA Number)</td>
</tr>
<tr>
<td>Account Name*</td>
</tr>
<tr>
<td>Account Number</td>
</tr>
<tr>
<td>FFC Account Name (if applicable)</td>
</tr>
<tr>
<td>FFC Account Number (if applicable)</td>
</tr>
<tr>
<td>Bank Contact/Telephone Number</td>
</tr>
</tbody>
</table>

*Please provide the name on the account not the type of account. (If wire is to be issued to an account in a name other than that set forth above, See Instructions 3, 4, 5 and 7).

### SPECIAL DELIVERY INSTRUCTIONS

If you wish to have the Merger cash consideration mailed to an address other than as shown in the box on page 1, please complete this box and the remainder of this Letter of Transmittal.

<table>
<thead>
<tr>
<th>Address</th>
</tr>
</thead>
<tbody>
<tr>
<td>City, State, Zip</td>
</tr>
<tr>
<td>Country</td>
</tr>
</tbody>
</table>

### SPECIAL PAYMENT INSTRUCTIONS

(See Instructions 3, 4, 5, 7 and 11)

If you wish to have the cash consideration to be paid in the Merger (as defined herein) in exchange for your Unit(s) to someone other than the named Unitholder, please complete the remainder of this Letter of Transmittal and provide the payment instructions below.**

<table>
<thead>
<tr>
<th>Payee Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>Address</td>
</tr>
<tr>
<td>City, State, Zip</td>
</tr>
<tr>
<td>Country</td>
</tr>
<tr>
<td>Tax Identification Number***</td>
</tr>
</tbody>
</table>

**Requires signature guarantee. See Instruction No. 3 to this Letter of Transmittal.

***Fill in Taxpayer Identification Number of Payee. See Instruction 11 to this Letter of Transmittal.
Reference is made to that certain Agreement and Plan of Merger, dated as of January 13, 2016, ("Merger Agreement"), by and among Crealta Holdings LLC, a Delaware limited liability company ("Company"), Criostail LLC, a Delaware limited liability company ("Merger Sub"), Horizon Pharma USA, Inc., a Delaware corporation [...***...], HZNP Limited, a private company limited by shares organized under the laws of Ireland ("Purchaser," and together with [...***...], “Purchasers”), GTCR Fund X/C LP, a Delaware limited partnership, and GTCR Fund X/B LP, a Delaware limited partnership. Capitalized terms used herein but not defined shall have the meanings specified in the Merger Agreement.

In connection with the merger of Merger Sub with and into Company pursuant to the Merger Agreement (the “Merger”), and as part of the transactions described in the Merger Agreement, the undersigned hereby surrenders the below-described unit certificate(s) (the “Certificate(s)”) representing the Company’s Units ("Company Units"), in exchange for the right to receive, on the terms and subject to the conditions set forth in the Merger Agreement, an amount of cash equal to the Allocable Portion of the Closing Merger Consideration attributable to such Company Unit plus any Additional Merger Consideration attributable to such Company Unit plus any Escrow Distribution attributable to such Company Unit, at the times specified therein.

The undersigned (i) acknowledges that the undersigned has reviewed the Merger Agreement, and understands that the only consideration that the undersigned may be entitled to receive with respect to the undersigned’s Company Units in connection with the Merger is the consideration pursuant to the Merger Agreement (ii) consents to to the adoption and approval of the Merger Agreement and the transactions contemplated thereby, (iii) irrevocably waives any right of dissent under applicable law and (iv) affirms the undersigned’s appointment of the Representative (as defined in the Merger Agreement) pursuant to Section 12.07I of the Merger Agreement (including the limitations set forth therein), which is incorporated by reference herein.

The undersigned acknowledges that, until surrendered in accordance with the terms of the Merger Agreement, each outstanding certificate representing Company Units will be deemed from and after the effective time of the Merger, for all purposes, to evidence only the right to receive cash amounts on the terms and subject to the conditions set forth in the Merger Agreement.

Unless otherwise indicated, the name and address of the owner of the Company Units represented by the Certificate(s) are correctly identified in the table entitled “Description of Units Surrendered” below. The undersigned represents and warrants that the undersigned is the owner of such units or has full power and authority to surrender the Certificate(s) on behalf of such owner, free and clear of all liens, claims and encumbrances. The undersigned will, upon request, execute and deliver any additional documents (the “Additional Documents”) reasonably deemed appropriate or necessary by Continental Stock Transfer & Trust Company (the “Paying Agent”) in connection with the surrender of the Certificate(s), and hereby permits the Paying Agent to send a copy of this Letter of Transmittal and any Additional Documents to the Purchaser. All authority conferred or agreed to be conferred in this Letter of Transmittal shall not be affected by, and shall survive, the undersigned’s death or incapacity, and all of the undersigned’s obligations under this Letter of Transmittal shall be binding upon the undersigned’s successors, assigns, heirs, executors, administrators and legal representatives.

The undersigned understands that surrender of the Certificate(s) will not be in acceptable form until receipt by the Paying Agent of this Letter of Transmittal, duly completed and signed with an original signature, together with all and any Certificate(s).

All questions as to validity, form and eligibility of any surrender of the Certificate(s) hereunder will be determined by the Purchaser (which may delegate power in whole or in part to the Paying Agent) in its reasonable discretion and such determination shall be final and binding. The undersigned understands that delivery of any cash amounts to which the holder of the Certificate(s) is entitled will be made as promptly as practicable after surrender of the Certificate(s) along with the properly completed and executed Letter of Transmittal; provided, however, that the actual amount of consideration to be received by the undersigned is subject to adjustment and the results of certain post-Closing items. The undersigned understands and agrees that a portion of the consideration to which the undersigned may be entitled under the Merger Agreement will be included in (i) escrow funds that will be delivered to an escrow agent (the “Escrow Agent”) and held in escrow pursuant to Section 3.02(e) of the Merger Agreement

***Confidential Treatment Requested
and the terms of the escrow agreement executed among the Escrow Agent, the Representative, the Purchaser and certain other parties thereto on the closing of the Merger (the “Escrow Agreement”), with such amounts to be disbursed by the Escrow Agent in accordance with the Escrow Agreement and (ii) a holdback amount which will be delivered to the Representative and held by the Representative pursuant to Section 1.08 of the Merger Agreement, with such amount to be disbursed by the Representative in accordance with the Merger Agreement. The undersigned further understands that the undersigned may in the future become entitled to receive all, a portion or none of the cash deposited in escrow with the Escrow Agent and of the holdback amount held by the Representative pursuant to Section 1.08 of the Merger Agreement.

The undersigned hereby acknowledges receipt of the documents delivered with this Letter of Transmittal, including, without limitation the Merger Agreement and a Form W-9 or Form W-8 (collectively with this Letter of Transmittal, the “Specified Documents”). The undersigned acknowledges that the undersigned has had the opportunity to review the Specified Documents, that the undersigned has consulted, or had the full opportunity to consult, with independent legal, tax, accounting, regulatory and financial advisors regarding the undersigned’s rights and obligations under the Specified Documents and that the undersigned fully understands the terms and conditions contained, and the transactions provided for, herein and therein. The undersigned further acknowledges and agrees to follow the instructions in the “Instructions” section in this Letter of Transmittal.

The undersigned hereby irrevocably constitutes and appoints the Representative as the true and lawful agent, proxy and attorney-in-fact of the undersigned with respect to the Company Units listed in the “Description of Units Surrendered” section of this Letter of Transmittal, and any and all rights represented thereby, with full power of substitution and resubstitution (such power of attorney being deemed to be an irrevocable power coupled with an interest) and authority, to act in the name, place and stead of the undersigned for purposes of executing any documents and taking any actions that the Representative may, in its sole discretion, determine to be necessary, desirable or appropriate within the bounds of the Representative’s authority under the express terms of the Merger Agreement, including in connection with any claim for indemnification, compensation or reimbursement under Article XII of the Merger Agreement or any of the transactions contemplated thereby (subject to the limitations set forth therein). The authority herein conferred or agreed to be conferred shall not be affected by, and shall survive, the death, incapacity or dissolution of the undersigned, and all grants, appointments, acknowledgments, conveyances, deliveries, waivers and obligations of the undersigned hereunder shall be binding upon the heirs, executors, administrators, trustees in bankruptcy, personal and legal representatives, successors and assigns of the undersigned. This transmittal, and the surrender of Company Unit(s) transmitted by this Letter of Transmittal, are irrevocable, provided that, if the Transaction is not consummated, this Letter of Transmittal will be returned to the undersigned.

The undersigned hereby irrevocably waives all right to trial by jury in any action, proceeding or counterclaim (whether based on contract, tort or otherwise) arising out of or relating to this Letter of Transmittal or the actions of the parties hereto in the negotiation, administration, performance and enforcement hereof.

The undersigned understands and agrees that the method of delivery of the Company Units and this Letter of Transmittal is at the election and risk of the holder of the Company Units. The undersigned hereby acknowledges that the undersigned has read the “Instructions” section in this Letter of Transmittal.

With respect to the undersigned’s surrendered Company Units, this Letter of Transmittal shall be void and of no force and effect if the Closing pursuant to the Merger Agreement fails to occur for any reason and the Merger Agreement is terminated in accordance with its terms.

The undersigned hereby (i) forever waives all dissenter’s, appraisal or similar rights under Delaware law and any other applicable laws, and (ii) withdraws all written objections to the Merger and/or demands for appraisal, if any, with respect to the Company Units owned by the undersigned.
IMPORTANT - UNITHOLDER SIGNATURE PAGE

Must be signed by the named unitholder exactly as his, her or its name appears on the unit certificate(s). Signature below certifies that no language alterations have been made in any way to this form of Letter of Transmittal. If signature is by a trustee, executor, administrator, guardian, attorney-in-fact, officer of a corporation or other person acting in a fiduciary or representative capacity, please set forth full title. See Instruction 4. (For information concerning signature guarantees see Instruction 3.)

Dated ________________

Sign Here X__________________________

(Signature of Owner)

Name(s) ________________________________

(Please Print)

Capacity ________________________________

(See Instruction 4)

Address ______________________________________________________________________

Area Code & Telephone No. ______________

Email Address __________________________________________________________________

Tax Identification No. (e.g., Social Security No.)

(Also complete the enclosed Form W-9 or provide the appropriate Form W-8, as applicable.)

STOP – CAREFULLY REVIEW INSTRUCTION 3 PRIOR TO COMPLETING REMAINDER OF PAGE

SIGNATURE GUARANTEE

(This section should be completed by the individual applying the MSG Stamp)

(Apply Medallion Signature Guarantee Stamp Here)
INSTRUCTIONS

Delivery of Letter of Transmittal and Certificate(s). This Letter of Transmittal or a facsimile hereof, filled in and signed with an original signature, must be used in connection with the delivery and surrender of the Certificate(s). A Letter of Transmittal and the Certificate(s) must be received by the Paying Agent, in satisfactory form, in order to make an effective surrender. Delivery of the Certificate(s) and other documents shall be effected, and the risk of loss and title to the Certificate(s) shall pass, only upon proper delivery of the Certificate(s) to the Paying Agent. The method of delivery of the Certificate(s) and other documents is at the election and risk of the unitholder. If such delivery is by mail, registered mail with return receipt requested, properly insured, is recommended. Surrender may be made by mail, by hand or by overnight courier to Continental Stock Transfer & Trust Company, as Paying Agent, at the address shown above.

Terms of Conversion of the Units. Each Company Unit (as shown in the box on the first page of this Letter of Transmittal) will be converted at the effective time of the Merger into the right to receive the cash amounts as set forth and described in the Merger Agreement, without interest, and subject to applicable withholding.

Guarantee of Signature. The Certificate(s) need not be endorsed and unit powers and signature guarantees are unnecessary unless (a) the Certificate(s) is registered in a name other than that of the person surrendering the Certificate(s) or (b) such registered holder completes the Special Payment Instructions or Special Delivery Instructions. In the case of (a) above, any such Certificate(s) must be duly endorsed or accompanied by a properly executed unit power with the signature on the endorsement or unit power and on the Letter of Transmittal guaranteed by a participant in the Security Transfer Agents Medallion Program, the New York Stock Exchange Medallion Signature Guarantee Program or the Stock Exchange Medallion Program (each, an “Eligible Institution”). In the case of (b) above, only the signature on the Letter of Transmittal should be similarly guaranteed.

Signatures on Letter of Transmittal and Endorsements. The signature must correspond with the name as written on the face of the Certificate(s) without alteration, enlargement or any change whatsoever.

If this Letter of Transmittal is signed by a trustee, executor, administrator, guardian, attorney-in-fact, officer of a corporation or other person acting in a fiduciary or representative capacity, such person should so indicate when signing, and proper evidence reasonably satisfactory to the Paying Agent of the authority of such person so to act must be submitted.

Unit Transfer Taxes. If any payment for surrendered Company Units is to be made to any person(s) other than the person whose name is written on the face of the Certificate(s) representing such surrendered Company Units, it shall be a condition of the issuance and delivery of such check that the amount of any unit transfer taxes (whether imposed on the named unitholder or such person(s)) payable on account of the transfer (or transfers) of the surrendered Company Units shall be delivered to the Paying Agent or satisfactory evidence of the payment of such taxes or nonapplicability thereof shall be submitted to the Paying Agent before such check will be issued.

Validity of Surrender, Irregularities. All questions as to validity, form and eligibility of any surrender of Company Units hereby will be determined by Purchaser (which may delegate power in whole or in part to the Paying Agent) and such determination shall be final and binding; provided that if there are any defects in the surrender of the Certificate(s), Purchaser or the Paying Agent shall give notice of such defects to the named unitholder. Purchaser reserve the right to waive any irregularities or defects in the surrender of any Company Units and its interpretations of the terms and conditions of the Merger Agreement and of this Letter of Transmittal (including these instructions) with respect to such irregularities or defects shall be final and binding. A surrender will not be deemed to have been made until all irregularities have been cured or waived.

Special Payment Instructions. Indicate the name (and address) to which payment for the Company Units is to be made if different from the name of the person(s) signing this Letter of Transmittal. This transfer requires a Medallion Guarantee Program stamp which can be found at most banks and brokerages.
Requests for Information or Additional Copies. Information or additional copies of this Letter of Transmittal may be obtained from the Paying Agent by writing to the address on the front of this Letter of Transmittal or by calling the Paying Agent at (917) 262-2378.

Inadequate Space. If the space provided on this Letter of Transmittal is inadequate, the Company Unit certificate numbers and number of Company Units should be listed on a separate signed schedule affixed hereto.

Letter of Transmittal Required; Surrender of Certificate(s); Lost Certificate(s). You will not receive any consideration for your Company Units unless and until you deliver this Letter of Transmittal or a facsimile hereof, duly completed and signed, with original signature to the Paying Agent, together with the Certificate(s) representing such Company Units and any required accompanying evidences of authority in form satisfactory to Purchaser. If the Certificate(s) has (have) been lost or destroyed, such fact should be indicated on the face of this Letter of Transmittal. In such event, the Paying Agent will forward additional documentation and instructions necessary to be completed in order to effectively surrender the Company Units represented by such lost or destroyed Certificate(s) (including instructions relating to payment by holder of such lost or destroyed Certificate(s) of an indemnity/surety bond premium equal to 3% of the cash value of the Company Units represented by such Certificate(s) with a minimum of $100.00. No interest will be paid on amounts due for the Company Units.

11. Form W-9. Each unitholder surrendering Units for payment is required to provide the Paying Agent with such holder’s correct Taxpayer Identification Number (“TIN”) and certain other information on a Form W-9 (included in this Letter of Transmittal), or an appropriate IRS Form W-8, as described below. Failure to provide such information or an adequate basis for exemption from backup withholding on the form may subject such holder to federal income tax withholding on cash payments made with respect to certificates by the Payor (as defined below). Please consult the instructions to the enclosed Form W-9 for instructions on how to complete the Form W-9.
IMPORTANT TAX INFORMATION

United States federal income tax law generally requires that if your units are accepted for payment and you are a U.S. Person (as defined below), you or your assignee (in either case, the “Payee”), must provide Purchaser (the “Payor”) with the Payee’s correct TIN, which, in the case of a Payee who is an individual, is generally the Payee’s social security number. If the Payor is not provided with the correct TIN or an adequate basis for an exemption, the Payee may be subject to a $50 penalty imposed by the IRS and backup withholding in an amount equal to 28% (or the then-prevailing rate) of the proceeds received by the Payee pursuant to the Merger. Backup withholding is not an additional tax. Rather, the tax liability of a person subject to backup withholding will be reduced by the amount withheld by the Payor (through the Paying Agent). If withholding results in an overpayment of taxes, a refund may be obtained from the IRS, provided the appropriate information and forms are provided to the IRS and other requirements are satisfied.

To prevent backup withholding, each Payee that is a U.S. Person must provide such Payee’s correct TIN by completing the Form W-9 set forth herein, certifying that (i) the TIN provided is correct, (ii) (a) the Payee is exempt from backup withholding, (b) the Payee has not been notified by the IRS that such Payee is subject to backup withholding as a result of a failure to report all interest or dividends, or (c) the IRS has notified the payee that such Payee is no longer subject to backup withholding, and (iii) the Payee is a U.S. Person (including a U.S. resident alien). For these purposes, a “U.S. Person” is (a) an individual who is a U.S. citizen or U.S. resident alien, (b) a partnership, corporation, company or association created or organized in the United States or under the laws of the United States, (c) an estate (other than a foreign estate), or (d) a domestic U.S. trust (as defined in Treasury Regulation Section 301.7701-7).

If the Payee does not have a TIN, such Payee should apply for and receive a TIN prior to submitting the Form W-9; please consult the instructions to the enclosed Form W-9 (the “W-9 Instructions”) for instructions on applying for a TIN. If the Payee does not provide such Payee’s TIN to the Payor by the time of payment, backup withholding will apply.

If the Company Units are held in more than one name or held in a name other than the name of the actual owner, consult the W-9 Instructions for information on which TIN to report.

Exempt Payees are not subject to these backup withholding and reporting requirements. To prevent possible erroneous backup withholding, an exempt Payee that is a U.S. Person should check the “exempt from backup withholding” box on the Form W-9. See the W-9 Instructions for additional instructions. In order for a Payee that is not a U.S. Person to avoid backup withholding, such Payee must submit an appropriate and properly completed Form W-8BEN, W-8BEN-E, W-8ECI, W-8EXP or W-8IMY, signed under penalties of perjury. Such forms, as well as instructions for the same, may be obtained from the IRS at its Internet website: www.irs.gov.
EXHIBIT C

AMENDED AND RESTATED LIMITED LIABILITY COMPANY AGREEMENT

OF

CREALTA HOLDINGS LLC

This Amended and Restated Limited Liability Company Agreement (this “Agreement”) of Crealta Holdings LLC a Delaware limited liability company (the “Company”), is entered into as of [_____] by the parties listed on the attached Exhibit A as the members of the Company (the “Members”).

RECITALS

WHEREAS, the Company was formed on July 26, 2013, as a limited liability company under the Delaware Limited Liability Company Act (6 Del.C. §18-101, et seq.), as amended from time to time (the “Act”);

WHEREAS, the Company adopted a limited liability company agreement on July 26, 2013, (the “Prior Agreement”);

WHEREAS, the Members now desire to amend and restate the terms of the Prior Agreement to provide for the rights and obligations set forth herein;

WHEREAS, upon the effectiveness of this Agreement, the Prior Agreement will be superseded in all respects by the terms of this Agreement.

NOW, THEREFORE, for good and valuable consideration, the receipt and sufficiency of which are hereby established, the Company and the Members hereby agree as follows:

AGREEMENT

1. **Formation.** The Company has been organized as a Delaware limited liability company by the filing of a Certificate of Formation (the “Certificate”) under and pursuant to the Act.

2. **Name.** The name of the Company is Crealta Holdings LLC.

3. **Registered Office; Registered Agent; Principal Office; Other Offices.** The registered office of the Company required by the Act to be maintained in the State of Delaware shall be the registered office set forth in the Certificate or such other office (which need not be a place of business of the Company) as the Board may designate from time to time in the manner provided by law. The registered agent of the Company in the State of Delaware shall be the initial registered agent named in the Certificate or such other person or persons as the Board may designate from time to time in the manner provided by law. The principal office of the Company shall be at such place as the Board may designate from time to time, which need not be in the State of Delaware, and the Company shall maintain records there.

4. **Purposes.** The purposes of the Company are to engage in any business or activity that is not prohibited by the Act.
5. **Term.** The existence of the Company commenced on the date the Certificate was filed with the office of the Secretary of State of Delaware and shall continue until the Company is dissolved pursuant to Section 13 of this Agreement.

6. **Members.** The names of each Member and the membership interests held by each Member are listed on the attached Exhibit A.

7. **Liability of Members.** Except as otherwise required by the Act, no Member shall have any personal liability whatsoever in such Member’s capacity as a Member, whether to the Company, to the creditors of the Company or to any other third party, for the debts, liabilities, commitments or any other obligations of the Company or for any losses of the Company.

8. **Management.**

   (a) All management powers over the business and affairs of the Company shall be exclusively vested in a board of managers (the “Board”) appointed from time to time by the Members, and the Board shall conduct, direct and exercise full control over all activities of the Company. Each member of the Board is referred to herein as a “Manager.” The Managers shall be the “managers” of the Company for the purposes of the Act. The Board has the full power on the Company’s behalf, in its name, to manage, control, administer and operate its business and affairs and to do or cause to be done anything necessary or appropriate for the Company’s business. The Managers are hereby designated as authorized persons, within the meaning of the Act, to execute, deliver and file the certificate of formation of the Company and all other certificates (and any amendments and/or restatements hereof) required or permitted by the Act to be filed in the Office of the Secretary of State of the State of Delaware.

   (b) The initial number of Managers shall be two (2). The number of Managers of the Company shall be fixed from time to time by the Members. The initial Managers shall be Timothy P. Walbert and Paul W. Hoelscher. Each Manager shall hold his office for the term for which he was appointed and thereafter until his successor shall have been appointed, or until his earlier death, resignation or removal. A Manager need not be a Member or a resident of the State of Delaware.

   (c) Any Manager position to be filled by reason of an increase in the number of Managers or by any other reason shall be filled by the Members. Any Manager may be removed by the Members at any time. Any Manager may resign at any time. Such resignation shall be made in writing and shall take effect at the time specified therein, or if no time is specified, at the time of its receipt by the remaining Manager(s). The acceptance of a resignation shall not be necessary to make it effective, unless expressly so provided in the resignation.

   (d) The Board may act (i) through meetings and written consents pursuant to Section 8(e) and (ii) through any person or persons to whom authority and duties have been delegated pursuant to Section 8(f).

   (e) Each Manager shall have one vote on all matters submitted to the Board (whether the consideration of such matter is taken at a meeting, by written consent or otherwise). The affirmative vote of the Managers holding a majority of the votes of the Managers shall be the act of the Board. Meetings of the Board shall be held at the principal office of the Company or at such other place as may be determined by the Board. A majority of the Managers, present in person or through their duly authorized attorneys-in-fact, shall constitute a quorum at any meeting of the Board. Business may be conducted once a quorum is present. Regular meetings of the Board shall be held on such dates and at such times as shall be determined by the Board. Special meetings of the Board may be called by a majority of all of the Managers on at least 24 hours’ prior written notice to the other Managers, which
notice shall state the purpose or purposes for which such meeting is being called. The actions taken by the Board at any meeting, however called and noticed, shall be as valid as though taken at a meeting duly held after regular call and notice if (but not until), either before, at or after the meeting, the Manager as to whom it was improperly held signs a written waiver of notice or a consent to the holding of such meeting or an approval of the minutes thereof. The actions by the Board may be taken by vote of the Board at a meeting of the Managers thereof or by written consent (without a meeting, without notice and without a vote) so long as such consent is signed by at least the minimum number of Managers that would be necessary to authorize or take such action at a meeting of the Board in which all Managers were present. Prompt notice of the action so taken without a meeting shall be given to those Managers who have not consented in writing. Each meeting of the Board shall, at the request of any Manager, be held by conference telephone or similar communications equipment by means of which all individuals participating in the meeting can be heard.

(f) The Board may, from time to time, designate one or more persons to be officers of the Company. No officer need be a resident of the State of Delaware, a Member or a Manager. Any officers so designated shall have such authority and perform such duties as the Board may, from time to time, delegate to them. The Board may assign titles to particular officers. Unless the Board otherwise decides, if the title is one commonly used for officers of a business corporation, the assignment of such title shall constitute the delegation to such officer of the authority and duties that are normally associated with that office, subject to any specific delegation of authority and duties made to such officer by the Board. Each officer shall hold office until his successor shall be duly designated and shall qualify or until his death or until he shall resign or shall have been removed in the manner hereinafter provided. Any number of offices may be held by the same individual. Any officer may resign as such at any time. Such resignation shall be made in writing and shall take effect at the time specified therein, or if no time be specified, at the time of its receipt by the Board. The acceptance of a resignation shall not be necessary to make it effective, unless expressly so provided in the resignation. Any officer may be removed as such, either with or without cause, by the Board whenever in its judgment the best interests of the Company shall be served thereby. The initial officers of the Company shall be as follows:

- President and Chief Executive Officer — [***...]
- Chief Financial Officer and Secretary – [***...]
- Executive Vice President and Chief Medical Officer – [***...]
- Executive Vice President and Chief Business Officer – [***...]

(g) Each Manager of the Company may at any time and from time to time engage in and own interests in other business ventures of any and every type and description, independently or with others (including ones in competition with the Company) with no obligation to offer to the Company the right to participate therein.

9. Member Meetings, etc.

(a) No Member, unless such Member is also a Manager, shall have any right, power or duty, including the right to approve or vote on any matter, except as expressly required by the Act or other applicable law or as expressly provided for hereunder. Except as otherwise expressly provided by this Agreement or as required by the Delaware Act, acts by the Members holding a majority of the membership interests of the Company shall be the act of the Members.

(b) The actions by the Members permitted hereunder may be taken at a meeting called by the Board or by Members holding a majority of the membership interests of the Company on at least twenty-four hours’ prior written notice to the other Members entitled to vote, which notice shall state the purpose or purposes for which such meeting is being called. The actions taken by the Members

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entitled to vote or consent at any meeting (as opposed to by written consent), however called and noticed, shall be as valid as though
taken at a meeting duly held after regular call and notice if (but not until), either before, at or after the meeting, the Members entitled to
vote or consent as to whom it was improperly held signs a written waiver of notice or a consent to the holding of such meeting or an
approval of the minutes thereof.

(c) The actions by the Members entitled to vote or consent may be taken by vote of the Members entitled to vote
or consent by written consent (without a meeting, without notice, and without a vote) so long as such consent is signed by the Members
having not less than the minimum number of membership interests that would be necessary to authorize or take such action at a
meeting at which all Members entitled to vote thereon were present and voted. Prompt notice of the action so taken without a meeting
shall be given to those Members entitled to vote or consent who have not consented in writing. Any action taken pursuant to such
written consent of the Members shall have the same force and effect as if taken by the Members at a meeting thereof. A meeting of the
Members may be held by conference telephone or similar communications equipment by means of which all individuals participating in
the meeting can be heard.

10. Indemnification.

(a) No officer or Manager shall be liable to any other officer, Manager, the Company or to any Member for any
loss suffered by the Company or any Member unless such loss is caused by such person’s willful misconduct, violation of law or
material breach of this Agreement. The officers and Managers shall not be liable for errors in judgment or for any acts or omissions that
do not constitute willful misconduct, violation of law or material breach of this Agreement; provided, however, that each Manager and
each officer shall discharge his duties hereunder in good faith, with the care a corporate director or officer of like position would
exercise under similar circumstances, in the manner he, she or it reasonably believes to be in the best interest of the Company. Any
officer or Manager may consult with counsel and accountants in respect of Company affairs, and provided such person acts in good
faith reliance upon the advice or opinion of such counsel or accountants, such person shall not be liable for any loss suffered by the
Company or any Member in reliance thereon.

(b) Subject to the limitations and conditions as provided in this Section 10, each person who was or is made a party or is
threatened to be made a party to or is involved in any threatened, pending or completed action, suit or proceeding, whether civil,
criminal, administrative, arbitrage (hereinafter, a “Proceeding”), or any appeal in such a Proceeding or any inquiry or investigation that
could lead to such a Proceeding, by reason of the fact that he or she, or a person of whom he or she is the legal representative, is or was
a member, Manager or officer, or while a member, Manager or officer is or was serving at the request of the Company as a manager,
director, officer, partner, venturer, proprietor, trustee, employee, agent or similar functionary of another foreign or domestic limited
liability company, corporation, partnership, joint venture, sole proprietorship, trust, employee benefit plan or other enterprise, shall be,
indemnified by the Company to the fullest extent permitted by the Delaware Act, as the same exists or may hereafter be amended (but,
in the case of any such amendment, only to the extent that such amendment permits the Company to provide broader indemnification
rights than said law permitted the Company to provide prior to such amendment) against judgments, penalties (including excise and
similar taxes and punitive damages), fines, settlements and reasonable expenses (including attorney’s fees actually incurred by such
person in connection with such Proceeding, and. Indemnification under this Section 10 shall continue as to a person who has ceased to
serve in the capacity which initially entitled such person to indemnity hereunder. The rights granted pursuant to this Section 10 shall be
deemed contract rights and shall vest immediately upon commencement of such person’s status as a member, Manager, officer,
manager, director, partner, venturer, proprietor, trustee, employee, agent or similar functionary, and no amendment, modification or
repeal of this Section 10 shall have the effect of limiting

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or denying any such rights with respect to actions taken or Proceedings arising prior to any amendment, modification or repeal. It is expressly acknowledged that the indemnification provided in this Section 10 could involve indemnification for negligence or under theories of strict liability.

(c) Reasonable expenses incurred by a person of the type entitled to be indemnified under Section 10(b) who was, is or is threatened to be made a named defendant or respondent in a Proceeding shall be paid by the Company in advance of the final disposition of the Proceeding upon receipt of an undertaking by or on behalf of such person to repay such amount if it shall ultimately be determined that he or she is not entitled to be indemnified by the Company; provided that, except as otherwise determined by the Board of Managers, no expenses shall be paid by the Company pursuant to this Section 10(c) in advance of the final disposition of a Proceeding if the party initiating the Proceeding is the Company, any of its subsidiaries or any of their respective securityholders acting by or in the right of the Company or any its subsidiaries.

(d) The Company, by adoption of a resolution of the Board of Managers, may indemnify and advance expenses to an employee or agent of the Company to the same extent and subject to the same conditions under which it may indemnify and advance expenses to persons who are not or were not Managers or officers but who are or were serving at the request of the Company as a manager, director, officer, partner, venturer, proprietor, trustee, employee, agent or similar functionary of another foreign or domestic limited liability company, corporation, partnership, joint venture, sole-proprietorship, trust, employee benefit plan or other enterprise against any liability asserted against him and incurred by him in such a capacity or arising out of his status as such a person to the same extent that it may indemnify and advance expenses to Managers and officers under this Section 10.

(d) Notwithstanding any other provision of this Section 10, the Company shall pay or reimburse reasonable out-of-pocket expenses incurred by a Manager or officer in connection with his appearance as a witness or other participation in a Proceeding at a time when he is not a named defendant or respondent in the Proceeding.

(e) The right to indemnification and the advancement and payment of expenses conferred in this Section 10 shall not be exclusive of any other right which Manager, officer or other person indemnified pursuant to Section 10(b) (an “Indemnitee”) may have or hereafter acquire under any law (common or statutory), provision of the Company’s certificate of formation, this Agreement, vote of the Members or disinterested Managers or otherwise.

(f) The Company may purchase and maintain insurance, or cause its subsidiaries to purchase and maintain insurance, at its or their expense, to protect itself and any person who is or was serving as a Manager, officer or agent of the Company or is or was serving at the request of the Company as a manager, director, officer, partner, venturer, proprietor, trustee, employee, agent or similar functionary of another foreign or domestic limited liability company, corporation, partnership, joint venture, sole proprietorship, trust, employee benefits plan or other enterprise against any expense, liability or loss, whether or not the Company would have the power to indemnify such person against such expense, liability or loss under this Section 10.

(g) Each Member and its affiliates shall be considered express third party beneficiaries of this Section 10, and in the event that such Member or any of its affiliates indemnifies any person who has a right to indemnification from the Company pursuant to this Section 10, such Member or affiliate thereof shall be entitled to subrogation against the Company. The Company is primarily obligated to provide indemnity pursuant to this Section 10 and waives any right to indemnification, subrogation, or contribution against such Member or affiliate thereof.
(h) If this Section 10 or any portion hereof shall be invalidated on any ground by any court of competent jurisdiction, then the Company shall nevertheless indemnify and hold harmless each Manager, officer or any other person indemnified pursuant to this Section 10 as to costs, charges and expenses (including attorneys’ fees), judgments, fines and amounts paid in settlement with respect to any action, suit or proceeding, whether civil, criminal, administrative or investigative to the full extent permitted by any applicable portion of this Section 10 that shall not have been invalidated and to the fullest extent permitted by applicable law.

11. **Certificates.** The membership interests of each Member shall be uncertificated unless otherwise determined by the Board.

12. **Distributions.** Distributions shall be made to the Members at the time and in the aggregate amounts determined by the Board.

13. **Allocations of Profits and Losses.** The Company’s profits and losses shall be allocated to the Members in accordance with the membership interests held by each Member as set forth on the attached [Exhibit A](#).

14. **Dissolution.** The Company shall dissolve, and its affairs shall be wound up upon the first to occur of the following: (a) the written consent of the Members, (b) any time there are no members of the Company unless the Company is continued in accordance with the Act, or (c) the entry of a decree of judicial dissolution under Section 18-802.

15. **Capital Contributions.** The Members have contributed the amount in cash set forth on [Exhibit A](#) hereto.

16. **Additional Contributions.** The Members are not required to make any additional capital contribution to the Company.

17. **Assignments.** Each Member may assign in whole or in part its limited liability company interest.

18. **Admission of Additional Members.** One or more additional members of the Company may be admitted to the Company with the consent of the Board.

19. **Governing Law.** This Agreement shall be governed by, and construed under, the laws of the State of Delaware, all rights and remedies being governed by said laws.

* * * * * * *

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IN WITNESS WHEREOF, the undersigned, intending to be legally bound hereby, have duly executed this Amended and Restated Limited Liability Company Agreement as of the date first written above.

MEMBERS:

[...***...]

By: __________________________
Name:
Title:

[...***...]

By: __________________________
Name:
Title:

***Confidential Treatment Requested

[Amended and Restated Limited Liability Company Agreement]
Exhibit A

Names and Capital Contributions, and Membership Interests of the Members

[…***…]

***Confidential Treatment Requested
Rules of Engagement for Accounting Firm

If an Accounting Firm is engaged pursuant to Section 2.01, the parties will instruct the Accounting Firm to analyze and resolve the parties’ dispute in accordance with the following guidelines (which guidelines and relevant portions of this Agreement the Accounting Firm will be required to review and commit to acting in accordance with):

Retainer and Fees

The fees, costs and expenses of the Accounting Firm shall be borne by the parties in inverse proportion to the relative success of the parties relating to the disputed items submitted to the Accounting Firm, with such determination of relative success made by the Accounting Firm, or if the Accounting Firm is unwilling to make such a determination, then such fees, costs and expenses shall be borne 50% by the Purchaser and 50% by the Representative (on behalf of the Sellers).

To the extent the Accounting Firm requires a retainer or payment of expenses prior to its final determination, the Purchaser and the Representative (on behalf of the Sellers) will each pay 50% of any retainer and, during the engagement, the Accounting Firm will bill 50% of the total charges to the Purchaser and 50% of the total charges to the Representative (on behalf of the Sellers). Such fees, costs and expenses of the Accounting Firm shall be adjusted, if necessary, pursuant to the first paragraph of this “Retainer and Fees” section.

Parameters of Arbitration

Except as permitted herein in order to clarify or understand any position or argument made by a party in its written submission, the Accounting Firm's determination of the Net Working Capital, the Closing Date Indebtedness, the Transaction Expenses, and the amount of the Closing Date Cash and the resulting Final Merger Consideration shall be based solely on written presentations submitted by the Purchaser and the Representative which are in accordance with the guidelines and procedures (including the definitions of Closing Date Cash, Closing Date Indebtedness, Transaction Expenses and Net Working Capital) set forth in this Agreement (i.e., not on the basis of an independent review). The Accounting Firm shall consider only the disputed matters that were included in the Objections Statement and the Accounting Firm may not assign a value to any item in dispute greater than the greatest value assigned by the Purchaser in the Preliminary Statement, on the one hand, or the Representative in the Objections Statement, on the other hand, or less than the smallest value for such item assigned by the Purchaser in the Preliminary Statement, on the one hand, or the Representative in the Objections Statement, on the other hand.

The timetable for these proceedings will be governed by the following procedures:

- Within fourteen (14) calendar days of retaining the Accounting Firm, each of the Purchaser and the Representative shall submit to the Accounting Firm a memorandum (which may include supporting exhibits) setting forth their respective
positions of all unresolved disputed items in accordance with Section 2.01 of this Agreement (the “Initial Report”).

• Within one (1) Business Day upon receipt of both the Purchaser’s and the Representative’s Initial Reports, the Accounting Firm will distribute a copy of each Initial Report to the other party.

• Within fourteen (14) calendar days of receiving the other party’s Initial Report from the Accounting Firm, each of the Purchaser and the Representative may (but shall not be required to) submit to the Accounting Firm a memorandum responding to the Initial Report submitted to the Accounting Firm by the other party (the “Rebuttal Report”). The Rebuttal Report is to be responsive solely to the arguments raised, and information submitted, by the other party in its Initial Report and no party may introduce new arguments or rely on new information in the Rebuttal Report that was not part of such party’s Initial Report or which are not directly responsive to an argument raised by the other party’s Initial Report, except to the extent such new arguments or new information are used in direct response to arguments raised and information submitted by the other party in its Initial Report.

• Within one (1) Business Day upon receipt of the Rebuttal Reports from the Purchaser and the Representative, the Accounting Firm will distribute a copy of each Rebuttal Report to the other party.

• At any time before or within fifteen (15) calendar days after the submission of the Initial Reports or any Rebuttal Reports by the Purchaser and the Representative, the Accounting Firm may submit written questions to either party following the procedures set forth below in the Section titled “Submission of Questions by the Accounting Firm.”

• Upon receipt of the Rebuttal Report or notice waiving the right to file such report from both the Purchaser and the Representative and receipt of all responses to any written questions submitted by the Accounting Firm (and responses thereto), the Accounting Firm will endeavor to issue a report containing its findings within fifteen (15) calendar days after the later of (i) receiving both the Purchaser’s and the Representative’s Rebuttal Reports or notice waiving the right to file such report, as applicable, or (ii) any responses (if any) to any written questions submitted by the Accounting Firm to either party following the procedures set forth below in the Section titled “Submission of Questions by the Accounting Firm.”

• Unless requested by the Accounting Firm in writing pursuant to the terms of the Section titled “Submission of Questions by the Accounting Firm”, neither the Purchaser nor the Representative may present any additional information or arguments to the Accounting Firm, either orally or in writing.

• The Accounting Firm shall render its decision without conducting a hearing.

Submission of Questions by the Accounting Firm

After receiving both Initial Reports and Rebuttal Reports, if any, the Accounting Firm may submit written questions to the parties for written responses or may direct requests for additional information, calculations, or supporting documentation to the parties reasonably needed by the Accounting Firm in order to clarify or understand any position or argument made by a party in
its written submission, in which case the parties agree to use commercially reasonable efforts to cooperate with such requests (including, without limitation, by ensuring that the Accounting Firm is provided copies of all relevant records of the business in accordance with Article 1.10(b) of this Agreement) in the manner and procedural timing described in this paragraph. If any such questions are addressed to only one party, the Accounting Firm shall submit the questions to that party, with a copy to the other parties. Once received, the party (or parties) to whom the questions are addressed shall have five (5) Business Days to answer the Accounting Firm's questions, and shall provide a copy of its written answers to the other party at the time they are provided to the Accounting Firm. In response thereto, the other party may, within five (5) Business Days, submit a response to such answer(s) to the Accounting Firm and shall provide a copy of a response to the other party at the time it is provided to the Accounting Firm. If any such questions are addressed to both parties, each party shall have five (5) Business Days from the date of receipt to respond to the Accounting Firm and shall provide a copy of its written answers to the other parties at the time they are provided to the Accounting Firm. In response thereto, each party may, within five (5) Business Days, submit a response to the other party’s answer(s) to the Accounting Firm and shall provide a copy to the other party at the time it is provided to the Accounting Firm.

**Adjustment of Time Periods**

If the due date for any written submissions to be submitted to the Accounting Firm falls on a day that is not a Business Day, the written submission shall take place on the next Business Day.

**Communication between the Accounting Firm and the Parties**

The parties agree not to engage in any ex parte communication with the Accounting Firm.

The Accounting Firm will be required to include a representation in its engagement letter that it has not discussed the substance of the disputed matter with either party prior to its joint retention by the parties, and to include a covenant in its engagement letter not to engage in ex parte communications with either party throughout the course of the engagement.

The engagement letter will specifically require the Accounting Firm to review Article 1.10(b) of this Agreement, as well as any other provisions of this Agreement deemed relevant by any of the Purchaser, the Seller or the Accounting Firm.

**Nature of Review by Accounting Firm**

The Accounting Firm will make its determination in an objective, impartial manner based on inquiry, investigation, and other procedures as it, in its sole discretion may deem necessary, but in all cases consistent with the terms of this Agreement and this Exhibit D.

The Accounting Firm shall agree that between the time the Representative delivered the Objections Statement to the Purchaser and the date hereof, the Purchaser and the Representative may have exchanged certain proposals relating to the disputed items that were intended solely for purposes of facilitating settlement discussions and such proposals were confidential and were provided solely on the condition and understanding that such proposals would not be permitted to be disclosed in any court or arbitration hearing, including with respect to the Accounting
Firm’s engagement in the dispute. The Accounting Firm will be instructed to disregard any evidence of such settlement proposals and negotiations in its consideration of the disputed matter.

Confidentiality

With respect to any information supplied in connection with the Accounting Firm’s engagement and designated by either party as confidential, or which either party should reasonably believe is confidential based on the subject matter or the circumstances of its disclosure, the other party agrees to protect such confidential information in a reasonable and appropriate manner, and use confidential information only to perform its obligations under this Agreement and for no other purpose. This will not apply to information which is: (i) already publicly known prior to such disclosure (and through no breach of the confidentiality obligations hereunder by the recipient thereof), or (ii) disclosed pursuant to legal requirement or order. Notwithstanding the foregoing, no information (whether or not designated as confidential) may be provided to the Accounting Firm without being made available to all parties in accordance with the requirements of this Agreement and this Exhibit D. The Accounting Firm shall not publicly disclose that it has been retained to resolve any dispute relating to this Agreement or that it is involved in the dispute, or any information relating to the dispute.

At the conclusion of the engagement contemplated hereby, confidential information made available hereunder, including copies thereof, shall be returned or destroyed upon request by the disclosing party.

Other Procedural Matters

Procedural matters for the conduct of the dispute resolution, other than as specified herein, will be determined by the Accounting Firm in consultation with the Purchaser and the Representative; provided, however, that any such procedural matters shall in all cases be consistent with the terms of this Agreement and this Exhibit D.

Conflicts of Interest

Except in connection with the dispute being resolved with respect to this Agreement, during the term of this engagement, neither the Accounting Firm nor any member of the Accounting Firm’s team may work on any matters related to the Purchaser, the Representative, the Sellers or any of their respective Affiliates (or such Affiliates’ portfolio companies) or Subsidiaries or otherwise perform services to any entity or individual that may present a conflict of interest that could reasonably affect the Accounting Firm’s services or the unbiased performance of services by any member of the Accounting Firm’s team. The foregoing restrictions on the Accounting Firm will not apply to employees of the Accounting Firm not assigned to work on this engagement.
Citi Preferred Custody Services

Agreement
Between
Citibank, N. A.
as “Escrow Agent”
and

HZNP Limited
(“Parent”)

and

GTCR Fund X/B LP
(“Representative”)

(Account Number)

Citi Escrow Agent Custody Account
THIS ESCROW AGREEMENT (the “Escrow Agreement”) is made this [_____] day of [______], 20[_____] by and among HZNP Limited, a private company limited by shares organized under the laws of Ireland (“Parent”), GTCR FUND X/B LP, a Delaware limited partnership (the “Representative”), solely in its capacity as the representative of [...]***... and the Unitholders and the Optionholders (collectively, the “Participating Securityholders”), and CITIBANK, N.A. (the “Escrow Agent”). Parent and the Representative are sometimes referred to, individually, as a “Party” and, collectively, as the “Parties”.

Parent and the Representative appoint said Escrow Agent as their escrow agent with the duties and responsibilities and upon the terms and conditions provided herein, including Schedule A and any additional schedules annexed hereto and made apart hereof. The Escrow Agent hereby accepts such appointment and agrees to act as escrow agent in accordance with the terms and conditions provided herein, including Schedule A and any additional schedules annexed hereto and made apart hereof. Capitalized terms not defined herein shall have the meanings assigned to them in that certain Agreement and Plan of Merger, dated as of [______], 2015 (as amended or otherwise modified from time to time, the “Merger Agreement”), by and among Crescita Holdings LLC, a Delaware limited liability company (the “Target”), Parent, Horizon Pharma USA, Inc., a Delaware corporation, Criostail LLC, a Delaware limited liability company and wholly-owned subsidiary of Parent, GTCR Fund X/C LP, a Delaware limited Partnership, and the Representative.

ARTICLE FIRST: The above-named parties agree that the following provisions shall control with respect to the rights, duties, liabilities, privileges and immunities of the Escrow Agent:

a) The Escrow Agent hereby agrees and covenants with Parent and the Representative that it shall perform all of its obligations hereunder and shall not deliver custody or possession of any of the Escrow Funds (as defined in Schedule A annexed hereto) to anyone except pursuant to the express terms of this Escrow Agreement, including Schedule A and any additional schedules annexed hereto and made apart hereof, or as otherwise required by law.

b) The Escrow Agent shall neither be responsible for or under, nor chargeable with knowledge of, the terms and conditions of any other agreement, instrument or document executed between/among the Parties hereto, except as may be specifically provided in Schedule A annexed hereto. This Escrow Agreement (including all schedules annexed hereto) sets forth all of the obligations of the Escrow Agent, and no additional obligations shall be implied from the terms of this Escrow Agreement or any other agreement, instrument or document. Nothing in this Escrow Agreement shall create a fiduciary or partnership relationship between the Escrow Agent and any other party to this Escrow Agreement.

***Confidential Treatment Requested
c) The Escrow Agent may act in reliance upon any instructions, notice, certification, demand, consent, authorization, receipt, power of attorney or other writing delivered to it by any of the Parties and reasonably believed by it to be genuine without being required to determine the authenticity or validity thereof or the correctness of any fact stated therein, the propriety or validity of the service thereof, or the jurisdiction of the court issuing any judgment or order. The Escrow Agent may act in reliance upon any signature reasonably believed by it to be genuine, and may assume that such person has been properly authorized to do so.

d) Each of the Parties (in the case of the Representative, solely on behalf of the Participating Securityholders and in its capacity as the Representative, not in its individual capacity) severally and Jointly, agrees to reimburse the Escrow Agent on demand for, and to indemnify and hold the Escrow Agent harmless against and with respect to, any and all loss, liability, damage or reasonable and documented expense (including, but without limitation, reasonable and documented attorneys’ fees, costs and disbursements) that the Escrow Agent may suffer or incur in connection with this Escrow Agreement and its performance hereunder, except to the extent such loss, liability, damage or expense arises from its fraud, willful misconduct or gross negligence as adjudicated by a court of competent jurisdiction. Notwithstanding anything to the contrary set forth herein, Parent, on the one hand, and the Representative (solely on behalf of the Participating Securityholders and in its capacity as the Representative, not in its individual capacity), on the other hand, agree, solely as between themselves, that any obligation to the Escrow Agent for loss, liability, damage or expense under this subsection (d) of Article First shall be borne by the Party or Parties determined by a court of competent jurisdiction through a final order to be responsible for causing the loss, liability, damage or expense for which the Escrow Agent is entitled to reimbursement; provided, however, that if no such determination is made, then Parent on the one hand and the Representative (solely on behalf of the Participating Securityholders and in its capacity as the Representative, not in its individual capacity), on the other hand, shall each be responsible for 50% of any such losses, liabilities, damages or expenses (it being agreed and understood that, in the event that either Parent, on the one hand, or the Representative (solely on behalf of the Participating Securityholders and in its capacity as the Representative, not in its individual capacity), on the other hand, are obligated to make any payment in excess of 50% of any such losses, liabilities, damages or expenses, the paying Party shall be entitled to reimbursement from the non-paying Party). In no event shall the Escrow Agent be responsible for special, indirect or consequential loss or damage of any kind whatsoever, even if the Escrow Agent has been advised of the likelihood of such loss or damage and regardless of the form of action.

e) The Escrow Agent may consult with legal counsel of its selection in the event of any dispute or question as to the meaning or construction of any of the provisions hereof or its duties hereunder, and it shall incur no liability and shall be fully protected in acting in accordance with the opinion and instructions of such counsel in respect of such matters.
The Escrow Agent shall be under no duty to give the property held in escrow by it hereunder any greater degree of care than it gives its own similar property, but in any event the Escrow Agent shall give the Escrow Funds not less than reasonable care and not less than the care it gives its own similar property.

The Escrow Agent shall invest the property held in escrow in such a manner as directed in Schedule A annexed hereto, which may include deposits in Citibank and mutual funds advised, serviced or made available by Citibank or its affiliates even though Citibank or its affiliates may receive a benefit or profit therefrom. The Escrow Agent and any of its affiliates are authorized to act as counterparty, principal, agent, broker or dealer while purchasing or selling investments as specified herein. The Escrow Agent and its affiliates are authorized to receive, directly or indirectly, fees or other profits or benefits for each service, task or function performed, in addition to any fees as specified in Schedule B hereof, without any requirement for special accounting related thereto.

The Parties to this Escrow Agreement acknowledge that non-deposit investment products are not obligations of, or guaranteed, by Citibank/Citigroup nor any of its affiliates; are not FDIC insured; and are subject to investment risks, including the possible loss of principal amount invested. Only deposits in the United States are subject to FDIC insurance.

The Escrow Agent shall have no obligation to invest or reinvest the property held in escrow if all or a portion of such property is deposited with the Escrow Agent after 11:00 AM Eastern Time on the day of deposit. Instructions to invest or reinvest that are received after 11:00 AM Eastern Time will be treated as if received on the following business day in New York. The Escrow Agent shall have the power to sell or liquidate the foregoing investments whenever the Escrow Agent shall be required to distribute amounts from the escrow property pursuant to the terms of this Escrow Agreement. Requests or instructions received after 11:00 AM Eastern Time by the Escrow Agent to liquidate all or any portion of the escrowed property will be treated as if received on the following business day in New York. The Escrow Agent shall have no responsibility for any investment losses resulting from the investment, reinvestment or liquidation of the escrowed property, as applicable, provided that the Escrow Agent has made such investment, reinvestment or liquidation of the escrowed property in accordance with the terms, and subject to the conditions, of this Escrow Agreement; provided that the foregoing shall not limit the Escrow Agent’s liability for its fraud, willful misconduct or gross negligence.

In the event of any disagreement between/among any of the Parties to this Escrow Agreement, or between/among them or either or any of them and any other person, resulting in adverse claims or demands being made in connection with the subject
matter of this Escrow Agreement, or in the event that the Escrow Agent, in good faith, be in doubt as to what action it should take hereunder, the Escrow Agent may, at its option, refuse to comply with any claims or demands on it, or refuse to take any other action hereunder, so long as such disagreement continues or such doubt exists, and in any such event, the Escrow Agent shall not become liable in any way or to any person for its failure or refusal to act, and the Escrow Agent shall be entitled to continue so to refrain from acting until the earlier of such time (i) the rights of all Parties shall have been fully and finally adjudicated by a court of competent jurisdiction, or (ii) all differences shall have been adjusted and all doubt resolved by agreement among all of the interested persons, and the Escrow Agent shall have been notified thereof in writing signed by all such persons. The Escrow Agent shall have the option, after 30 calendar days’ notice to the Parties of its intention to do so, to file an action in interpleader requiring the Parties to answer and litigate any claims and rights among themselves. The rights of the Escrow Agent under this paragraph are cumulative of all other rights which it may have by law or otherwise.

j) The Escrow Agent is authorized, for any securities at any time held hereunder, to register such securities in the name of its nominee(s) or the nominees of any securities depository, and such nominee(s) may sign the name of any of the Parties hereto to whom or to which such securities belong and guarantee such signature in order to transfer securities or certify ownership thereof to tax or other governmental authorities.

k) For purposes of this Escrow Agreement, a “business day” shall mean a day, other than a Saturday, a Sunday or other day on which banks are required or authorized by Law to be closed in New York City.

l) Any court order presented hereunder shall be accompanied by a written certification from the presenting Party satisfactory to the Escrow Agent to the effect that said court order is final and non-appealable. The Escrow Agent shall act on such court order and certification without further question.

m) Notice to the Escrow Agent and the Parties shall be given as provided in Schedule A annexed hereto.

n) The Escrow Agent shall not have the right to set off or deduct from the Escrow Funds any unpaid fees, non-reimbursed expenses or unsatisfied indemnification rights, and the Escrow Funds shall not be used by the Escrow Agent to set off any other obligations of any of the Parties owing to the Escrow Agent.

o) The Escrow Funds shall not be subject to any lien, attachment, trustee process or any other judicial process of any creditor of the Escrow Agent or any of the Parties.

p) The provisions of this Article First shall survive the termination or expiration of this Escrow Agreement or the removal or resignation of the Escrow Agent in accordance with the terms hereof.
ARTICLE SECOND:

a) The Parties to this Escrow Agreement other than the Escrow Agent acknowledge that they are solely responsible for, and that neither Citibank nor any of its affiliates have any responsibility for, any Party’s compliance with any laws, regulations or rules applicable to the use of the services provided by Citibank under this Escrow Agreement, including, but not limited to, any laws, regulations or rules, in such Party’s jurisdiction or any other jurisdiction, relating to tax, foreign exchange and capital control, and for reporting or filing requirements that may apply as a result of such Party’s country of citizenship, domicile, residence or taxing status.

b) Citigroup, Inc., its affiliates, and its employees are not in the business of providing tax or legal advice to any taxpayer outside of Citigroup, Inc. and its affiliates. This Escrow Agreement and any amendments or attachments are not intended or written to be used, and cannot be used or relied upon, by any such taxpayer or for the purpose of avoiding tax penalties. Any such taxpayer should seek advice based on the taxpayer’s particular circumstances from an independent tax advisor.

ARTICLE THIRD: The Escrow Agent (a) may, in its sole discretion, resign and terminate its position hereunder at any time following 30 calendar days’ written notice to the Parties to the Escrow Agreement herein or (b) may be removed, with or without cause, by Parent and the Representative acting jointly at any time by providing written notice to the Escrow Agent. Within 30 calendar days after receiving the foregoing notice of resignation from the Escrow Agent or within 30 calendar days after giving the foregoing notice of removal to the Escrow Agent, the Parties shall appoint a successor escrow agent and give notice of such successor escrow agent to the Escrow Agent. If a successor escrow agent has not been appointed prior to the expiration of such 30 calendar days, the then acting Escrow Agent may either (i) hold and safeguard the Escrow Funds (without any obligation to reinvest the same) until a successor escrow agent is appointed or (ii) petition any court of competent jurisdiction for the appointment of a successor escrow agent, or other appropriate relief. Any such resulting appointment shall be binding upon all of the parties to this Escrow Agreement. Upon receipt of the identity of the successor escrow agent, the Escrow Agent shall distribute the Escrow Funds then held hereunder and deliver any and all related information and documentation to the successor escrow agent, subject to this Escrow Agreement herein, whereupon the Escrow Agent shall, upon such distribution and delivery, have no further duties, responsibilities or obligations hereunder, except the Escrow Agent shall not be discharged from any liability for actions taken as Escrow Agent under this Escrow Agreement prior to such resignation or removal. Any corporation or association into which the Escrow Agent may be merged or converted or with which it may be consolidated, or any corporation or association to which all or substantially all of the escrow business of the Escrow Agent’s corporate trust line of business may be transferred, shall be the Escrow Agent under this Escrow Agreement without further act.
ARTICLE FOURTH: The Escrow Agent shall receive the fees provided in Schedule B annexed hereto, which shall be paid by Parent. The provisions of this Article Fourth shall survive the termination or expiration of this Escrow Agreement or the removal or resignation of the Escrow Agent with respect to any fees earned but unpaid as of such termination, expiration, removal or resignation.

ARTICLE FIFTH: Any modification of this Escrow Agreement or any additional obligations assumed by any party hereto shall be binding only if evidenced by a writing signed by each of the Parties hereto.

ARTICLE SIXTH: In the event funds transfer instructions are given (other than in writing at the time of execution of this Escrow Agreement), whether in writing, by telex or otherwise, the Escrow Agent is authorized to seek confirmation of such instructions by telephone call back to the person or persons designated in Schedule A, including Exhibit A-1 and Exhibit A-2 annexed hereto (the “Call Back Authorized Individuals”), and the Escrow Agent may rely upon the confirmations of anyone purporting to be a Call Back Authorized Individual. To assure accuracy of the instructions it receives, the Escrow Agent may record such call backs. If the Escrow Agent is unable to verify the instructions, or is not satisfied with the verification it receives, it will not execute the instruction until all issues have been resolved. The persons and telephone numbers for call backs may be changed only in writing actually received and acknowledged by the Escrow Agent. The parties agree to notify the Escrow Agent of any errors, delays or other problems within 30 calendar days after receiving notification that a transaction has been executed. If it is determined that the transaction was delayed or erroneously executed as a result of the Escrow Agent’s error, the Escrow Agent’s sole obligation is to pay or refund such amounts as may be required by applicable law. Any claim for interest payable will be at the Escrow Agent’s published savings account rate in effect in New York, New York.

ARTICLE SEVENTH:

a) This Escrow Agreement shall be governed by the law of the State of Delaware in all respects. The parties hereto irrevocably and unconditionally submit to the jurisdiction and venue of the Court of Chancery for the State of Delaware (the “Chancery Court”) and any state appellate court therefrom located within the State of Delaware (or, only if the Chancery Court declines to accept jurisdiction over a particular matter, any state or federal court within the State of Delaware), in connection with any proceedings commenced regarding this Escrow Agreement, including but not limited to, any interpleader proceeding or proceeding for the appointment of a successor escrow agent the Escrow Agent may commence pursuant to this Escrow Agreement, and all parties irrevocably submit to the jurisdiction of such courts for the determination of all issues in such proceedings, without regard to any principles of conflicts of laws, and irrevocably waive any objection to venue of inconvenient forum.
b) THE ESCROW AGENT AND THE PARTIES EACH FURTHER HEREBY WAIVES, TO THE FULLEST EXTENT PERMITTED BY LAW, ANY RIGHT TO A TRIAL BY JURY WITH RESPECT TO ANY CLAIM, DEMAND, ACTION OR CAUSE OF ACTION ARISING UNDER THIS ESCROW AGREEMENT, WHETHER NOW EXISTING OR HEREAFTER ARISING AND WHETHER IN CONTRACT, TORT, EQUITY OR OTHERWISE. THE ESCROW AGENT AND THE PARTIES EACH HEREBY FURTHER AGREES AND CONSENTS THAT ANY SUCH CLAIM, DEMAND, ACTION, OR CAUSE OF ACTION SHALL BE DECIDED BY COURT TRIAL WITHOUT A JURY AND THAT EACH MAY FILE A COPY OF THIS AGREEMENT WITH ANY COURT AS WRITTEN EVIDENCE OF THE CONSENT OF THE ESCROW AGENT AND THE PARTIES TO THE WAIVER OF THEIR RIGHT TO TRIAL BY JURY.

ARTICLE EIGHTH: This Escrow Agreement may be executed in one or more counterparts, each of which counterparts shall be deemed to be an original and all of which counterparts, taken together, shall constitute one and the same Escrow Agreement. Facsimile signatures or signatures transmitted by electronic exchange of PDF files on counterparts of this Escrow Agreement shall be deemed original signatures with all rights accruing thereto.

ARTICLE NINTH: The Escrow Agent shall not incur any liability for not performing any act or fulfilling any obligation hereunder by reason of any occurrence beyond its control (including, but not limited to, any provision of any present or future law or regulation or any act of any governmental authority, any act of God or war or terrorism, or the unavailability of the Federal Reserve Bank wire services or any electronic communication facility); provided, however, that the Escrow Agent shall use commercially reasonable efforts to resume such performance or fulfillment as soon as reasonably practicable.

ARTICLE TENTH: Notwithstanding anything to the contrary herein, any and all e-mail communications (both text and attachments) by or from the Escrow Agent that the Escrow Agent deems to contain confidential, proprietary, and/or sensitive information shall be encrypted. The recipient (the “E-mail Recipient”) of the encrypted email communication will be required to complete a customary registration process. Instructions on how to register and/or retrieve an encrypted message will be included in the first secure email sent by the Escrow Agent to the E-mail Recipient. Additional information and assistance on using the encryption technology can be found at Citibank’s Secure Email website at:

https://securemailserver.citigroup.com/index_en_us.html

or by calling (866) 535-2504 (in the United States) or (904) 954-6181 (collect calls accepted).
ARTICLE ELEVENTH: Except with respect to (a) the Representative’s communications with the Participating Securityholders or (b) internal communications between Parent and its employees, representatives or advisors in connection with the performance under or enforcement of this Escrow Agreement, no publicly distributed printed or other material in any language, including prospectuses, notices, reports, and promotional material which mentions “Citibank” by name or the rights, powers, or duties of the Escrow Agent under this Escrow Agreement shall be issued by any Party hereto, or on such Party's behalf, without the prior written consent of the Escrow Agent.

ARTICLE TWELFTH: This Escrow Agreement shall terminate on the first to occur of the (a) distribution of all of the amounts in the Escrow Funds in accordance with this Escrow Agreement or (b) delivery to the Escrow Agent of a written notice of termination executed jointly by Parent and the Representative.

ARTICLE THIRTEENTH: Except as provided in this paragraph and in Article Third, neither this Escrow Agreement nor any right or interest hereunder may be assigned in whole or in part by any party without the prior consent of the other parties. Notwithstanding anything herein to the contrary, Parent may, without prior written consent of the Escrow Agent, assign all or a portion of its rights, interests or obligations hereunder to one or more of its affiliates or one or more entities managed by one of its affiliates; provided, that no such assignment shall relieve Parent of any obligation hereunder except to the extent actually performed or satisfied by the assignee and provided that Parent provides written notice of such assignment to the Escrow Agent.

[signature page follows]
In witness whereof the parties have executed this Escrow Agreement as of the date first above written. If a date is not referenced in the opening paragraph, the date of this Escrow Agreement shall be the date this Escrow Agreement is accepted by Citibank, N.A. as set forth below.

CITIBANK, N.A.

as Escrow Agent

By: ____________________________

Title: ____________________________ (Signature)

Date: ____________________________

[Signature Page to Escrow Agreement]
HZNP LIMITED

By: ____________________________

Timothy P. Walbert, President and
Chief Executive Officer

Title: ____________________________

Date: ____________________________

[Signature Page to Escrow Agreement]
GTCR FUND X/B LP
SOLELY IN ITS CAPACITY AS THE REPRESENTATIVE

By: ____________________________
Title: __________________________ (Signature)
Date: ____________________________

[Signature Page to Escrow Agreement]
Schedule A

This “Schedule A” is the Schedule A referred to in that certain Escrow Agreement dated [_______], 20[____] (the Escrow Agreement, including this Schedule A and any other schedules and/or exhibits attached hereto, all of the terms and conditions of which are incorporated herein by reference, in each case as amended and/or supplemented from time to time in accordance with the terms hereof, the “Escrow Agreement”) by and among HZNP Limited, a private company limited by shares organized under the laws of Ireland (“Parent”), GTCR FUND X/B LP, a Delaware limited partnership (the “Representative”), solely in its capacity as the representative of […***…] and the Unitholders and Optionholders (the “Participating Securityholders”), and CITIBANK, N.A. (the “Escrow Agent” herein). Capitalized terms not defined herein shall have the meanings assigned to them in that certain Agreement and Plan of Merger, dated as of [_____] 2015 (as amended or otherwise modified from time to time, the “Merger Agreement”), by and among Crealta Holdings LLC, a Delaware limited liability company (the “Target”), Parent, Horizon Pharma USA, Inc., a Delaware corporation ([…***…] and, together with Parent, “Purchasers”), Criostail LLC, a Delaware limited liability company and wholly-owned subsidiary of Parent, GTCR Fund X/C LP, a Delaware limited Partnership, and the Representative. Parent and the Representative are sometimes referred to, individually, as a “Party” and, collectively, as the “Parties” herein.

WHEREAS, the Merger Agreement contemplates the execution and delivery of the Escrow Agreement and the deposit by Purchasers with the Escrow Agent of $[…***…] in the aggregate (the “Escrow Amount”) subject to the terms and conditions hereof, in order to provide a source of funding as described in the Merger Agreement; and

WHEREAS, the parties to the Escrow Agreement wish such Escrow Amount to be subject to the terms and conditions set forth herein and in the Merger Agreement.

NOW THEREFORE, in consideration of the foregoing and of the mutual covenants hereinafter set forth, the parties hereto agree as follows:

I. Escrow Funds

On the Closing Date, Purchasers shall deposit, or cause to be deposited, with the Escrow Agent, in accordance with Section 3.02(e) of the Merger Agreement, the Escrow Amount. The Escrow Agent shall hold the Escrow Amount, together with all products and proceeds thereof, including all interest, dividends, gains, earnings and other income (collectively, the “Escrow Earnings”) earned with respect thereto (collectively, the “Escrow Funds”) in a separate and distinct account, subject to the terms and conditions of this Schedule A and the Escrow Agreement. For clarity, all Escrow Earnings shall be retained by the Escrow Agent and reinvested in the Escrow Funds and shall become part of the Escrow Funds and shall be disbursed as part of the Escrow Funds in accordance with the terms and conditions of this Schedule A and the Escrow Agreement.

***Confidential Treatment Requested
II. **Investment Instructions**

Unless otherwise instructed in writing by Parent and the Representative, the Escrow Agent shall invest and reinvest the Escrow Funds in an non-interest bearing deposit account “insured by the Federal Deposit Insurance Corporation (“FDIC”)” to the applicable limits. The Escrow Funds shall at all times remain available for distribution in accordance with Section III below.

The Escrow Agent shall send an account statement to each of Parent and the Representative on a monthly basis reflecting activity in the Escrow Funds for the preceding month.

III. **Disposition and Termination of the Escrow Funds**

The Parties shall act in accordance with, and the Escrow Agent shall hold and release the Escrow Funds as provided in, this Section III as follows:

(a) The Escrow Agent shall distribute the Escrow Funds only in accordance with (i) a joint written instrument delivered to the Escrow Agent that on its face purports to be executed by an authorized representative, designated in the certificates set forth in Exhibit A-1 and Exhibit A-2 annexed hereto, of each of Parent and the Representative (each, a “Joint Instruction”) that instructs the Escrow Agent as to the distribution of some or all of the Escrow Funds as indicated therein, or (ii) a final and non-appealable award, order or judgment of a court of competent jurisdiction (an “Order”), a certified copy of which is delivered to the Escrow Agent by either Parent or the Representative (with a copy to the other party), that instructs the Escrow Agent as to the distribution of some or all of the Escrow Funds as indicated therein. A Joint Instruction shall specify the portion of the Escrow Funds (the “Escrow Payment Amount”) to be distributed and the party or parties to whom such distribution is to be made. The Escrow Agent will make no distributions of any Escrow Funds without first receiving a Joint Instruction or an Order. Each of the Representative and Parent agrees to provide the Escrow Agent with an appropriate Joint Instruction as promptly as practicable following an event requiring a release of all or a portion of the Escrow Funds as provided for under the Merger Agreement, including, without limitation, as set forth in Section 9.03(a)(ii) and Article XII of the Merger Agreement. With respect to Section III(a)(ii) above, (A) in addition to a certified copy of the Order, a cover letter detailing all appropriate wire transfer instructions shall be forwarded to the Escrow Agent by the presenting Party, (B) the Escrow Agent may conclusively rely upon a written certification of the presenting Party to the effect that the Order is final and non-appealable, and (C) the Escrow Agent shall have no independent duty to determine whether any Order delivered to it by any Party is final or non-appealable.
Notwithstanding the foregoing, on the first Business Day following the termination of the Escrow Period, the Escrow Agent shall release the then remaining Escrow Funds to the Paying Agent and the Surviving Company in accordance with Section 12.06 of the Merger Agreement, provided, that the Escrow Agent shall retain an amount (up to the total amount of the then remaining Escrow Funds) equal to the amount of any Unresolved Claims. The Escrow Agent shall only release the amount of the Escrow Funds retained for each Unresolved Claim upon receipt of a Joint Instruction or an Order.

(c) Upon receipt of a Joint Instruction with respect to the Escrow Funds, the Escrow Agent shall promptly, but in any event within two (2) Business Days after receipt of a Joint Instruction, disburse all or part of the Escrow Funds in accordance with such Joint Instruction.

(d) All payments of any part of the Escrow Funds shall be made by wire transfer of immediately available funds as set forth in the Joint Instruction or Order, as applicable. Except as otherwise specified in a Joint Instruction, (i) any distributions for the benefit of the Purchasers shall be distributed [85%] to Parent and [15%] to […***…], and (ii) any distributions for the benefit of the Sellers shall be distributed to the Paying Agent and the Surviving Company in accordance with Section 12.06 of the Merger Agreement in such amounts as shall be set forth on each Joint Instruction.

(e) Call Back Authorized Individuals for the Representative are set forth in Exhibit A-1 annexed hereto. Call Back Authorized Individuals for Parent are set forth in Exhibit A-2 annexed hereto.

IV. **Tax Matters**

(a) Each of the Parties and […***…] shall provide an Internal Revenue Service (“IRS”) Form W-9 or appropriate IRS Form W-8, as applicable, to the Escrow Agent upon reasonable request, and in any event upon execution of this Escrow Agreement. The Parties understand that if such tax reporting documentation is not provided and certified to the Escrow Agent, the Escrow Agent may be required by the Internal Revenue Code of 1986, as amended, and the regulations promulgated thereunder, to withhold a portion of any interest or other income earned on the investment of the Escrow Funds.

(b) The Parties hereto agree that for tax reporting purposes the Escrow Funds shall be deemed owned [85%] by Parent and [15%] by […***…], and that all Escrow Earnings, if any, earned from the investment of Escrow Funds pursuant to this Agreement shall be treated for tax purposes as earned [85%] by Parent and [15%] by […***…]. Escrow Earnings shall be reported by Citibank to the IRS, or any other taxing authority, as required by law and in accordance with this clause (b) of Article Second.
(c) Upon reasonable request, each distributee of Escrow Funds shall provide an IRS Form W-9 or appropriate IRS Form W-8, as applicable, to the Escrow Agent; provided that the Escrow Agent shall have no responsibility under this Escrow Agreement for the preparation or filing of any tax return in respect of the Escrow Funds except as provided in Section IV(b) of this Schedule A.

V. Fees and Expenses

Unless otherwise provided for in Schedule B to the Escrow Agreement, the Escrow Agent shall not otherwise charge fees for the services provided by the Escrow Agent hereunder.

VI. Notices

All notices, requests, demands and other communications required under this Escrow Agreement shall be in writing, in English, and shall be deemed to have been duly given and received (i) upon receipt when delivered personally, (ii) upon transmission if sent by facsimile transmission with electronic confirmation of receipt, (iii) upon transmission if sent by electronic mail (“e-mail”) to the e-mail address given below with electronic confirmation of receipt or (iv) one Business Day after being sent by courier or express delivery service. If notice is given to a party, it shall be given at the address for such party set forth below. It shall be the responsibility of the Parties to notify the Escrow Agent and the other Party in writing of any name or address changes.

If to Parent:
Name: HZNP Limited
Address: HP House
21 Laffan Street
Hamilton HM-09
Bermuda
Attn: Attn: Kevin Insley
Facsimile: 441-292-1244
E-mail: Kinsley@zobec.bm

With a copy to (which shall not constitute notice):
Name: Cooley LLP
Address: 4401 Eastgate Mall
San Diego, CA 921210-1909
Attn: Barbara Borden
Facsimile: 858-550-6420
E-mail: bbordenbl@cooley.com
If to Representative:
Name: GTCR Fund X/B LP; c/o GTCR LLC
Address: 300 North LaSalle Street
          Suite 5600
          Chicago, Illinois 60654
Attn: Constantine S. Mihas
Facsimile: 312-382-220

With a copy to (which shall not constitute notice):
Name: Kirkland & Ellis LLP
Address: 300 North LaSalle Street
          Chicago, Illinois 60654
Attn: Sanford E. Perl, P.C.; Michael H. Weed, P.C.
Facsimile: 312-862-2200

If to the Escrow Agent:
Name: Citibank, N.A.
Address: Citi Private Bank
          One Sansome Street, 23rd Floor
          San Francisco, CA 94104
Attn: Raafat Sarkis
Telephone: 415-627-6327
Facsimile: 415-592-5584
E-mail: Raafat.sarkis@citi.com
EXHIBIT A-1
Certificate as to Representative’s Authorized Signatures

The specimen signatures shown below are the specimen signatures of the individuals who have been designated as authorized representatives of the Representative and are authorized to initiate and approve transactions of all types for the escrow account or accounts established under this Escrow Agreement, on behalf of the Representative. The below listed persons (must list at least two individuals) have also been designated Call Back Authorized Individuals and will be notified by Citibank N.A. upon the release of Escrow Funds from the escrow account(s) unless an original “Standing or Predefined Instruction” letter is on file with the Escrow Agent file with the Escrow Agent.

<table>
<thead>
<tr>
<th>Name / Title / Telephone #</th>
<th>Specimen Signature</th>
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</table>
The specimen signatures shown below are the specimen signatures of the individuals who have been designated as authorized representatives of Parent and are authorized to initiate and approve transactions of all types for the escrow account or accounts established under this Agreement, on behalf of Parent. The below listed persons (must list at least two individuals) have also been designated Call Back Authorized Individuals and will be notified by Citibank N.A. upon the release of Escrow Funds from the escrow account(s) unless an original “Standing or Predefined Instruction” letter is on file with the Escrow Agent.

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Acceptance Fee  
WAIVED
To cover the acceptance of the Escrow Agency appointment, the study of the Escrow Agreement, and supporting documents submitted in connection with the execution and delivery thereof, and communication with other members of the working group:

Administration Fee  
WAIVED
The annual administration fee covers maintenance of the Escrow Account including safekeeping of assets in the escrow account, normal administrative functions of the Escrow Agent, including maintenance of the Escrow Agent’s records, follow-up of the Escrow Agreement’s provisions, and any other safekeeping duties required by the Escrow Agent under the terms of the Escrow Agreement. Fee is based on Escrow Amount being deposited in a non-interest bearing deposit account, FDIC insured to the applicable limits.

1099 Tax Preparation Fee  
INCLUDED
To cover preparation of Form 1099-INT for the applicable escrow party for each calendar year:

Transaction Fees  
INCLUDED
To cover all required disbursements from escrow account, including disbursements made via check, payments to all parties as designated by client, fees associated with postage and overnight delivery charges incurred by the Escrow Agent as required under the terms and conditions of the Escrow Agreement:

Legal Fees  
N/A

Other Fees  
N/A
Citi Private Bank is a business of Citigroup Inc. ("Citigroup"), which provides its clients access to a broad array of products and services available through bank and non-bank affiliates of Citigroup. Not all products and services are provided by all affiliates or are available at all locations.

Investment Products: •No Bank Guarantee •Not FDIC Insured •May Lose Value

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Custody Services are provided by Citibank N.A.

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Citibank, N.A. Member FDIC
Important information about opening a new account at Citi Private Bank:

To help the United States Government fight terrorism and money laundering, Federal law requires financial institutions to obtain, verify, and record information that identifies each individual, business or entity that opens an account or establishes a relationship. What this means for you:

For individuals — when you open an account or establish a relationship, we will ask for your:

- name,
- date of birth,
- residential street address, and
- identification number, such as a social security number, taxpayer identification number, national identification number or passport number.

For businesses and other entities, such as corporations, trusts, etc. — when you open an account or establish a relationship, we will ask for your:

- official name,
- principal place of business or local business street address, and
- taxpayer identification number or other registration number.

For individuals, we may also ask to see (and retain a copy of) your driver’s license, passport or other identifying documents that will help us identify you. For businesses or entities, we may also ask for a copy of your formation documents or other related documentation. If we have difficulty verifying an accountholder’s identity, we may not be able to open an account or establish a relationship, or we may have to block or close the account.

Thank you for your cooperation.
LICENSE AGREEMENT

THIS LICENSE AGREEMENT is made and entered into as of the 12th day of August 1998, by and among Mountain View Pharmaceuticals, Inc., Duke University, and Bio-Technology General Corporation.

WHEREAS, DUKE has developed certain recombinant mammalian uricases prior to the start of the GRANT, including PBC URICASE;

WHEREAS, DUKE and/or MVP have developed, pursuant to the GRANT, additional recombinant mammalian uricases;

WHEREAS, DUKE and MVP have developed, pursuant to the GRANT, PEG conjugates of PBC URICASE and other mammalian uricases;

WHEREAS, MVP has developed PEG conjugates of non-mammalian uricases;

WHEREAS, DUKE and MVP, in order to have the benefits of these developments made available to the public, desire to license their rights therein exclusively, on a worldwide basis, to BTG in the FIELD; and

WHEREAS, BTG desires to obtain such a license.

NOW THEREFORE, in consideration of the premises and the faithful performance of the covenants herein contained, the PARTIES agree as follows:

ARTICLE 1 – INDEPENDENT CONTRACTORS

1.0 MVP’s and DUKE’S relationships to one another and to BTG under this AGREEMENT are those of independent contractors and not as agents, joint venturers or partners.

ARTICLE 2 – DEFINITIONS

2.0 As used throughout this AGREEMENT, the terms and phrases set forth herein in capital letters shall be defined as set forth in this Article 2.

2.1 “AFFILIATES” of a person or an entity shall mean any individual, sole proprietorship, firm, partnership, corporation, trust, joint venture or other entity, whether de jure or de facto, which, directly or indirectly, controls, is controlled by or is under common control with such person or entity. As used in this definition, “control” means the possession, directly or indirectly, of the power to direct or cause the direction of the policies and management of a person or entity, whether by the ownership of stock, by contract or otherwise.
“AGREEMENT” shall mean this License Agreement as amended from time to time.

“BIRD” shall mean the U.S.-Israel Binational Industrial Research and Development Foundation.

“BTG” shall mean Bio-Technology General Corporation, a corporation organized under the laws of Delaware, and having its principal offices at Iselin, New Jersey 08830, and its AFFILIATES.

“DUKE” shall mean Duke University, a North Carolina not-for-profit corporation, having its principal office at Durham, North Carolina 27710, and its AFFILIATES.

“DUKE TECHNOLOGY” shall mean technologies conceived, reduced to practice, developed, or acquired, by or for DUKE, or licensed to DUKE, or developed jointly with MVP, relating to mammalian urate oxidase (mammalian uricase), including the know-how and other information described in detail in Exhibit A attached hereto and made a part hereof, as of the EFFECTIVE DATE, and including any improvement made by DUKE thereon during the TERM of this AGREEMENT, for use in the FIELD; provided, however, that with respect to such improvements, DUKE shall promptly disclose each such improvement to BTG and it shall be included in the license only if, within six (6) months after disclosure, BTG elects to incorporate the improvement into LICENSED PRODUCTS or the manufacturing process thereof.

“EFFECTIVE DATE” shall mean the date first written above.

“FIELD” shall mean the treatment of humans.

“GRANT” shall mean the STTR grant from NIH (Grant No. DK48529) for a research project titled, “Mammalian PEG-Uricase for Therapy of Intractable Gout” under which LICENSORS received funding from September 30, 1996, through August 31, 1998.

“IMPUTED NET SALES” shall have the meaning ascribed to it in Section 2.17(a).

“INFORMATION” shall have the meaning ascribed to it in Section 11.1.

“LICENSED PRODUCTS” shall mean any products (including all dosage forms, strengths, and package sizes) that utilize TECHNOLOGY in whole or in part.

“LICENSEE” shall mean BTG.

“LICENSOR” shall mean MVP, DUKE or both of them, depending on the context.

“MVP” shall mean Mountain View Pharmaceuticals, Inc., a corporation organized under the laws of California, and having its principal place of business at Menlo Park, California 94025, and its AFFILIATES.
2.16 “MVP TECHNOLOGY” shall mean technologies conceived, reduced to practice, developed, or acquired, by or for MVP, or licensed to MVP, or developed jointly with DUKE, relating to mammalian urate oxidase (mammalian uricase) and non-mammalian urate oxidase (non-mammalian uricase) and PEG conjugates of both mammalian uricase and non-mammalian uricase, including the know-how and other information described in detail in Exhibit B attached hereto and made a part hereof, as of the EFFECTIVE DATE, including any improvements made by MVP thereon during the TERM of this AGREEMENT, for use in the FIELD; provided, however, that with respect to such improvements, MVP shall promptly disclose each such improvement to BTG and it shall be included in the license only if, within six (6) months after disclosure, BTG elects to incorporate the improvement into LICENSED PRODUCTS or the manufacturing process thereof.

2.17 “NET SALES” shall mean LICENSEE’s aggregate arm’s length gross charges to the trade, physicians or patients charged for sales by LICENSEE of the LICENSED PRODUCTS, less all normal and customary trade and quantity discounts and less any sales and excise taxes and duties paid by LICENSEE.

(a) In the event that the LICENSED PRODUCTS are distributed by LICENSEE at no cost to the recipient for revenue-producing activities, these shall be deemed to be NET SALES (“IMPUTED NET SALES”) for purposes of computing royalty obligations, except for LICENSED PRODUCTS distributed that are not reimbursable or which are used for non-revenue-producing activities such as promotional samples and supplies for clinical studies or field trials.

(b) IMPUTED NET SALES shall be valued at the mean price for such respective LICENSED PRODUCTS sold by LICENSEE during the calendar quarter preceding the calendar quarter during which such IMPUTED NET SALES occur.

(c) Transfer prices for LICENSED PRODUCTS between AFFILIATES shall not be considered for the purpose of computing NET SALES or IMPUTED NET SALES.

2.18 “NIH” shall mean the U.S. National Institutes of Health.

2.19 “PATENT RIGHTS” shall mean rights to any claims directed to any aspect of the TECHNOLOGY in all United States and foreign patent applications filed and any patents now issued or hereinafter issuing from such patent applications, substitutes, continuations, continuations-in-part, divisional applications, reexaminations or reissues thereof, which contain at least one claim directed to any aspect of the TECHNOLOGY, a current listing of which appears in Exhibit C attached hereto and made a part hereof, as amended from time to time during the TERM of this AGREEMENT.

2.20 “PARTY” or “PARTIES” shall mean LICENSEE on the one hand and DUKE and/or MVP on the other hand, or all three, depending on the context.
2.21 “PBC URICASE” shall mean […***…].

2.22 “PEG” shall mean poly(ethylene glycol) or poly(ethylene oxide).

2.23 “SALES AND REVENUE REPORTS” shall have the meaning ascribed to it in Section 6.9.

2.24 “STTR” shall mean the Small Business Technology Transfer Research program.

2.25 “SUBLICENSE REVENUES” shall mean all revenues or other consideration received by LICENSEE from sublicensees, including, without limitation, sublicense issue fees, other sublicense fees, royalties, and milestone payments.

2.26 “TECHNOLOGY” shall mean the DUKE TECHNOLOGY and the MVP TECHNOLOGY.

2.27 “TERM” shall have the meaning ascribed to it in Section 10.1.

2.28 “TERRITORY” shall mean each and every country of the world, including, with respect to each country, its territories and possessions.

2.29 “TOP […***…] MARKETS” shall mean the […***…] countries with the greatest dollar volume of sales of allopurinol during the twelve (12) months preceding any particular date, based on monthly data compiled by IMS America.

2.30 “TOTAL REVENUES” shall mean the sum of NET SALES plus SUBLICENSE REVENUES.

2.31 “TOTAL SALES” shall mean the cumulative sum of NET SALES of LICENSED PRODUCTS by LICENSEE plus net sales of LICENSED PRODUCTS by its sublicensees from the EFFECTIVE DATE.

2.32 “USPTO” shall mean the United States Patent and Trademark Office.

ARTICLE 3 – SPONSORED RESEARCH

3.1 LICENSEE shall sponsor research relevant to the TECHNOLOGY at the facilities of each of the LICENSORS.

3.2 LICENSEE agrees to provide not less than $[…***…] to DUKE and $[…***…] to MVP (less any amounts received by MVP from BIRD) for sponsored research during the first twenty-four (24) months following the EFFECTIVE DATE.

3.3 Payments for such sponsored research shall be made at least semiannually to each of the LICENSORS at the annual rate of at least $[…***…] per year; provided,
however, that with respect to MVP, these payments shall be reduced by the amounts received by MVP from BIRD.

3.4 The funding for sponsored research at DUKE is to support research at DUKE by Dr. […]***…], and it is understood that if for any reason, Dr. […]***…] should no longer be affiliated with DUKE during the period for which the funding is provided, then DUKE will transfer the funding to another institution with which Dr. […]***…] may affiliate, upon his departure from DUKE.

ARTICLE 4 – LICENSE AND TRANSFER OF TECHNOLOGY

4.1 LICENSORS hereby grant to LICENSEE and LICENSEE hereby accepts from LICENSORS, upon the terms and conditions herein specified, an exclusive, royalty-bearing license in the TERRITORY, with the right to grant sublicenses, under the TECHNOLOGY and PATENT RIGHTS, subject to U.S. Government rights in the TECHNOLOGY, to make and have made, use and have used, and sell and have sold, LICENSED PRODUCTS for use in the FIELD. In recognition of the general applicability to other drugs of MVP’s technology for the production of PEG conjugates of uricases, BTG expressly agrees that it shall not utilize such technology in any manner except for the production of PEG conjugates of uricases and only as provided in this AGREEMENT; provided, however, that MVP expressly agrees that nothing contained in this AGREEMENT shall be read to preclude LICENSEE from using technology for the production of PEG conjugates which is in the public domain, or which is developed by LICENSEE independent of MVP’s technology for the production of PEG conjugates, or which LICENSEE acquires or licenses from a third party.

4.2 Within sixty (60) days after the execution of this AGREEMENT:

(a) DUKE agrees to provide LICENSEE with the materials and copies of the protocols and representative results for the methods listed in Exhibit A.

(b) MVP agrees to provide LICENSEE with the materials and copies of the protocols and representative results for the methods listed in Exhibit B.

(c) LICENSORS agree to provide LICENSEE with copies of any and all patents and patent applications identified in Exhibit C.

4.3 MVP hereby grants to LICENSEE the exclusive, royalty-free, right and license in the TERRITORY and in the FIELD to use such rights as MVP may possess in the trademark, PURICASE™, the registration of which has been published in the Official Gazette of the USPTO (Volume 1211, Number 2, page TM 100) and is pending in the European Community (Application No. 716019).

(a) LICENSEE may use whichever trademark or trademarks it may elect, in its sole discretion, in connection with the marketing of LICENSED

***Confidential Treatment Requested
PRODUCTS, and shall be under no obligation to use the trademark, PURICASE™.

(b) If LICENSEE elects not to use the trademark PURICASE™ or otherwise fails to use such trademark by one (1) year after the first sale of any LICENSED PRODUCT, MVP shall retain all rights to its use.

4.4 LICENSEE shall comply with all obligations imposed by the U.S. Government on exclusive licenses of inventions made under a U.S. Government funding agreement including, but not limited to, the requirement that any products which are sold in the United States be substantially manufactured in the United States, if such products are based on inventions conceived or first actually reduced to practice under such funding agreements.

(a) LICENSORS recognize that the currently projected market for LICENSED PRODUCTS does not justify a second manufacturing facility, and that LICENSEE currently has a manufacturing facility in Israel, and, therefore, LICENSORS and LICENSEE agree to cooperate and use their best efforts to promptly obtain a waiver of the U.S. manufacturing requirement.

(b) DUKE represents that PBC URICASE was constructed at DUKE prior to its receipt of the GRANT and that U.S. Government funds did not support its development; and represents further that subject to review and determination by DUKE, other uricases may also have been constructed at DUKE prior to its receipt of the GRANT, developed without the support of U.S. Government funds, and that DUKE shall promptly identify any such uricases for LICENSEE.

4.5 Any sublicenses granted by LICENSEE shall be on such financial terms as LICENSEE may negotiate in its sole discretion but otherwise shall be subject to, and shall incorporate therein, conditions at least as stringent as those imposed on LICENSEE by the terms of this AGREEMENT.

(a) LICENSEE agrees to be responsible for any obligations assumed hereunder by its sublicensees.

(b) LICENSEE further agrees that all sublicense agreements will provide that if LICENSORS terminate this AGREEMENT pursuant to Section 10.3 or 10.6 prior to the end of the TERM in one or more countries, or if LICENSEE terminates this AGREEMENT pursuant to Section 10.2, all such sublicenses in those countries shall be assigned directly to LICENSORS; provided, however, that LICENSORS first agree, in writing, to assume all of LICENSEE’s obligations under such sublicenses and to hold LICENSEE harmless with respect to any claims made by such sublicensees as a result of such termination; provided, however, that LICENSORS shall not be liable for any claims against LICENSEE arising out of LICENSEE’s negligence or willful wrongdoing, or claims arising from LICENSEE’s breach, prior to termination, of its obligations under a sublicense.
(c) LICENSORS shall promptly be provided a copy of each sublicense agreement, provided, however, that during the TERM of this AGREEMENT, LICENSORS shall maintain such agreements in confidence and shall not contact any such sublicensee without LICENSEE’s prior written consent.

4.6 Upon expiration of the TERM of this AGREEMENT with respect to each country as set forth in Article 10, the licenses granted in this Article 4 shall become fully paid-up, irrevocable and non-exclusive in each such country.

ARTICLE 5 – LICENSE FEES AND MILESTONE PAYMENTS

5.1 The LICENSEE shall make separate payments to MVP and to DUKE according to the following schedule:

<table>
<thead>
<tr>
<th>Event Triggering Payments</th>
<th>To MVP</th>
<th>To DUKE</th>
<th>Total</th>
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<tbody>
<tr>
<td>1) Execution of this AGREEMENT</td>
<td>[...***...</td>
<td>[...***...</td>
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<tr>
<td>2) Successful transfer of the technology for the production of PEG conjugates of uricase</td>
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<td>[...***...</td>
<td>[...***...</td>
</tr>
<tr>
<td>3) First anniversary of execution of this AGREEMENT</td>
<td>[...***...</td>
<td>[...***...</td>
<td>[...***...</td>
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<tr>
<td>4) Filing for an investigational new drug exemption</td>
<td>[...***...</td>
<td>[...***...</td>
<td>[...***...</td>
</tr>
<tr>
<td>5) Commencement of a Phase 2 clinical study</td>
<td>[...***...</td>
<td>[...***...</td>
<td>[...***...</td>
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<tr>
<td>6) Filing of an application to permit marketing in any one of the [...***...</td>
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<tr>
<td>7) Marketing approval in any one of the [...***...</td>
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<tr>
<td>8) Cumulative TOTAL REVENUES of $[...***...]</td>
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<td>[...***...</td>
<td>[...***...</td>
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<tr>
<td>9) Cumulative TOTAL REVENUES of $[...***...]</td>
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<td>[...***...</td>
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<td>Totals:</td>
<td>[...***...</td>
<td>[...***...</td>
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</table>

5.2 LICENSEE shall make the payments identified in Section 5.1 as follows:

(a) Payments 1) upon execution of this AGREEMENT.

(b) Payments 2) not later than thirty (30) days after successful transfer of the technology for the production of PEG conjugates of uricase, as set forth in Section 5.10.

(c) Payment 3) on the first anniversary of the EFFECTIVE DATE.

***Confidential Treatment Requested
(d) Payments 4) not later than thirty (30) days after the first filing of an application for an investigational new drug exemption for LICENSED PRODUCTS.

(e) Payments 5) not later than thirty (30) days after enrolling the first patient in a Phase 2 clinical study of LICENSED PRODUCTS.

(f) Payments 6) not later than thirty (30) days after filing an application to permit marketing of LICENSED PRODUCTS in any one of the […]***…].

(g) Payments 7) not later than thirty (30) days after obtaining approval to market LICENSED PRODUCTS in any one of the […]***…].

(h) Payments 8) not later than sixty (60) days after the end of the calendar quarter in which cumulative TOTAL REVENUES from LICENSED PRODUCTS exceed the equivalent of $[…***…].

(i) Payments 9) not later than sixty (60) days after the end of the calendar quarter in which cumulative TOTAL REVENUES from LICENSED PRODUCTS exceed the equivalent of $[…***…].

5.3 All of the payments in this Article 5 are in addition to the royalties specified in Article 6.

5.4 All payments required by this AGREEMENT, if not paid when due, shall bear interest at the rate of one and one-half percent (1 1/2%) per month or fraction thereof, or the maximum interest rate allowed by applicable law, whichever is less.

5.5 If this AGREEMENT is executed before LICENSEE has had the opportunity to review and approve the version of the patent application (titled “PEG-URATE OXIDASE CONJUGATES AND USE THEREOF”) that has been filed with the United States Patent and Trademark Office, then:

(a) If upon such review subsequent to execution of this AGREEMENT, which LICENSEE shall complete within sixty (60) days after receipt of such application, LICENSEE determines in good faith that such application is inadequate (e.g., for lack of support in the specification or in view of the prior art), LICENSEE may elect, in its sole discretion, to terminate this AGREEMENT.

(b) If LICENSEE does so elect to terminate, MVP and DUKE shall each refund to LICENSEE all payments made to them by LICENSEE as of the date of termination, and MVP shall be solely responsible for the repayment to BIRD, should such repayment be required, of any funds received by MVP from BIRD.

5.6 MVP shall commence the transfer to BTG of its proprietary technology for the production of PEG conjugates of uricases once the following conditions have been met:

***Confidential Treatment Requested
(a) MVP and DUKE have been notified, in writing, by BTG following the review of their patent application as set forth in Section 5.5, either that such patent application is acceptable or, if unacceptable, that BTG nonetheless elects not to terminate the AGREEMENT, and that, therefore, the payments made by BTG to MVP and DUKE as of the date of such written notice are irrevocable;

(b) BTG and MVP have selected a specific uricase and BTG has provided at least [...] from a single batch to MVP for each [...] of PEG conjugate to be prepared by MVP as part of the technology transfer; and

(c) BTG has installed at its facility in Israel all of the necessary instruments, accessories, columns and other materials for assessing the activity of uricase, the purity of the PEG-uricase conjugates and the number of strands of PEG attached per uricase subunit according to MVP’s protocols. [...]  

5.7 Such transfer shall commence as soon as practical after BTG has met all of the conditions in Section 5.6.

5.8 The technology transfer shall include the following steps:

[...]  

***Confidential Treatment Requested***
5.9 BTG and MVP shall use their best efforts to complete successful transfer of such technology as promptly as possible and each company shall therefore assign appropriately skilled personnel to this task.

5.10 The technology transfer shall be complete once Sections 5.8(c) and 5.8(d) have been completed and BTG shall notify LICENSORS in writing within thirty (30) days of such completion.

5.11 Failure to successfully transfer the technology within one (1) year after the transfer is initiated by MVP, unless such failure is caused by BTG’s failing to comply with Section 5.9, shall have the following consequences:

(a) MVP and DUKE shall forfeit payments 2) in Section 5.1 and they shall not be made pursuant to Section 5.2 or otherwise; and

(b) MVP and DUKE shall forfeit the royalties attributable to know-how pursuant to Section 6.4 as further defined in Section 6.5.

5.12 If the U.S. Government declines to waive the U.S. manufacturing requirement, MVP shall cooperate with LICENSEE to transfer such technology to a U.S. manufacturer selected by LICENSEE; provided, however:

(a) that payments 2) in Section 5.1 shall have been made;

(b) that such manufacturer shall first agree to maintain such technology in confidence on terms no less restrictive than those applicable to LICENSEE under this AGREEMENT, and to use such technology only for the production of PEG-uricase conjugates for LICENSEE;

(c) that such manufacturer does not manufacture PEG-uricase conjugates for itself or any third party;

(d) that such manufacturer is not […***…], or […***…]; and

(e) that such manufacturer is a company for which, as of the effective date of the agreement between LICENSEE and such company, none of the following three (3) individuals: […***…], is an employee, director, consultant, or shareholder possessing at least ten percent of the outstanding shares of common stock, unless MVP’s prior written consent has been obtained, which consent shall not be unreasonably withheld.

***Confidential Treatment Requested
ARTICLE 6 – ROYALTIES, RECORDS AND REPORTS

6.1 Within sixty (60) days after the end of each calendar quarter, LICENSEE shall pay to LICENSORS, in equal shares, any running royalties due pursuant to this Article 6 on NET SALES of LICENSED PRODUCTS made by LICENSEE during the preceding calendar quarter.

6.2 The total rates of such running royalties, subject to adjustment pursuant to Section 6.5, shall be:

   (a) Eight percent (8%) of the NET SALES of LICENSED PRODUCTS made by LICENSEE until the TOTAL SALES equal $[...***...];

   (b) [...***...] percent ([...***...]% of NET SALES of LICENSED PRODUCTS made by LICENSEE once the TOTAL SALES exceed $[...***...] and until such TOTAL SALES equal $[...***...]; and

   (c) Twelve percent (12%) of NET SALES of LICENSED PRODUCTS made by LICENSEE once the TOTAL SALES exceed $[...***...].

6.3 Concurrent with the payments provided for in Sections 6.1 and 6.2 and subject to Sections 6.5 and 6.6, LICENSEE shall pay to LICENSORS, in United States Dollars, royalty payments in the amount of twenty percent (20%) of SUBLICENSE REVENUES accrued by LICENSEE during the preceding calendar quarter.

6.4 Of the percentages specified in Sections 6.2 and 6.3, one half (1/2) shall be considered a patent royalty, and one half (1/2) shall be considered a royalty for use of know-how.

6.5 Subject to Article 8, the actual royalty rates payable in any country pursuant to Sections 6.1, 6.2 and 6.3 shall be determined as follows:

   (a) If there is no patent protection under PATENT RIGHTS in a country in the TERRITORY and no protection under the U.S. Orphan Drug Act or any foreign equivalent in such country, then the applicable royalty rates for such country shall be [...***...] percent ([...***...]% of the royalty rates specified in Sections 6.2 and 6.3 if there has been a successful transfer of technology pursuant to Section 5.10, and [...***...] percent ([...***...]% if there has not been a successful transfer.

   (b) If there is patent protection under PATENT RIGHTS in a country in the TERRITORY or protection under the U.S. Orphan Drug Act or any foreign equivalent in such country, then the applicable royalty rates for such country shall be the royalty rates specified in Section 6.2 and 6.3 if there has been a successful transfer of technology pursuant to Section 5.10, and [...***...] percent ([...***...]% of the royalty rates specified in Sections 6.2 and 6.3 if there has not been a successful transfer.
6.6 For the purpose of calculating royalties due to LICENSORS, revenues in currencies other than United States Dollars shall be converted to United States Dollars using the exchange rates that were published in the *Wall Street Journal* on the last business day of the calendar quarter during which LICENSEE accrued such revenues.

6.7 LICENSEE shall keep full, true and accurate books of accounts and other records containing all particulars that may be necessary to properly ascertain and verify the royalties payable by LICENSEE hereunder.

6.8 Upon the request of LICENSORS, LICENSEE shall permit an independent Certified Public Accountant selected by LICENSORS (except one to whom the LICENSEE has some reasonable objection, such as that the accountant represents either of LICENSORS with respect to its own matters) to have access, not more than once in any calendar year, and during ordinary business hours, to such of LICENSEE’S records as may be necessary to determine, in respect of any quarter ending not more than three (3) years prior to the date of such request, the correctness of any report and/or payment made under this AGREEMENT.

(a) If such examination results in a determination that LICENSEE has underpaid its obligations to LICENSORS by more than three percent (3%), the cost of such examination shall be borne by LICENSEE.

(b) If such examination results in a determination that LICENSEE has correctly paid or overpaid its obligations to LICENSORS, the cost of such examination shall be borne by LICENSORS.

(c) All adjustments resulting from such examinations shall be made by appropriate payments within thirty (30) days after the results of the examination become known to the PARTIES.

(d) Such accountant shall maintain all information learned during such inspection in confidence and shall report to LICENSORS whether there has been an overpayment, correct payment or underpayment of royalties and, if applicable, the amount of such overpayment or underpayment.

6.9 For each quarterly payment, LICENSEE shall render to each of the LICENSORS written accounts (“SALES AND REVENUE REPORTS”) of the NET SALES of LICENSED PRODUCTS by LICENSEE and AFFILIATES, net sales by SUBLICENSEES, and the SUBLICENSE REVENUES accrued by LICENSEE during the preceding quarter.

(a) LICENSEE warrants that such SALES AND REVENUE REPORTS will be prepared in accordance with Generally Accepted Accounting Principles.

(b) SALES AND REVENUE REPORTS will be supplied to each of the LICENSORS not later than sixty (60) days after the end of each calendar quarter in which the LICENSEE accrues revenue from sales of LICENSED PRODUCTS or from sublicenses of the LICENSED PRODUCTS.
(c) LICENSORS agree to hold such SALES AND REVENUE REPORTS in confidence.

ARTICLE 7 – PERFORMANCE OBLIGATIONS

7.1 The LICENSEE shall use its best efforts to bring LICENSED PRODUCTS to market and to diligently market LICENSED PRODUCTS during the TERM of this AGREEMENT.

7.2 LICENSEE and MVP shall commit such funds as each may receive from BIRD solely to the development of LICENSED PRODUCTS.

7.3 LICENSEE shall repay all funds provided by BIRD to LICENSEE and MVP, up to […]% of the grant, as required by BIRD.

7.4 Beginning in 1999 (for calendar year 1998), and continuing until the year following the year of the first commercial sale of LICENSED PRODUCTS, the LICENSEE shall submit annual progress reports to LICENSORS by February 28th of each year, which reports shall discuss the progress and results, as well as ongoing plans, with respect to the development of LICENSED PRODUCTS.

ARTICLE 8 – PATENTS AND INFRINGEMENT

8.1 Subsequent to the EFFECTIVE DATE, LICENSORS shall continue to have responsibility, at their shared expense, for filing, prosecuting and maintaining their jointly owned patent applications in the USPTO on TECHNOLOGY; DUKE shall continue to have responsibility, at its own expense, for filing, prosecuting and maintaining its solely owned patent applications in the USPTO on DUKE TECHNOLOGY; and MVP shall continue to have responsibility, at its own expense, for filing, prosecuting and maintaining its solely owned patent applications in the USPTO on MVP TECHNOLOGY. LICENSORS shall keep LICENSEE advised as to the prosecution of such applications by forwarding to LICENSEE copies of all official correspondence relating thereto, and shall give LICENSEE an opportunity to comment on all applications, responses to Office Actions, Declarations and other papers before they are filed with the USPTO, and shall consult with LICENSEE concerning the scope of allowed claims before paying any issue fee.

8.2 LICENSEE agrees to cooperate with the LICENSORS in the prosecution of the U.S. patent applications to ensure that the applications reflect, to the best of LICENSEE’s knowledge, all items of commercial and technical interest and importance.

***Confidential Treatment Requested
8.3 LICENSORS shall seek patent protection in Europe (including the United Kingdom), Japan and such other countries as LICENSEE may designate, and LICENSEE shall reimburse LICENSORS within thirty (30) days for their reasonable, out-of-pocket costs associated with obtaining such protection; provided, however, that the prosecution of such applications shall be at the direction of LICENSEE and LICENSEE may elect to prosecute such applications itself or have them prosecuted through LICENSEE’s agents.

(a) Regardless of whether LICENSORS or LICENSEE prosecute(s) such application, the resultant patents shall be owned by LICENSORS.

(b) LICENSORS may elect to seek patent protection in countries not designated by LICENSEE, in which case LICENSORS shall be responsible for all expenses attendant thereto.

(c) In the event that LICENSEE elects to prosecute foreign patent applications itself, LICENSORS will be kept informed, will have an opportunity to comment, and shall have the right to approve such applications, which approval will not be unreasonably withheld.

(d) If LICENSEE decides to abandon or not pursue any application, LICENSEE shall notify LICENSORS in a timely manner so that LICENSORS can decide whether or not to assume the prosecution.

8.4 Any inventions made, during the TERM of this AGREEMENT, with respect to the manufacture, use or sale of LICENSED PRODUCTS shall be:

(a) the sole property of LICENSEE if made solely by LICENSEE;

(b) the joint property of LICENSEE and LICENSORS if made jointly by LICENSEE and LICENSORS; and

(c) the sole property of LICENSORS if made solely by LICENSORS;

provided, however, that any such invention made solely by LICENSORS shall be included within PATENT RIGHTS.

8.5 Upon learning of the infringement by a third party of PATENT RIGHTS, the PARTY learning of such infringement shall promptly inform the other PARTIES, in writing, of that fact and shall provide any evidence available pertaining to such infringement.

(a) LICENSEE may elect, within sixty (60) days after notice and at its own expense, to take whatever steps are necessary to stop the infringement and recover damages.

(i) If LICENSEE elects to take such action, it will:
(A) keep LICENSORS informed of the steps taken and the progress of any legal actions taken;

(B) during the pendency of such actions, offset against royalties owed to LICENSORS on NET SALES in the country or countries affected by the infringement, the costs of any actions taken to stop such infringement up to a maximum of fifty percent (50%) of the royalties owed or owing to LICENSORS;

(C) be entitled to enter into a settlement on such terms as it may elect;

(D) retain for its own account, after first deducting the costs of any actions taken to stop such infringement, seventy-five percent (75%) of any amounts received in settlement or awarded as damages with the remaining twenty-five percent (25%) being paid in equal shares to LICENSORS; and

(E) if unsuccessful in halting such infringement, be entitled to reduce its royalties owed to LICENSORS, with respect to the country or countries affected by such infringement, by fifty percent (50%) during the remaining TERM of the Agreement in each of those countries; provided that the infringer has achieved ten percent (10%) or more of the market defined by LICENSED PRODUCTS and the infringing product in those countries in which the infringement exists.

(ii) If LICENSEE does not elect to take such action within such period, it will promptly inform LICENSORS, in which event LICENSORS may elect within thirty (30) days:

(A) to take such action as is required to stop such infringement, and will then be entitled to settle such actions on such terms as they may elect (provided, however, that if they grant a license to the infringer, LICENSEE shall be entitled to reduce its royalties owed to LICENSORS for the country or countries affected by fifty percent (50%) and shall be entitled to the benefit of any terms which are more favorable than those granted to LICENSEE under this AGREEMENT), will keep LICENSEE informed of the steps taken and the progress of any legal actions taken, and will be entitled to retain any amounts received in settlement or awarded in damages; provided, however, that during the period and for the country or countries in which LICENSEE does not enjoy exclusivity, or with respect to which LICENSORS are not able to stop such infringement, LICENSEE shall be entitled to reduce the applicable royalty rate by fifty percent (50%); provided that the infringer has achieved ten percent (10%) or more of the market defined by LICENSED PRODUCTS and the infringing product; or
(B) not to take any action against such infringers, in which event LICENSEE shall be entitled to elect either:

(1) to terminate this AGREEMENT pursuant to Section 8.8; or

(2) to reduce the applicable royalty rate by fifty percent (50%) for each country affected by such infringement; provided that the infringer has achieved ten percent (10%) or more of the market defined by LICENSED PRODUCTS and the infringing product in the countries where such infringement exists.

8.6 LICENSORS shall give prompt notice to LICENSEE of any inquiry received with respect to the availability of a license under PATENT RIGHTS or TECHNOLOGY and also of any third party patent of which LICENSORS become aware that may present an issue of infringement with respect to LICENSEE’s activities under this AGREEMENT.

8.7 LICENSEE shall give LICENSORS prompt notice of each claim or allegation received by it that the manufacture, use or sale of LICENSED PRODUCTS constitutes an infringement of a third party patent or other intellectual property rights. If such alleged infringement is due to the incorporation of DUKE TECHNOLOGY or MVP TECHNOLOGY in the LICENSED PRODUCTS, then:

(a) LICENSEE shall have the primary right and responsibility, but not the obligation, at its own expense to defend and control the defense of any such claims against LICENSEE, using counsel of its choosing.

(b) During the pendency of any such action, no royalties shall be payable to LICENSORS on account of NET SALES of LICENSED PRODUCTS in any countries affected by such action.

(c) LICENSEE’s attorneys’ fees and any amounts agreed to be paid in settlement of any such action or awarded against LICENSEE as damages, shall be deducted by LICENSEE from any future royalties due to LICENSORS.

(d) If LICENSEE is required to pay a royalty to any third party as a result of settlement of any such claim or allegation of infringement, it shall be entitled to deduct such royalty from the royalties due to LICENSORS under this AGREEMENT.

(e) The settlement of any such action must be approved by LICENSORS, which approval shall not be unreasonably withheld.

8.8 Independent of any action which LICENSEE or LICENSORS may elect to take pursuant to Section 8.5 or 8.7 with respect to the prosecution, defense or compromise of any such allegation or claim, LICENSEE may elect to terminate this AGREEMENT solely with respect to the country or countries to which such claim or allegation pertains. In such event, all rights to the use and sale of LICENSED PRODUCTS and regulatory filings in that country or those countries
shall revert to LICENSORS.

8.9 In any action brought under this Article 8, the PARTIES not bringing or defending the action shall, in their sole discretion, be entitled to participate through counsel of their own choosing in any such action; provided, however, that such participation shall be limited to an advisory role and counsel for the PARTY bringing or defending the action shall be lead counsel and the action shall be directed by such PARTY.

8.10 Each PARTY agrees to cooperate with the other PARTIES in any reasonable manner deemed by the PARTY defending or prosecuting an action under this Article 8, to be necessary in defending or prosecuting such action.

ARTICLE 9 – REGULATORY, PUBLICATION, OTHER USE, AND EXPORT

9.1 LICENSEE agrees to use its best efforts to have the LICENSED PRODUCTS cleared by the responsible government agencies requiring such clearance for marketing in those countries in which LICENSEE intends to sell LICENSED PRODUCTS or award sublicenses.

(a) To accomplish such clearances at the earliest possible dates, LICENSEE agrees to file, according to the standard practice in the industry, any and all necessary data with the appropriate government agencies.

(b) Where permitted by law, LICENSEE shall include the names of both LICENSORS as co-registrants on all regulatory filings.

9.2 LICENSEE further agrees that the right of publication of the TECHNOLOGY shall reside in the inventor(s) and other personnel of LICENSORS and the LICENSORS shall use their best efforts to provide a copy of such publication forty-five (45) days in advance of publication for review by LICENSEE. If LICENSEE determines that the publication by LICENSORS will disclose any trade secrets, LICENSORS shall delay publication for an additional sixty (60) days after the forty-five (45) day period to allow patent applications to be filed.

9.3 It is agreed that, notwithstanding any provisions herein, LICENSORS are free to use the TECHNOLOGY and PATENT RIGHTS for their own non-commercial purposes, whether educational, teaching, research or clinical purposes, without payment of royalties or other fees.

9.4 LICENSEE and LICENSORS agree to comply with all United States laws and regulations controlling the export of technical data, computer software, laboratory prototypes and other commodities and technology.
ARTICLE 10 – DURATION AND TERMINATION

10.1 This AGREEMENT shall become effective upon the EFFECTIVE DATE and shall remain in full force and effect, on a country-by-country basis, for the longer of: ten (10) years from the date of first sale of LICENSED PRODUCTS in each country, or the date of expiration of the last-to-expire patent, of those patents included in the PATENT RIGHTS, in each country; such period of time with respect to each country being known as the TERM of this AGREEMENT; provided, however, that this AGREEMENT may be terminated in one or more countries prior to the TERM in accordance with Sections 8.8, 10.2, 10.3 or 10.6.

10.2 LICENSEE may, prior to expiration of the TERM, elect to terminate this AGREEMENT with respect to any one or more countries in the TERRITORY, at any time, effective after the first anniversary of the EFFECTIVE DATE, by giving LICENSORS written notice at least six (6) months prior to each such termination. On the effective date of each such termination, LICENSEE shall cease the manufacture, use and sale of LICENSED PRODUCTS in the country or countries in which LICENSEE has elected to terminate prior to expiration of the TERM.

10.3 As used in this Section 10.3, PARTY shall mean either (1) BTG or (2) MVP and DUKE, jointly. Any PARTY may immediately terminate this AGREEMENT for fraud, willful misconduct, or illegal conduct of the other PARTY upon written notice of same to such PARTY. Except as provided above, if a PARTY fails to fulfill any of its material obligations under this AGREEMENT, the non-breaching PARTY may terminate this AGREEMENT, with respect to the country or countries affected, upon written notice to the other PARTY, as provided below. Such notice must contain a full description of the event or occurrence constituting a breach of this AGREEMENT. A PARTY receiving notice that it has breached the AGREEMENT will have the opportunity to cure that breach within thirty (30) days of the receipt of notice. A PARTY’s ability to cure a breach will apply only to the first two (2) material breaches properly noticed to that PARTY under the terms of this AGREEMENT. Any subsequent material breach by that PARTY will entitle the other PARTY to terminate this AGREEMENT immediately upon proper notice to such PARTY without a cure period. In the event that a PARTY commits such a subsequent breach, the non-breaching PARTY may, at its option and in addition to any other remedies it may have in law or in equity, terminate this AGREEMENT for default by sending to the breaching PARTY written notice of termination, effective immediately upon receipt.

10.4 Upon the termination of this AGREEMENT in one or more countries prior to the end of the TERM, LICENSEE shall notify LICENSORS of the quantity of LICENSED PRODUCTS that LICENSEE then has in inventory with respect to the country or countries for which the termination is effective and LICENSEE shall then have a license in each such country to sell that amount of LICENSED PRODUCTS, but no more, provided that the LICENSEE shall pay the royalty thereon at the rate and at the time provided for herein.
10.5 If this AGREEMENT is terminated pursuant to Section 8.8 or pursuant to this Article 10 by either LICENSEE or LICENSORS prior to the end of the TERM in one or more countries, then all intellectual property rights conveyed by LICENSORS to LICENSEE under this AGREEMENT (including, without limitation: rights in the mark, PURICASE™, approved and pending regulatory applications, Orphan Drug Designations, Drug Master Files, sublicenses, preclinical data and clinical data) shall revert to LICENSORS with respect to those countries.

10.6 If, during the TERM of this AGREEMENT, a PARTY shall become bankrupt or insolvent, or if the business of a PARTY shall be placed in the hands of a receiver or trustee, whether by the voluntary act of such PARTY or otherwise, or if a PARTY shall cease to exist as an active concern, then if the PARTY experiencing such event is:

(a) LICENSEE, then this AGREEMENT shall terminate immediately, and all rights to LICENSED PRODUCTS and the TECHNOLOGY shall revert to the LICENSORS or their respective successors or assignees;

(b) MVP or DUKE, then the rights granted to LICENSEE under this AGREEMENT by such LICENSOR shall become paid-up, exclusive, and irrevocable, this AGREEMENT shall terminate with respect to such LICENSOR, and LICENSEE shall make such payments to the remaining LICENSOR that it would have received absent termination of the AGREEMENT with respect to the other LICENSOR.

10.7 Expiration or termination of this AGREEMENT shall be without prejudice to or limitation on any other remedies or any accrued obligations of any of the PARTIES.

ARTICLE 11 – CONFIDENTIAL INFORMATION

11.1 Confidential information (“INFORMATION”) shall mean all information provided by LICENSORS to LICENSEE or by LICENSEE to LICENSORS and identified as confidential at the time of disclosure. Specifically excepted from this definition is all information that is:

(a) already known by the receiving PARTY at the time of disclosure, as demonstrated by clear and convincing evidence contemporaneous with or preceding the disclosure;

(b) publicly disclosed through no improper act or omission of the receiving PARTY;

(c) rightfully received by the receiving PARTY from a third party without any obligation of confidentiality; or
(d) disclosed pursuant to any judicial or government requirement or order, provided that the receiving PARTY takes reasonable steps to provide the disclosing PARTY with sufficient prior notice in order to allow the disclosing PARTY to contest such requirement or order; or

(e) independently developed by DUKE alone, without reference or access to the disclosing PARTY’s INFORMATION.

11.2 In the event the receiving PARTY is required by law, regulation or court order to disclose any of the disclosing PARTY’s INFORMATION, the receiving PARTY will promptly notify the disclosing PARTY in writing prior to making any such disclosure in order to facilitate the disclosing PARTY seeking a protective order or other appropriate remedy from the proper authority. The receiving PARTY agrees to cooperate with the disclosing PARTY in seeking such order or other remedy. The receiving PARTY further agrees that if the disclosing PARTY is not successful in precluding the requesting legal body from requiring the disclosure of the INFORMATION, it will furnish only that portion of the INFORMATION that is legally required and will exercise all reasonable efforts to obtain reliable assurances that confidential treatment will be accorded the INFORMATION.

11.3 The receiving PARTY agrees to hold INFORMATION in trust and confidence for the disclosing PARTY, using the same care and discretion that the receiving PARTY uses with respect to its own proprietary information that it considers confidential and, in any event, at least the care that is standard in the industry for confidential, proprietary information of another. The receiving PARTY will not use such information for any purpose except those expressly set forth in this AGREEMENT and will not disclose such information to any third party without the prior written authorization from the disclosing PARTY.

(a) Any INFORMATION that MVP discloses to BTG related to PEGylation of proteins or to purification or analysis of PEG-protein conjugates may not be disclosed to DUKE. Except as provided in the foregoing sentence, any other INFORMATION that MVP discloses to BTG may be disclosed by BTG to DUKE.

(b) Obligations of this Section 11.3 shall remain in effect during the TERM of this AGREEMENT and for a period of five (5) years after the expiration or termination of the AGREEMENT in the last-to-expire or last-to-terminate country, whichever occurs later.

(c) No provision contained in this AGREEMENT shall be read to preclude BTG from providing PEGylated uricase to DUKE for research or clinical purposes, or from informing DUKE of the number of strands and molecular weight of the PEG and other descriptive characteristics of the PEGylated uricase provided to DUKE.

(d) Notwithstanding the foregoing, DUKE shall not be obligated to hold in confidence another PARTY’s INFORMATION for longer than five (5) years after such INFORMATION is disclosed to it.
ARTICLE 12 – LAW TO GOVERN

12.1 The laws of the State of California will govern the construction, interpretation and performance of this AGREEMENT, without giving effect to conflicts of law rules thereof.

ARTICLE 13 – ASSIGNMENT

13.1 No PARTY may assign any of its rights or delegate any of its duties under this AGREEMENT without the prior written consent of the other PARTIES except:

(a) In connection with the sale of a PARTY’s entire business operation; or

(b) In connection with the assignment of the rights or delegation of the duties of any PARTY to any of its AFFILIATES.

13.2 Any unauthorized attempted assignment or delegation shall be null and void and of no force or effect.

ARTICLE 14 – NOTICES

14.1 Any notice or other communication required or permitted under this AGREEMENT will be in writing and will be deemed given as of the date it is: (a) delivered by hand, or (b) mailed, postage prepaid, first class, certified mail, return receipt requested, to the PARTY/PARTIES at the address listed below or subsequently specified in writing, or (c) sent, postage prepaid, return receipt requested, by courier service, to the PARTY/PARTIES at the address listed below or subsequently specified in writing:

If to the LICENSORS:

Mountain View Pharmaceuticals, Inc.
3475-S Edison Way
Menlo Park, California 94025
Attn.: Merry R. Sherman, Ph.D.

AND:

Office of Science and Technology
North Building, Room 230
Research Drive
Duke University, Box 90083
Durham, North Carolina 27708
Attn.: License Administrator
ARTICLE 15 – INDEMNITY, INSURANCE AND REPRESENTATIONS

15.1 LICENSEE agrees to indemnify, hold harmless and defend LICENSORS, their officers, employees, and agents, against any and all claims, suits, losses, damages, costs, fees, and expenses, including reasonable attorneys’ fees, asserted by third parties, both government and non-government, resulting from or arising out of LICENSEE’s exercise of the rights granted under this AGREEMENT. LICENSEE shall not be responsible for the intentional wrongdoing of LICENSORS.

15.2 LICENSORS agree to indemnify, hold harmless and defend LICENSEE, its officers, employees, and agents, against any and all claims, suits, losses, damages, costs, fees, and expenses, including reasonable attorneys’ fees, asserted by third parties, both government and non-government, resulting from or arising out of LICENSORS’s exercise of their rights and obligations under this AGREEMENT. LICENSORS shall not be responsible for the intentional wrongdoing of LICENSEE.

15.3 The PARTIES shall maintain in force at their sole cost and expense general liability insurance coverage in an amount reasonably sufficient to protect against liability under this Article 15. LICENSEE also shall maintain in force at its sole cost and
expense product liability insurance coverage in an amount reasonably sufficient to protect against liability under this Article 15. Each PARTY shall have the right to request and to receive copies of the appropriate certificates of insurance from the other PARTIES for the purpose of ascertaining the sufficiency and currency of such coverage.

15.4 Except as provided in Section 15.8, nothing in this AGREEMENT shall be deemed to be a representation or warranty by LICENSORS of the validity of any of the patents or the accuracy, safety, efficacy, or usefulness, for any purpose, of any TECHNOLOGY.

15.5 LICENSORS shall have no obligation, expressed or implied, to supervise, monitor, review or otherwise assume responsibility for the production, manufacture, testing, clinical trials, marketing or sale of any LICENSED PRODUCTS, and LICENSORS shall have no liability whatsoever to LICENSEE, its officers, employees or agents for or on account of any injury, loss, or damage, of any kind or nature, sustained by, or any damage assessed or asserted against, or any other liability incurred by or imposed upon LICENSEE, its officers, employees or agents or any other person or entity, arising out of or in connection with or resulting from LICENSEE’s:

(a) production, use, or sale of any LICENSED PRODUCTS;

(b) use of any TECHNOLOGY; or

(c) advertising or other promotional activities with respect to any of the foregoing.

15.6 MVP hereby represents and warrants to BTG and DUKE that MVP has the right to grant the licenses set forth herein under PATENT RIGHTS and MVP TECHNOLOGY, including the license to the technical know-how summarized in Exhibit B, and to the use of the trademark, PURICASE™.

15.7 DUKE hereby represents and warrants to BTG and MVP that DUKE has the right to grant the licenses set forth herein under PATENT RIGHTS and DUKE TECHNOLOGY, including the license to the technical know-how and materials summarized in Exhibit A.

15.8 Each of the LICENSORS hereby separately represents and warrants to BTG that:

(a) it has no actual knowledge, as of the EFFECTIVE DATE, that the use of TECHNOLOGY for the manufacture, use or sale of LICENSED PRODUCTS will infringe any patent or other intellectual property right of any third party in any country in the world, and that, if at any time during the TERM of this AGREEMENT, it becomes aware of any such information, it will promptly disclose such to BTG;
(b) it has no actual knowledge, as of the EFFECTIVE DATE, of any prior art that would raise any issue concerning the validity of any patents issued or to issue on any applications which are included in PATENT RIGHTS, and that, if at any time during the TERM of this AGREEMENT, it becomes aware of any such information, it will promptly disclose such to BTG;

(c) it is not aware of any other agreements, amendments or licenses that affect its authority or ability to enter into this AGREEMENT;

(d) prior to the execution of this AGREEMENT, it has not assigned, encumbered, pledged, mortgaged, used as collateral, granted a security interest or lien in or otherwise engaged in any action that affects its ability to grant LICENSEE the rights granted pursuant to the terms of this AGREEMENT; and

(e) during the TERM of this AGREEMENT, it will not engage in any action that could reasonably be anticipated to adversely affect its ability to grant LICENSEE the rights to manufacture, use and sell LICENSED PRODUCTS anywhere in the world pursuant to the terms of this AGREEMENT.

ARTICLE 16 – USE OF A PARTY’S NAME

16.1 Except for the rights granted to LICENSEE herein with respect to the mark PURICASE™, no PARTY to this AGREEMENT will, without the prior written consent of another party:

(a) use in advertising, publicity or otherwise, the name of any employee or agent, any trade-name, trademark, trade dress, service mark, symbol, or any abbreviation, contraction or simulation thereof owned by another PARTY; or

(b) represent, either directly or indirectly, that any product or service of another PARTY is a product or service of the representing PARTY or that it is made in accordance with or utilizes the information or documents of another PARTY.

16.2 No PARTY will originate any publicity, news release or other public announcement or comment, written or oral, related to this AGREEMENT without the prior written consent of the other PARTIES, except as may be required by law. The PARTY making any announcement, which it reasonably believes to be required by law, will first give the other PARTIES an opportunity to review the form and content of any such announcement and comment upon it before it is made.
Notwithstanding the foregoing, LICENSORS acknowledge that BTG is a publicly traded company, and hereby consent to BTG’s disclosure of this AGREEMENT and its relationship with LICENSORS in its filings with the Securities and Exchange Commission and its disclosures to its stockholders.

ARTICLE 17 – SEVERABILITY

17.1 Each clause of this AGREEMENT is distinct and severable. If any clause is deemed illegal, void or unenforceable, it is the PARTIES’ intent that all other clauses or portions of this AGREEMENT shall remain in effect to the maximum extent possible.

ARTICLE 18 – WAIVER

18.1 The failure of any PARTY in any instance to insist upon the strict performance of the terms of this AGREEMENT will not be construed to be a waiver or relinquishment of any of the terms of this AGREEMENT, either at the time of the PARTY’s failure to insist upon strict performance or at any subsequent time, and such terms will continue in full force and effect.

ARTICLE 19 – TITLES

19.1 All titles and article headings contained in this AGREEMENT are inserted only as a matter of convenience and reference. They do not define, limit, extend or describe the scope of this AGREEMENT or the intent of any of its provisions.

ARTICLE 20 — ENTIRE UNDERSTANDING

20.1 This AGREEMENT represents the entire understanding between the LICENSEE and the LICENSORS, and supersedes all other agreements, expressed or implied,
between the LICENSEE and the LICENSORS, with the sole exception of the agreement dated July 30, 1998 among BIRD, BTG and MVP.

IN WITNESS WHEREOF, the PARTIES have caused this AGREEMENT to be executed by their duly authorized representatives as of the EFFECTIVE DATE.

MOUNTAIN VIEW PHARMACEUTICALS, INC.

By: /s/ Merry R. Sherman, Ph.D.
    Merry R. Sherman, Ph.D.
    President

DUKE UNIVERSITY

By: /s/ Robert L. Taber
    Robert L. Taber, Ph.D.
    Associate Vice-Chancellor and Director,
    Office of Science and Technology

BIO-TECHNOLOGY GENERAL CORP.

By: /s/ Robert M. Shaw
    Robert M. Shaw
    Vice President, General Counsel
Exhibit A
Summary of Know-how, Information and Materials to be Provided by
DUKE to BTG as Part of DUKE TECHNOLOGY

[...***…]

***Confidential Treatment Requested
Exhibit B

Summary of Know-how, Information and Materials to be Provided by MVP to BTG as Part of MVP TECHNOLOGY

[... *** ...]

***Confidential Treatment Requested
Exhibit C

Patents and Patent Applications included within PATENT RIGHTS
(To Be Amended from Time to Time during the TERM)

[...***…]

***Confidential Treatment Requested
Amendment

BTG, Duke and MVP agree as follows:

Article 1 - Definitions

1.0 Unless specifically defined in this Amendment, the capitalized terms shall have the meanings ascribed to them in the Agreement.

1.1 “Agreement” shall mean the License Agreement entered into by and among BTG, Duke and MVP on August 12, 1998.

1.2 “Amendment” shall mean this amendment to the Agreement entered into by and among BTG, Duke and MVP as of the Amendment Date.

1.3 “Amendment Date” shall mean November 12, 2001.

Article 2 — Amendments.

3.0 Effective as of the Amendment Date, the Agreement is amended to delete Section 9.1(b) in its entirety.

3.1 This amendment is conditioned upon the payment to MVP by BTG (by wire transfer) of $[…***…], (consisting of $[…***…] allocated to Milestone No. 4 and $[…***…] allocated to Milestone No. 5), as an advance payment in partial satisfaction of the payments due under Milestone Nos. 4 and 5.

3.2 BTG shall provide to MVP complete copies of all written and electronic communications related to PEG-uricase, such as regulatory filings and other correspondence, to and from government regulatory agencies (including, without limitation, the U.S. Food and Drug Administration), within five (5) business days of BTG’s filing or receipt, respectively, of such communications.

Article 3 — Miscellaneous

3.1 This Amendment shall be effective as of the Amendment Date.

3.2 Except as expressly modified in this Amendment, the Agreement shall remain in full force and effect according to its terms.

IN WITNESS WHEREOF, BTG, Duke and MVP have caused this Amendment to be executed as of the Amendment Date by their duly authorized officers.

BIO-TECHNOLOGY GENERAL CORP.

By: /s/ Norman W. Barton

Name: Norman W. Barton

Title: Chief Medical Officer

***Confidential Treatment Requested
DUKE UNIVERSITY

By: /s/ Robert L. Taber

Name: Robert L. Taber, Ph.D.

Title: Vice Chancellor, Science & Tech. Dev.

MOUNTAIN VIEW PHARMACEUTICALS, INC.

By: /s/ Mark Saifer

Name: Mark Saifer

Title: Vice President
SECOND AMENDMENT TO LICENSE AGREEMENT

THIS SECOND AMENDMENT is made and entered effective as of the 30th day of August, 2010, (hereinafter, the “SECOND AMENDMENT EFFECTIVE DATE”).

AMONG:

SAVIENT PHARMACEUTICALS, INC.
a Delaware corporation, formerly known as Bio-Technology General Corporation (hereinafter, “SAVIENT”)

AND

MOUNTAIN VIEW PHARMACEUTICALS, INC.
a California corporation, (hereinafter, “MVP”)

AND

DUKE UNIVERSITY
a North Carolina not-for-profit corporation, (hereinafter, “DUKE”).

WHEREAS:

SAVIENT, MVP and DUKE are PARTIES to a License Agreement dated August 12, 1998, as amended by the Amendment effective as of November 21, 2001 (hereinafter, the “AGREEMENT”) pursuant to which SAVIENT licensed from MVP and DUKE the exclusive rights to develop, manufacture and sell certain LICENSED PRODUCTS, as defined in the AGREEMENT,

NOW THEREFORE in consideration of the mutual promises, agreements and covenants contained herein, the adequacy of such consideration having been agreed and acknowledged by each PARTY, the PARTIES agree to further amend the AGREEMENT as follows:

1. Definitions. All capitalized terms utilized herein shall have the same meaning ascribed to them and set forth in Article 2, DEFINITIONS of the AGREEMENT, unless specifically stated otherwise herein or unless a defined term is specifically modified hereby. For the avoidance of doubt, as used throughout the AGREEMENT, the term “LICENSORS” is meant to designate one or both of MVP and DUKE, as the context requires.

2. Change of Name Acknowledgement. Section 2.4 of the AGREEMENT is hereby deleted in its entirety and replaced as follows:

“SAVIENT” shall mean Savient Pharmaceuticals, Inc., formerly known as Bio-Technology General Corporation (“BTG”), a corporation organized under the laws of Delaware, and having its principal offices located at One Tower Center, East Brunswick, New Jersey 08816, and its AFFILIATES. The PARTIES acknowledge that Bio-Technology General Corporation formally changed its name to Savient Pharmaceuticals, Inc. on June 24, 2003. All references to “BTG” in the AGREEMENT are hereby deleted and replaced with “SAVIENT” and SAVIENT assumes all rights,
assignments and responsibilities under this AGREEMENT previously due to, owned by, assigned to or due or responsible from BTG.

3. **Activities of [...] of LICENSED PRODUCTS.** Section 5.12(d) of the AGREEMENT is hereby deleted in its entirety and replaced as follows:

“(d) that such manufacturer is not [...] (hereinafter, “[...]”), or [...] or any AFFILIATE, subsidiary or successor thereof; [...]. Except with respect to the matters specifically contemplated herein; the PARTIES agree that no PARTY waives any claim that may have arisen prior to the date hereof under the terms and conditions of the AGREEMENT; and”

4. **Completion of Technology transfer and Payment of Milestones.** The PARTIES acknowledge and agree that the technology transfer contemplated in Section 5.8 of the AGREEMENT has been successfully completed and that all milestone payments identified in Section 5.1(1) through and including Section 5.1(6) have been made by SAVIENT to each of the LICENSORS in accordance with the relevant terms of Section 5.2 of the AGREEMENT as of the Effective Date of this SECOND AMENDMENT.

5. **No Notice of Breach of Agreement.** The PARTIES acknowledge and agree that the AGREEMENT is in full force and effect and that no PARTY has provided notice to any other PARTY of any breach of the AGREEMENT pursuant to Section 10.3 of the AGREEMENT.

6. **Updated Patent Rights.** The PARTIES acknowledge and agree that Exhibit C to the AGREEMENT is hereby amended to reflect the PATENT RIGHTS contemplated under the AGREEMENT as of the SECOND AMENDMENT EFFECTIVE DATE and as set forth in the attached Exhibit C-1 and that the

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Second Amendment to License Agreement

Page 2 of 15 (excluding Appendices)
7. **Representation of LICENSORS.** The LICENSORS and LICENSEE represent and warrant that Exhibit C-1 is complete and accurate in all material respects.

8. Section 8.4 is hereby deleted in its entirety and replaced as follows:

“8.4 Any inventions made, during the TERM of this AGREEMENT, with respect to the manufacture, use or sale of LICENSED PRODUCTS shall be:

(a) the sole property of LICENSEE if made solely by LICENSEE;

(b) the joint property of LICENSEE and both LICENSORS if made jointly by LICENSEE and both LICENSORS;

(c) the joint property of LICENSEE and a LICENSOR if made jointly by LICENSEE and that LICENSOR and not by the other LICENSOR;

(d) the joint property of LICENSORS if made jointly by LICENSORS and not by LICENSEE; and

(e) the sole property of a LICENSOR if made solely by that LICENSOR;

*Provided, however,* that any such invention that is DUKE TECHNOLOGY and/or MVP TECHNOLOGY as defined in Sections 2.6 and 2.16, respectively, made solely by a LICENSOR or jointly by the LICENSORS (i) shall be automatically included within the TECHNOLOGY (ii) shall be promptly disclosed by the LICENSORS or relevant LICENSOR to LICENSEE and (iii) any patents and patent applications in which at least one claim is directed to any such invention so included in the TECHNOLOGY shall be automatically included within the PATENT RIGHTS.

*Provided, further,* that in the event that a patent application on any invention coveted by section 8.4 (a), (b), or (c) is directed to subject matter described or disclosed in or claimed by any PATENT RIGHTS: (A) LICENSEE will advise the applicable LICENSOR that such LICENSOR’S PATENT RIGHTS are implicated by the prosecution of such LICENSEE patent application by forwarding to such LICENSOR a copy of any application and all official correspondence relating thereto received from any patent office and any proposed material response thereto drafted by LICENSEE no later than […***…] ([…***…]) business days prior to the anticipated filing date for such application or response (except in the event of a provisional patent application filed on an emergency basis, LICENSEE shall provide a commercially reasonable period dictated by the prevailing circumstances), to allow LICENSOR a reasonable opportunity to provide appropriate written comments on LICENSEE’S draft application, responses to Office Actions,

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Declarations, and any other papers affecting the prosecution of the patent application before such papers are filed with the USPTO or an equivalent non-US patent authority, such comments provided by such LICENSOR shall be limited to that portion of LICENSEE’S draft application, responses to Office Actions, Declarations, and any other papers affecting the prosecution of the patent application which relate, are directed to or implicate the subject matter described or disclosed in or claimed by such LICENSOR’S PATENT RIGHTS; (B) LICENSEE will reasonably incorporate or otherwise appropriately address any such written comments received from such LICENSOR in such papers to be so filed; and (C) LICENSEE will provide each such LICENSOR with a reasonable opportunity to timely consult with LICENSEE concerning the scope of allowed claims before paying any issue or equivalent non-US fee. In no event, however will LICENSEE’S acceptance or non-acceptance of any comments from any LICENSOR provided in accordance with this section, in whole or in part, be a basis for alleging a breach of this Section 8.4.”

9. Notices. Section 14.1 of the AGREEMENT is hereby deleted in its entirety and replaced as follows:

14.1 Any notice or other communication required or permitted under this AGREEMENT will be in writing and will be deemed given as of the date it is: (a) delivered by hand, or (b) mailed, postage prepaid, first class, certified mail, return receipt requested, to the PARTY/PARTIES at the address(es) listed below or subsequently specified in writing, or (c) sent, postage prepaid, return receipt requested, by courier service, to the PARTY/PARTIES at the address(es) listed below or subsequently specified in writing:

If to the LICENSORS:

Mountain View Pharmaceuticals, Inc.
3475-S Edison Way
Menlo Park, California 94025-1821
Attn: Merry R. Sherman, Ph.D.

AND:

Duke University School of Medicine
Office of Corporate Research Collaborations
2200 W. Main St., Suite 700
Box 104025
Durham, North Carolina 27710
Attn: Director

With a copy to:

Skadden, Arps, Slate, Meagher & Flom LLP
Four Times Square
New York, New York 10036
Attn: Matthew B. Zisk, Ph.D., Esq.

AND:

Duke University
Office of University Counsel
310 Blackwell Street, 4th Floor
Box 104124
Durham, North Carolina 27710

With a copy to:

Duke University School of Medicine
Office of Corporate Research Collaborations
2200 W. Main St., Suite 700
Box 104025
Durham, North Carolina 27710

9. **No Modification.** Except as expressly provided for herein, the AGREEMENT shall remain in full force and effect without amendment. The AGREEMENT, as amended by this SECOND AMENDMENT, contains the entire agreement among the PARTIES with respect to the subject matter contemplated herein and from and after the SECOND AMENDMENT EFFECTIVE DATE, the AGREEMENT shall mean the AGREEMENT as so further amended by this SECOND AMENDMENT. The PARTIES agree that no further amendment or modification to the AGREEMENT shall become binding unless such further amendment or modification is reduced to writing and is contained in a written amendment signed by all PARTIES hereto.

[The remainder or this page is intentionally blank.]
IN WITNESS WHEREOF, the PARTIES have caused this SECOND AMENDMENT to be executed by their respective duly authorized representatives as of the date first written above.

SAVIENT PHARMACEUTICALS, INC.

By: /s/ Philip K. Yachmetz
   Philip K. Yachmetz, Esq.
   Senior Vice President &
   General Counsel

DUKE UNIVERSITY

By: /s/ H. Gilbert Smith
   Name: H. Gilbert Smith, Ph. D
   Title: Managing Director, Corporate Research
         Collaborations & Licensing Officer

MOUNTAIN VIEW PHARMACEUTICALS, INC.

By: /s/ Merry R. Sherman
   Merry R. Sherman, Ph.D.
   CEO and President

Second Amendment to License Agreement
Exhibit C-1

Patents and Patent Applications included within PATENT RIGHTS
(To Be Amended from Time to Time during, the TERM)

[...***...]

***Confidential Treatment Requested
[...***...]

***Confidential Treatment Requested
April 14, 2014

Merry R. Sherman, Ph.D.
CEO and President
Mountain View Pharmaceuticals, Inc.
3475 Edison Way, Suite S
Menlo Park, CA 94025-1821

H. Gilbert Smith, Ph.D.
Associate Dean & Managing Director
Corporate Research Collaborations
Duke University School of Medicine
2200 W. Main Street, Suite 910B
Durham, NC 27705

Re: Third Amendment to License Agreement by and among Mountain View Pharmaceuticals, Inc. (“MVP”), Duke University (“Duke”), and Savient Pharmaceuticals, Inc. (formerly known as Bio-Technology General Corporation (“BTG)) dated August 12, 1998, as amended November 12, 2001 and August 30, 2010 (the “License”)

Dear Drs. Sherman and Smith:

The purpose of this letter agreement (this “Third Amendment”) is to amend the License effective as of March 12, 2014 (the “Effective Date”). In connection with the acquisition by Crealta Pharmaceuticals LLC (“Crealta”) of the business operations of Savient Pharmaceuticals, Inc. (“Savient”), Savient assigned all of its rights and obligations under the License to Crealta effective as of January 9, 2014 (the “Assignment Effective Date”). As a result, all references in the License to either BTG or Savient are hereby understood to refer to Crealta, provided that the foregoing shall not be interpreted as granting Crealta any rights prior to the Assignment Effective Date, granting MVP or Duke any additional rights under the License, requiring MVP or Duke to render performance to Crealta of any obligations satisfied by MVP or Duke prior to the Assignment Effective Date, or requiring Crealta to render performance to MVP or Duke of any obligations satisfied by BTG or Savient prior to the Assignment Effective Date. Crealta, MVP and Duke are the “Parties” hereto and each, individually, is a “Party”.

In addition, the Parties confirm that the current notice information for each of the Parties for the purposes of Section 14.1 of the License is as follows:

[Contact information for Crealta]
Further, attached to this Third Amendment is Exhibit C-2, which reflects the Patent Rights contemplated under the License as of the Effective Date. This Exhibit C-2 replaces Exhibit C of the License and Exhibit C-1 of the Second Amendment, and it is subject to further updating by the Parties during the Term as contemplated in Section 2.19 of the License.

The Parties also acknowledge and agree that: (i) all milestone payments identified in Section 5.1(1) through and including Section 5.1(9) have been made by Licensee to each of the Licensors; (ii) the License is in full force and effect; and (iii) that no Party to the License has provided notice to any other Party to the License of any breach of the License pursuant to Section 10.3 of the License.

Finally, the Parties agree that: (i) in Article 2 of the Amendment of the License dated November 12, 2001, the section numbers shall be corrected to read 2.0, 2.1, and 2.2, respectively; and (ii) in the Second Amendment of the License dated August 30, 2010, Section 9 titled “No Modification” shall be corrected to Section 10.

Except as previously provided for herein, the License shall remain in full force and effect without amendment. The License, as amended by this Third Amendment, contains the entire agreement among the Parties with respect to the subject matter contemplated herein and from and after the Effective Date, the License shall mean the License as so further amended by this Third Amendment. The Parties agree that no further amendment or modification to the License shall become binding unless such further
amendment or modification is reduced to writing and is contained in a written amendment signed by all Parties hereto.

All capitalized terms used in this Third Amendment that are not otherwise defined herein shall have the meanings set forth in the License.

Please confirm MVP’s and Duke’s agreement with the foregoing by signing and dating where indicated below and returning the countersigned Third Amendment to me.

Sincerely,

/s/ Edward Donovan

Edward Donovan
General Counsel, Crealta Pharmaceuticals LLC

Acknowledged and Agreed:

MOUNTAIN VIEW PHARMACEUTICALS, INC.

By: /s/ Merry R. Sherman
Name: Merry R. Sherman
Title: CEO and President
Date: April 14, 2014

DUKE UNIVERSITY

By: /s/ H. Gilbert Smith
Name: H. Gilbert Smith, Ph.D.
   Assoc. Dean and Managing Director
Title: Corporate Research Collaborations
Date: April 14, 2014

Cc: Marya Postner, Ph.D., Esq.
    Cooley LLP
    3175 Hanover Street
    Palo Alto, CA 94304-1130
Exhibit C-2

See attached.
SCHEDULE A

Patents and Patent Applications included within PATENT RIGHTS
(To Be Amended from Time to Time during the TERM)

[...***...]

***Confidential Treatment Requested

page 1 of 10
FOURTH AMENDMENT
TO LICENSE AGREEMENT BY AND AMONG
MOUNTAIN VIEW PHARMACEUTICALS, INC., DUKE UNIVERSITY AND
CREALTA PHARMACEUTICALS LLC,
INCLUDING PATENT ASSIGNMENT

BACKGROUND

Mountain View Pharmaceuticals, Inc. ("MVP"), Duke University ("Duke"), and Crealta Pharmaceuticals LLC ("Licensee") are parties to that certain License Agreement dated August 12, 1998, as previously amended on November 12, 2001, August 30, 2010 and March 12, 2014 (the "Agreement"). The Parties now wish to further amend the Agreement, in accordance with the terms and conditions set forth in this Fourth Amendment to the Agreement (this "Amendment").

AGREEMENT

NOW, THEREFORE, in consideration of the foregoing and the covenants and promises contained herein, the Parties hereby agree to amend the Agreement as follows, effective as of the last date signed by all of the Parties (the "Amendment Effective Date"), subject to being binding on MVP and Licensee as set forth in Section 9:

1. Definitions. Capitalized terms used herein and not otherwise defined shall have the meaning ascribed in the Agreement.

   (a) The following definitions are hereby added to Article 2 of the Agreement:

      2.33 “Assigned Patent Rights” means the U.S. patents and patent applications set forth in Exhibit A hereto, together with all substitutes, continuations, divisional applications, reexaminations or reissues of the foregoing. For the avoidance of doubt, the Assigned Patent Rights do not include any patents or patent applications in any country or jurisdiction other than the United States.

      2.34 “Ex-U.S. Net Sales” means [***].

      2.35 “United States” or “U.S.” means the United States and its 50 States and territories.

      2.36 “U.S. Net Sales” means [***].

   (b) The following sentence is hereby added to the end of the definition of Patent Rights in Section 2.19 of the Agreement: Notwithstanding the foregoing, Patent Rights shall not include MVP’s interest in the Assigned Patent Rights.

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2. **Consideration.** Within […***…] days of the Amendment Effective Date, Licensee shall pay to MVP the non-creditable, non-refundable amount of […***…] U.S. Dollars ($[…***…]) in immediately available funds in consideration of the assignment of MVP’s interest in the Assigned Patent Rights and the other modifications to the Agreement set forth herein. Licensee shall make such payment to MVP by wire transfer to the bank account specified in Exhibit B of this Amendment. The modifications to Licensee’s rights and obligations under the Agreement set forth in Sections 3 and 4 below and the assignment of MVP’s interest in the Assigned Patent Rights are contingent upon, and shall not become effective until, MVP’s receipt of such payment in full (the date of MVP’s receipt of such payment, the “Modification Effective Date”). Upon the Modification Effective Date, the transfer of MVP’s interest in the Assigned Patent Rights shall be final and irrevocable, and MVP shall not have any of MVP’s interest in the Assigned Patent Rights returned, reverted, or otherwise assigned back to MVP, unless agreed to in writing by Licensee and MVP.

3. **Modifications with respect to Licensee’s U.S. Royalty Obligations to MVP.** Subject to Section 2 above, and without affecting any rights of Duke or any obligations of Licensee to Duke:

   (a) Commencing as of […***…] (the “Royalty Adjustment Date”), the license granted to Licensee pursuant to Section 4.1 of the Agreement shall become royalty-free and fully paid up solely with respect to MVP’s interest in the Technology, Assigned Patent Rights, and the Patent Rights, in each case, solely with respect to the U.S. Accordingly, U.S. Net Sales made prior to the Royalty Adjustment Date shall remain royalty-bearing under Article 6 of the Agreement, and U.S. Net Sales made on or after the Royalty Adjustment Date shall be royalty-free, as further set forth in subsection (b) below.

   (b) Commencing upon the Royalty Adjustment Date, Licensee shall be relieved of its obligations (i) under Section 6.1 of the Agreement to pay any royalty to MVP on U.S. Net Sales, and (ii) under Section 6.3 of the Agreement to pay any royalty to MVP on Sublicense Revenues solely to the extent arising from sublicenses granted by Licensee to use, sell or offer to sell Licensed Products in the U.S. (and to manufacture, have manufactured and/or import Licensed Products in connection therewith) (such Sublicense Revenues, “U.S. Sublicense Revenues”). If Licensee grants a sublicense that either (A) includes both the U.S. and territories outside of the U.S., or (B) is made with respect to the U.S. and is in connection with a sublicense of a territory outside of the U.S., then the Parties shall reasonably establish an equitable allocation of the consideration paid to Licensee with respect to such sublicense(s) as between U.S. Sublicense Revenues and Sublicense Revenues allocable to such other territory(ies). For clarity, following the Royalty Adjustment Date, Licensee’s payment obligation under Sections 6.1, 6.2, and 6.3 solely with respect to U.S. Net Sales and U.S. Sublince Revenues shall be to pay Duke […***…] percent ([…***…]%) of U.S. Net Sales and […***…] percent ([…***…]%) of U.S. Sublicense Revenues, and Licensee’s payment obligation under Sections 6.1, 6.2, and 6.3 with respect to all other Net Sales and all other Sublicense Revenues shall remained unchanged.

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MVP’s rights under Section 4.5(c), Section 6.7, Section 6.8, and Section 6.9 of the Agreement shall cease to apply with respect to any U.S. Net Sales or any U.S. Sublicense Revenues accrued by Licensee on or following the Royalty Adjustment Date. For clarity, Section 4.5(c), Section 6.7, Section 6.8 and Section 6.9 of the Agreement shall continue to apply with respect to (i) any sales of Licensed Products by Licensee in the U.S. prior to the Royalty Adjustment Date, (ii) any U.S. Sublicense Revenues accrued by Licensee prior to the Royalty Adjustment Date, and (iii) all Ex-U.S. Net Sales and all Sublicense Revenues in the Territory other than U.S. Sublicense Revenues, whether accrued prior to, on or after the Royalty Adjustment Date.

MVP shall have no further right to enforce Section 7.1 or Section 9.1 of the Agreement, in each case, solely with respect to Licensed Products in the U.S. For clarity, if Licensee fails to fulfill any of its material obligations under the Agreement with respect to any country or countries outside of the U.S., then the Licensors retain their rights to terminate the Agreement with respect to the country or countries affected in accordance with Section 10.3 of the Agreement.

4. Assignment of Interest in Assigned Patent Rights; Modifications with respect to Patent-Related Rights and Obligations. Subject to Section 2 above, and, except as expressly set forth in this Section 4, without affecting any rights of Duke or any obligations of Licensee to Duke, effective as of the Modification Effective Date:

(a) MVP hereby sells, assigns, transfers and conveys to Licensee, free and clear of all liens and encumbrances (subject to subsection (b) below), all of MVP’s right, title, and interest in and to the Assigned Patent Rights. Within [***] following the Modification Effective Date, MVP shall execute and deliver to Licensee a patent assignment for the Assigned Patent Rights in the form attached as Exhibit C hereto. MVP shall take all reasonable further actions, and provide Licensee, Licensee’s successors, assigns or other legal representatives, all such cooperation and assistance (including the execution and delivery of any and all affidavits, declarations, oaths, exhibits, assignments, powers of attorney or other documentation) reasonably requested by Licensee to more fully and effectively effectuate the purposes of this assignment, including, without limitation with respect to the following: (1) the prosecution of any applications assigned herein; (2) the prosecution or defense of any interference, opposition, reexamination, reissue, infringement or other proceedings that may arise in connection with any of the Assigned Patent Rights, including, but not limited to, testifying as to any facts relating to the Assigned Patent Rights and to this assignment; and (3) in the implementation or perfection of this assignment in the United States. [***] For the avoidance of doubt, the Parties acknowledge and agree that this Amendment shall have no effect on Licensee’s receipt and enjoyment of the exclusive license to or **Confidential Treatment Requested**
under the Patent Rights and Technology (including MVP Technology) granted to Licensee pursuant to Section 4.1 of
the Agreement, which license shall remain in full force and effect.

(b) Licensee acknowledges that: (i) all of the Assigned Patent Rights are jointly owned by MVP and Duke (prior to the
assignment set forth in subsection (a) above); (ii) Duke's ownership in the Assigned Patent Rights remains
unchanged by the assignment set forth in subsection (a) above; and (iii) the Assigned Patent Rights are subject to
retained government rights in connection with the funding of the inventions claimed therein.

(c) Licensee hereby grants to MVP the exclusive, perpetual, irrevocable, royalty-free, fully paid-up, world-wide,
non-transferable license (except as permitted by Sections 13.1 and 13.3) under Licensee's interest in the Assigned Patent
Rights, subject to all encumbrances therein as of the Modification Effective Date, sublicenseable through multiple
tiers of sublicensees, for [...***...]. THE FOREGOING ARE LICENSED TO MVP "AS IS" AND WITHOUT
WARRANTY OF ANY KIND. LICENSEE DISCLAIMS ALL EXPRESS AND IMPLIED WARRANTIES,
INCLUDING THE IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR
PURPOSE, TITLE, AND NON-INFRINGEMENT.

(d) Section 8.1 of the Agreement shall hereby be labeled Section 8.1(a). The following is added to the Agreement as
Section 8.1(b): Notwithstanding the foregoing, and solely with respect to the Assigned Patent Rights in the U.S.,
Duke and Licensee shall have responsibility, at their shared expense (or as they may otherwise decide between them),
for filing, prosecuting and maintaining their jointly owned patent applications within the Assigned Patent Rights in
the USPTO. Licensee shall keep MVP advised as to the prosecution of such applications by forwarding to MVP
copies of all official correspondence relating thereto, and shall give MVP an opportunity to comment on all
applications, responses to office actions, declarations and other papers before they are filed with the USPTO, and
shall consult with MVP concerning the scope of allowed claims before paying any issue fee. MVP shall be
responsible for any costs incurred by MVP in connection with MVP's receipt, review, comment, consultation, or
other activities it takes with respect to any of the documentation provided Licensee pursuant to this Section 8.1(b).

(e) Solely with respect to the [...***...], if Licensee elects to stop an infringement of the [...***...] and recover
damages as set forth in Section 8.5(a) of the Agreement, then the following shall apply in lieu of Section 8.5(a)(i)(D):
Licensee shall be entitled to retain for its own account, after first deducting the costs of any actions taken to stop such
infringement, [...***... percent ([...***...%]) of any amounts received in settlement or awarded as damages, with
the remaining [...***... percent ([...***...%]) being paid to Duke.

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(f) Solely with respect to an infringement of the Assigned Patent Rights, the references in Section 8.5(a)(ii)(A) to
“Licensors” shall be deemed to refer solely to Duke and the references in Section 8.9 to “Parties” shall be deemed to
refer solely to Duke and Licensee.

(g) Solely with respect to inquiries regarding licenses in the U.S. or third party patents in the U.S., the references in
Section 8.6 to “Licensors” shall be deemed to refer solely to Duke.

(h) Licensee shall not have the right under Section 8.7(c) or Section 8.7(d) to offset any attorneys’ fees, settlement
amounts and/or royalties due to a third party in connection with a third party infringement action to the extent based
on the inclusion of the Assigned Patent Rights in the U.S. that are incurred after the Royalty Adjustment Date against
any royalties owed to MVP by Licensee based on Ex-U.S. Net Sales or on Sublicense Revenues attributable to any
territory outside of the U.S.

(i) If the Licensee terminates the Agreement in the U.S. pursuant to Section 8.8 thereof, or if Licensee or Licensors
terminate the Agreement in the U.S. pursuant to Article 10 thereof, then MVP’s rights in the Assigned Patent Rights
conveyed to Licensee pursuant to Section 4(a) of this Amendment shall not revert to MVP and instead shall remain
with Licensee; however, Licensee shall remain subject to the prohibition of the manufacture, use and sale of Licensed
Products in the country or countries in which Licensee has elected to terminate as set forth in Sections 8.8 and 10.2 of
the Agreement.

(j) The Parties acknowledge that, as between Duke and Licensee, Licensee shall have, subject to Licensee’s continued
compliance with the terms of the Agreement (but provided, however, that Duke provides the appropriate notice and
opportunity to cure in the event of any non-compliance), the sole and exclusive right to use the Assigned Patent
Rights in connection with […***…].

(k) Upon the Modification Effective Date, MVP shall deliver to Licensee, to the extent not already in Licensee’s or its
patent counsel’s possession:

(i) copies of the Assigned Patent Rights and, to the extent reasonably available to MVP and reasonably
requested by Licensee, other manifestations or embodiments of the Assigned Patent Rights;

(ii) all internal and outside patent counsel files that comprise U.S. Patent and Trademark Office (“USPTO”)
notices, and correspondence from and to the USPTO relating to the prosecution and maintenance of the
Assigned Patent Rights; and

(iii) accurate and complete copies of all unpublished patent applications, if any, included in the Assigned
Patent Rights.

For clarity, MVP may retain copies of the foregoing consistent with its obligations under Article 11 of the
Agreement.

***Confidential Treatment Requested
Solely with respect to inventory of the Licensed Products in the U.S., the references in Section 10.4 of the Agreement to “Licensors” shall be deemed to refer solely to Duke.

(i) Upon learning of an actual or reasonably suspected infringement by a third party of the Assigned Patent Rights exclusively licensed to MVP, the Party learning of such infringement shall promptly inform the other Parties in writing of that fact and shall provide any evidence available pertaining to such infringement.

(ii) MVP may elect, within [...] days after notice and at its own expense, to take whatever steps are necessary to enforce against such third party the Assigned Patent Rights exclusively licensed to MVP.

1. If MVP elects to take such action, it will: (a) keep Duke and Licensee informed of the steps taken and the progress of any legal actions taken; and (b) be entitled to enter into a settlement on such terms as it may elect, subject to Duke and Licensee’s consent; and

2. If MVP does not elect to take such action within such period, it will promptly inform Duke and Licensee, in which event Duke and Licensee may elect within [...] days: (a) to take such action as is required to stop such infringement, and will then be entitled to settle such actions on such terms as they may elect, subject to MVP’s consent, will keep MVP informed of the steps taken and the progress of any legal actions taken, and will be entitled to retain any amounts received in settlement or awarded in damages; or (b) not to take any action against such infringers.

MVP shall give Duke and Licensee prompt notice of each claim or allegation received by MVP that the manufacture, use or sale of products under MVP’s exclusive license constitutes an infringement of a third party patent or other intellectual property rights. If such alleged infringement is due to MVP’s or its sublicensee’s manufacture, use, sale, offer for sale or U.S. importation of one or more products that incorporate subject matter disclosed in the Assigned Patent Rights, then:

(i) MVP shall have the primary right and responsibility, but not the obligation, at its own expense to defend and control the defense of any claims against MVP, using counsel of its choosing; and

(ii) The settlement of any such action must be approved by Duke and Licensee, which approval shall not be unreasonably withheld.

In any action brought under Section 4(m) or Section 4(n), the Parties not bringing or defending the action shall, in their sole discretion, be entitled to participate through counsel of their own choosing in any such action; provided however, that such participation shall be limited to an advisory role and counsel for the Party bringing or defending the action shall be lead counsel and the action shall be directed by such Party. Each Party agrees to cooperate with the other Parties in any reasonable

***Confidential Treatment Requested
manner deemed by the Party defending or prosecuting an action under Section 4(m), or defending an action under Section 4(n) of this Amendment, to be necessary in defending or prosecuting such action.

5. **Representations and Warranties.** MVP represents and warrants to Licensee that:

   (a) MVP’s right, title and interest in and to the Assigned Patent Rights are free and clear of any liens, security interests or other encumbrances, subject to Section 4(b) of this Amendment;

   (b) MVP has the full right and authority to execute this Amendment and to assign to Licensee the rights assigned herein; and

   (c) MVP has not executed, and will not execute, any agreement or other instrument: (i) in conflict herewith; or (ii) that would permit MVP to make or have made, use or have used, sell or have sold, or license or sublicense, any drug that relates to (a) mammalian or non-mammalian uricases or (b) PEG conjugates of mammalian or non-mammalian uricases, in each case that is indicated for any of the treatments for which the drug marketed or sold as of the Modification Effective Date under the brand or name Krystexxa is or was indicated.

6. **Indemnification.** MVP agrees to indemnify, hold harmless and defend Licensee, its officers, employees, and agents, against any and all claims, suits, losses, damages, costs, fees, and expenses, including reasonable attorneys’ fees, asserted by third parties, both government and non-government, resulting from or arising out of the misrepresentation or breach of: (a) any representation, warranty or covenant of MVP under Section 5 of this Amendment; or (b) any covenant of MVP under any other Section of this Amendment.
7. Effect of MVP Corporate Liquidation and Assignment.

(a) The following is added at the end of Section 10.6(b) of the Agreement:

“provided, however, that this Section 10.6(b) shall not apply by reason of a transaction by MVP that satisfies the conditions of Section 13.3.”

(b) The following is added at the beginning of Section 13.1 of the Agreement:

“Except as provided in Section 13.3,”.

(c) The following is added as a new Section 13.3 of the Agreement:

“At any time after the Amendment Effective Date, MVP may effect a corporate liquidation and associated assignment of this Agreement without the consent of the other Parties, provided, however, that following such liquidation event (1) MVP’s rights and obligations under this Agreement have been assigned to an entity formed by MVP or one or more of its stockholders, and (2) such entity is also the assignee of all of or substantially all of MVP’s Patent Rights and the MVP Technology, and all related obligations, in each case as then existing. Any such entity must agree to be bound by all terms and conditions of this Agreement.”

8. Miscellaneous. Except as expressly set forth in this Amendment, all terms and conditions of the Agreement remain in full force and effect. This Amendment sets forth and constitutes the entire agreement and understanding between the Parties with respect to the subject matter hereof and all prior agreements, understanding, promises and representations, whether written or oral, with respect thereto. Each Party confirms that it is not relying on any representations or warranties of any other Party except as specifically set forth herein. No amendment or modification of this Amendment will be binding upon the Parties unless in writing and duly executed by an authorized representative of each Party. In the event of a conflict or inconsistency between the terms of this Amendment and the terms of the Agreement (or any other amendment), the terms of this Amendment shall control with respect to such conflict or inconsistency. Any term or condition of this Amendment may be waived at any time by the Party that is entitled to the benefit thereof, but no such waiver will be effective unless set forth in a written instrument duly executed by or on behalf of the Party waiving such term or condition. The waiver by any Party hereto of any right hereunder or of claims based on the failure to perform or a breach by another Party will not be deemed a waiver of any other right hereunder or of any other breach or failure by said other Party whether of a similar nature or otherwise. Each Party acknowledges that it has been represented by legal counsel with respect to the negotiation and preparation of this Amendment and agrees that no provision hereof shall be strictly construed against any Party, irrespective of which Party is deemed to have drafted such provision. The captions of this Amendment are for convenience of reference only and in no way define, describe, extend or limit the scope or intent of this Amendment or the intent of any provision contained in this Amendment. This Amendment may be executed in two or more counterparts, each of which will be deemed an original, but all of which together will

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constitute one and the same instrument. In addition, this Amendment may be executed by facsimile or PDF and such facsimile or PDF signature shall be deemed to be an original.

9. **Execution by All Parties.** This Amendment shall be binding upon MVP and Licensee effective on the date last signed by both of them. If this Amendment has not been also executed by Duke by midnight, Pacific Daylight Time, July 24, 2015, then upon written notice from MVP or Licensee to the other Parties, this Amendment shall be terminated and all terms and conditions hereof shall be deemed null, void and of no further effect.

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9
IN WITNESS WHEREOF, the Parties have duly executed this Amendment.

MOUNTAIN VIEW PHARMACEUTICALS, INC.
By: /s/Merry R. Sherman
Name: Merry R. Sherman
Title: CEO and President
Date: July 15, 2015

CREALTA PHARMACEUTICALS LLC
By: /s/Edward Fiorentino
Name: Edward Fiorentino
Title: Chairman & CEO
Date: 7/15/15

DUKE UNIVERSITY
By: /s/Rose Ritts
Name: Rose Ritts
Title: Executive Dir., OCU
Date: July 16, 2015

CREALTA PHARMACEUTICALS LLC
By: /s/Edward Fiorentino
Name: Edward Fiorentino
Title: Chairman & CEO
Date: 7/15/15
Exhibit A

Patents and Patent Applications included within the Assigned Patent Rights

[…***…]

***Confidential Treatment Requested
Exhibit B

Bank Wiring Instructions

[...***...]

***Confidential Treatment Requested
THIS PATENT ASSIGNMENT (“Assignment”) is made and entered into by and between Mountain View Pharmaceuticals, Inc., a California corporation having its principal offices at 3475 Edison Way, Suite S, Menlo Park, CA, USA 94025 (“Assignor”), and Crealta Pharmaceuticals LLC, a Delaware limited liability company having its principal offices at 500 W. Silver Spring Dr., Suite K-200, Glendale, WI, USA 53217 (“Assignee”).

WHEREAS, Assignor and Assignee are parties to a Fourth Amendment to License Agreement By and Among Mountain View Pharmaceuticals, Inc., Duke University, and Crealta Pharmaceuticals LLC, Including Patent Assignment, dated as of July __, 2015 (the “Amendment”); and

WHEREAS, pursuant to the Amendment, Assignor wishes to assign to Assignee, and Assignee wishes to acquire from Assignor, the patents and patent applications set forth on Schedule A attached hereto, including any substitutes, continuations, divisions, reissues reexaminations or extensions thereof, and including the subject matter of all claims thereof (collectively, the “ Assigned Patent Rights”).

NOW, THEREFORE, for good and valuable consideration, Assignor does hereby sell, assign, transfer and set over to Assignee, subject to the terms of the Amendment, Assignor’s right, title and interest in and to the Assigned Patent Rights, for the United States, including, without limitation, all corresponding rights that are or may be secured under the laws of the United States, now or hereafter in effect, for Assignee’s use and enjoyment, and for the use and enjoyment of Assignee’s successors, assigns or other legal representatives, as fully and entirely as the same would have been held and enjoyed by Assignor if this Assignment had not been made, including, without limitation, all claims for damages by reason of infringement occurring on or after the Modification Effective Date as defined in the Amendment or other unauthorized use of the Assigned Patent Rights occurring on or after the Modification Effective Date, with the right to sue for, and collect the same for Assignee’s use and enjoyment and for the use and enjoyment of its successors, assigns or other legal representatives.

Assignor hereby permits the Commissioner for Patents to record Assignee as an assignee and owner of the Assigned Patent Rights.

REMAINDER OF PAGE INTENTIONALLY BLANK;

SIGNATURE PAGE FOLLOWS.
MOUNTAIN VIEW PHARMACEUTICALS, INC.

By: ____________________________

Name: __________________________

Title: ___________________________

CREALTA PHARMACEUTICALS LLC

By: ____________________________

Name: __________________________

Title: ___________________________
COMMERCIAL SUPPLY AGREEMENT

between

SAVIENT PHARMACEUTICALS INC.

and

BIO-TECHNOLOGY GENERAL (ISRAEL) LTD.
This Commercial Supply Agreement (the “Agreement”) is made and entered into as of the 20th day of March 2007, (hereinafter the “Effective Date”), by and between Savient Pharmaceuticals, Inc., a public company organized under the laws of the State of Delaware having its principal place of business at One Tower Center, 14th Floor, East Brunswick, New Jersey 08816, USA (“Savient”), and Bio-Technology General (Israel) Ltd., a private company organized under the laws of the State of Israel having its principal place of business at Beer Tuvia Industrial Zone, POB 571, Kiryat Malachi 83104, Israel (“BTG”) (hereinafter, each of Savient and BTG a “Party” and, collectively, the “Parties”).

WITNESSETH:

WHEREAS, pursuant to the Share Purchase Agreement (the “SPA”) and the Asset Purchase Agreement (“APA”), each dated March 23, 2005 (the SPA and APA, collectively, the “Divestiture Agreements”), Savient has, on 17 July 2005, sold to Ferring B.V. all of the issued and outstanding share capital of BTG, and to Ferring International Centre S.A. all of Savient’s right, title and interest in certain drug products and drug candidates developed and/or manufactured by BTG, but not in any case in the drug candidate known as “PEG-uricase” (or also known as “Puricase”); and

WHEREAS, the Parties to this Agreement have entered into a development agreement dated March 20, 2007, (the “Development Agreement”) according to which BTG renders continued development, manufacturing and other services in relation to Puricase.

WHEREAS, Savient wishes BTG, and BTG is willing, to supply Bulk Product for Commercial Launch and further commercial sales.

NOW THEREFORE, in consideration of the foregoing premises, which are incorporated into and made a part of this Agreement, and of the mutual covenants which are recited herein, the Parties agree as follows:

ARTICLE 1
DEFINITIONS

1.01 “AE” shall mean, with respect to the Product, any adverse event associated with the use of the Product in a patient or clinical investigation, whether or not considered drug related, including the following: an adverse event occurring in the course of the use of the Product in professional practice; an adverse event occurring from drug overdose whether accidental or intentional; an adverse event occurring from drug abuse; an adverse event occurring from drug withdrawal; and any significant and consistent failure of expected pharmacological action. AE shall include, without limitation, any unfavorable and unintended sign (including, without limitation, an abnormal laboratory finding), an exacerbation of a pre-existing condition, intercurrent illness, drug interaction, significant worsening of a disease under investigation or treatment, significant failure of expected pharmacological or biological action, symptom or disease temporarily associated with the use of the Product, whether or not considered related to...
the Product. Notwithstanding anything foregoing to the contrary, with respect to the Territory in which the Product is marketed, AEs shall include any experience required to be reported to a relevant authority in any such country.

1.02 “Affiliate” shall mean any business entity which directly or indirectly controls, is controlled by, or is under common control with any Party to this Agreement. A business entity shall be deemed to “control” another business entity if (i) it owns, directly or indirectly, at least fifty percent (50%) of the issued and outstanding voting securities, capital stock, or other comparable equity or ownership interest of such business entity, or (ii) it has the de facto ability to control or direct the management of such business entity. If the laws of the jurisdiction in which such entity operates prohibit ownership by a Party of fifty percent (50%) or more, “control” shall be deemed to exist at the maximum level of ownership allowed by such jurisdiction; provided, however, that there is a de facto ability to direct or control its management.

1.03 “BLA” means a regulatory application filed with a governmental agency in a country or a group of countries (e.g. FDA or EMEA) for the purpose of lawfully marketing, selling, distributing, importing, exporting, manufacturing, developing or using a therapeutic or prophylactic product for the treatment or prevention of a disease or physical condition; a BLA shall include, without limitation, a Product License Application or Marketing Authorization in the European Union, and a Biologics License Application or a New Drug Application in the United States.

1.04 “BTG Assigned Improvements” shall mean all developments, discoveries, inventions, improvements, designs, methods, processes, techniques, devices, formulae and trade secrets related to the Product (including, without limitation, its pharmaceutical utility) and/or Processing of the Bulk Product or Product which are (i) made, created, developed or conceived, or reduced to practice, by BTG or an Affiliate of BTG and (ii) dominated by the Savient Patent Rights or necessary or useful in the Processing of the Bulk Product or Product. Notwithstanding the foregoing, BTG Assigned Improvements shall not include any innovations which are of general use in biopharmaceutical manufacturing.

1.05 “BTG Licensed Improvements” shall mean all developments, discoveries, inventions, improvements, designs, methods, processes, techniques, devices, formulae and trade secrets related to the Product (including, without limitation, its pharmaceutical utility) and/or Processing of the Bulk Product or Product which are (i) made, created, developed or conceived, or reduced to practice, by BTG or an Affiliate of BTG, and (ii) necessary or useful in the Processing of the Bulk Product or (iii) of general use in biopharmaceutical manufacturing.

1.06 “BTG Indemnitee” shall mean BTG and its Affiliates, and each of their respective directors, officers, employees and agents.

1.07 “BTG Know-How” shall mean all Know-How developed by BTG or any of its Affiliates during the Term or by BTG prior to July 17, 2005 relating to (i) the Bulk Product or Product (including, without limitation, its pharmaceutical utility) or (ii) the Processing of the Bulk Product or Product, and shall include, without limitation, all data (in any form, raw or analyzed or reported and whether maintained in paper, electronic or other media forms) relating to
formulation, analytical methods, pre-clinical and clinical trials, pharmacology, toxicology, regulatory information, and data relating to the manufacture and use of such Bulk Product or Product.

1.08 “Bulk Product” shall mean the bulk solution of polyethylene glycol (PEG) conjugate of uricase ordered by Savient from BTG pursuant to this Agreement.

1.09 “Business Day” shall mean any day other than (i) Friday, Saturday or Sunday or (ii) a day on which banking institutions located in New York, New York, United States of America or in Israel are permitted or required by law, executive order or governmental decree to remain closed.

1.10 “cGMP” shall mean current good manufacturing practices as set forth in Title 21, Parts 210 and 211 of the C.F.R. and 21 C.F.R. Part 312 (IND) and Part 314 (NDA), and 21 C.F.R. Part 600 (Biological Products), as established and amended by the FDA.

1.11 “Claim” shall mean all charges, complaints, actions, suits, proceedings, hearings, investigations, claims, demands, judgments, orders, decrees, stipulations, injunctions, damages (including all incidental and consequential damages claimed by Third Parties), deficiencies, defaults, assessments, dues, penalties, fines, costs, amounts paid in settlement, liabilities, obligations, taxes, liens, losses, lost profits claimed by Third Parties, expenses, costs and fees (including without limitation interest, court costs, reasonable fees of attorneys, accountants and other experts or other expenses of litigation or other proceedings or of any claim, default or assessment), and includes all damagesawardable pursuant to statute and treble damages.

1.12 “Commercial Bulk Product Specifications” shall mean the manufacturing and quality specifications for the Bulk Product, including, without limitation, unit descriptions established initially in accordance with Section 3.01(ii) and amended from time to time in accordance with Section 3.01(iii).

1.13 “Commercial Launch” shall mean the first commercial sale of the Product in any country of the Territory.

1.14 “Competing Product” shall mean any prescription pharmaceutical product that (i) contains uricase as an active ingredient or (ii) is used for the therapeutic or prophylactic treatment of gout (in any form) or other diseases and conditions involving hyperuricemia and/or monosodium urate crystals.

1.15 “Current Provisional Bulk Product Specifications” shall mean those provisional specifications set forth on Exhibit C hereto and any amended and restated Bulk Product specifications which are agreed to by the Parties in accordance with Section 3.01(i).

1.16 “Development Agreement” shall mean that certain Development Agreement by and between the Parties hereto, dated as of the date hereof.

1.17 “Dollar” shall mean the United States dollar.
1.18 "FDA" shall mean the United States Food and Drug Administration or its foreign equivalent as may be appropriate in any given context.

1.19 "Facility" shall mean, the BTG facility located at Be’er Tuvia Industrial Zone, POB 571, Kiryat Malachi 83104, Israel, within which, and for the purposes of the calculation of “Pro Rata Basis” as defined in Section 1.37 there is the:

(i) “Purification Area” of the Facility used in the Processing of Bulk Product and comprising the small purification line totaling 166 square meters;

(ii) “Fermentation Area” of the Facility used from time to time for the Processing of Bulk Product and comprising the fermentation suite, totaling 245 square meters;

(iii) “Recovery Area” of the Facility used from time to time for the Processing of Bulk Product and comprising the recovery suite, totaling 124 square meters, and;

(iv) “Total Manufacturing Area” of the Facility comprising the portion of the Facility dedicated to product manufacturing, excluding common areas such as buffer preparation, totaling 1182 square meters.

1.20 "Field" shall mean human therapeutic or prophylactic or diagnostic applications for the prevention, treatment and/or cure of diseases and physical conditions.

1.21 “Filled Product” shall mean sterile Product that is in Process and has been filled into its final primary packaging for further labeling or packaging activities.

1.22 "Genetic Material" shall mean the master cell bank of the E. coli strain expressing the recombinant uricase variant used in the Processing of the Bulk Product.

1.23 “IND” shall mean an Investigational New Drug application, as defined in 21 C.F.R. 312.3, and filed with the FDA or any equivalent foreign Regulatory Agency.

1.24 “Joint Inventions” shall mean (i) all patentable inventions jointly invented (as determined in accordance with United States patent law) by Savient (or its Affiliates) and BTG (or its Affiliates) pursuant to their activities relating to this Agreement during the Term, and (ii) all Know-How that Savient (or its Affiliates) and BTG (or its Affiliates) jointly make, create, develop, discover, conceive or reduce to practice pursuant to their activities relating to this Agreement during the Term other than those inventions described in the preceding clause (i).

1.25 “Know-How” shall mean all technical information, data (including, without limitation, regulatory data) patentable and unpatentable inventions, developments, discoveries, methods and processes that are, in each case, not disclosed in a published patent application or patent or otherwise publicly available, and includes, without limitation, BTG Know-How.

1.26 “Legal Requirements” shall mean (i) any present and future national, state, local or similar laws (whether under statute, rule, regulation or otherwise), (ii) requirements under permits, orders, decrees, judgments or directives, and requirements of applicable Regulatory Agencies (including, without limitation, cGMP) and (iii) regulations pertaining to commercially
available biologic pharmaceutical products or to maintaining a BLA (with respect to each of the foregoing, as amended or revised from
time to time).

1.27 “Negligence” shall mean an act or omission implying either a failure to exercise the care which a reasonable or prudent person
would do in the circumstances, or taking action which such a reasonable person would not; as used herein, a reasonable or prudent
person shall be considered to have such expertise as would be required in order to allow such party to perform the obligations of the
parties hereunder with the level of skill and competence which prevail in the pharmaceutical industry.

1.28 “Non-Conforming Bulk Product” shall mean any Bulk Product which, at the time of delivery in accordance with ARTICLE 7,
does not meet the Commercial Bulk Product Specifications.

1.29 “OCS” shall mean Office of Chief Scientist, The Ministry of Industry and Trade, State of Israel.

1.30 “OCS Requirements” shall mean the requirements of OCS which apply to the Product, including, without limitation, as
specified pursuant to The Encouragement of Research and Development in Industry Law of 1984, as amended, and in the agreements
by and among Savient, BTG and the OCS.

1.31 “Person” shall mean any individual, partnership, corporation, limited liability company, unincorporated organization or
association, any trust or any other business entity.

1.32 “Process” or “Processing” shall mean the act of purification, preparation, filling, testing and any other pharmaceutical
manufacturing procedures, or any part thereof (including, but not limited to, product or process specifications, testing or test methods,
raw material specifications or suppliers, equipment, etc.), relating to, as applicable, the Bulk Product and Product.

1.33 “Product” shall mean pharmaceutical products containing Bulk Product ordered by Savient pursuant to this Agreement.

1.34 “Product Liability Claim” shall mean a Claim of a Third Party (other than a Claim arising out of use of the Product in a clinical
trial) that (i) arises as a result of the use of the Product during the Term that results in personal injury or death or (ii) is in anticipation of
or intended to prevent or forestall personal injury or death as a result of the use of the Product during the Term.

1.35 “Product Technology” shall mean the (i) Savient Patent Rights, (ii) Savient Know-How, (iii) BTG Assigned Improvements,
(iv) BTG Licensed Improvements, (v) BTG Know-How, (vi) any developments, discoveries, inventions, improvements, designs,
methods, processes, techniques, devices, formulae, and trade secrets which are or may be (A) developed, acquired or conceived by
Savient and/or BTG and are derived from the Development Plan performed under the terms of the Development Agreement,
developed by BTG prior to July 17, 2005 and related to the Bulk Product or used in the Processing of Bulk Product, or are derived
from the manufacture and supply of Bulk Product, or (B) used in the Processing of Bulk Product.
1.36 “Product Specifications” shall mean the manufacturing and quality specifications for the Product as attached hereto as Exhibit G as they may be modified from time to time.

1.37 “Pro-Rata Basis” shall mean when Facility changes will be implemented pursuant to the provisions of Section 6.03(ii)(B) and:

(i) such Facility changes will impact the totality of the Total Manufacturing Area and/or the common and technical areas related to manufacturing, the cost of the changes multiplied by a percentage, where such percentage equals

\[
\frac{\text{Purification Area}}{\text{Total Manufacturing Area}} \quad \text{PLUS} \quad \frac{\text{Fermentation Area}}{\text{Total Manufacturing Area}} \quad \times \text{Time} \quad \text{PLUS} \quad \frac{\text{Recovery Area}}{\text{Total Manufacturing Area}} \quad \times \text{Time}
\]

(ii) when such Facility changes will impact only the Fermentation Area, the cost of the changes multiplied by Time;

(iii) when such Facility changes will impact only the Recovery Area, the cost of the changes multiplied by Time;

1.38 “Quality Agreement” shall mean that certain Quality Agreement by and between the Parties hereto, dated as of the date hereof and attached to this Agreement as Exhibit D.

1.39 “Regulatory Agency” shall mean with respect to the United States, the FDA, or, in the case of a country in the Territory other than the United States, such other appropriate regulatory agency with similar responsibilities.

1.40 “Residual Rights Agreement” shall mean that certain Amended and Restated Residual Rights Agreement by and between Savient and BTG, effective as of July 17, 2005, and attached hereto as Exhibit F.

1.41 “SAE” shall mean, with respect to the Product, any serious adverse event occurring during clinical trials of the drug at any dose that results in any of the following outcomes: death, a life-threatening adverse drug experience, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant disability/incapacity, or a congenital anomaly/birth defect. Important medical events that may not result in death, be life-threatening or require hospitalization may be considered a serious adverse drug experience when, based upon appropriate medical judgment, they may jeopardize the patient or subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition. Examples of such medical events include allergic bronchospasm requiring intensive treatment in an emergency room or at home, blood dyscrasias or convulsions that do not result in patient hospitalization, or the development of drug dependency or drug abuse.

1.42 “Savient Improvements” shall mean all inventions related to the Bulk Product or Product (including, without limitation, its pharmaceutical utility) and/or Processing of the Bulk Product or Product which are made, created, developed or conceived, or reduced to practice or come to be owned, by Savient or an Affiliate of Savient and are dominated by the Savient Patent Rights.
“Savient Indemnitee” shall mean Savient and its Affiliates, and each of their respective directors, officers, employees and agents.

“Savient Know-How” shall mean all Know-How developed by Savient or any of its Affiliates during the Term relating to (i) the Bulk Product or Product (including, without limitation, its pharmaceutical utility) or (ii) the Processing of the Bulk Product or Product, and shall include, without limitation, all data relating to formulation, analytical methods, pre-clinical and clinical trials, pharmacology, toxicology, regulatory information, and data relating to the manufacture and use of such Bulk Product or Product.

“Savient Patent Rights” shall mean all valid patent claims contained in (i) the patent(s) and patent applications listed on Exhibit A; (ii) all converted provisionals, divisions, continuations, continuations-in-part, reissues, reexaminations or extensions thereof; (iii) any corresponding foreign counterparts and equivalents thereof; and (iv) any patents or patent applications filed after July 17, 2005.

“Sublicensee” shall mean any Third Party or Affiliate to whom a sublicense has been granted pursuant to Section 2.05.

“Term” shall have the meaning set forth in Section 11.01.

“Territory” shall mean, collectively, each country in the world.

“Third Party” shall mean any Person who is not a Party or an Affiliate under this Agreement.

“Time” shall mean for the purposes of the calculation of Pro Rata Basis, as defined in Section 1.37, the percentage based on the number of weeks that either the Fermentation Area or the Recovery Area, as applicable, is used for the Processing of Bulk Product divided by (i) 46 in the case of an entire year or (ii) the respective number of weeks in the billing term if the period is less than a year.

“United States” shall mean the fifty states of the United States of America, the District of Columbia and all territories and possessions of the United States of America and any other location where the FDA has jurisdiction over medicinal products intended for human use.

ARTICLE 2
INTELLECTUAL PROPERTY LICENSES

2.01 Grant of Licenses; Assignment.

(i) No restriction of license rights under the Residual Rights Agreement. The parties are agreed that the following provisions shall not in any way remove or restrict the rights pertaining to the grant of licenses to either party (“RRA License Rights”) as they exist pursuant to the Residual Rights Agreement. In the event of a conflict between this Agreement
and the Residual Rights Agreement with respect to the RRA License Rights, the relevant provisions of the Residual Rights Agreement shall take precedence.

(ii) **Grant by Savient.** Savient hereby grants to BTG, and, if applicable, shall cause its Affiliates to grant to BTG, a fully paid-up, royalty-free, non-exclusive license within the State of Israel ("BTG Territory") to manufacture, have manufactured, produce, have produced, develop, have developed, use, have used, offer for sale, have offered for sale, sell, have sold, export, and have exported Bulk Product under the Savient Patent Rights, the Savient Know-How, and the rights to the Savient Improvements for supply exclusively to Savient.

(iii) **Grant by BTG.** BTG hereby grants to Savient and, if applicable, shall cause its Affiliates to grant to Savient, a fully paid-up, royalty-free, non-exclusive license in the Territory to manufacture, have manufactured, produce, have produced, develop, have developed, use, have used, offer for sale, have offered for sale, sell, have sold, export, and have exported Bulk Product under the BTG Licensed Improvements and BTG Know-How.

(iv) **Assignment by BTG.** BTG shall promptly assign (and, if applicable, shall cause its Affiliates to assign) to Savient all right title and interest in and to any invention or discovery which may be claimed as a BTG Assigned Improvement. BTG shall execute (and, if applicable, shall cause its Affiliates to execute) such documents as may be necessary to obtain, perfect or maintain any patent rights arising out of the BTG Assigned Improvements, and shall cooperate with Savient so far as reasonably necessary with respect to furnishing all information and data in its possession which is reasonably necessary or useful to obtain and maintain such patent rights.

2.02 **Notice of Improvements & Joint Inventions.** BTG shall give Notice to Savient of all BTG Assigned Improvements, BTG Licensed Improvements and Joint Inventions promptly within due course of the discovery or creation thereof, but in any event at least thirty (30) days prior to any proposed publication thereof by BTG, its Affiliates or Sublicensees. Savient shall give Notice to BTG of all Savient Improvements and Joint Inventions promptly within due course of the discovery or creation thereof, but in any event at least thirty (30) days prior to any proposed publication thereof by Savient, its Affiliates or Sublicensees. The Parties shall, in any event, notify each other no less than annually, of whether they have made any BTG Assigned Improvements, BTG Licensed Improvements, Savient Improvements or Joint Inventions, as the case may be.

2.03 **Disclosure of Know-How.** BTG shall disclose, and shall cause its Affiliates to disclose, as soon as reasonably practicable, to Savient all BTG Know-How acquired, developed or which comes to be possessed by the BTG or any of its Affiliates after the date hereof (and upon reasonable request by Savient, shall make such disclosure in writing).

2.04 **Use of Joint Inventions.**

(i) Subject to subsections (ii) and (iii) hereof, each Party shall have the right to practice under the Joint Invention rights without any duty of accounting to the other Party.

(ii) BTG agrees that, except as otherwise agreed by the Parties in writing, it shall not (and shall, if applicable, ensure that its Affiliates shall not) (A) grant any license under the
Joint Invention Rights to any other Person to manufacture, have manufactured, produce, have produced, develop, have developed, use, have used, market, have marketed, import, have imported, export, have exported, sell or have sold any Competing Product, or (B) practice any Claim under the Joint Inventions rights to manufacture, have manufactured, produce, have produced, develop, have developed, use, have used, market, have marketed, import, have imported, export, have exported, sell or have sold any Competing Product.

(iii) Each Party agrees that it shall (and shall, if applicable, ensure that its Affiliates shall) notify the other Party before granting any license to any other Person to manufacture, have manufactured, produce, have produced, develop, have developed, use, have used, import, have imported, export, have exported, offer for sale, have offered for sale, sell or have sold any product outside the Field under the Joint Invention rights; provided, however, that neither Party shall grant or purport to grant any license under the Joint Invention rights that is exclusive as to the other Party or its assignees or Sublicensees without the prior written consent of such other Party.

2.05 Sublicensing. Savient shall have the right to grant sublicenses of licenses granted to it in Section 2.01 of this Agreement to its Affiliates and to any Third Party; provided, however, that Savient, to the extent applicable, (i) ensures that each such Sublicensee and Third Party shall consent to be bound by the terms of this Agreement as a Sublicensee or Third Party and to the same extent as Savient with respect to such Sublicenses or Third Party’s activities, (ii) informs BTG, in confidence, of each sublicense granted, and any modification or termination thereof, within sixty (60) days after the modification, or termination of a sublicense and (iii) guarantees to BTG the performance of any of its obligations which it fulfills through sublicensing and remains primarily liable for the performance of such obligations.

2.06 OCS Requirements. BTG shall not without prior written approval of Savient (and, if applicable, shall ensure that its Affiliates shall not) take any action (including, without limitation, Processing the Bulk Product outside the State of Israel) which would (i) cause either Party (or any of their Affiliates) to violate any of the OCS Requirements or (ii) result in any increase of royalties due to OCS. Additionally, upon request by Savient, BTG shall cooperate and collaborate with Savient in applying to the OCS for Savient to carry out the manufacture of the Bulk Product through a Third Party outside the State of Israel. The Parties acknowledge the rights and obligations of each Party under Section 5 of the Residual Rights Agreement and each Party shall honor such rights and obligations set forth therein.

ARTICLE 3
SPECIFICATIONS; ONGOING REGULATORY ASSISTANCE

3.01 Specifications.

(i) Current Provisional Bulk Product Specifications. The Current Provisional Bulk Product Specifications are attached as Exhibit C. The Parties are agreed that the Current Provisional Bulk Product Specifications may still be subject to modification based on the outcome of the Validation, as defined and performed pursuant to the Development.

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Agreement, and subject to the mutual agreement of the parties, such agreement not to be unreasonably conditioned, delayed or withheld.

(ii) **Initial Commercial Bulk Product Specifications.** The initial Commercial Bulk Product Specifications shall be agreed upon in writing by the Parties, as soon as reasonably practicable after the conclusion of the Validation, as defined and performed pursuant to the Development Agreement, but in no event later than ninety (90) days from the conclusion of the Validation, unless the Parties shall mutually agree to extend such time period (hereinafter the “Commercial Bulk Product Specifications”). The Commercial Bulk Product Specifications shall be incorporated into this Agreement by formal amendment as Exhibit C-1 and shall be the controlling standards for the manufacture of Bulk Product pursuant to this Agreement unless and until they are changed by written agreement between the parties. In determining the Commercial Bulk Product Specifications, the Parties shall take into consideration particularly (i) the results of the subsequent development activity of BTG under the Development Agreement and (ii) the results of the Validation as defined and performed pursuant to the Development Agreement.

(iii) **Amendment of Commercial Bulk Product Specifications.** Subject to the provisions of Section 6.02 and 6.03 (including the cost reimbursements provisions thereof), Savient shall have the right to amend the Commercial Bulk Product Specifications from time to time; provided, however, that (i) Savient shall use commercially reasonable efforts to minimize the frequency of such changes and shall provide BTG with reasonable advance notice of any changes to the Commercial Bulk Product Specifications (but, in any event, at least ninety (90) days advance notice) and (ii) the Parties have agreed in writing upon the implications and costs related to any contemplated changes pursuant to this Section 3.01, which agreement shall not be unreasonably conditioned, withheld or delayed. Without in any way limiting the foregoing, any modifications to the Commercial Bulk Product Specifications required by any Regulatory Agency with jurisdiction to require such modifications shall be made in accordance therewith.

3.02 **Ongoing Assistance by BTG for Initial and Subsequent Filings or Applications.**

(i) Upon the expiration or earlier termination of the Development Agreement, BTG hereby agrees to provide, in respect to any jurisdiction within the Territory (A) all information and assistance which is reasonably necessary for or useful in the preparation of (i) comprehensive and complete INDs and BLAs, including, without limitation, the Chemistry Manufacturing and Controls (CMC) section of the BLAs for the Product, (ii) any amendments and supplements to such filings and applications, (iii) subsequent filings and applications for secondary indications or additional marketing, sale, importing, exporting authorizations, or (iv) similar filings and applications and (B) access to the Facility and pertinent information to FDA inspectors conducting the pre-approval inspection. All documents to be supplied by BTG pursuant to this Section 3.02 or any other provision of this Agreement shall be translated by BTG into the English language as may be necessary. Any labor costs of BTG employees and/or Third Party expenses incurred by BTG related to this assistance shall be reimbursed by Savient in the manner and at the rates set forth on Exhibit B hereto.
(ii) **Ownership.** The Parties agree that all INDs and BLAs arising under this Agreement, including any and all modifications and supplements thereto, will be owned by and held in the name of Savient and will list BTG in accordance with its role as contemplated under this Agreement and in compliance with the Legal Requirements. BTG shall have no rights in or to the IND or BLA and any and all modifications and supplements thereto, other than any rights specifically granted pursuant to this Agreement.

3.03 **Record and Files.** Upon the expiration or earlier termination of the Development Agreement, BTG shall maintain those documents required by the applicable Legal Requirements during the Term and for any period required by such Legal Requirements. BTG shall maintain those records specified in 21 C.F.R. § 600.12(e) for cases of divided manufacturing responsibility for biologics and shall provide the records as specified therein to any Third Party fillers or manufacturers designated by Savient.

**ARTICLE 4**

SUPPLY OF INGREDIENTS AND MATERIALS

4.01 **Procurement of Ingredients and Materials.**

(i) **Ordinary and Safety Stocks.** Ingredients and materials necessary for the Processing of Bulk Product shall be purchased and stored by BTG in accordance with the terms of the Quality Agreement and in commercially reasonable and prudent production and safety stock quantities necessary to meet the Bulk Product Forecast (as defined in Section 5.03) giving due regard to the potential for production and batch failures, Bulk Product loss until delivery to Savient and the amendment of the Bulk Product Forecast in accordance with Section 5.06.

(ii) **PEG Purchases from NOF.** The foregoing notwithstanding, Savient, in its sole and absolute discretion, shall have the right, but not the obligation, to directly contract with NOF Corporation for m-PEG-NPC (mono-methoxy polyethylene glycol nitro-phenyl carbonate) (hereinafter the “PEG”) necessary for BTG to Process the Bulk Product, provided, however, in the event Savient elects to do so, then (i) Savient shall use best efforts to ensure that adequate stock, including safety stock quantities, of PEG, in amounts to be agreed upon between the Parties, are delivered to BTG in a timely manner in order to enable BTG to fulfill its obligations to Process Bulk Product to meet the requirements of all Purchase Orders placed by Savient pursuant to Section 5.05; (ii) BTG agrees that it will, in accordance with the terms of the Quality Agreement, store and test, as applicable, such stock of PEG delivered by NOF; (iii) BTG shall reimburse Savient for the cost of any PEG utilized in the Processing of Bulk Product that is determined to be (a) Non-Conforming Bulk Product, or (b) a failed batch; (iv) that such agreement between Savient and NOF shall not materially interfere with the terms of this Agreement or unduly interfere with BTG’s ability to carry out its work; and (v) the inability of BTG to perform under the terms of this Agreement, where such failure is due to the failure of Savient to ensure the timely delivery to BTG of adequate stock of PEG shall not be deemed to be a breach by BTG of its obligations under this Agreement.
4.02 Maintenance of Genetic Material. From the Effective Date, BTG shall (or shall procure one of its Affiliates to) maintain such quantity of Genetic Material to meet Purchase Orders placed and the Bulk Product Forecast provided by Savient pursuant to ARTICLE 5. In the event of the expiration or termination of this Agreement, BTG shall, within thirty (30) days of the effective date of such expiration or termination, transfer to Savient or its designee any and all remaining quantities of Genetic Material. Any labor costs of BTG employees and/or Third Party expenses incurred by BTG related to transfer of Genetic Material shall be reimbursed by Savient in the manner and at the rates set forth on Exhibit B hereto.

4.03 Reference Materials. BTG shall provide Savient with any physical, chemical or biological material that is otherwise unavailable, which is to be used as a reference standard in the testing of Bulk Product, ingredients or raw materials. Such physical, chemical or biological material shall be provided to Savient at cost plus 50% (fifty percent). Payments due by Savient under this Section 4.03 shall be payable no later than forty-five (45) days after the invoice date.

ARTICLE 5
BTG FACILITY CAPACITY, FORECASTING, PURCHASE ORDERS AND ORDER CONFIRMATIONS

5.01 BTG Facility Bulk Product Processing Capacity and Capacity Reservation Fee.

(i) Existing Facility Capacity. Savient and BTG acknowledge that based on the (A) Purification Area used in the Processing of Bulk Product, (B) the Fermentation Area and the Recovery Area used from time to time for the Processing of Bulk Product, (C) methods, processes and procedures currently utilized in the Processing of Bulk Material as of the Effective Date, and (D) the current shift arrangement (one (1) — eight (8) hour shift operating five (5) days per calendar week during a forty-six (46) work week calendar year) in the Facility as of the Effective Date (hereinafter the “Capacity Parameters”), the BTG Facility has the projected capacity to Process up to forty-two (42) batches of Bulk Product per calendar year in the absence of other products manufactured in the areas specified above. Additionally, Savient and BTG acknowledge that this capacity could be increased, upon appropriate advance notice, if additional shift operations were implemented and/or certain Facility changes were made.

(ii) Subject to the terms set forth in this Section 5.01(ii), in order to reserve capacity at BTG for the Processing of Bulk Product, for all Bulk Product forecasted by Savient to be Processed by BTG and purchased by Savient prior to the Commercial Launch of the Product and through December 31, 2010 (hereinafter the “Reservation Fee Period”), Savient shall remit to BTG a Processing Capacity Reservation Fee in the amounts and manner set forth below:

(A) Within ten (10) Business Days of the provision of the Preliminary Bulk Product Forecast pursuant to Section 5.02, Savient shall remit to BTG a Processing Capacity Reservation Fee of Three Million Dollars ($3,000,000).
Within ten (10) Business Days of the provision of the Bulk Product Launch Forecast pursuant to Section 5.03, Savient shall remit to BTG a Processing Capacity Reservation Fee equal to the amount required to bring Savient’s Processing Capacity Reservation Fee, when added to the amount remitted under Section 5.01(ii)(A), to twenty percent (20%) of the applicable Price, as defined in Section 8.01, of the number of batches of Bulk Product reflected on such Bulk Product Launch Forecast, provided, however, if the amount calculated under this Section 5.01(ii)(B) is less than the Processing Capacity Reservation Fee remitted under Section 5.01(ii)(A) the Processing Capacity Reservation Fee shall remain at such higher amount. In the event that the initial Bulk Product Launch Forecast pursuant to section 5.03 is not provided by September 30, 2007, then Savient shall remit monthly to BTG an additional Processing Capacity Reservation Fee of $125,000 for each additional month that passes until the provision of the initial Bulk Product Launch Forecast.

Within ten (10) Business Days of the provision of any Bulk Product Forecast pursuant to Section 5.03 or any Amended Bulk Product Forecast provided by Savient pursuant to Section 5.06 provided by Savient on or before July 1, 2009, Savient shall remit to BTG a Processing Capacity Reservation Fee equal to the amount required to bring Savient’s Processing Capacity Reservation Fee, when added to the amount remitted under Sections 5.01(ii)(A) and 5.01(ii)(B), to twenty percent (20%) of the applicable Price, as defined in Section 8.01, of the number of batches of Bulk Product reflected on such Bulk Product Forecast or Amended Bulk Product Forecast that are projected for purchase during the Reservation Fee Period, provided, however, if the amount calculated under this Section 5.01(ii)(C) is less than the aggregate of the Processing Capacity Reservation Fee remitted under Sections 5.01(ii)(A) and 5.01(B) the Processing Capacity Reservation Fee shall remain at such higher amount.

All Processing Capacity Reservation Fee amounts remitted by Savient to BTG under this Section 5.01(ii) shall:

(1) earn interest at the one (1) year London Interbank Offering Rate (“LIBOR”) with the interest earned thereon inuring to the sole benefit of Savient;

(2) be credited, inclusive of interest, by BTG on a per batch basis by providing a 20% discount on the value of each batch at the time of invoicing for Bulk Product purchased by Savient during the Reservation Fee Period until it is fully utilized, provided however, except as otherwise provided in Sections 5.01(ii)(F), 5.01(ii)(G) and 5.01(ii)(H), any uncredited Processing Capacity Reservation Fee, inclusive of interest, remaining at the end of the Reservation Fee Period due to a failure by Savient to take delivery of Bulk Product which conforms to the Commercial Bulk Product Specifications and which is ordered pursuant to a Bulk Product Forecast provided pursuant to Section 5.03 or an Amended Bulk Product Forecast provided pursuant to Section 5.06 and which is otherwise properly amended pursuant to Section 5.05 shall be forfeited by Savient to BTG. For purposes of clarity, the credit of the Processing
Capacity Reservation Fee shall accrue upon the delivery of the Bulk Product by BTG to Savient and shall be reflected on the invoice which relates to the Bulk Product shipment in question; and

(3) BTG shall provide to Savient a quarterly statement within ten (10) Business Days of the end of each calendar quarter of the then current balance of the Processing Capacity Reservation Fee, inclusive of interest, available for credit to the purchase of Bulk Product by Savient.

(E) Subject to the last sentence of this Section 5.01(ii)(E), Savient and BTG acknowledge and agree that by the conclusion of the Reservation Fee Period the demand for Savient’s Product will be sufficiently capable of reliable forecasting as to negate the need for a Processing Capacity Reservation Fee and that such will not be required for Bulk Product forecasted for purchase beyond the expiration of the Reservation Fee Period. On that basis, the final Processing Capacity Reservation Fee shall be due based on twenty percent (20%) of the applicable Price, as defined in Section 8.01, of the number of batches of Bulk Product reflected on the Bulk Product Forecast or Amended Bulk Product Forecast that is submitted for the period July 2009 through December 2010. If there is a delay in the commercial launch of the Product beyond the first calendar quarter of 2009 or any other factor reasonably preventing a reliable Bulk Product forecasting by the conclusion of the Reservation Fee Period, then the Parties will meet in good faith and discuss whether a further capacity reservation fee is necessary or appropriate and, if it is agreed necessary, for what duration and amount, if any.

(F) Anything to the contrary notwithstanding, in the event that any amount of the Processing Capacity Reservation Fee, inclusive of interest, remains unused or unapplied at the end of the Reservation Fee Period due to a failure by BTG for any reason, including Force Majeure conditions affecting BTG or the import, export or transportation of the Bulk Product which is beyond the reasonable control of BTG or Savient, to timely deliver any number of batches of Bulk Product properly ordered and accepted in accordance with the terms of this Agreement, then any amount of the Processing Capacity Reservation Fee, inclusive of interest, which would have been used for or applied to the purchase of Bulk Product but for the non-delivery or untimely delivery thereof, shall be refunded to Savient by wire transfer within fifteen (15) Business Days of the end of the Reservation Fee Period. For purposes of determining timely delivery pursuant to this section, the delivery dates identified in a Purchase Order submitted and accepted in accordance with Section 5.05 herein shall be considered binding, except in the event of a Force Majeure condition affecting BTG or the import, export or transportation of the Bulk Product which is beyond the reasonable control of BTG or Savient, in which case the Parties shall agree upon a reasonable extension of the delivery date in accordance with Section 14.14 hereof.

(G) In the event this Agreement is terminated by Savient pursuant to Sections 11.02 (ii) (for Force Majeure conditions affecting BTG), 11.02 (iii) (Material Breach by BTG), or 11.02 (v) (for insolvency of BTG) hereof, any amount of the Processing Capacity Reservation Fee and accrued interest thereon which has not been applied to payments for Bulk Product actually purchased by and delivered to Savient, shall be
returned to Savient via wire transfer within thirty (30) days of the effective date of termination of this Agreement. In the event this Agreement is terminated with the mutual consent of both Parties, then, as part of such mutual consent, the Parties shall discuss in good faith and reach resolution with regard to the disposition of the then-existing Capacity Reservation Fee, including any interest thereon, having due regard for the reasons and basis that lead the Parties to terminate this Agreement by mutual consent.

(H) Savient and BTG further acknowledge and agree that in the event the BLA for Savient’s Product is not filed with the FDA on or before December 31, 2008 then the Processing Capacity Reservation Fee previously paid by Savient to BTG and accrued interest thereon relating to Bulk Product Forecasts provided by Savient before December 31, 2008 shall be refundable to Savient only in the event and to the extent that BTG is able, with the use of best efforts, to mitigate its losses by scheduling into the Processing Capacity reserved for Savient during such period production of a product or products on behalf of BTG, an Affiliate, or a third party, or any combination thereof.

5.02 Preliminary Bulk Product Forecast. As soon as reasonably practicable, but in no event later than thirty (30) days from the date of full execution of this Agreement, Savient shall provide BTG a preliminary, non-binding projection of its first eighteen month rolling forecast that sets forth Savient’s then best estimate of the date for the delivery of the first commercial quantity of Bulk Product and the total quantity of Bulk Product for commercial supply that Savient expects to order from BTG within the eighteen (18) month period following delivery of such first commercial quantity (“Preliminary Bulk Product Forecast”). In the Preliminary Bulk Product Forecast, Savient shall:

(i) set forth the assumptions it is utilizing for the establishment of the date for the delivery of the first commercial quantity of Bulk Product;
(ii) include a breakdown of the total quantity of Bulk Product by month for the eighteen months following the delivery of the first commercial order; and
(iii) identify the variables, Process and regulatory questions and issues and logistical considerations that could impact the date for the delivery of the first commercial quantity of Bulk Product.

Within thirty (30) days of the issuance of the Preliminary Bulk Product Forecast, Savient and BTG shall meet to commence good faith discussions and agree on the methodology and timeline for bringing to resolution and conclusion any and all Process and regulatory questions, issues and logistical considerations outlined in the Preliminary Bulk Product Forecast. Savient and BTG shall use their mutual best efforts to conclude these discussions and reach final resolution as soon as reasonably practicable, but in no event later than July 30, 2007, unless the parties mutually agree that additional time is required.

5.03 Bulk Product Launch Forecast and Bulk Product Forecast. Commencing at least twelve (12) months prior to the delivery date of the first Firm Order, Savient shall submit to BTG its final initial launch Bulk Product forecast which shall set forth month by month an eighteen (18) month rolling forecast that sets forth the total quantity of Bulk Product for commercial supply.
that Savient either has ordered, desires to order, or expects to order from BTG within the eighteen (18) month period following
delivery of such first commercial quantity (“Bulk Product Launch Forecast”). Thereafter, Savient shall provide on a monthly basis on
or before the first Business Day of each calendar month an updated Bulk Product forecast for the next ensuing eighteen (18) month
rolling period (“Bulk Product Forecast”). In the Bulk Product Forecast, Savient shall:

(i) include a breakdown of the total quantity of Bulk Product by month for the following eighteen (18) month rolling period;

(ii) in respect of the monthly breakdown under (i) above, identify the relevant set of Bulk Product Specifications.

As used herein, the term “Forecast” shall mean, as applicable, the Bulk Product Launch Forecast or Bulk Product Forecast, as may be
amended from time to time pursuant to Section 5.06 hereof.

5.04 Firm Orders and Firm Forecasts. The Bulk Product Forecast submitted monthly by Savient shall breakdown by month of the
next ensuing eighteen (18) months of the Bulk Product Forecast and shall consist of:

i. a rolling firm irrevocable order for the first two (2) quarters (i.e. quarters 1 and 2) of the Bulk Product Forecast (“Firm
Order”), which shall each be the subject of a Purchase Order delivered and confirmed in accordance with Section 5.05;

ii. a rolling two (2) quarter forecast for the second two (2) quarters (i.e. quarters 3 and 4) of the Bulk Product Forecast
(each a quarterly “Firm Forecast”); and

iii. a rolling two (2) quarter estimate for the third two (2) quarters (i.e. quarters 5 and 6) of the Bulk Forecast (each a
quarterly “Estimated Forecast”).

5.05 Purchase Orders and Order Confirmations. Savient will accompany its monthly update of the Bulk Product Forecast with a
written purchase order (“Purchase Order”) for each new Firm Order that was only a Firm Forecast in the previous month’s Bulk
Product Forecast. Each Purchase Order shall specify the Bulk Product ordered and the time, manner and address of delivery, all of
which shall be subject to this ARTICLE 5. BTG shall confirm each Purchase Order in a written order confirmation within seven
(7) Business Days after receipt of the Purchase Order.

5.06 Amending Forecasts. Any Bulk Product Forecast that is not a Firm Order is to be considered a forecast or estimate to be used
for planning purposes, and shall not be construed as a firm commitment by Savient to BTG and thus can be increased or reduced by
Savient from time to time. Savient shall be entitled at any time up until and including the time that a Firm Forecast or Estimated
Forecast becomes a Firm Order, to increase or decrease such monthly Firm Forecast or Estimated Forecast for Bulk Product, provided,
however, such increases or decreases on a monthly basis shall not be greater than twenty-five percent (25%) of the originally
forecasted quantity for such month and each month may not be increased and decreased more than one time. As a request by Savient to
increase the quantity of Bulk Product in a Firm Forecast prior to its becoming a Firm Order may require longer lead times for delivery
than
requested by Savient, both Parties shall agree jointly on a new delivery date as close as possible to the requested date having due regard for BTG’s commercial commitments to Third Parties and its own production needs, such agreement to not be unreasonably withheld, conditioned or delayed. Once a Firm Forecast becomes a Firm Order, Savient may not reduce it, but may request that BTG increase the quantity of Bulk Product subject to a Firm Order and BTG shall use commercially reasonable efforts to fill the increased order.

5.07 Fulfillment of Purchase Orders; Review of Forecasts.

(i) BTG shall satisfy, in accordance with their terms, Savient’s Purchase Orders, provided and confirmed in accordance with Section 5.05. BTG shall promptly notify Savient if it becomes aware or believes that it will not be able to satisfy such Purchase Orders on time, in full, or at all, which Notice shall include an explanation in reasonable detail of the reason for BTG’s failure to comply with a confirmed Purchase Order and its proposed course of action for remedying such failure. Savient shall be entitled to request BTG to produce evidence to support its Notice, BTG’s response to such request shall not be unreasonably denied or delayed.

(ii) Within ten (10) Business Days of its receipt of the Bulk Product Launch Forecast or a Bulk Product Forecast or any amendment thereto, BTG shall review such Forecast and in the event that BTG believes that it will not be able to satisfy the quantity, time or manner for delivery of any portion of the order for any amount of Bulk Product identified in any portion therein (i.e.: in the Firm Order, Firm Forecast or Estimated Forecast portions), BTG shall notify Savient of the same, provide a reasonable explanation of the cause of its inability to do so and provide alternatives for the delivery of the quantity and/or scheduling or manner of delivery to satisfy the requirements of Savient.

(iii) Unless BTG has indicated, in accordance with Section 5.07(ii), an inability to satisfy the identified quantities of Bulk Product in the Bulk Product Launch Forecast, any Bulk Product Forecast, or any amendment thereto, BTG may not refuse to accept a Purchase Order which does not deviate from the previously provided Bulk Product Launch Forecast, Bulk Product Forecast or amended forecast, as the case may be when, on a rolling basis, months contained in a Firm Forecast or Estimated Forecast period becomes a Firm Order.

(iv) In the event that BTG notifies Savient of its inability to supply any subject quantity of Bulk Product identified in the Bulk Product Launch Forecast, any Bulk Product Forecast or amended forecast, the parties agree to work together in good faith to expeditiously resolve the discrepancy between the subject forecast and BTG’s inability to supply Bulk Product in accordance therewith.

5.08 Effect of Supply Failure. In the event of a Supply Failure (as defined herein), no forecast or estimate shall be considered a Firm Order until such time as BTG proves to Savient’s reasonable satisfaction that the cause of such Supply Failure has been corrected. “Supply Failure” shall mean BTG has experienced three (3) failed batches of Bulk Product within a calendar quarter, or four (4) failed batches of Bulk Product aggregated over the course of two consecutive quarters, or six (6) failed batches of Bulk Product aggregated over the course of a calendar year. For purposes of this definition, any Bulk Product that is discovered and notified by Savient in accordance with Section 6.04 (iv) to be Non-Conforming Bulk Product after
delivery shall be considered a failed batch. In the event of a Supply Failure during the Reservation Fee Period, the period covered by the Reservation Fee Period shall be extended by the quarterly or other period of such Supply Failure.

5.09 **Preferential Right of Supply.** BTG shall schedule its own products or those of an Affiliate for processing at the Facility and shall not accept from a customer that is a Third Party any orders for product processed at the Facility to the extent the fulfillment of such scheduling or order could, at the time of BTG’s scheduling or acceptance of such Third Party order, reasonably be expected to impede BTG’s ability to fulfill Savient’s Bulk Product Requirements as reflected on the then current monthly Firm Orders, Firm Forecast and Estimated Forecast submitted by Savient pursuant to Section 5.04 and acted upon by the Parties pursuant to Sections 5.05, 5.06, and 5.07 supra.

5.10 **Alternative Supplier.** Savient shall have the right to establish an alternative supplier for Bulk Product for up to twenty percent (20%) of its annual world-wide Bulk Product requirements; *provided, however,*

(i) in the event of a Supply Failure under Section 5.08 above, Savient shall have the right to purchase all of its Bulk Product requirements from an alternative supplier upon reasonable prior written notice to BTG until BTG demonstrates to Savient’s reasonable satisfaction that BTG has fully remedied such Supply Failure, and

(ii) if despite the good faith efforts of BTG to modify its Capacity Parameters to meet the needs of Savient, or, as applicable, the Parties good faith efforts to agree on cooperative methods to modify the BTG Capacity Parameters, Savient’s Forecasts for orders of Bulk Product up to the OCS Requirements are reasonably anticipated to exceed BTG’s available capacity for the Processing of Bulk Product, then Savient shall have the right to purchase any and all of its requirements of Bulk Product that Savient reasonably determines in good faith may exceed BTG’s available capacity from Savient’s alternate supplier.

BTG acknowledges its obligation to assist Savient with Technology Transfer to an alternative contract manufacturing organization in accordance with the terms and conditions of Section 5.02 of the Development Agreement.

5.11 **Effect of Termination on Purchase Order.** Unless otherwise agreed to in writing by the Parties, the termination of this Agreement shall automatically terminate all then existing Purchase Orders, except when the termination of this Agreement is pursuant to Sections 11.02 (i) (Elective) and 11.02(iv) (Material Breach by Savient), provided such material breach by Savient is not based on the non-payment of non-disputed amounts for Bulk Product deliveries, in which case BTG shall honor and fulfill any then existing Purchase Order and Savient shall pay BTG for any Purchase Order so honored and fulfilled by BTG pursuant to the terms of this Agreement.
ARTICLE 6
PRODUCTION

6.01   Obligation to Supply and Purchase. BTG shall manufacture and supply all Bulk Product quantities ordered by Savient and confirmed by BTG in accordance with the provisions of this Agreement. The Parties acknowledge and agree that, pursuant to the OCS Requirements and subject to the terms of this Agreement, Savient is obligated to order at least 80% of its annual world-wide Bulk Product requirements from BTG (“OCS Annual Requirements”) and BTG is obligated to provide such OCS Annual Requirements. BTG shall bear all risk of loss associated with production and batch failures or loss of Bulk Product until delivery to Savient, in accordance with the provisions of Section 7.01.

6.02   Process Changes.

   (i)   Prior Approval of Savient Required. Except as set forth in this Section 6.02, BTG shall not make any change to the Process for the Bulk Product that would have an impact on the Bulk Product or Product, result in a change to the Commercial Bulk Product Specifications or the Product Specifications or require submissions to or approvals from any Regulatory Agency, except by prior written approval of Savient for such change, which approval shall not be unreasonably conditioned, withheld or delayed.

   (ii)  Changes Based on Applicable Legal Requirements. BTG shall make such changes to the Process for the Bulk Product as may be required pursuant to applicable Legal Requirements; provided that BTG shall have notified Savient in advance of any required change and shall have obtained the prior written approval of Savient for such change, which approval shall not be unreasonably conditioned, withheld or delayed. Costs incurred by BTG in connection with changes to the Process for the Bulk Product that are required pursuant to Legal Requirements applicable solely to the Process for the Bulk Product, including but not limited to the purchase of equipment, shall be paid by Savient in advance, or on such other basis as the parties may agree at such time, of the incurrence of such charges at (x) one hundred fifteen percent (115%) of cost excluding labor and equipment; (y) labor costs, if applicable, as per Exhibit B; (z) equipment at one hundred eight percent (108%) of cost; provided, however, that Savient shall have explicitly approved in writing any contemplated changes pursuant to this Section 6.02(ii) prior to BTG implementing any such changes. To the extent that the cost of any purchase of equipment is fully allocated to Savient, title to such equipment shall vest in Savient and Savient shall have the right, but not the obligation, to remove such equipment at its sole cost and expense upon the expiration or termination of this Agreement.

   (iii) Changes Made at the Request of Savient. From time to time, Savient may request that BTG make certain changes (other than those required by Legal Requirements) to the Processing of the Bulk Product; provided, however, that (A) Savient shall seek to minimize such changes, (B) Savient shall enter into good faith negotiations with BTG regarding the implementation of any such change to the Processing of the Bulk Product, with BTG’s consent to such change not being unreasonably withheld, conditioned, delayed or denied and (C) after the Parties have agreed upon the implications and costs related to a change to the Processing
of the Bulk Product, BTG shall implement such change. Costs incurred by BTG in connection with such changes shall be reimbursed by Savient at (x) one hundred fifteen percent (115%) of cost excluding labor and equipment; (y) labor costs, if applicable, as per Exhibit B; (z) equipment at one hundred eight percent (108%) of cost. To the extent that the contemplated changes requested by Savient necessitate the purchase of equipment and the cost of such purchase of equipment is fully allocated to Savient, title to such equipment shall vest in Savient and Savient shall have the right, but not the obligation, to remove such equipment at its sole cost and expense upon the expiration or termination of this Agreement.

(iv) Improvements by BTG. If BTG identifies a potential improvement that would (A) require changes to the Process, (B) have an impact on the Product or Bulk Product or (C) require submissions to or approvals from any Regulatory Agency, then BTG shall notify Savient of such improvement and the Parties shall, in good faith, discuss implementation of such improvement. Such improvement shall not be made unless the Parties reach agreement including, without limitation, agreement on allocation of cost, which agreement shall be at the sole discretion of the Parties. To the extent that the contemplated changes necessitate the purchase of equipment and the cost of such purchase of equipment is fully allocated to Savient, title to such equipment shall vest in Savient and Savient shall have the right, but not the obligation, to remove such equipment at its sole cost and expense upon the expiration or termination of this Agreement.

(v) Price Adjustment. In the event of any changes to the Process, pursuant to this Section 6.02, the Parties will meet and discuss the impact such Process changes have on the cost of Processing Bulk Product, either negative or positive, and will negotiate the resulting adjustment to the Price, as defined in Section 8.01, such adjustment to appropriately reflect the investment made by each Party in such Process changes relative to the manner in which such changes impact the cost of Processing the Bulk Product. To effectuate this Section 6.02(v), both parties shall exchange appropriately detailed documentation and analysis required to adequately assess the negative or positive impact such Process changes have on the cost of Processing Bulk Product.

6.03 Facility Changes.

(i) Facility Changes by BTG. From time to time, BTG may desire to make certain changes or modifications to its Facility (other than those required by Legal Requirements) (“Facility Changes”) which Facility Changes impact, directly or indirectly, the Processing of the Bulk Product. BTG shall be entitled to make Facility Changes which impact, directly or indirectly, the Processing of the Bulk Product without the prior approval of Savient, provided, however:

(A) prior to the approval of the BLA for Savient’s Product, BTG shall (x) use its best efforts to minimize Facility Changes which impact, directly or indirectly, the Processing of the Bulk Product, and (y) not implement any Facility Changes that will inhibit BTG’s ability to meet its obligations to supply Savient’s requirements under this Agreement or require the approval of a Supplement to the BLA for Savient’s Product, unless such change is unavoidable;
(B) after the approval of the BLA for Savient’s Product, BTG shall not implement any Facility Changes that will inhibit BTG’s ability to meet its obligations to supply Savient’s requirement under this Agreement unless and until the Parties have agreed to a plan for inventory stockpiling to satisfy Savient’s requirements, and;

(C) BTG shall promptly provide Savient notice of its Facility Changes which may impact, directly or indirectly, the Processing of the Bulk Product prior to the anticipated commencement of such Facility Changes and shall enter into good faith negotiations with Savient regarding the implementation of any such Facility Change and the satisfaction of Savient’s requirements for the stockpiling of safety stocks on Bulk Product in order that Savient can meet the clinical and market demands of its Product.

Under no circumstances shall BTG implement a Facility Change which may endanger the quality of the Bulk Product. Costs incurred by BTG in connection with such Facility Changes shall be borne by BTG. As used in this Section 6.03(i), “promptly” shall mean, given the nature and substance of the Facility Change, that period of time commercially reasonably necessary to complete the discussions and negotiations envisaged herein.

(ii) **Facility Changes Based on Applicable Legal Requirements.** BTG shall make such changes to the Facility as may be required pursuant to applicable Legal Requirements; provided that BTG shall promptly notify Savient in advance of such planned Facility Change; *provided, however*, that such notice from BTG shall be provided not later than ten (10) Business Days following BTG’s being notified of the necessity of changes to the Facility pursuant to Legal Requirements. Costs incurred by BTG in connection with such changes shall be reimbursed by Savient as follows:

(A) **Changes Specific to Savient’s Bulk Product.** To the extent that changes to the Facility, including but not limited to the purchase of equipment, are required pursuant to Legal Requirements applicable solely to the Bulk Product, costs incurred for such changes shall be paid by Savient in advance of the incurrence of such charges, or on such other basis as the parties may agree at such time, at (x) one hundred fifteen percent (115%) of cost excluding labor and equipment; (y) labor costs, if applicable, as per Exhibit B, and; (z) equipment at one hundred eight percent (108%) of cost; provided, however, that the Parties shall have agreed to a plan for the satisfaction of Savient’s requirements for safety stock of the Bulk Product to meet the clinical and market demands of its Product. To the extent that the cost of any purchase of equipment is fully allocated to Savient, title to such equipment shall vest in Savient and Savient shall have the right, but not the obligation, to remove such equipment at its sole cost and expense upon the expiration or termination of this Agreement.

(B) **Changes Not Specific to Savient’s Bulk Product.** To the extent that changes to the Facility are required pursuant to Legal Requirements applicable to biopharmaceutical manufacturing in general, costs incurred for such changes shall be reimbursed by Savient on a Pro Rata Basis, at cost.

(C) **Changes in Connection With Another Product.** If changes to the Facility are required pursuant to Legal Requirements applicable solely to other activities or the
manufacture of other products in the Facility (even if such changes would not be required in the absence of the Processing of the Bulk Product at the Facility or if the Processing of the Bulk Product benefits from such changes) the costs incurred for such changes shall not be reimbursed by Savient.

Provided, however, that in the event of changes to the Facility required pursuant to applicable Legal Requirements, the Parties shall enter into good faith negotiations regarding the implementation of any such Facility Change in a manner intended to minimize the interruption of the supply of Bulk Product and, in any event, shall agree on a method for the satisfaction of Savient’s requirements for the stockpiling of safety stocks of Bulk Product in order that Savient can meet the clinical and market demands of its Product.

(iii) Changes Made at the Request of Savient. From time to time, Savient may request that BTG make certain changes to the Purification Area (other than those required by Legal Requirements); provided, however, that

(A) Savient shall seek to minimize such changes,

(B) Savient shall enter into good faith negotiations with BTG regarding the implementation of any such change, with BTG’s consent to such change not being unreasonably withheld, conditioned, delayed or denied and

(C) after the Parties have agreed upon the implications and costs related to the Savient requested changes, BTG shall implement such changes.

Costs incurred by BTG in connection with such changes to the Facility shall be reimbursed by Savient at (x) one hundred fifteen percent (115%) of cost excluding labor and equipment; (y) labor costs, if applicable, as per Exhibit B, and; (z) equipment at one hundred eight percent (108%) of cost. To the extent that the contemplated changes requested by Savient necessitate the purchase of equipment and the cost of such purchase of equipment is fully allocated to Savient, title to such equipment shall vest in Savient and Savient shall have the right, but not the obligation, to remove such equipment at its sole cost and expense upon the expiration or termination of this Agreement.

(iv) Price Adjustment. In the event of any changes to the Facility, pursuant to this Section 6.03, the Parties will meet and discuss the impact such Facility changes have on the cost of Processing Bulk Product, either negative or positive, and will negotiate the resulting adjustment to the Price, as defined in Section 8.01, such adjustment to appropriately reflect the investment made by each Party in such Facility changes relative to the manner in which such changes impact the cost of Processing the Bulk Product. To effectuate this Section 6.03(iv), both parties shall exchange appropriately detailed documentation and analysis required to adequately assess the negative or positive impact such Facility changes have on the cost of Processing Bulk Product.

(v) Alternate Use of Purification Area. BTG shall have the right, but not the obligation, to utilize the Purification Area for the production, handling or storage of other
products during periods when the Purification Area is not being utilized for the Processing of Bulk Product pursuant to the terms and conditions of Section 5.7 in the Quality Agreement.

6.04 Quality Assurance.

   (i) Testing by BTG. BTG shall perform quality testing using assays proposed by BTG and acceptable to Savient (which acceptance shall not be unreasonably conditioned, withheld or delayed) in order to assure that the Bulk Product complies with the Commercial Bulk Product Specifications, and shall retain samples of Bulk Product produced and records of the tests made on each such batch in accordance with applicable Legal Requirements. In addition, except as otherwise agreed by the Parties in writing, no Bulk Product shall be delivered until such Bulk Product has been processed in accordance with the tests, inspections and controls required under the Commercial Bulk Product Specifications and such other tests as the Parties may mutually agree upon in writing; provided, however, that the foregoing shall not relieve BTG of its obligation under ARTICLE 5. BTG shall maintain records with respect to the quality testing and shall deliver such records to Savient by facsimile or email and overnight courier prior to shipment of the Bulk Product. Savient shall pay for any and all costs and expenses related to the delivery of records to Savient by overnight courier. Such records shall also be made available to Savient during normal Israeli business hours, upon prior written request.

   (ii) Notice of Non-Conforming Bulk Product. BTG shall promptly notify Savient of any Non-Conforming Bulk Product of which it becomes aware, whether or not such Non-Conforming Bulk Product been delivered to Savient or its designee, specifying the Bulk Product release testing and batch number.

   (iii) Testing by Savient. At Savient’s election, Bulk Product may be subjected to testing by Savient at Savient’s facilities or facilities of a Third Party designated by Savient in order to verify conformance with the Commercial Bulk Product Specifications, using assays proposed by BTG and acceptable to Savient (which acceptance shall not be unreasonably conditioned, withheld or delayed). Savient shall maintain records with respect to the scope and nature of any such testing and shall disclose such records to BTG in a timely fashion.

   (iv) Notice of Delivery of Non-Conforming Bulk Product. Savient shall notify BTG in writing of any Non-Conforming Bulk Product within

   (A) forty-five (45) days of delivery of such Non-Conforming Bulk Product in the event of a defect which was discovered or could have been discovered by Savient through the use of reasonable testing methods and procedures mutually agreed to by the Parties in writing or

   (B) ten (10) Business Days of Savient’s discovery of the Non-Conforming status of the Bulk Product in the event of a defect not recognizable for Savient through the use of such testing methods and procedures (hereinafter “Hidden Defect”).

Savient’s notices of any non-conforming Bulk Product shall specify the manner in which the Bulk Product fails to meet the Commercial Bulk Product Specifications., BTG shall have the
right to examine and test any Bulk Product in Savient's possession that Savient claims is Non-Conforming. The Parties shall cooperate to determine the point at which the Bulk Product became Non-Conforming. In the event that the Parties cannot agree as to whether any Bulk Product was Non-Conforming at the time of delivery, the Parties shall promptly appoint an independent specialist (appointed by mutual agreement between the Parties, which agreement shall not be unreasonably withheld, conditioned or delayed) who shall determine whether such Bulk Product was Non-Conforming at the time of delivery. In the absence of manifest error, the independent specialist's decision shall be conclusive and binding on the Parties.

Except as otherwise provided herein relating to Hidden Defects in the Bulk Product, if Savient fails to notify BTG in writing of any non-conforming Bulk Product within forty-five (45) days of delivery, then the Bulk Product delivered by BTG to Savient shall be deemed to be in all respects in accordance with this Agreement and Savient shall be bound to accept and pay for the same accordingly. For the avoidance of doubt, this shall apply irrespective of whether or not Savient has carried out quality testing in accordance with Section 6.04 (iii).

(v) **Observation by Savient.** During the Term, Savient (including Savient’s agents and consultants) shall have the right, at Savient’s sole cost and expense, during normal business hours and upon reasonable notice, to visit the Facility as per the Quality Agreement.

(vi) **Recalls and Voluntary Withdrawals.** If either Party becomes aware of information about distributed Product containing Bulk Product indicating that it may be Non-Conforming with respect to the Bulk Product or that there is potential adulteration, misbranding and/or any potential issues regarding safety or effectiveness with respect to the Bulk Product, it shall promptly serve Notice to that effect on the other Party. Savient will initiate an investigation and assessment of such circumstances and shall promptly notify BTG of its findings and any proposed course of action. The Parties shall meet to discuss such circumstances and to consider appropriate courses of action. Savient shall bear all costs associated with a recall of the Product unless such recall is caused by a Hidden Defect with respect to the Bulk Product, in which case BTG shall pay all costs associated with the recall, up to the maximum value of the Product Price paid by Savient to BTG for the Bulk Product containing such Hidden Defect.

(vii) **Filled Product Release Testing.** The Parties acknowledge that BTG is performing the Filled Product release testing for Savient under the terms of this Agreement and the Development Agreement until such time as the Filled Product release testing and methods can be transferred to Savient’s new third party fill/finisher of Product (hereinafter “Third Party Fill/Finisher”) or alternate Bulk Product or Product supplier. Savient will use its best efforts to effectuate the Technology Transfer of Product Technology to enable such Filled Product release testing to be performed by Savient’s Third Party Fill/Finisher or its alternate Product supplier as expeditiously as commercially practicable, and upon the approval of such amendments to this Agreement, and, if still in effect at such time, the Development Agreement shall be entered into relieving BTG of its obligation to perform release testing on Filled Product. It is the express intention of the Parties to mutually use best efforts to accomplish this Technology Transfer in adequate time to file the Product BLA with both BTG and Savient’s Third Party Fill/Finisher as alternate parties designated to perform the release testing of Filled Product, *provided, however,* the failure to succeed in this regard shall not be deemed

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6.05 **Labeling and Packaging.** BTG shall label and package the Bulk Product in accordance with Legal Requirements applicable to pharmaceutical products shipped in bulk for further processing, labeling, or repackaging.

6.06 **Stability.** Stability related activities for which BTG is responsible shall be completed in accordance with Quality Agreement. All costs incurred by BTG related to such activities shall be reimbursed by Savient in the manner and at the rates set forth on Exhibit B hereto.

**ARTICLE 7**

**DELIVERY; INVOICES; WARRANTY**

7.01 **Shipment and Delivery.** BTG shall use its best efforts to deliver Bulk Product in accordance with the delivery dates specified in its order confirmations or the Purchase Orders, as may be appropriate. All shipments shall be made by BTG pursuant to Savient’s instructions FCA Ben Gurion Airport, Tel Aviv, Israel, (Incoterms 2000) with BTG being responsible for delivering the Bulk Product cleared for export to the freight forwarder nominated by Savient.

7.02 **Certificate of Analysis.** An appropriate Certificate of Analysis and all relevant batch records shall precede the shipment of each Bulk Product batch delivered to Savient. BTG shall, for customs purposes, upon delivery of the Bulk Product, provide Savient with a valid declaration of origin, in a form reasonably acceptable to Savient, in respect of all Bulk Product supplied to Savient under this Agreement, together with such other supporting documents relating to the origin of such Bulk Product as Savient may reasonably require. If any of the foregoing documents are only available in a language other than English, the Parties shall agree upon an English language template for such document(s), and BTG shall provide to Savient an English language translation of any deviations from the template(s); provided, however, that any documentation required by any Regulatory Authority to be supplied for the purpose of importing, exporting, selling, storing, transferring, or otherwise disposing of Bulk Product, shall be provided in the English language.

7.03 **Method of Invoicing.** All orders under this Agreement shall be invoiced at the price which is in effect at the time of shipment.

7.04 **Warranty.** BTG hereby represents and warrants to Savient that (i) the quality (purity, physical and chemical properties) of the Bulk Product supplied by it to Savient shall be in accordance with its Specifications, shall not be adulterated or misbranded within the meaning of the applicable US food and/or drug law or regulation, and shall comply with all Legal Requirements (including cGMP) and those applicable laws, rules and regulations governing the formulation, manufacture, testing prior to delivery, packaging, labeling according to the Specifications for the Bulk Product and storage and delivery of the Bulk Product and (ii) the Processing of the Bulk Product at the Facility shall be in compliance with the CMC section of
the BLA, as reviewed and attested to as accurate by BTG. This warranty is exclusive and is in lieu of all other warranties, whether written or oral, express, implied or statutory.

**ARTICLE 8**

**PRICE**

8.01 **Price.** The Parties agree that the Bulk Product shall be charged to Savient at the price set out in Exhibit E attached hereto (the “Price”).

8.02 **Remittance of Payments.** Payments due by Savient under Section 8.01 shall be payable by Savient no later than forty-five (45) days after the invoice date; *provided, however,* that Bulk Product associated with such payment was actually delivered in accordance with Section 7.01. Savient shall make payment by wire transfer of Dollars from a single source in the United States to a bank account designated by BTG or by such other payment method as the Parties may agree upon from time to time. Except where any amounts payable are in dispute under this Agreement and to the extent such dispute is resolved in favor of Savient, in the event of late payment, interest on any past due payments shall accrue at the rate of 1.5 percent per month, or if such rate shall exceed the maximum rate allowed by law, then at such maximum rate, and shall be payable on demand.

**ARTICLE 9**

**REPORTING OF EVENTS**

9.01 **Exchange of Drug Safety Information.** The Parties shall have the rights and responsibilities pertaining to AEs, SAEs and biologic product deviations in accordance with the provisions of the Quality Agreement attached hereto as Exhibit D.

9.02 **Events Affecting Integrity or Reputation.** During the Term, the Parties shall notify each other immediately of any circumstances of which they are or become aware of whereby the integrity and reputation of the Product or of the Parties are threatened by the unlawful activity of any Third Party in relation to the Product. In any such circumstances, the Parties shall cooperate to limit any damage to the Parties and/or to the Product.

9.03 **Governmental Inspection.** Each Party shall advise the other of any governmental communication, inspection or report which addresses or affects the Bulk Product promptly after becoming aware of it. Savient shall have the right to observe any such governmental inspection; *provided, however* that such governmental inspection is specifically related to the Bulk Product.
ARTICLE 10
NON-COMPETITION AND NON-SOLICITATION

10.01 Non-Competition. During the Term of this Agreement, and for a period of thirty (30) months after the termination thereof, BTG agrees not to, and shall cause its Affiliates not to, use the Product Technology to manufacture, promote, market or sell any Competing Product in the Territory, nor will BTG acquire directly or indirectly any rights or interest in or to a Competing Product which is being manufactured, promoted, marketed or sold in the Territory. The Parties agree that an acquisition by BTG’s Affiliates of any rights or interest in or to a Competing Product which is being manufactured, promoted, marketed or sold in the Territory shall not be deemed to be an indirect acquisition by BTG, provided BTG has not participated in the acquisition process of its Affiliate.

10.02 Non-Solicitation. During the Term and for a period of thirty (30) months after the termination of this Agreement, the Parties agree that neither Party shall solicit any employee of the other Party or any of its Affiliates, with whom it has come in contact or interacted for the purposes of the performance of this Agreement, to leave the employment of the other Party or its Affiliate and accept employment or work as a consultant with the first Party, except in the event the other Party has approved such solicitation in writing. Notwithstanding the foregoing, nothing herein shall restrict or preclude either Party’s right to make generalized searches for employees by the issue of advertisement in the media (including trade media) or by engaging search firms to engage in searches that are not targeted or focused on an employee or employees of the other Party.

ARTICLE 11
TERM & TERMINATION

11.01 Term. This Agreement shall be in effect from the Effective Date and shall continue in effect until terminated pursuant to a Notice served by either Party in accordance with Section (the “Term”).

11.02 Termination. This Agreement may be terminated in accordance with the following sections:

   (i) Elective. Either Party may terminate this Agreement by giving at least three (3) years’ advance Notice (“Elective Termination Notice”) to the other Party, which Elective Termination Notice may not be given prior to the seventh (7th) anniversary of the first delivery of Bulk Product by BTG under this Agreement but may be given at any time thereafter. Upon the third (3rd) anniversary of the Elective Termination Notice, this Agreement shall terminate, unless extended by mutual agreement of the Parties.

   (ii) Force Majeure. In the event a Party (“Affected Party”) continues to experience a Force Majeure condition for a period of at least six (6) months after Notice of the Force Majeure was given pursuant to Section 14.04, the other Party shall be entitled to terminate this Agreement by giving a Notice of termination to Affected Party at any time while such Force
Majeure persists thereafter with the termination becoming effective on the date specified in the Notice of termination.

(iii) **Material Breach by BTG.** Savient shall be entitled to terminate this Agreement, in the event that BTG commits a material breach of this Agreement (including, without limitation, in the event of a Supply Failure pursuant to Section 5.08 that is not due to an event of Force Majeure or a failure on the part of Savient to supply critical raw materials which it is obligated to supply pursuant to the terms of this Agreement) and BTG fails to cure such breach within sixty (60) days of receiving a Notice of default from Savient (or such longer period as Savient may reasonably agree if said breach is incapable of cure within such sixty (60) days (“BTG’s Cure Period”), by giving a Notice of Termination to BTG (after expiration of BTG’s Cure Period, if applicable), with the termination to take effect on the date specified therein, provided, however, that if BTG experiences a second Supply Failure within any twelve (12) month period then BTG’s Cure Period shall be zero (0) days unless otherwise specified in the Notice of Termination provided by Savient in its sole discretion.

(iv) **Material Breach by Savient.** BTG shall be entitled to terminate this Agreement, in the event that Savient commits a material breach of this Agreement and Savient fails to cure such breach within sixty (60) days of receiving a Notice of default from BTG (or such longer period as BTG may reasonably agree if said breach is incapable of cure within such sixty (60) days (“Savient’s Cure Period”), by giving a Notice of termination to Savient (after expiration of the Savient Cure Period, if applicable), with the termination to take effect on the date specified therein. For purposes of this Section only, any amount of the Processing Capacity Reservation Fee and accrued interest thereon which has not been applied to payments for Bulk Product actually purchased by and delivered to Savient shall be forfeited by Savient to BTG as of the effective date of termination of this Agreement.

(v) **Insolvency.** Either Party shall be entitled to terminate this Agreement, by giving Notice to the other Party ("Insolvent Party"), in the event of an Insolvency Event occurring in relation to the Insolvent Party, such termination to take effect upon delivery of the Notice of termination to the Insolvent Party. “Insolvency Event” for the purpose of this Clause shall mean any commencement – whether voluntarily or involuntarily – of any action seeking any relief by liquidation, reorganization (other than for corporate reorganization), dissolution or similar act under any bankruptcy, insolvency or similar law or otherwise any action seeking any arrangement between or with its creditors or any commencement of a proceeding or receipt of an order, judgment or decree seeking the liquidation, reorganization or dissolution of a Party or any other relief under any bankruptcy, insolvency or similar law or an arrangement is made with respect to such Party’s debts or business by its creditors with or without the consent of that Party.

11.03 **Savient’s Rights Upon Termination.** In the event Savient terminates this Agreement pursuant to Sections 11.02 (i) (Elective), 11.02 (ii) (for Force Majeure conditions affecting BTG), 11.02 (iii) (Material Breach by BTG), or 11.02 (v) (for insolvency of BTG) or in the event BTG terminates this Agreement pursuant to Section 11.02 (i), BTG shall promptly, upon request by Savient, convey to Savient all Know-How, BTG Licensed Improvements and other information related to the Processing of the Product and/or Bulk Product sufficient to enable Savient or any other Persons engaged by Savient to manufacture, produce or provide the Product

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and/or Bulk Product and BTG shall provide all other assistance that Savient may reasonably request, at no cost to Savient. Such Know-How, BTG Licensed Improvements and other information shall include, without limitation, all records and reports related to (i) the development of the Bulk Product, Product and/or Process, (ii) the Processing of the Bulk Product and Product, (iii) testing for compliance with the Specifications, and (iv) batch records. Unless this Agreement is terminated pursuant to Section 11.02 (iii), Savient shall be responsible for the reasonable labor costs and expenses incurred by BTG in conveying such Know-How, BTG Licensed Improvements and other information and providing such assistance. Such labor costs of BTG employees and/or Third Party expenses shall be reimbursed by Savient in the manner and at the rates set forth on Exhibit B hereto.

11.04 **BTG’s Rights Upon Termination.** In the event that BTG terminates this Agreement pursuant to Sections 11.02(i) (Elective), 11.02(ii) (for Force Majeure conditions affecting Savient), 11.02(iv) (Material Breach by Savient) or 11.02(v) (for insolvency of Savient), any and all outstanding non-disputed payments due from Savient pursuant to this Agreement shall become immediately due and payable. Anything to the contrary notwithstanding, upon termination by BTG, BTG shall promptly, upon request by Savient and at Savient’s cost, convey to Savient, all Know-How, BTG Licensed Improvements and other information related to the Processing of the Bulk Product and/or Product sufficient to enable Savient or any other Persons engaged by Savient to manufacture, product or provide the Bulk Product and/or Product and BTG shall provide all other assistance that Savient may reasonably request, at Savient’s sole cost.

11.05 **Effect of Termination.** Termination of this Agreement for any reason is without prejudice to the Parties’ accrued rights and shall not be construed to release either Party of any obligation matured prior to the effective date of such termination.

11.06 **Survival.** The following provisions shall survive the expiration or termination of this Agreement: 2.01(iii), 2.01(iv), 2.04, 3.02, 3.03, 4.01 (ii), 5.11, 6.04 (i), 6.04(ii), 6.04 (iv), 6.04 (vi), 6.04 (vii), 6.06, ARTICLE 7, ARTICLE 8, ARTICLE 9, Section 10.01 (except in the event of a termination by BTG pursuant to Section 11.02 (iv) (Material Breach by Savient)), 10.02, 11.03, 11.04, 11.05, 11.06, ARTICLE 12, ARTICLE 13, ARTICLE 14. The survival of Sections 3.02, 3.03, 6.04 (vii) and 6.06 shall be subject to BTG being compensated for any actions on their part under these provisions post expiration or termination on the basis of the principles set forth in this Agreement. The Parties expressly understand and agree that Section 2.01 (ii) shall not survive the expiration or termination of this Agreement. For the avoidance of doubt, even after the termination of this Commercial Agreement pursuant to either Section 11.02 (iii) or Section 11.02 (iv), each Party’s rights under the Residual Rights Agreement shall subsist in full and irrespective of the grounds for such termination, except Savient may not compel BTG to perform any additional manufacturing services as may be required by the Residual Rights Agreement.
ARTICLE 12
REMEDIES

12.01 Remedies for Non-Conforming Bulk Product. In the event BTG delivers to Savient Bulk Product that does not meet the Commercial Bulk Product Specifications, Savient shall, at its option, be entitled to (A) the replacement of such Non-Conforming Bulk Product with corresponding Bulk Product meeting the Bulk Product Specifications and with the cost of the PEG material supplied by Savient and the cost of shipment for such replacement Bulk Product being borne by BTG; or (B) a refund of (x) any price paid by Savient for such Non-Conforming Bulk Product, (y) the cost of the PEG material supplied by Savient for such Non-Conforming Bulk Product, and (z) the shipment costs associated with such Non-Conforming Bulk Product, provided, however, that Savient has notified BTG in writing of the non-conforming Bulk Product in accordance with Section 6.04 (iv). In addition, Savient shall, at BTG’s option and cost, either destroy or return to BTG at its Facility any Non-Conforming Bulk Product.

12.02 Indemnity by BTG.

(i) BTG shall defend, indemnify and hold harmless each Savient Indemnitee from and against (i) all Claims of Third Parties that arise as a result of a material breach of any covenant, agreement, warranty or representation made by BTG under this Agreement, and (ii) all Product Liability Claims, or such portion of Product Liability Claims, as are allocated to BTG pursuant to Section 12.04.

(ii) BTG shall not be obligated under this Section 12.02 to the extent it is shown that the Claim was the direct result of a material breach of any covenant, warranty or representation made by Savient under this Agreement.

(iii) BTG shall have no obligation under this Section 12.02 unless

(A) Savient gives BTG prompt written notice of any Claim for which it seeks to be indemnified under this Agreement,

(B) BTG is granted full authority and control over the defense against such Claim, and

(C) Savient cooperates fully with BTG in defense of the Claim (all reasonable out-of-pocket expenses of such cooperation to be borne by BTG).

Savient shall have the right to participate in the defense of any such Claim utilizing attorneys of its choice, at its own expense; provided, however, that BTG shall have full authority and control to handle any such Claim, including without limitation any settlement or other disposition thereof, for which Savient seeks indemnification under this Section 12.02; provided, however, further that any settlement that includes an admission of fault, culpability or liability on the part of Savient shall not be concluded without Savient’s consent, which consent shall not be unreasonably conditioned, withheld, delayed or denied.
(iv) BTG shall indemnify and hold Savient harmless for any income tax or other taxes which Savient may be required by current or future Legal Requirements to pay on behalf of BTG with respect to any monies payable to BTG under this Agreement, including without limitation, any associated penalties, fines and interest (hereinafter, a “Tax Claim”); provided, however, that if Savient becomes aware of any Legal Requirements according to which Savient is required to pay any taxes on behalf of BTG or to withhold any amounts with respect to any such Tax Claim, then Savient shall act in strict compliance with such Legal Requirements and shall promptly serve written notice to that effect on BTG. Furthermore, upon learning of the existence of a Tax Claim, Savient shall provide prompt written notice to BTG where such notice shall include copies of all materials received by Savient which pertain to the Tax Claim. Additionally, upon request by BTG, Savient shall provide reasonable assistance to BTG to enable BTG to defend any such Tax Claim and/or support a claim for a refund or a foreign tax credit with respect to any such Tax Claim; provided that BTG shall reimburse Savient for any out-of-pocket expenses which Savient incurs in rendering any assistance to BTG pursuant to this provision within thirty (30) days of receipt of a reasonably specific demand for reimbursement with accompanying documentation demonstrating such amounts claimed. Savient shall obtain the approval of BTG for any individual out-of-pocket expense in excess of Fifty Thousand Dollars ($50,000), such approval not to be unreasonably withheld, delayed or conditioned. BTG shall have the sole right to handle any such Tax Claim utilizing attorneys of its choice, at its own expense; provided, however, that any settlement that includes an admission of fault, culpability, penalty fine or any other liability on the part of Savient shall not be concluded without Savient’s consent, which consent shall not be unreasonably conditioned, withheld, delayed or denied.

12.03 Indemnity by Savient.

(i) Savient shall defend, indemnify and hold harmless each BTG Indemnitee from and against all Claims of Third Parties that arise as a result of (A) a material breach of any covenant, agreement, warranty or representation made by Savient under this Agreement, and (B) patent infringement involving the manufacture, use, importation, sale or marketing of the Bulk Product or Product, and (C) all Product Liability Claims, or such portion of Product Liability Claims, as are allocated to Savient pursuant to Section 12.04.

(ii) Savient shall not be obligated under this Section 12.03 to the extent it is shown that the Claim was the direct result of a material breach of any covenant, warranty or representation made by BTG under this Agreement.

(iii) Savient shall not be obligated under this Section 12.03 unless

(A) BTG provides Savient with prompt written Notice of any Claim for which it seeks to be indemnified under this Agreement,

(B) Savient is granted full authority and control over the defense against such Claim, and
BTG cooperates fully with Savient in defense of the Claim (all reasonable out-of-pocket expenses of such cooperation to be borne by Savient).

BTG shall have the right to participate in the defense of any such Claim utilizing attorneys of its choice, at its own expense; provided, however, that Savient shall have full authority and control to handle any such Claim, including without limitation any settlement or other disposition thereof, for which BTG seeks indemnification under this Section 12.03; provided, however, further that any settlement that includes an admission of fault, culpability or liability on the part of BTG shall not be concluded without BTG’s consent, which consent shall not be unreasonably conditioned, withheld, delayed or denied.

12.04 Product Liability Claims. Notwithstanding the foregoing Sections 12.02 and 12.03, the Parties’ responsibilities with respect to Product Liability Claims shall be governed by this Section 12.04.

(i) BTG shall be solely responsible for all Product Liability Claims that arise out of Non-Conforming Bulk Product, provided, however, that the following conditions are cumulatively satisfied: (A) such nonconformance existed at the time the Bulk Product was delivered by BTG and (B) such nonconformance was the result of BTG’s failure to manufacture the Bulk Product in strict adherence with the Process and (C) such Non-Conformance was the result of a Hidden Defect. Savient shall be solely responsible for all Product Liability Claims that arise out of Non-Conforming Bulk Product in each of the following cases: (A) such non-conformance occurred after the Bulk Product was delivered to Savient or (B) the Non-Conforming Bulk Product was manufactured by BTG in strict adherence with the Process or (C) such Non-Conformance was not the result of a Hidden Defect.

(ii) Each Party shall give the other prompt written notice of any Product Liability Claim, but the omission of such notice shall not relieve either Party from its obligations under this Section 12.04, except to the extent the other Party can establish actual prejudice and direct damages as a result thereof. With respect to each Product Liability Claim, Savient shall have the first right to defend and settle such Product Liability Claim. In the event that Savient does not assume the defense of such Product Liability Claim within ninety (90) days following Savient’s receipt of notice of the commencement or assertion of such Product Liability Claim, BTG may notify Savient of BTG’s desire to take the lead role in the defense of such Product Liability Claim. If, within ten (10) days after BTG notifies Savient of such desire, Savient does not assume the defense of such Product Liability Claim, then BTG may take the lead role in the defense of such Product Liability Claim.

The Party assuming the defense of any Product Liability Claim as permitted under this Section 12.04 (the “Controlling Party”) shall consult with the other Party on all material aspects of the defense, including without limitation settlement, of such Product Liability Claim, and the Parties shall cooperate fully with each other in connection therewith. The non-defending Party shall also have the right to participate in the defense of any Product Liability Claim utilizing attorneys of its choice, at its own expense. In furtherance of the Parties’ cooperation, the Controlling Party will consult with the other Party regarding strategic decisions, including without limitation the retention of counsel and defense of each Product Liability Claim. The Controlling Party will otherwise keep the other Party fully informed of the status and progress of the defense and any
settlement discussions concerning the Product Liability Claim. Any settlement of a Product Liability Claim that would admit liability on the part of any Party or its Affiliates or Agents, or that would involve any relief other than the payment of money damages, shall be subject to the prior written approval of both Parties, such approval not to be unreasonably withheld or delayed. All damages and expenses (including attorney’s fees) incurred in connection with the defense of a Product Liability Claim shall be allocated between the Parties in accordance with Section 12.04 (i).

12.05 Limitation of Damages. Notwithstanding anything to the contrary set forth in this Agreement, in no event shall either Party be liable to the other Party for, and each Party shall procure that none of its Affiliates or Sublicensees shall make any claim against the other Party (or its Affiliates and Sublicensees) for, any lost profits, loss of business, loss of contracts, diminished goodwill, diminished reputation, or consequential, indirect, incidental or special damages arising under or in connection with this Agreement or the Bulk Product.

ARTICLE 13

DISPUTE RESOLUTION AND ARBITRATION

13.01 Governing Law. This Agreement and any and all matters arising directly or indirectly herefrom shall be governed by and construed in accordance with the laws of the State of New York, United States of America, without giving effect to (A) its conflict of law principles and (B) the United Nations Convention on Contracts for the International Sale of Goods.

13.02 Arbitration. Any dispute, controversy or claim arising out of or in relation to this contract, including the validity, invalidity, breach or termination thereof, shall be resolved by arbitration in accordance with the Swiss Rules of International Arbitration of the Swiss Chambers of Commerce in force on the date when the Notice of Arbitration is submitted in accordance with these Rules. The number of arbitrators shall be three; the seat of the arbitration shall be Zurich, Switzerland; the arbitral proceedings shall be conducted in English and shall take place in London, England.

ARTICLE 14

MISCELLANEOUS

14.01 Confidentiality. During the Term of this Agreement or the Commercial Agreement, whichever expires later, and for a period of three (3) years thereafter, each Party (the “Receiving Party”) shall keep strictly confidential any Confidential Information disclosed by any other Party (the “Disclosing Party”), using at least the same degree of care that it uses to protect its own confidential or proprietary information, but in no event less than reasonable care. The provisions of this ARTICLE 14 shall apply to all Confidential Information, and to all proprietary information of the Disclosing Party relating to the Product and/or the Process that is disclosed (or known) to a Receiving Party prior to the date hereof (which shall be deemed to be Confidential Information, subject to the exceptions in clauses (i) through (iv) below, for purposes of this Agreement). The nature and terms of this Agreement shall be deemed to be Confidential.
Information of each Party, subject to the exceptions set forth in clauses (i) through (iv) below, for purposes of this Agreement. The Receiving Party shall use Confidential Information solely for the purposes of this Agreement and the activities contemplated hereby and shall not disclose or disseminate any Confidential Information to any Person at any time, except for disclosure to those of its Affiliates, directors, officers, employees, consultants, accountants, attorneys, advisers and agents that have a need to know such information to permit the Receiving Party to exercise its rights or fulfill its obligations pursuant to this Agreement, provided that such Persons are bound to maintain the confidentiality of such Confidential Information to the same extent as if they were parties hereto. The obligations set forth in this Section 14.01 are subject to the following exceptions:

(i) The Receiving Party may disclose the Disclosing Party’s Confidential Information that is required to be publicly disclosed by law or by regulation; provided, however, that: (A) the Receiving Party shall, where possible, seek confidential treatment for any Confidential Information of the Disclosing Party, and shall provide the Disclosing Party with prompt advance notice of such disclosure and reasonable opportunity to review any such disclosure so that the Disclosing Party may, if it desires, seek a protective order or other appropriate remedy; and (B) the Parties or their Affiliates may disclose the terms of this Agreement in any filings with the U.S. Securities and Exchange Commission (provided that the Parties or their Affiliates, as applicable, use commercially reasonable efforts to seek confidential treatment for any trade secrets, commercial terms or information, or financial terms or information).

(ii) Pursuant to an agreement to maintain confidentiality, any Party may discuss, or provide a copy of, this Agreement to its accountants, its attorneys, and its current, future or potential investors or shareholders.

(iii) Pursuant to an agreement containing confidentiality obligations and subject to the other Parties’ written consent, either Party may provide a copy of this Agreement or relevant portions thereof to any Third Party sublicensee, if required pursuant to the relevant license agreement with such Third Party.

(iv) Any other disclosure of the nature or terms of this Agreement (including, without limitation, any public announcements, press releases or similar publicity with respect to this Agreement) by any Party, must be approved in advance in writing by Savient, in its sole discretion, as to form and content of such disclosure; provided, however, that the contents of any public announcement, press release or similar publicity which has been reviewed and approved can be re-released by any Party in any form without a requirement for re-approval.

14.02 BTG Insurance. BTG and/or its Affiliates shall obtain and maintain during the Term and for five (5) years thereafter comprehensive general liability insurance on a claims-made basis, with endorsements for product liability with annual coverage limits of not less than one million Dollars ($1,000,000) per claim and ten million Dollars ($10,000,000) annual aggregate. All of BTG’s insurance policies shall be issued by “A-rated” insurers as designated by Standard and Poor’s Corporation and/or by acceptable other means. The minimum level of insurance set forth herein shall not be construed to create a limit on BTG’s liability hereunder. On the Effective Date and upon the request of Savient (provided that such request shall be made no more than
once per calendar year), BTG shall furnish to Savient a certificate of insurance evidencing such coverage as of such date. Each such certificate of insurance, as well as any certificates evidencing new or modified coverages of BTG, shall include a provision whereby thirty (30) days written notice must be received by Savient prior to coverage modification or cancellation by either BTG or the insurer. In addition, BTG shall promptly notify Savient of any cancellation or modification of such insurance coverage and of any new or modified coverage. In the case of a modification or cancellation of such coverage, BTG shall promptly provide Savient with a new certificate of insurance evidencing that BTG’s coverage meets the requirements in the first sentence of this Section 14.02.

14.03 Savient Insurance. Savient shall obtain and maintain during the Term and for five (5) years thereafter comprehensive general liability insurance on a claims-made basis, with endorsements for product liability with annual coverage limits of not less than one million Dollars ($1,000,000) per claim and fifteen million Dollars ($15,000,000) annual aggregate. All of Savient’s insurance policies shall be issued by “A-rated” insurers as designated by Standard and Poor’s Corporation and/or by acceptable other means. The minimum level of insurance set forth herein shall not be construed to create a limit on Savient’s liability hereunder. On the Effective Date and upon the request of BTG (provided that such request shall be made no more than once per calendar year), Savient shall furnish to BTG a certificate of insurance evidencing such coverage as of such date. Each such certificate of insurance, as well as any certificates evidencing new or modified coverages of Savient, shall include a provision whereby thirty (30) days written notice must be received by BTG prior to coverage modification or cancellation by either Savient or the insurer. In addition, Savient shall promptly notify BTG of any cancellation or modification of such insurance coverage and of any new or modified coverage. In the case of a modification or cancellation of such coverage, Savient shall promptly provide BTG with a new certificate of insurance evidencing that Savient’s coverage meets the requirements in the first sentence of this Section 14.03.

14.04 Notices. All notices, requests, demands, claims and other communications hereunder (each, a “Notice”) shall be in writing. Any notice, request, demand, claim or other communication hereunder shall be deemed duly delivered four (4) Business Days after it is sent by registered or certified mail, return receipt requested, postage prepaid, or one (1) Business Day after it is sent by overnight delivery via a reputable national courier service, in each case to the intended recipient as set forth below:

If to Savient, to:

Savient Pharmaceuticals Inc.
One Tower Center, 14th Floor
East Brunswick, New Jersey 08816, USA
Telecopy: +1-732-418-9065
Attention: Philip K. Yachmetz, EVP & CBO
with copies, which shall not constitute notice hereunder, sent to:

Savient Pharmaceuticals, Inc. and Wilmer Cutler Pickering Hale and Dorr LLP
One Tower Center, 14th Floor 60 State Street
East Brunswick, NJ 08816 U.S.A. Boston, MA 02109
Attention: John Petrolino Telecopy: +1-617-526-5000
Attention: David E. Redlick, Esq.

If to BTG, to:

Bio-Technology General (Israel) Ltd. Ferring International Center SA
Beer Tuvia Industrial Zone and Ferring International Center SA
POB 571 Chemin de la Vergognausaz 50
Kiryat Malachi 83104, Israel CH-1162 Saint-Prex
Telecopy: +972-8-8612288 Switzerland
Attention: General Manager Attention: General Counsel

with copies, which shall not constitute notice hereunder, sent to:

Ferring International Center SA and Ferring International Center SA
Chemin de la Vergognausaz 50 Chemin de la Vergognausaz 50
CH-1162 Saint-Prex CH-1162 Saint-Prex
Switzerland Switzerland
Attention: General Counsel Attention: EVP, Technical Operations

Any Party may give any notice, request, demand, claim, or other communication hereunder using any other means (including personal delivery, expedited courier, messenger service, telecopy, telex, ordinary mail, or electronic mail), but no such notice, request, demand, claim or other communication shall be deemed to have been duly given unless and until it actually is received by the Party for whom it is intended. Any Party may change the address to which notices, requests, demands, claims and other communications hereunder are not be delivered by giving the other Party notice in the manner herein set forth.

14.05 Entire Agreement. This Agreement and all attachments, including the exhibits hereto, constitutes the entire agreement between Savient and BTG with respect to the subject matter hereof, and supersedes any prior agreements or understandings, both written and oral, between Savient and BTG with respect to such matters, other than the Divestiture Agreements and the Residual Rights Agreement, which shall be read together with this Agreement.

14.06 Order of Precedence. In the event of a conflict or inconsistency that relates to the subject matter hereof between any of the terms of the following documents, the following order of precedence shall control:
Without limiting the generality of the foregoing, and for the avoidance of any doubt, the following sections of the Residual Rights Agreement are hereby superseded by this Agreement as far as the subject matter hereof is concerned: (A) Section 3 - Research & Development; Regulatory Services; Manufacturing Services; (B) Section 4 - Technology Transfer; (C) Section 9 - Indemnification; (D) Section 13 – Governing Law and Dispute Resolution; (E) Annex C (Development and Regulatory Work-Puricase); (F) Annex D (Term Sheet Manufacturing Services); and (G) Annex E (Term Sheet for Technology Transfer). In resolving any such conflicts, these documents shall be read as a whole and in a manner most likely to accomplish their purposes. Any amendments to these documents on which the Parties may agree to in accordance with the terms of each document shall take precedence over any conflicting terms in the prior release of each document. Each Party shall promptly report to the other in writing any inconsistencies in these documents, even if the inconsistency is resolvable using the above order of precedence.

14.07 **Covenant of Further Assurances.** The Parties covenant and agree that, subsequent to the execution and delivery of this Agreement and without any additional consideration, each of the Parties shall execute and deliver any further legal instruments and perform such acts which are or may become reasonably necessary to effectuate the purposes of this Agreement.

14.08 **Waivers; Amendments.** The failure of either Party to insist, in any one or more instances, upon the performance of any of the terms, covenants or conditions of this Agreement or to exercise any right hereunder, shall not be construed as a waiver or relinquishment of the future performance of any such term, covenant or conditions or the future exercise of such right, and the obligation of the other Party with respect to such future performance shall continue in full force and effect. Savient and BTG may (A) mutually amend or waive any provision of this Agreement at any time and (B), from time to time after the date hereof, modify and/or replace any of the exhibits hereto, which modified or replaced exhibits shall automatically constitute part of this Agreement; provided, however, that no amendment or waiver of any provision of this Agreement and no modification and/or replacement of any exhibits hereto shall be valid unless the same shall be in writing and duly signed by both of the Parties.

14.09 **Relationship.** BTG is an independent contractor engaged by Savient for the provision of the Bulk Product and certain services as set forth in this Agreement. Nothing in this Agreement shall constitute BTG as an employee, agent or general representative of Savient. This Agreement shall not constitute either Party as the legal representative or agent of the other, nor shall either Party have the right or authority to assume, create or incur any liability or any obligation of any kind, express or implied, against, or in the name of or on behalf of, the other Party. This Agreement shall not constitute, create or in any way be interpreted as a joint venture, partnership or formal business organization of any kind.
14.10 **Publicity.** Except as otherwise required by Legal Requirements, neither Party shall use the other’s name or refer to it directly or indirectly in an advertisement, news release or release to any professional or trade publication or issue any news release relating to this Agreement, without the prior written approval from such Party for such use or release. The Parties agree that a news release with respect to the consummation of this transaction and the details thereof will be made, the content and form of which shall be reasonably agreed between the Parties. In addition, the Parties agree that Savient shall be permitted to disclose this Agreement and the transactions contemplated hereby in filings made with the U.S. Securities and Exchange Commission or other regulatory authorities in accordance with Section 14.01.

14.11 **Severability.** If any term of other provision of this Agreement is invalid, illegal or incapable of being enforced by any rule of law or public policy, all other conditions and provisions of this Agreement shall nevertheless remain in full force and effect so long as the economic and legal substance of the underlying transaction in any country in the Territory is not affected in any manner materially adverse to either Party. Upon such determination that (i) any term of other provision is invalid, illegal or incapable of being enforced and (ii) the economic or legal substance of the underlying transaction in any country in the Territory is affected in a manner materially adverse to either Party, the Parties shall modify this Agreement, with respect to such country in the Territory, so as to effect the original intent of the Parties as closely as possible in a mutually acceptable manner to the fullest extent permitted by Legal Requirements in such country in the Territory in order that the underlying transaction be completed as originally contemplated to the fullest extent possible.

14.12 **No Assignment.** Neither this Agreement nor any of the rights, interests, or obligations hereunder may be assigned by either Party without the prior written consent of the other Party hereto, except that Savient may assign its rights, interests, or obligations hereunder to any Third Party acquiring rights to the Product and either Party may assign its rights hereunder to any Affiliates or any entity that acquires all or substantially all of such Party’s business or assets (provided that no such assignment shall relieve the assigning Party of its obligations hereunder, and the assigning Party shall remain primarily liable for such obligations). Subject to the foregoing, this Agreement shall be binding upon and inure to the benefit of the Parties and their respective successors and permitted assigns.

14.13 **Headings.** The headings used in this Agreement are included for convenience only and are not to be used in construing or interpreting this Agreement.

14.14 **Force Majeure.** If either of the Parties is impeded in fulfilling its undertakings in accordance with this Agreement by circumstances beyond its reasonable control, such as, but not limited to, labor conflict, lightening striking, acts of God, fire, war, mobilization or unforeseen military call-up of a large magnitude, requisition, confiscation, commandeering, public decrees, riots, insurrections, general shortage of transport, goods or energy and faults or delays in deliveries from subcontractor or suppliers caused by any circumstances referred to in this Section 14.14, the impediment shall be considered a Force Majeure condition and the Party shall be exempted from liability for delays due to such reasons; provided, however, that it notifies the other Party thereof without undue delay after such a circumstance has occurred. Upon such notification, the Parties shall agree upon a reasonable extension of the time for performance, not to exceed an extension equal to the period the Force Majeure condition continues to exist.
14.15 **Counterparts.** This Agreement may be executed in any number of counterparts, each of which will be deemed an original, but all of which together will constitute one and same instrument.

IN WITNESS WHEREOF, the Parties hereto have caused this Agreement to be executed by their respective officers hereunto duly authorized as of the Effective Date.

SAVIENT PHARMACEUTICALS, INC. 

By: /s/ Philip K. Yachmetz 
Name: Philip K. Yachmetz 
Title: EVP & CBO

BIO-TECHNOLOGY GENERAL (ISRAEL) LTD. 

By: /s/ Dov Kanner 
Name: Dov Kanner 
Title: Managing Director
Exhibit A

Savient Patent Rights
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Exhibit B

Compensation for Services and Reimbursement of Expenses

BTG shall submit invoices to Savient on a quarterly basis in arrears, which invoices shall provide an account of (i) detailed descriptions of the services performed, (ii) the number of hours such services were performed, (iii) the levels of the individuals performing such services and (iv) detailed descriptions of any Third Party expenses incurred (documentation of such expenses shall be provided to Savient upon request).

Payment to BTG shall be due within forty-five (45) days of the date of the invoice (provided that the invoice is received by Savient within three (3) Business Days of the date thereof) or within forty-five (45) days of Savient’s receipt of the invoice (if received by Savient four (4) or more Business Days after the date thereof).

Compensation Rates:

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<td>Exempt Non-Management Employee, Group Leader &amp; others</td>
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Beginning on January 1, 2008, and on each successive January 1st thereafter, the above rates shall increase by an amount equal to the average increase in the United States Consumer Pricing Index (CPI) over the immediately preceding twelve (12) month period.

Third Party Expenses:

Savient shall reimburse BTG for documented expenses paid to a Third Party; provided that, other than BTG’s travel expenses for travel at the request of Savient, expenses for raw materials, expenses for subcontractors/consultants, BTG shall be required to obtain Savient’s pre-approval in writing for any expenses to be incurred in excess of Twenty thousand Dollars ($20,000).
Exhibit C

Current Provisional Bulk Product Specifications
## SPECIFICATION PEG-URICASE API

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Exhibit D

Quality Agreement
QUALITY ASSURANCE RESPONSIBILITY AGREEMENT

BETWEEN

SAVIENT PHARMACEUTICALS, INC.

AND

BIO-TECHNOLOGY GENERAL (ISRAEL) LTD.

(COMMERCIAL PHASE)

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ARTICLE 1

PURPOSE AND SCOPE:

1.01        Savient Pharmaceuticals, Inc. (“SAVIENT”) and Bio-Technology General (Israel) Ltd. (“BTG”) have entered into a Supply Agreement of (event date) herewith (the “Supply Agreement”).

This document (the “Quality Agreement”) defines the quality assurance responsibilities between SAVIENT and BTG. This Quality Agreement applies only to the manufacture and supply by BTG to SAVIENT of the Product (as defined in the Supply Agreement).

ARTICLE 2

DEFINITIONS:

2.01        Capitalized terms used but not otherwise defined in this Quality Agreement will have the meanings ascribed thereto in the Supply Agreement. For ease of reference, the following definitions from the Supply Agreement which are used in this Quality Agreement are copied in full below, amended where appropriate for the purposes of this Quality Agreement:

(i)        “BLA” means a Biologics License Application filed with the FDA and/or any other application required for the purpose of marketing or selling or using a therapeutic or prophylactic product to be filed with a governmental agency in a non-U.S. country or group of countries, including, without limitation, a Product License Application or Marketing Authorization in the European Union.

(ii)       “Bulk Product” shall mean the bulk solution of polyethylene glycol (PEG) conjugate of uricase ordered by Savient from BTG pursuant to the Supply Agreement.

(iii)      “Bulk Product Specifications” shall mean the manufacturing and quality specifications for the Bulk Product, including, without limitation, unit descriptions established from time to time in accordance with section 3.01 of the Supply Agreement.

(iv)       “Business Day” shall mean any day other than (i) Friday, Saturday or Sunday or (ii) a day on which banking institutions located in New York, New York, United States of America or in Israel are permitted or required by law, executive order or governmental decree to remain closed.

(v)        “cGMP” shall mean current good manufacturing practices as set forth in Title 21, Parts 210 and 211 of the C.F.R. and 21 C.F.R. Part 312 (IND) and Part 314 (NDA), and 21 C.F.R. Part 600 (Biological Products), as established and amended by the FDA.
“FDA” shall mean the United States Food and Drug Administration or, where applicable, its regulatory equivalent in a foreign jurisdiction.

“Facility” shall mean, as applicable, the Be’er Tuvia manufacturing facility located at Beer Tuvia Industrial Zone, POB 571, Kiryat Malachi 83104, Israel.

“IND” shall mean an Investigational New Drug application, as defined in 21 C.F.R. 312.3, and filed with the FDA or any equivalent foreign Regulatory Agency.

“Legal Requirements” shall mean (i) any present and future national, state, local or similar laws (whether under statute, rule, regulation or otherwise), (ii) requirements under permits, orders, decrees, judgements or directives, and requirements of applicable Regulatory Agencies (including, without limitation, cGMP) and (iii) regulations pertaining to BLAs (with respect to each of the foregoing, as amended or revised from time to time).

“Process” or “Processing” shall mean the act of purification, preparation, filling, testing and any other pharmaceutical manufacturing procedures, or any part thereof (including, but not limited to, product or process specifications, testing or test methods, raw material specifications or suppliers, equipment, etc.), relating to, as applicable, Bulk Product and Product.

“Product” shall mean pharmaceutical products containing Bulk Product ordered by Savient pursuant to the Supply Agreement.

“Regulatory Agency” shall mean with respect to the United States, the FDA, or, in the case of a country in the Territory other than the United States, such other appropriate regulatory agency with similar responsibilities.

2.03 In addition, the following definitions apply to this Quality Agreement:

(i) “Bulk Product” shall mean bulk solution of polyethylene glycol (PEG) conjugate of uricase in its final formulation which is in Process, and has been produced for sterilization, filling or other finishing activities.

(ii) “Filled Product” shall mean sterile Product that is in Process and has been filled into its final primary packaging for further labelling or packaging activities.

(iii) “Final Product” shall mean finished Product in its final packaged and labeled form which is ready for distribution to the marketplace or third party distributors for sale or clinical use.

(iv) “Release” shall mean control, approval and authorization of shipment.
ARTICLE 3

NOTIFICATION OF PROCESS DEVIATIONS AND DOCUMENTATION OF CHANGES:

3.01        BTG shall provide to SAVIENT, within two Business Days of BTG’s discovery of its occurrence, written notification of (i) any deviation from the Process as set forth in the Bulk Product Specifications and the BLA and any deviation from cGMP requirements, regulations and standards, and any event that represents an unexpected or unforeseeable event that may affect safety, purity or potency of Bulk Product; and (ii) any deviation in the quality (purity, physical and chemical properties) of the Bulk Product from the Bulk Product Specifications. Appendix I sets forth a list of examples of deviations from the Process, for purposes of illustration only, and is not intended to be comprehensive or definitive.

(i)        BTG shall not conduct any retesting or reprocessing as the result of deviations described above without prior written authorization from SAVIENT Quality Assurance unless a delay of retesting or reprocessing would result in increased risk to the safety, purity or potency of the Bulk Product or Product.

3.02        Any changes to be made to this Quality Agreement in accordance with the provisions set out in this section 3 must be documented as an addendum to this Quality Agreement, and must be signed by authorized representatives from each of the BTG QA department and the SAVIENT QA department, in addition to authorized representatives from any other departments as may be specified in relation to the matters set forth in section 3.3 below. This Quality Agreement will be reviewed by BTG and SAVIENT on a periodic basis (approximately once per year) and revised as appropriate.

3.03        Change Control

(i)        Specifications that control the Process for the manufacture, including packaging, holding, and test of Bulk Product and Product, must be signed by authorized representatives from BTG and SAVIENT Quality Assurance, SAVIENT Regulatory Affairs, and SAVIENT Manufacturing. Such documents include, but are not limited to Bulk Product Specifications (including specifications for intermediate), Product Specifications (including specifications for product, component and packaging). Changes to such documents must be signed by authorized representatives from SAVIENT Quality Assurance, SAVIENT Manufacturing and SAVIENT Regulatory Affairs.

(ii)        Changes to additional documents that control the Process for the manufacture of Bulk Product and Product (including test methods, manufacturing procedures and batch records) must be assessed according to the BTG change control process described in section 3.4. Any change that would have an impact on the Process, Bulk Product or Product, or require submissions to or approvals from any Regulatory Agency must receive prior written approval by authorized representatives from SAVIENT Quality Assurance, SAVIENT Manufacturing and SAVIENT Regulatory Affairs. If there is no such impact, BTG may proceed with the change, but must notify SAVIENT Quality...
Assurance no later than 5 days from the initiation of the BTG change control process. If SAVIENT does not agree with BTG’s assessment of impact, SAVIENT must respond to BTG no later than within 5 days of receipt of notification.

(iii) The stability protocol as well as any changes to the stability protocol must be approved by SAVIENT QA and SAVIENT Regulatory Affairs.

(iv) Critical Raw Materials. The current specifications for Critical Raw Materials are attached as Appendix III. The Parties acknowledge and agree that these specifications may be amended from time to time by the supplier of the material. With respect to such amendments:

BTG shall notify SAVIENT as soon as reasonable practicable, but no later than within 5 days of receipt of notification by BTG.

The Parties will meet and agree as to suitability of the material produced according to the amended specification for manufacture of the Bulk Product.

3.04 BTG will utilize a documented system of written procedures for the control of changes to documents relating to raw materials, packaging materials, labeling, suppliers, equipment, manufacturing methods, batch size, product, intermediates and raw materials specifications, sampling, analytical test methods and Release requirements and any other Processing by BTG, relating to the Bulk Product.

3.05 Any changes to any matter relating to the manufacture and supply of Bulk Product by BTG shall be governed by the procedures set out in the Supply Agreement at Article 3 in relation to changes to the Bulk Product Specifications, and Article 6 in relation to changes to the Process.

3.06 SAVIENT Regulatory Affairs will have responsibility for determining the regulatory impact of any proposed change. SAVIENT Regulatory Affairs will determine the classification and requirements for notification to, or approval by FDA. SAVIENT is responsible for communication of any changes to FDA. SAVIENT Regulatory Affairs will have responsibility to advise BTG of any changes to the BLA prior to submission.

BTG will ensure that changes are evaluated and qualified in accordance with all applicable ICH (International Conference on Harmonization) requirements in addition to all Legal Requirements, including but not limited to:

ICH Guideline Q5E Comparability of Biotechnological/Biological Products Subject to Changes in Their Manufacturing Process.

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ARTICLE 4
MATERIALS:

4.01 Procurement of Components
BTG will procure all the components described in the Bulk Product Specifications in such quantities as may be necessary to meet Purchase Orders placed by SAVIENT pursuant to the Supply Agreement, and store the components in appropriate storage conditions under quarantine until tested.

4.02 Inspection and Testing of Materials
Upon receipt, BTG shall sample in accordance with acceptable statistical methods, inspect and test containers of all materials to be used in the Process or in connection with the supply and manufacture of Bulk Product on a batch-by-batch basis, in accordance with the Bulk Product Specifications.

4.03 Bulk Product
BTG will be responsible for ensuring that Bulk Product is manufactured, tested and stored in compliance with all applicable ICH guidance documents (including, without limitation, the guidance contained therein for master and working cell banks) in addition to all Legal Requirements. ICH Guidance includes, but is not limited to:

Q5D Quality of Biotechnological Products: Derivation and Characterization of Cell Substrates Used for Production of Biotechnological/Biological Products.

Q7A, Good Manufacturing Practices Guidance for Active Pharmaceutical Ingredients

4.04 Retention, Storage and Handling of Materials and Product Samples
BTG shall sample and retain such amounts of Bulk Product and of all materials to be used in the Process or in connection with the supply and manufacture of Bulk Product (“Retains”) except water, compressed gasses and any highly volatile compounds as set forth in Appendix II or as otherwise required in accordance with applicable Legal Requirements. BTG will store for five years, or such longer period as may be required in accordance with Appendix II or by Legal Requirement, sample Product and Retains for each batch or lot of intermediates and raw materials. Reasonably prior to the expiry of such retention period, or upon termination of this Quality Agreement, BTG shall offer all such materials to SAVIENT. Any labor costs of BTG employees and/or Third Party expenses incurred by BTG related to the transfer of such materials shall be reimbursed by SAVIENT in the manner and at the rates set forth on Exhibit B to the Supply Agreement.

A schedule of specific Retains, storage conditions and retention periods for Puricase® is listed in Appendix II.

4.05 Transmissible Spongiform Encephalopathy (TSE)
BTG will provide a written TSE declaration that all materials (including non-dedicated equipment) used in the manufacturing process are free from animal derived material. In addition, BTG must have available, on site, written TSE declarations from the supplier, where appropriate, of raw material used in the manufacturing process verifying exclusion
of animal derived material. If BTG is unable to provide the above declarations, BTG will comply with applicable TSE laws and regulations and will obtain all associated TSE documentation as requested by SAVIENT. This documentation may include a TSE Certificate of Suitability in accordance with European directive 75/318/EEC as amended by directive 1999/82/EEC, the note for guidance EMEA/410/01 rev2 as amended and AP-CSP(99)4, Appendix 2, as amended.

4.06 Supplier Audits

BTG and SAVIENT will provide each other with copies of supplier audit reports for materials used in the Process or manufacture of the Product.

ARTICLE 5

MANUFACTURING, PACKAGING, INSPECTION AND TEST:

5.01 The Processing, packaging, and labeling of Bulk Product will be performed and documented by BTG. BTG will not subcontract any of the Processing, packaging, and labeling functions except as may be permitted in accordance with the Bulk Product Specifications, and if so permitted, in accordance with the provision set forth in Section 2.05 of the Supply Agreement.

5.02 BTG shall not Process or store Bulk Product in the same building in which BTG manufactures, stores or processes potentially hazardous substances (including, without limitation, certain antibiotics such as beta-lactam and cephalosporins, cytotoxic compounds, toxins or poisons such as pesticides or herbicides, collectively, “Potential Contaminants”) unless the Potential Contaminants are stored or manufactured in contained environments and in compliance with all Legal Requirements and the Bulk Product is Processed and stored in compliance with building, cleaning, validation and changeover requirements of all cGMPs and all Legal Requirements. BTG shall promptly notify SAVIENT if any of the Potential Contaminants are manufactured, processed or stored in any portion of the Facility which may result in the introduction of Potential Contaminants into the areas of such facilities where the Bulk Product is Processed. Savient is aware that other products are processed in the Facility, the nature of those other products existing today and that certain equipment (multi-use equipment) is used in the processing of both the Bulk Product and these other existing products. Savient has also had the opportunity to assess the risk to the Processing of Bulk Product with this new product or substance utilizing the multi-use equipment. Therefore, whenever BTG plans to introduce a new product or molecular entity which is out of the matrix of existing products to equipment shared with Puricase production, BTG will provide no less than 30 days prior notice of its intent, and will contemporaneously make supporting cleaning validation data/rationale available to Savient. Savient will make its assessment of the risk potential for adulteration of its own product through examination of cleaning validation
5.03 BTG will provide to SAVIENT: a copy of all master batch record documents and production and control records, a Certificate of Analysis (PEG-uricase API and uricase), executed batch records and associated batch documentation, which shall include, without limitation: formulation records, label records, manufacturing records, environmental monitoring data, microbiological data, in-process and final analytical data, including lab control results, sterility data, deviations/out-of-specification reports and cleaning records for any critical product contact equipment (for example, fermentors or any other non-dedicated product contact equipment).

Translation: BTG will provide an English translation of all such documents, including, without limitation, all reports, notes or comments on records that are not part of the master batch record but if any of the foregoing documents are only available in a language other than English, the Parties shall agree upon an English language template for such document(s), and BTG shall provide to Savient an English language translation of any deviations from the template(s). When required by SAVIENT, translations shall be performed by an independent, translation firm. Translations by a third party firm must be verified by BTG to ensure translation of company or process specific language. Any labor costs of BTG employees and/or Third Party expenses incurred by BTG in relation thereto shall be reimbursed by SAVIENT in the manner and at the rates set forth on Exhibit B to the Supply Agreement.

5.04 Upon request by SAVIENT, BTG will provide access to additional records that are not normally part of the batch record but which bear a reasonable relation to the Bulk Product for SAVIENT to review, which may include, without limitation, maintenance and use records, water testing data, training records, raw material release records, log books, receiving and shipping records, inventory records and vendor qualification records Any labor costs of BTG employees and/or Third Party expenses incurred by BTG in relation thereto shall be reimbursed by SAVIENT in the manner and at the rates set forth on Exhibit B to the Supply Agreement.

5.05 BTG will retain copies of all completed batch records for a minimum of five years, or such longer period as may be required by Legal Requirement. Reasonably prior to the expiry of such retention period, or upon termination of this Quality Agreement, BTG shall offer such completed batch records to SAVIENT. Any labor costs of BTG employees and/or Third Party expenses incurred by BTG related to the transfer of such materials shall be reimbursed by SAVIENT in the manner and at the rates set forth on Exhibit B to the Supply Agreement.

5.06 Use of BTG Manufacturing Space for Bulk Product

BTG has allotted an amount of manufacturing floor space at the Facility for the Processing of Bulk Product (Purification Area in the Agreement). This space may be used for the production of other products subject to the following limitations:
BTG may use the Purification Area for alternate product manufacturing only during periods when the Purification Area is not used for the Processing of Bulk Product.

BTG adheres to all relevant cGMPs including, without limitation, procedures for prevention of mix-ups, prevention of contamination, labeling requirements, cleaning requirements and changeover requirements.

BTG shall not, under any circumstances utilize any equipment dedicated to the Processing of Bulk Product for such alternate product manufacturing.

BTG adheres to limits and procedures described in section 5.2 for Potential Contaminants.

**ARTICLE 6**

**RELEASE AND SHIPMENT OF PRODUCT(S):**

6.01 Bulk Product shall be Released in accordance with the procedures set forth in the Supply Agreement, together with the additional obligations described in this section 0 of the Quality Agreement. BTG QA will review the records described in section 5.3 above. Following review and acceptance by BTG QA, BTG will send copies of these documents to SAVIENT QA. SAVIENT QA and Manufacturing will then review the documentation and notify BTG whether or not documentation is acceptable. If such documentation is not reasonably acceptable to SAVIENT, BTG will cooperate in taking such steps as SAVIENT may reasonably require to ensure that the documentation, and any Processing described therein complies with the Bulk Product Specifications and all Legal Requirements.

6.02 BTG QA will be responsible for the QC testing of Filled Product until such time as a third party laboratory has been qualified to perform such testing. BTG will provide a Certificate of Analysis and/or stability results for each batch that BTG tests. Savient QA will be responsible for the review of the manufacturing batch record for Filled Product, review of the Certificate of Analysis and Release of the Filled Product.

6.03 SAVIENT QA will be responsible for the Release of the Final Product.

6.04 Product shall be delivered in accordance with the provisions of Article 7 of the Supply Agreement.

6.05 BTG will not ship any SAVIENT products to any destination, as identified by SAVIENT, unless prior approval has been received from SAVIENT.

**ARTICLE 7**

**DEViations IN PROCESS OR BULK PRODUCT:**

In the event of a notification of a deviation by BTG in accordance with section 0 above, BTG shall investigate and fully document in English such deviation within 30 days of its discovery. If BTG cannot resolve the deviation within the 30-day period, BTG will provide
weekly updates of the investigation progress. At SAVIENT’s request, BTG shall conduct such additional or more detailed investigation of the deviation as SAVIENT may reasonably instruct. Investigation documentation will be retained by BTG as part of the batch documentation for the batch affected. When a deviation has occurred, SAVIENT will have the final review and decision making responsibility as to the impact of the deviation on the Bulk Product or Product, which will include the disposition of affected lots.

ARTICLE 8

STORAGE OF PRODUCT(S):

Bulk Product will be stored under appropriate storage conditions and in a secure area to ensure that they comply with the Bulk Product Specifications, including all the label requirements, quality specifications and attributes as well as Legal Requirements.

ARTICLE 9

TRACEABILITY OF PRODUCT(S):

SAVIENT will be responsible for traceability of products to first consignee within the US. BTG will be responsible for traceability from the finished product lot number to raw material and component lots used in manufacture.

ARTICLE 10

CONFLICT OF TERMS:

To the extent that there exists any conflict between the terms of this Quality Agreement and the Supply Agreement, the latter shall prevail. To the extent that there exists any conflict between the terms of this Quality Agreement and any Legal Requirements, the latter shall prevail.

ARTICLE 11

COMPLIANCE WITH LAWS:

BTG will ensure that all of its activities pursuant to this Agreement are performed in accordance with all Legal Requirements (including cGMPs), the respective Bulk Product Specifications, conditions of the BLA, and BTG’s Standard Operating Procedures (SOPs). BTG will ensure that the Bulk Product supplied by it to SAVIENT shall not itself cause the Final Product to be adulterated or misbranded within the meaning of the Federal Food, Drug, and Cosmetic Act and regulations.

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ARTICLE 12

INSPECTIONS:

Each party shall advise the other of any governmental communication, inspection or report, including, without limitation, that of any appropriate regulatory agency in any jurisdiction with responsibilities similar to those of the FDA in respect of the United States, any environmental agency, health agency or other governmental or administrative agency having jurisdiction over the Product or the Processing. The notifying party shall promptly notify the other party by fax and telephone, to the person and on the contact numbers set out below:

TO SAVIENT:

- Contact Name: Robert Lamm, Ph.D., Sr. VP of Quality and Regulatory Affairs
- Telephone: 732-418-9300
- Fax: 732-418-0766

TO BTG:

- Contact Name: Rivka Zaibel, VP, Quality Assurance
- Telephone: 972-8-861-2007
- Fax: 972-8-861-2166
ARTICLE 13

OBSERVATION BY SAVIENT:

Observation by SAVIENT or its authorized representative shall be governed by the following. Observation will be limited to not more than one quality audit every 12 months. One additional quality audit may be conducted within the 12 month period if BTG receives a communication from any regulatory authority threatening license approval or supply of the Product due to compliance deficiencies at BTG facilities or if BTG was found to be in material non-compliance of this Agreement during or since the last quality audit. Person-in-Plant visits may be conducted at the discretion of SAVIENT during the manufacture of Bulk Product at BTG facilities. The frequency and duration of any additional visits must be agreed to by SAVIENT and BTG.

ARTICLE 14

ADVERSE EVENTS:

14.1 BTG will provide to SAVIENT within 48 hours of becoming aware, any information from any source that suggests an adverse event or serious adverse event has occurred. This information will include any adverse drug experience or reaction reports or any other information indicating that the product has any toxicity, sensitivity reactions or is otherwise alleged to cause illness or injury due to a possible product quality problem, adulteration or misbranding.

14.2 Quality Assurance Investigations. Upon notification to BTG that SAVIENT has received an SAE, AE, product complaint or inquiry regarding a Product supplied or incorporating a Bulk Product supplied, BTG shall conduct a quality assurance investigation to determine if any process or testing deviations or events may have contributed to the SAE, AE, product complaint or inquiry. BTG shall provide a written report on the results of the investigation to SAVIENT in not more than 30 days from Savient’s notification. In cases where a more comprehensive investigation might be required, the Parties will jointly develop an investigation plan. BTG shall reasonably cooperate with SAVIENT and regulatory agencies regarding an investigation or inquiry that may be initiated by a regulatory agency or otherwise required in response to a consumer or healthcare professional. BTG shall further provide SAVIENT with all data or other information that SAVIENT may reasonably require in connection with any reports or correspondence that SAVIENT provides to the regulatory agency, consumer or healthcare professional relative to any such AE, SAE or product complaint. BTG shall make records accessible to SAVIENT for purposes of FDA or other regulatory agency inspection.

14.3 Exchange of Drug Safety Requests. The Parties shall immediately provide each other with copies of all drug safety requests from all governmental and other regulatory health authorities. Proposed answers affecting the Product will be exchanged between the Parties before submission and the Parties shall cooperate with respect to such answers. SAVIENT shall
have the ultimate decision-making authority with respect to the answers relating to the Product. The Parties shall exchange decisions from applicable health authorities immediately.

**ARTICLE 15**

**STABILITY:**

BTG will perform the stability testing, data interpretation, reporting and updating of stability information to regulatory documents for the Product and Bulk Product and for Product until such time as a third party laboratory has been qualified to perform such testing. Stability related activities for which BTG is responsible shall be completed in accordance with the timing specified in stability protocols and BTG procedures.

**ARTICLE 16**

**REGULATORY AFFAIRS:**

Each Party shall advise the other Party of any regulatory action of which it is aware which would affect the Product in any country of the Territory.

**ARTICLE 17**

**ANNUAL REPORT TO FDA:**

BTG will prepare a summary of all changes to the product, production process, quality controls, equipment or facilities that have a potential to affect the identity, strength, quality, purity or potency of the Product. Such data will be prepared and sent to SAVIENT within thirty days of the end of the review period. BTG will also ensure that the results of all stability testing performed within the review period are sent to Savient within thirty days of the end of the review period.

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<table>
<thead>
<tr>
<th></th>
<th>Print Name</th>
<th>Signature</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>SAVIENT QA</td>
<td>Robert B. Lamm</td>
<td>/s/ Robert B. Lamm</td>
<td>20-Mar-07</td>
</tr>
<tr>
<td>BTG QA</td>
<td>Rivka Zaibel</td>
<td>/s/ Rivka Zaibel</td>
<td>20 March 2007</td>
</tr>
</tbody>
</table>
APPENDIX I

Listing of Example Deviations

The following is a non-exclusive list of deviations requiring notification in accordance with section 0:

- Deviation impacting any filed regulatory document.
- Use of manufacturing or testing site (finished products, intermediates, API or excipients) other than that specified in Bulk Product and Product Specifications and/or BLA.
- Change of manufacturing scale from that specified in Bulk Product Specifications and/or BLA.
- Deviation from packaging or packaging specifications from that specified in Bulk Product Specifications and/or BLA.
- Deviation from suppliers, sources or specifications of starting and Critical Raw Materials or supplier of any filters for Products or intermediates set forth in Bulk Product Specifications and/or BLA.
- Change in the layout, functioning or structure of the Facility, equipment or utilities (HVAC, nitrogen, water or compressed gasses) that may affect the quality of the Bulk Product.
- Use of solvents or reagents (including volatile reagents), other than those specified in Bulk Product Specifications and/or BLA, or change of specifications for such solvents, reagents, or intermediates, or change in analytical methods of solvents, reagents, or intermediates.
- Deviation in amounts of solvents or reagents used from that specified in the Process, Bulk Product Specifications and/or BLA.
- Change in Transmissible Spongiform Encephalopathy (TSE) status of any raw material or product(s).
- Any reprocessing or rework of any step of the Process.
- A physical contamination, cross-contamination or other chemical contamination.
- Any manufacturing, packaging, labeling, sampling or testing deviation that affects the quality, safety or purity of the Product.
- Departures from the SOPs, IPC tests, stability SOPs, the Stability Protocol or Batch Records outside the filed limits, excursions or any deviation with potential registration impact.
- Any unexpected results from stability testing.
- Environmental monitoring results that are out-of-specification.

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APPENDIX II

Schedule of Retains, Storage Conditions and Retention Periods for Puricase®

The following is a list of the reserve/retention samples that are taken during the manufacturing processes of bulk uricase and PEG-uricase as well as from the final bulk uricase and the final bulk PEG-uricase (Bulk Product).

The document was prepared based on the following BTG QC SOPs:

1. SOP 04-68-1288 (v2): QC Sampling Plan for Bulk Uricase
2. SOP 04-68-1830 (v1): QC Sampling Plan for PEG-Uricase API
3. SOP 04-68-1861 (v1): IPC Testing of Bulk Uricase Batches
4. SOP 04-68-1862 (v1): IPC Testing of PEG-Uricase

Table 1 details the reserve/retention samples that are taken during the manufacturing process of bulk uricase and from the final bulk uricase.

Table 2 details the reserve/retention samples that are taken during the manufacturing process of PEG-uricase and from the final bulk PEG-uricase (Bulk Product).

All IPC samples (including reserve/retention samples) are to be discarded after the Final Product is released by Savient.

Uricase retention and reserve samples will be kept for one year after manufacturing. PEG-Uricase retention and reserve samples will be kept for six years after manufacturing.
Table 1. Reserve/Retention Samples for Bulk Uricase (IPC and Final)

<table>
<thead>
<tr>
<th>Process Step</th>
<th>Sample name</th>
<th>Number of Samples</th>
<th>Storage Temperature</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fermentation - Beginning of Induction</td>
<td>0</td>
<td>1 x 0.1 ml</td>
<td>-20°C</td>
</tr>
<tr>
<td>Fermentation - After 3 hr of Induction</td>
<td>3</td>
<td>1 x 0.1 ml</td>
<td></td>
</tr>
<tr>
<td>Fermentation Harvest (End of Induction)</td>
<td>6</td>
<td>1 x 0.1 ml</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>1 x 50 ml</td>
<td></td>
</tr>
<tr>
<td>Harvest Supernatant</td>
<td>7</td>
<td>1 x 1 ml</td>
<td></td>
</tr>
<tr>
<td>Fermentation Bacterial Cake Diluted 10 Fold</td>
<td>9</td>
<td>1 x 0.1 ml</td>
<td></td>
</tr>
<tr>
<td>Crude Suspension</td>
<td>10</td>
<td>1 x 0.1 ml</td>
<td></td>
</tr>
<tr>
<td>Supernatant After 1st Centrifugation</td>
<td>11</td>
<td>1 x 1 ml</td>
<td></td>
</tr>
<tr>
<td>Pellet After 1st Centrifugation</td>
<td>12</td>
<td>1 x 0.1 ml</td>
<td></td>
</tr>
<tr>
<td>Supernatant After 2nd Centrifugation</td>
<td>13</td>
<td>1 x 1 ml</td>
<td></td>
</tr>
<tr>
<td>Pellet After 2nd Centrifugation</td>
<td>14</td>
<td>1 x 0.1 ml</td>
<td></td>
</tr>
<tr>
<td>Dissolution of IBs</td>
<td>DS</td>
<td>1 x 7 ml</td>
<td></td>
</tr>
<tr>
<td></td>
<td>End DS</td>
<td>1 x 7 ml</td>
<td></td>
</tr>
<tr>
<td>Centrifugation of Precipitate</td>
<td>CP</td>
<td>1 x 7 ml</td>
<td></td>
</tr>
<tr>
<td>Concentration / Diafiltration</td>
<td>30 ICD Filt.</td>
<td>1 x 7 ml</td>
<td></td>
</tr>
<tr>
<td></td>
<td>30 KD Ret (only if process is stopped)</td>
<td>1 x 7 ml</td>
<td></td>
</tr>
<tr>
<td>QS-1 Column</td>
<td>QS-1 Load</td>
<td>1 x 7 ml</td>
<td>2-8°C</td>
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<tr>
<td></td>
<td>QS-1 MP</td>
<td>1 x 7 ml</td>
<td></td>
</tr>
<tr>
<td>PS Column</td>
<td>PS Load</td>
<td>1 x 7 ml</td>
<td></td>
</tr>
<tr>
<td></td>
<td>PS MP</td>
<td>1 x 7 ml</td>
<td></td>
</tr>
<tr>
<td>Xanthine-Agarose Column</td>
<td>Xa Load Prep.*</td>
<td>1 x 7 ml</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Xa Load (from each day)</td>
<td>1 x 7 ml</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Each Xa MP</td>
<td>1 x 7 ml</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Xa MP (AC)</td>
<td>1 x 7 ml</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>1 x 50 ml</td>
<td></td>
</tr>
<tr>
<td>Bulk Uricase Reserve Samples</td>
<td></td>
<td>2 x 10 ml</td>
<td></td>
</tr>
<tr>
<td>Bulk Uricase Retention Samples</td>
<td></td>
<td>2 x 50 ml</td>
<td></td>
</tr>
</tbody>
</table>

* The number of Xa Load Prep. samples depends on the concentration measured after sample dilution.
<table>
<thead>
<tr>
<th>Process Step</th>
<th>Sample name</th>
<th>Number of Samples</th>
<th>Storage Temperature</th>
</tr>
</thead>
<tbody>
<tr>
<td>Concentration and dialysis</td>
<td>30K AD</td>
<td>3 x 5 ml</td>
<td>2-8°C</td>
</tr>
<tr>
<td>QS 2</td>
<td>QS2 MP</td>
<td>3 x 5 ml</td>
<td></td>
</tr>
<tr>
<td>PEGylation</td>
<td>PEG Solution</td>
<td>1 x 2 ml</td>
<td></td>
</tr>
<tr>
<td></td>
<td>End of PEGylation</td>
<td>2 x 5 ml</td>
<td></td>
</tr>
<tr>
<td>QS 3</td>
<td>QS 3 MP</td>
<td>2 x 5 ml</td>
<td></td>
</tr>
<tr>
<td>100K Dialysis</td>
<td>Dialysis Buffer</td>
<td>1 x 5 ml</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Pellicon Final Rinse Water</td>
<td>1 x 5 ml</td>
<td></td>
</tr>
<tr>
<td></td>
<td>100K Filtrate — After X Volumes</td>
<td>1 x 5 ml after each dialysis volume</td>
<td></td>
</tr>
<tr>
<td></td>
<td>(~15, 20, 25 volumes; to be determined based on Free PEG content)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>100K Retentate</td>
<td>2 x 5 ml</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>1 x 30 ml</td>
<td></td>
</tr>
</tbody>
</table>

PEG-Unease API Reserve Samples

PEG-Unease API Retention Samples

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## APPENDIX III

Critical Raw Materials Used in the Production of Recombinant Uricase and PEG-Uricase

<table>
<thead>
<tr>
<th>Material</th>
<th>Manufacturer</th>
<th>Cat. No.</th>
<th>Testing</th>
<th>Source</th>
<th>Origin</th>
</tr>
</thead>
<tbody>
<tr>
<td>N-Z-Amine AS</td>
<td>Kerry Bio-Science</td>
<td>5X59028/ 5X59039</td>
<td>Chem/NIR</td>
<td>Milk derivative</td>
<td>USA</td>
</tr>
<tr>
<td>N-Z-Amine B</td>
<td>Kerry Bio-Science</td>
<td>5X59032</td>
<td>Chem/NIR</td>
<td>Milk derivative</td>
<td>USA</td>
</tr>
<tr>
<td>Yeast Extract, microgranulated powder, without salt, type D</td>
<td>BioSpringer</td>
<td>0251/ 0-MG-L</td>
<td>Chem/NIR</td>
<td>Yeast</td>
<td>France</td>
</tr>
<tr>
<td>Q Sepharose™ Fast Flow</td>
<td>Amersham Pharmacia</td>
<td>17-4510-04</td>
<td>Chem</td>
<td>Chemical</td>
<td>Sweden</td>
</tr>
<tr>
<td>Phenyl Sepharose™ 6 Fast Flow low substitution</td>
<td>Amersham Pharmacia</td>
<td>17-0965-04</td>
<td>Chem</td>
<td>Chemical</td>
<td>Sweden</td>
</tr>
<tr>
<td>Xanthine-agarose</td>
<td>Sigma</td>
<td>X3128</td>
<td>CoA</td>
<td>Plant / Chemical</td>
<td>USA</td>
</tr>
<tr>
<td>Methoxypoly (ethylene glycol)-nitrophenyl carbonate MW 10 000, Sunbright MENP-10T</td>
<td>NOF Corporation</td>
<td>-</td>
<td>Chem</td>
<td>Chemical</td>
<td>Japan</td>
</tr>
<tr>
<td>Lysozyme, from egg white, 50,000 U/mg cryst. HCl salt, for biochemistry EC 3.2.1.17</td>
<td>Merck</td>
<td>1.05281</td>
<td>Chem</td>
<td>Egg, chicken</td>
<td>Germany</td>
</tr>
<tr>
<td>Lysozyme Chloride (pharmaceutical grade) (Mucopeptide N-Acetylmuramyl hydrolase, HCL, E.C. 3.2.1.17)(from egg white)</td>
<td>Belovo</td>
<td>PO-VEN-03 Appendix 13a</td>
<td>Egg chicken</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
## SPECIFICATION N-Z-AMINE AS

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Test</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Nitrogen (TN)</td>
<td>Combustion</td>
<td>11.0% minimum</td>
</tr>
<tr>
<td>Amino Nitrogen (AN)</td>
<td>HCHO Titration (%)</td>
<td>Record</td>
</tr>
<tr>
<td>Ratio AN/TN</td>
<td>Ratio</td>
<td>45 minimum</td>
</tr>
<tr>
<td>Ash Content</td>
<td>Oven</td>
<td>7.5% maximum</td>
</tr>
<tr>
<td>Loss on drying</td>
<td>Moisture balance</td>
<td>5.0% maximum</td>
</tr>
<tr>
<td>pH</td>
<td>2% autoclaved solution</td>
<td>6.4 — 7.0</td>
</tr>
<tr>
<td>Color</td>
<td>2% autoclaved solution, ABS</td>
<td>0.180 AU maximum</td>
</tr>
<tr>
<td>Clarity</td>
<td>2% autoclaved solution, 2100AN</td>
<td>0.76 NTU maximum</td>
</tr>
<tr>
<td>Standard Plate Count</td>
<td>USP</td>
<td>10,000 CFU/g maximum</td>
</tr>
<tr>
<td>Enterobacteriaceae</td>
<td>ISO</td>
<td>10 CFU/g maximum</td>
</tr>
<tr>
<td>Salmonella</td>
<td>USP</td>
<td>Absent in 25 g</td>
</tr>
</tbody>
</table>

D-22
## SPECIFICATION N-Z-AMINE B

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Test</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Nitrogen (TN)</td>
<td>Combustion</td>
<td>11.0% minimum</td>
</tr>
<tr>
<td>Amino Nitrogen (AN)</td>
<td>HCHO Titration (%)</td>
<td>Record</td>
</tr>
<tr>
<td>Ratio AN/TN</td>
<td>Ratio</td>
<td>39.0 minimum</td>
</tr>
<tr>
<td>Ash Content</td>
<td>Oven</td>
<td>7.0% maximum</td>
</tr>
<tr>
<td>Loss on drying</td>
<td>Moisture balance</td>
<td>5% maximum</td>
</tr>
<tr>
<td>pH</td>
<td>2% autoclaved solution</td>
<td>6.6 — 7.1</td>
</tr>
<tr>
<td>Color</td>
<td>2% autoclaved solution, ABS</td>
<td>0.160 AU maximum</td>
</tr>
<tr>
<td>Clarity</td>
<td>2% autoclaved solution, 2100AN</td>
<td>1.36 NTU maximum</td>
</tr>
<tr>
<td>Standard Plate Count</td>
<td>USP</td>
<td>10,000 CFU/g maximum</td>
</tr>
<tr>
<td>Enterobacteriaceae</td>
<td>ISO</td>
<td>10 CFU/g maximum</td>
</tr>
<tr>
<td>Salmonella</td>
<td>USP</td>
<td>Absent in 25 g</td>
</tr>
</tbody>
</table>

D-23
## SPECIFICATION YEAST EXTRACT

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dry matter</td>
<td>94.0 — 98.0 g per 100 g product</td>
</tr>
<tr>
<td>Total nitrogen</td>
<td>10.0 — 11.8 g per 100 g product</td>
</tr>
<tr>
<td>Amino nitrogen</td>
<td>4.5 — 5.8 g per 100 g product</td>
</tr>
<tr>
<td>pH</td>
<td>6.8 — 7.2</td>
</tr>
<tr>
<td>Sodium chloride</td>
<td>&lt; 0.5 g per 100 g product</td>
</tr>
<tr>
<td>Total plate count</td>
<td>&lt; 5,000 CFU per g product</td>
</tr>
<tr>
<td>Coliforms</td>
<td>&lt; 5 CFU per g product</td>
</tr>
<tr>
<td>Spores of Clostridium perfringens</td>
<td>&lt; 10 CFU per g product</td>
</tr>
<tr>
<td>Yeast</td>
<td>&lt; 50 CFU per g product</td>
</tr>
<tr>
<td>Mold</td>
<td>&lt; 50 CFU per g product</td>
</tr>
<tr>
<td>Salmonella</td>
<td>Negative (per 25 g)</td>
</tr>
<tr>
<td>E. coli</td>
<td>Negative</td>
</tr>
<tr>
<td>Staphylococcus aureus</td>
<td>Negative</td>
</tr>
</tbody>
</table>

D-24
<table>
<thead>
<tr>
<th>Parameter</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Function - retention volume; ml</td>
<td></td>
</tr>
<tr>
<td>- GammaBind™</td>
<td>40 — 50</td>
</tr>
<tr>
<td>- β-Lactoglobulin A</td>
<td>59 — 79</td>
</tr>
<tr>
<td>- β-Lactoglobulin B</td>
<td>72 — 92</td>
</tr>
<tr>
<td>Total capacity</td>
<td></td>
</tr>
<tr>
<td>mmol Cl⁻/mL packed gel</td>
<td>0.18 — 0.25</td>
</tr>
<tr>
<td>Flow rate at 0.1 MPa</td>
<td></td>
</tr>
<tr>
<td>cm/hour</td>
<td>400 — 700</td>
</tr>
<tr>
<td>Bed height: 14 — 16 cm</td>
<td></td>
</tr>
<tr>
<td>Particle size distribution</td>
<td></td>
</tr>
<tr>
<td>Volume share within 45 — 165 µm; %</td>
<td>95 minimum</td>
</tr>
<tr>
<td>Microbial contamination</td>
<td></td>
</tr>
<tr>
<td>microorganisms / mL suspension</td>
<td>100 maximum</td>
</tr>
</tbody>
</table>
## SPECIFICATION PHENYL SEPHAROSE™

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Function — Separation of Cytochrome C, Myoglobin and Lysozyme</td>
<td></td>
</tr>
<tr>
<td>Retention Time; minutes</td>
<td></td>
</tr>
<tr>
<td>Myoglobin</td>
<td>52 — 63</td>
</tr>
<tr>
<td>Lysozyme</td>
<td>80 — 90</td>
</tr>
<tr>
<td>Microbial contamination</td>
<td></td>
</tr>
<tr>
<td>microorganisms / mL suspension</td>
<td>100 maximum</td>
</tr>
<tr>
<td>Degree of substitution</td>
<td></td>
</tr>
<tr>
<td>µmol phenyl per ml drained gel</td>
<td>Record</td>
</tr>
</tbody>
</table>

D-26
## SPECIFICATION XANTHINE AGAROSE

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>White Suspension</td>
</tr>
<tr>
<td>Binding capacity</td>
<td>$\geq 1.5 \text{ mg/ml binding capacity}$</td>
</tr>
</tbody>
</table>

D-27
<table>
<thead>
<tr>
<th>Parameter</th>
<th>Test</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical description</td>
<td>Visual observation</td>
<td>White to off-white powder or granular solid</td>
</tr>
<tr>
<td>Appearance of acidic solution</td>
<td>Visual inspection of 1 mg/ml solution in 1mM HCL</td>
<td>Colorless and free of turbidity or suspended matter</td>
</tr>
<tr>
<td>Average molecular weight (Mn) (Daltons)</td>
<td>SEC monitored by RI</td>
<td>9,000 — 11,000</td>
</tr>
<tr>
<td>Polydispersity (Mw/Mn) main peak</td>
<td>SEC monitored by RI</td>
<td>NMT 1.1</td>
</tr>
<tr>
<td>PEG diol content (%)</td>
<td>SEC monitored by RI, 20 kD Peak</td>
<td>NMT 2</td>
</tr>
<tr>
<td>Content of active m-PEG-npc (%)</td>
<td>Spectrophotometric determination of pNP released by alkaline hydrolysis / H-NMR</td>
<td>NLT 90</td>
</tr>
<tr>
<td>Free p-nitrophenol (%)</td>
<td>Spectrophotometric determination of pNP released by alkaline hydrolysis / H-NMR</td>
<td>NMT 5 of total pNP measured after alkaline hydrolysis</td>
</tr>
<tr>
<td>Bacterial endotoxins (EU/g)</td>
<td>USP (gel clot)</td>
<td>NMT 20</td>
</tr>
<tr>
<td>Water content (%)</td>
<td>Karl Fischer</td>
<td>LT 2</td>
</tr>
<tr>
<td>Bioburden (cfu/g)</td>
<td>Microbial limit test (JP)</td>
<td>LT 100</td>
</tr>
<tr>
<td>Organic volatile impurities (%)</td>
<td>GC (Head-space)</td>
<td>NMT 0.1</td>
</tr>
</tbody>
</table>

acetonitrile, pyridine, toluene, hexane, ethyl acetate, triethanolamine
<table>
<thead>
<tr>
<th>Parameter</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Activity (Micrococcus luteus, FIP-Standard; pH 7.0; 25° C)</td>
<td>≥ 50,000 U/mg</td>
</tr>
</tbody>
</table>

D-29
<table>
<thead>
<tr>
<th>Parameter</th>
<th>Test</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Solubility in water (mg/ml)</td>
<td>HPLC on TSK-gel G2000SWXL detection 280 nm</td>
<td>&gt;100</td>
</tr>
<tr>
<td>Protein purity (%)</td>
<td>HPLC on TSK-gel G2000SWXL detection 280 nm</td>
<td>&gt;99.0</td>
</tr>
<tr>
<td>Identification</td>
<td>Nihydrin test: blue-purple color, maximum absorbance between 279 nm and 281 nm</td>
<td>Conforms</td>
</tr>
<tr>
<td>Transmittance @ 650 nm (%)</td>
<td>Of a 1.5% solution in water</td>
<td>&gt;99.5</td>
</tr>
<tr>
<td>Transmittance @ 400 nm (%)</td>
<td>Of a 10% solution in water</td>
<td>&gt;90</td>
</tr>
<tr>
<td>pH</td>
<td>Of a 1.5% solution in water</td>
<td>3.0 — 4.0</td>
</tr>
<tr>
<td>Activity * (FIP U/mg)</td>
<td>By comparison to a lysozyme standard FIP from Center for Standards, Gent (Belgium). According to FIP ref. Int. Pharm. J (1988) 2(5), 169-171</td>
<td>&gt;36,000</td>
</tr>
<tr>
<td>Assay * (mg/mg)</td>
<td>By comparison to a lysozyme reference standard according to the Japanese Pharmaceutical Codex. (JPC 1997 Part I)</td>
<td>0.9</td>
</tr>
<tr>
<td>Moisture (%)</td>
<td>105 °C — 4 hours</td>
<td>&lt;5</td>
</tr>
<tr>
<td>Ash (%)</td>
<td>800 °C — 3 hours</td>
<td>&lt;0.3</td>
</tr>
<tr>
<td>Chloride (%)</td>
<td>Potentiometric titration with ion selective electrode</td>
<td>&lt;4</td>
</tr>
<tr>
<td>Nitrogen* (%)</td>
<td>Kjeldahl method</td>
<td>16.8 — 17.8</td>
</tr>
<tr>
<td>Density (ml/g)</td>
<td>Bulk density by sieving the powder on the top of a cylinder of 30 ml capacity (diam. 22 mm, height 79 mm)</td>
<td>2 - 3</td>
</tr>
<tr>
<td>Particle size (p.m)</td>
<td>Opening: 0.077 mm; wire: 0.050mm; % opening 34</td>
<td>&lt;77</td>
</tr>
<tr>
<td>Arsenic (ppm)</td>
<td>Test strips semiquantitative Merckoquant 10 026 (Merck)</td>
<td>&lt;1</td>
</tr>
<tr>
<td>Heavy metals (ppm)</td>
<td>Atomic Absorption</td>
<td>&lt;10</td>
</tr>
<tr>
<td>Total viable count (/g)</td>
<td>Culture medium: OXOID CM1; on membrane filters; 0.45 µm pore size; 30°C 3 days</td>
<td>&lt;10</td>
</tr>
<tr>
<td>Pyrogens (IU/mg)</td>
<td>LAL: pyrogenRT plus kit Bio Whittaker</td>
<td>&lt;1</td>
</tr>
</tbody>
</table>

* on anhydrous basis

D-30
**Exhibit E**

**Product Price**

During the first three (3) years from the date of the receipt by Savient of the first commercial batch of the Product, the Price of the Product shall be as follows:

(i) For each gram, Eight Thousand Two Hundred Ninety United States Dollars (USD$8290) for any aggregated quantities of the Product up to and including Two point Four kilograms (2.4 kg) ordered during any calendar year that commercial batches of Product are shipped, i.e. after the first commercial batch of Product has been shipped.

(ii) For each gram, Seven Thousand Eight Hundred Sixty Five United States Dollars (USD$7865) for any aggregated quantities of the Product between Two point Four kilograms (2.4 kg) and Four point Eight kilograms (4.8 kg) ordered during any calendar year as above; and

(iii) For each gram, Seven Thousand Four Hundred Forty United States Dollars (USD$7440) for any aggregated quantities of the Product equal to or greater than Four point Eight kilograms (4.8 kg) ordered during any calendar year as above.

The Parties agree that Savient will enter into a supply agreement with NOF, the supplier of m-PEG-NPC (mono-methoxy polyethylene glycol nitro-phenyl carbonate), and will order and pay for PEG needed in Product manufacture on an ongoing basis. In the event that BTG purchases PEG directly from NOF or any other manufacturer, the cost of the PEG will be invoiced to Savient.

Beginning on the Third (3rd) anniversary of the date of receipt of the first commercial batch of Product by Savient, and on each successive first (1st) January thereafter, the Price of the Product shall increase by an amount equal to the average increase in the United States Consumer Pricing Index (CPI) over the immediately preceding twelve (12) month period; such percentage increase shall be applied to each amount specified in (i) through (iii) above.
Exhibit F

Residual Rights Agreement
This Amended and Restated Residual Rights Agreement ("Agreement") is entered into on the 17th day of July, 2005, by and between Savient Pharmaceuticals, Inc., a public company duly organized under the laws of the State of Delaware ("Savient") and Bio-Technology General (Israel) Ltd., a private company duly organized under the laws of the State of Israel ("BTG"), to replace and supersede the Residual Rights Agreement previously signed and dated 20 June, 2005.

(Savient and BTG shall be referred to jointly as the “Parties” and individually as a “Party”).

WHEREAS, BTG is a wholly owned subsidiary of Savient; and

WHEREAS, the Parties are parties to a Manufacturing Services Agreement effective January 1, 1996 (the “Manufacturing Agreement”) and a Research and Development Services Agreement dated January 1, 1996 (the “R & D Agreement”) (the Manufacturing Agreement and the R & D Agreement being collectively referred to hereunder as the “Inter-Company Agreements”); and

WHEREAS, pursuant to the Share Purchase Agreement (the “SPA”) and the Asset Purchase Agreement (“APA”), each dated March 23, 2005 (the SPA and APA, collectively, the “Divestiture Agreements”), Savient intends to sell to Ferring B.V. all of the issued and outstanding share capital of BTG, and to Ferring International Centre S.A. (together with Ferring B.V., the “Buyer”) all of Savient’s right, title and interest in and to certain assets and rights of Savient in the drug products and drug candidates developed and/or manufactured at BTG pursuant to the Inter-Company Agreements (the “Divestiture” and the “Divested Products”, respectively), but not in any case in the drug candidate known as “Peguricase” (a/k/a “Puricase”); and

WHEREAS, the development of Puricase is ongoing and Savient shall require, and BTG is willing to render, continued development, manufacturing and other services of BTG in relation to Puricase, following the Closing (as defined in the Divestiture Agreements); and

WHEREAS, the Parties wish to record certain specific understandings in relation to certain protein purification technology (the “CPC Technology”) as to which Savient has retained title, in furtherance of the understandings set out in the SPA in relation thereto, which CPC Technology forms part of the Puricase Technology, but which can also be used for the manufacture of other
products (all products that may be manufactured using the CPC Technology, other than Puricase, Divested Products and HA (as defined below), being referred to herein as “CPC Products”); and

WHEREAS, the Parties wish to record certain specific understandings in relation to the OCS-funded project, known as BTG-271 (“BTG-271”), in furtherance of the understandings set out in the SPA in relation thereto; and

WHEREAS, certain of the Divested Products, Puricase, the CPC Technology and BTG-271 were developed at BTG within the framework of research and development programs carried out with the support of the Office of the Chief Scientist at the Ministry of Industry, Trade and Labor (“Approved Programs” and the “OCS” respectively) and Savient has ownership rights thereto but BTG possesses other rights as set forth in Savient’s letter to the OCS of July 15, 2003 (the “OCS Letter”), a copy of which is attached as Annex “A”; and

WHEREAS, the Parties have agreed to terminate the Inter-Company Agreements and wish to record their understandings in relation to the continued development and/or manufacture of Puricase and/or other services that may be rendered by BTG in relation thereto; and

WHEREAS, the Parties wish to record their understandings in relation to the royalties that may be payable to the OCS (“Royalties”) in relation to the Divested Products, Puricase, other products embodying Puricase Technology, CPC Products and BTG-271, all subject to and effective as from the Closing.

Now therefore, in consideration of the foregoing premises, which are incorporated into and made a part of this Agreement, and of the mutual covenants which are recited herein, the Parties agree as follows:

1. **Termination of the Inter-Company Agreements**

1.1. Prior to the Closing, Savient and BTG shall comply with the terms and conditions of the Inter-Company Agreements, including any payment obligations by Savient thereunder. Notwithstanding anything to the contrary contained in the Inter-Company Agreements, all of the provisions of the Inter-Company Agreements shall automatically terminate effective as of the Closing, including provisions that were intended to survive termination. Savient shall not have any further obligation to pay BTG in respect of Reimbursable Costs (as such term is defined in the R & D Agreement) or Processing Fees (as such term is defined in the Manufacturing Agreement) that may be outstanding as of such time in relation to Divested Products, and BTG shall be considered as having waived such payments.
1.2. In connection with such terminations, and for the avoidance of doubt, the Parties agree that:

1.2.1. Notwithstanding the provisions of Section 1.1 and Section 3.2 of the Manufacturing Agreement, title to all work in process relating to Divested Products and inventory of Divested Products shall automatically vest in the Buyer, as of the Closing;

1.2.2. Notwithstanding the provisions of Section 1.1 above and Section 11.3 of the Manufacturing Agreement, as of the Closing, BTG shall process and deliver Divested Products ordered prior to the Closing to the Buyer or the Buyer’s designee, and Savient shall have no responsibilities in relation thereto;

1.2.3. As of the Closing, Savient and BTG agree that any liability of Savient to pay BTG for development activities, regulatory or other services of any nature that may have been carried out by BTG for Savient prior to the Closing under the R & D Agreement or otherwise have been satisfied as of the Closing; and

1.2.4. The provisions of the Manufacturing Term Sheet attached hereto as Annex “D” shall apply to work in process relating to Puricase existing as of the Closing and the delivery of Puricase that may have been ordered prior to the Closing.


2.1. Savient has and shall have the exclusive right, title and interest in and to Puricase and the Puricase Technology, subject to (i) BTG’s irrevocable and perpetual right to conduct research and development with the Puricase Technology developed in the course of Approved Programs, excluding clinical trials that BTG is not in a position to monitor from Israel and (ii) BTG’s right to manufacture Puricase in Israel. BTG shall have commercialization rights with respect thereto only as provided in Section 6 herein or as provided in the Divestiture Agreements. In the case of clauses (i) and (ii), BTG’s rights shall always remain subject to the terms and conditions of any existing supply, manufacturing or development agreement between the Parties. For the avoidance of doubt, Savient and an additional manufacturer on its behalf approved by the OCS, will have the right to use the CPC Technology in order to manufacture Puricase.
2.2. Savient has and shall have the exclusive right, title and interest in the CPC Products and the CPC Technology subject to BTG’s exclusive, irrevocable, perpetual and unconditional license for purposes of research and development and production. BTG shall have commercialization rights with respect thereto only as provided in Section 6 herein or as provided in the Divestiture Agreements.

2.3. For the purposes of this Agreement, the term “Puricase Technology” means the technology described in the patent applications listed on Annex “B” as 1.1 (the “Puricase Patents”), and any developments, discoveries, inventions, improvements, designs, methods, processes, techniques, devices, formulae and trade secrets which may be developed, acquired and conceived by BTG and are derived from any Development Program in relation to Puricase which have been or may be carried out at any time after the submission of the Puricase Patents and all patents that may be issue from patent applications claiming or describing such technology, information and know-how and filed in addition to the Puricase Patents after their submission.

For the purposes of this Agreement, the term “CPC Technology” means the technology described in the patent applications listed on Annex “B” as 1.2 (the “CPC Patents”) and any developments, discoveries, inventions, improvements, designs, methods, processes, techniques, devices, formulae and trade secrets which have been or may be developed, acquired and conceived by BTG and are derived from any Development Program which have been or may be carried out at any time after the submission of the CPC Patents and all patents that may issue from patent applications claiming or describing such technology, information and know-how and filed in addition to the CPC Patents after their submission.

For the purposes of this Agreement, “Development Programs” shall mean research and development work carried out by BTG for Savient.

2.4. The Puricase Patents, and the CPC Patents (collectively, the “Savient Patents”) are owned by Savient. BTG shall have no rights with respect to the Savient Patents, other than as provided herein or as provided in the Divestiture Agreements. Savient has the sole control over filing and prosecuting applications for United States and foreign patents covering the Puricase Technology and the CPC Technology and may file and prosecute the same in Savient’s name. The cost for all such filings and
prosecutions are and shall be borne by Savient. BTG and its employees and consultants shall provide Savient, without compensation other than recovery of out of pocket expenses, with the necessary authorizations, powers of attorney and other documents and assistance reasonably requested by Savient from time to time to file, secure and maintain Savient’s patent rights in connection with the Savient Patents and BTG hereby grants to Savient powers of attorney to execute and file on BTG’s behalf any documents reasonably necessary to secure and maintain such patent rights.

For the purposes of this Agreement, the term “Savient Patents” means the patents listed on Annex B and any disclosures, continuations, continuations-in-part, divisionals, provisionals, PCT applications, reissues, revisions, substitutions, conversions, renewals, extensions, prolongations, and reexaminations thereof, any technology and inventions covered thereby, and any corresponding international, regional, and national applications and patents.

2.5. BTG shall, from time to time and as soon as practicable following Savient’s request, provide Savient with documentation describing the current Puricase Technology and CPC Technology held by or under the control of BTG and any other report reasonably requested by Savient. For the avoidance of doubt, Puricase Technology and CPC Technology shall be described in sufficient detail to allow Savient to manufacture Puricase, or use the CPC Technology (as the case may be) it being understood and agreed, however, that Savient shall not commence manufacture of Puricase or of a CPC Product (i) unless so permitted by the OCS, if such permission is required; and (ii) unless in compliance with any agreement between the Parties relating to such manufacture and supply; and (iii) provided that such permission by the OCS does not trigger any additional obligations of BTG vis-à-vis Savient or the OCS, above and beyond those provided in such agreement of manufacture and supply or in this Agreement. In any event, BTG may retain copies of such documentation for archival purposes.

2.6. For the sake of clarity:

2.6.1. Nothing herein is intended to derogate from BTG’s ownership of the real property, tools, machinery and equipment which have been or may be acquired by it in furtherance of, or incidental to, the Development Programs;

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2.6.2. Neither “Puricase Technology” nor “CPC Technology” shall be deemed to include general methods of production or analysis that are generally known in the pharmaceutical industry but have been or will be applied to a Divested Product, HA, Puricase or any CPC Product.

2.7. Savient hereby grants BTG and its Affiliates a non-transferable, royalty-bearing, perpetual, worldwide nonexclusive, unconditional (save for the reasonable consideration to be paid for commercialization rights hereunder) license, under the Puricase Patent to develop products which are not PEGylated recombinant porcine uricase (urate oxidase), and to manufacture and commercialize any such product, it being understood and agreed, however, that the royalties that will be due and payable by BTG to Savient in respect of the commercialization rights to any such product, and other terms and conditions of such license, shall be subject to the negotiation, in good faith, of a mutually acceptable license agreement containing normal and customary terms for transactions of a similar nature (the “License Agreement”). Should the Parties fail to execute the License Agreement within 90 (ninety) days of either Party initiating such negotiations, then the matter may be referred for resolution by either Party, in accordance with the provisions and the procedures attached hereto as Annex F. Nothing in the Parties’ failing to execute the License Agreement or the initiation or conduct of any such procedures shall bar BTG from exercising the license granted to it pursuant to this Section 2.7 pending the decision of the expert.

2.8. The provisions of this Section 2 shall survive the termination or expiration of this Agreement.

3. **Research & Development; Regulatory Services; Manufacturing Services**

3.1. BTG hereby agrees to the extent and on the terms set out in Annexes “C” and “D” hereto (as such Annexes may be modified or superseded by a final definitive agreement between the Parties) to (i) complete the ongoing research and development currently being conducted in respect to Puricase; (ii) transfer the process to BTG’s facility in Be’er Tuvia, Israel; (iii) produce a sufficient quantity of Puricase as required for Phase 3 clinical trials and the initial commercial launch of Puricase and perform all related stability and other testing and activities required for worldwide regulatory filing; (iv) render assistance to Savient in
relation to the worldwide regulatory filings related thereto; and (v) remain a back-up supplier to the new manufacturer (if any) throughout the time period set forth in Section E of Annex “D” attached hereto or any successive Manufacturing Services Agreement between the Parties.

3.2. In the event that BTG breaches any of its obligations to Savient under this Section 3, in addition to any other remedies that may be available to Savient in law or equity, BTG shall, promptly upon Savient’s request, cooperate and collaborate with Savient in applying to the OCS for Savient to carry out the work in question through a third party. Nothing in the foregoing should be construed as relieving BTG from its contractual obligations pursuant to Section 3.1, and Annexes “C” and “D” attached hereto.

4. **Technology Transfer**

Subject to the approval of the OCS, Savient shall be entitled to request BTG to render to Savient and/or its third party manufacturer technical assistance relating to the transfer of the Puricase Technology or the CPC Technology. The terms and conditions upon which BTG shall be obligated to render such assistance in relation to the Puricase Technology are set out in Annex “E” attached hereto.

5. **Compliance with Law for the Encouragement of Research and Development in Industry and the Regulations, Rules and, Procedures Promulgated Thereunder (collectively, the “Law”)**

5.1. BTG hereby confirms and acknowledges that as from the Closing BTG and/or the Buyer (as the case may be) shall be fully responsible for the payment of Royalties pursuant to the Law in relation to income derived from the Divested Products and income derived by BTG from the commercial exploitation of a CPC Product pursuant to the license granted to it by Savient pursuant to Section 6.2 below, and BTG hereby agrees to indemnify Savient for any liability that may be imposed upon it by the OCS in relation thereto. BTG shall provide Savient with copies of its semi-annual reports to the OCS in relation to the payment of such Royalties, together with evidence of payment. Moreover, BTG shall notify Savient of any audit conducted by the OCS in respect thereto and the result of such audit, and provide Savient with copies of any written audit report. BTG has been using the CPC Technology in the production of carboxypeptidase as of February 2005, and Royalties pursuant to
the Law in relation to income derived from carboxypeptidase are thus payable to the OCS. As there is uncertainty as to whether these Royalties should be allocated to OCS file 27141 (Puricase) and/or OCS file 10281 (APA), it is hereby agreed that BTG and Savient shall mutually refer the question of the allocation of such Royalties and the relevant background information to Keren Tmurah at the OCS ("Keren Tmurah") within 30 days of this Agreement, and Keren Tmurah’s directives shall be binding upon the Parties.

5.2. Savient hereby confirms and acknowledges that as from the Closing Savient shall be fully responsible for the payment of Royalties pursuant to the Law in relation to income derived by Savient from Puricase, Puricase Technology, a CPC Product and the CPC Technology and hereby agrees to indemnify BTG for any liability that may be imposed upon it by the OCS in relation thereto.

5.3. Due to the fact that BTG shall remain a conduit for the payment of Royalties as set forth in Section 5.2, and in order to ensure Savient’s compliance with the requirements of the Law, Savient irrevocably and unconditionally undertakes to periodically provide BTG with the funds required for making such payments of Royalties in a timely manner. In furtherance thereof:

5.3.1. Savient shall provide BTG with semi-annual reports on its development and commercialization activities in respect of Puricase, Puricase Technology, the CPC Products and the CPC Technology, and any other information related thereto, that may be requested by the OCS from time to time, for conveyance to the OCS, as required. Such reports shall be accompanied by a financial report signed by Savient’s Chief Financial Officer showing the calculation of the amounts due to the OCS pursuant to the Law in respect of the period covered by the said report and the funds necessary to make the appropriate payments to the OCS, it being understood and agreed, however, that the funds will be transferred by Savient to BTG by no later than 15 (fifteen) days before timely payment has to be made by BTG to the OCS. Such financial reports shall be certified by an independent auditor, once a year, at Savient’s expense.

5.3.2. Savient shall keep complete, accurate and correct books of account and records consistent with sound business and US generally accepted accounting
principles and practices, in such form and in such details as to enable the verification and the
determination of the amounts due to the OCS in respect of Puricase, Puricase Technology,
the CPC Products and the CPC Technology. Savient shall retain such books of account for 7
(seven) years after the end of each calendar year.

5.4. BTG hereby undertakes to irrevocably and unconditionally remit the funds received from Savient
pursuant to Section 5.3.1 above to the OCS in a timely manner, without any set-offs, deductions or
withholdings of any nature.

5.5. BTG and Savient shall comply with any request by the OCS to conduct, *inter alia*, an audit at Savient.
In such event, BTG and/or the OCS shall be entitled to appoint a representative to inspect, during
normal business hours, and to take copies of Savient’s books of accounts, records and other
documentation to the extent relevant or necessary for the ascertainment or verification of the amounts
due to the OCS under the Law, at Savient’s expense.

6. **CPC Patents**

6.1. In addition to BTG’s rights in relation to the CPC Technology, as set out in Section 2.2 above, Savient
hereby grants BTG and its Affiliates an irrevocable, fully paid-up, transferable, non-royalty-bearing,
perpetual, worldwide, exclusive, unconditional license, under the CPC Patents, to offer for sale, sell and
import Divested Products and HA. Nothing in the foregoing shall be construed as a representation on
BTG’s part, that such license, or the rights set out in Section 2.2, are required in order to develop,
manufacture or commercialize any or all of the Divested Products or HA.

6.2. Savient hereby grants BTG and its Affiliates a non-transferable, royalty-bearing, perpetual, worldwide
nonexclusive, unconditional (save for the reasonable consideration to be paid for commercialization
rights hereunder) license, under the CPC Patents to offer for sale, sell and import CPC Products, it being
understood and agreed, however, that the royalties that will be due and payable by BTG to Savient in
respect of the commercialization rights and other terms and conditions of such license, shall be subject
to the negotiation, in good faith, of a mutually acceptable license agreement containing normal and
custmary terms for transactions of a similar nature (the “CPC License Agreement”). Should the
Parties fail to execute the CPC License Agreement within 90 (ninety) days of either Party
initiating such negotiations, then the matter may be referred for resolution by either Party, in accordance with the provisions and the procedures attached hereto as Annex F. Nothing in the Parties’ failing to execute the CPC License Agreement or the initiation or conduct of any such procedures shall bar BTG from exercising the license granted to it pursuant to this Section 6.2 pending the decision of the expert. Nothing in the foregoing shall derogate from the terms and conditions of any existing supply, manufacturing or development agreement between the Parties.

6.3. Should Savient decide to abandon a CPC Patent at any time during the first 5 (five) years following the Closing; Savient undertakes to notify BTG in writing at least 60 (sixty) days prior to the date on which such CPC Patent would become finally abandoned in the absence of action on the part of the party prosecuting or maintaining such patent. Savient shall afford BTG the right, during such 60 (sixty) day period, to acquire such patent application or patents. Should the Parties fail to reach a mutually acceptable agreement as to the terms and conditions upon which BTG may acquire such patent applications or patents, Savient shall be entitled to abandon the same.

7. **BTG-271**

7.1. Prior to the Closing, Savient shall either (a) transfer the patent applications listed in Annex “G” attached hereto (the “BTG-271 Patents”) to a third party and arrange with the OCS for a full release of BTG’s obligation to pay royalties to the OCS with respect to subsequent sales in relation thereto or (b) transfer the BTG-271 Patents to BTG.

7.2. Subject to OCS approval, BTG undertakes to relinquish its rights in the BTG-271 project under the OCS Letter in the event that the BTG-271 Patents are transferred to a third party prior to the Closing or as envisaged under Section 7.3 below.

7.3. Notwithstanding the foregoing, should negotiations between Savient and Eager BioGroup Ltd., a corporation registered in Israel, or any affiliated company registered in Israel and controlled by Prof. Max Herzberg, be ongoing at the time of the Closing, Savient shall have an additional period of 90 (ninety) days from the Closing in order to finalize such transaction (the “Eager Transaction”), and Savient shall bear the cost of the BTG-271 Patents throughout such time period. Should the Eager Transaction not be consummated with OCS approval within such time period, for any reason whatsoever, then the BTG-271 Patents shall be transferred to BTG.
7.4. Should the BTG-271 Patents be transferred to BTG, then BTG-271 shall be treated as a “Divested Product” for purposes hereof.

8. **Promoter Patents**

8.1. BTG hereby grants Savient a fully paid-up, non-royalty-bearing, perpetual, worldwide nonexclusive license, with the right to sub-license, under the patents and patent applications listed in Annex “H” attached hereto (the “Promoter Patents”), to use the Osm B promoter claimed therein to make, have made, use, offer for sale, sell and import Puricase, it being understood and agreed, however, that the manufacture of Puricase outside of Israel is subject to the approval of the OCS.

8.2. BTG shall favorably consider any request by Savient to expand the scope of the license granted to it under Section 8.1. In such circumstances, the Parties shall negotiate in good faith with a view towards entering into a mutually acceptable license agreement containing normal and customary terms for transactions of a similar nature.

8.3. Should BTG decide to abandon any of the Promoter Patents at any time during the first 5 (five) years following the Closing, BTG undertakes to notify Savient in writing, at least 60 (sixty) days prior to the date on which such Promoter Patent would become finally abandoned in the absence of action on the part of the party prosecuting or maintaining such patent. BTG shall afford Savient the right, during such 60 (sixty) day period, to acquire such patent application or patents. Should the Parties fail to reach a mutually acceptable agreement as to the terms and conditions upon which Savient may acquire such patent applications or patents, BTG shall be entitled to abandon the same.

9. **Indemnification**

Each Party shall indemnify, hold harmless and defend the other Party and its officers, directors and employees against damages, costs and expenses (including reasonable attorney’s fees) incurred as a result of such Party’s failure to comply with its undertakings under this Agreement.

10. **Term: Effect of Termination**

10.1. This Agreement shall enter into force and effect upon the Closing and shall continue to be in force for as long as the Puricase Technology and the CPC Technology is in use by either Party.
10.2. Should the Divestiture Agreements be terminated without the Closing taking place, for any reason whatsoever, this Agreement shall be null and void.

10.3. The termination of this Agreement for whatever cause shall not prejudice or affect the accrued rights and obligations of either Party.

11. Disclosure of Information

11.1. BTG and its Affiliates shall not furnish copies of documents, patents, patent applications, copyrights, drawings, specifications, bills of materials, devices, equipment, prototypes and other information relating to the Puricase Technology other than as contemplated by this Agreement (and other than to any of their respective Affiliates) and shall not, without the prior approval of Savient, disclose such information to any third party, except to the extent that such disclosure is necessary for BTG’s manufacture of Puricase for Savient, and then only if (i) such disclosure is subject to the same limitations on the recipient as on BTG, and (ii) such limitations are set forth in a written agreement in form and substance satisfactory to Savient. “Affiliate”, as used herein, means, any corporation which controls, is controlled by, or is under common control with, BTG, following the Closing. A corporation shall be deemed to control another corporation if it owns, directly or indirectly, more than 50% (fifty percent) of the voting shares, or has the power to elect more than half the directors, of such other corporation. For purposes of this Section 11.1, “Puricase Technology” shall not include information which is in or becomes, part of the public domains through no act or omission by BTG or any of its employees.

11.2. No publication with respect to any activity undertaken pursuant to a Development Program shall be made, nor any manuscript submitted for publication, without the prior review and written approval of Savient such approval not to be unreasonably withheld.

11.3. The Parties agree that remedies at law may be inadequate to protect against breach of this Section 11, and in case of such a breach BTG hereby consents to the granting of injunctive relief, whether temporary, preliminary or final, in favor of Savient without proof of actual damages.

11.4. The provisions of this Section 11 shall survive the termination or expiration of this Agreement.

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12. **Non-Compete**

From the Closing Date until the expiration of the later to expire (following issuance) of the Puricase Patents; BTG agrees not to, and shall cause its Affiliates not to, use the Puricase Technology to manufacture, promote, market or sell any Competing Product in the Territory, or to license or sublicense the Puricase Technology to any third party. As used in this Agreement, “Competing Product” shall mean any prescription pharmaceutical product that (i) contains uricase as an active ingredient or (ii) has a primary use in a particular country, based on a majority of prescription use in such country, for the treatment of gout (in any form). As used in this Agreement, “Territory” shall mean, collectively, every country in the world.

13. **Governing Law and Dispute Resolution**

13.1. This Agreement and any disputes hereunder shall be governed by and construed in accordance with the laws of the State of New York, United States of America, without giving effect to any choice or conflict of law provision or rule that would cause the application of any other laws.

13.2. Save as provided in Section 6.2 hereof, any disputes, claims or controversies between the Savient and BTG in connection with this Agreement, including any question regarding its formation, existence, validity, enforceability, performance, interpretation, breach or termination (any such dispute, claim or controversy, a “Dispute”), shall be finally resolved by binding arbitration.

13.3. Any arbitration hereunder shall be conducted under the Rules of Arbitration of the London Court of International Arbitration. The arbitration shall be conducted in the English language before three arbitrators chosen according to the following procedure: within 20 (twenty) days after commencement of the arbitration, each of Savient and BTG shall appoint one arbitrator, and within 20 (twenty) days after the appointment of both such arbitrators, the two arbitrators so chosen shall choose the third arbitrator. If the two arbitrators chosen by Savient and BTG cannot agree on the choice of the third arbitrator within a period of 20 (twenty) days after their appointment, then the third arbitrator shall be appointed by the London Court of International Arbitration.

13.4. Each of the arbitrators shall be a lawyer or former judge. The chairman of the three arbitrators shall have experience arbitrating disputes in the pharmaceutical industry.

13.5. Any arbitration that would otherwise be conducted pursuant to this Section 13 that relates to the subject matter of any arbitration
conducted pursuant to Section 10.15 of the SPA shall be combined into a single arbitration before the same panel of three arbitrators, conducted in accordance with Section 10.15 of the SPA.

13.6. Each of the Asset Buyer and the Seller hereby irrevocably waives all rights to trial by jury in any Dispute.


14. Miscellaneous

14.1. Unless the context explicitly dictates otherwise, all references herein to “patents” and/or “patent applications” herein shall be deemed to include any disclosures, continuations, continuations-in-part, divisionals, provisionals, PCT applications, reissuances, revisions, substitutions, conversions, renewals, extensions, prolongations, and re-examinations thereof, any technology and inventions covered thereby, and any corresponding international, regional and national applications.

14.2. From time to time after the date hereof and prior to the Closing, the Parties may modify and/or replace any of Annexes C, D or E hereto, which modified or replaced Annexes shall automatically constitute part of this Agreement.

14.3. Nothing in this Agreement or in the Divestiture Agreements shall derogate from BTG’s rights under the Technology Transfer Agreement effective February 1, 1998, pursuant to which BTG acquired Savient’s process for the manufacture of sodium hyaluronate (“HA”), as described and claimed in U.S. Patent No. 4,780,414, and the related patent applications, patents, trademarks and domain names listed in Annex “I”. Savient and its employees shall provide BTG, without compensation, with the necessary authorizations, powers of attorney and other documents and assistance reasonably requested by BTG from time to time to record the assignment of said intellectual property rights from Savient to BTG.

14.4. This Agreement constitutes the entire agreement between Savient and BTG with respect to the subject matter hereof, and supersedes any prior agreements or understandings between Savient and BTG with respect to such matters.

14.5. Each Party agrees to execute, acknowledge and deliver such further documents and instruments and do any other acts, from time to time, as may be reasonably necessary, to effectuate the purposes of this Agreement.
14.6. Neither this Agreement nor any of the rights, interests, or obligations hereunder may be assigned by either Party without the prior written consent of the other Party hereto, except that either Party may assign its rights hereunder to any entity that acquires all or substantially all of such Party’s business or assets (provided that no such assignment shall relieve the assigning Party of its obligations hereunder, and the assigning Party shall remain primarily liable for such obligations). Subject to the foregoing, this Agreement shall be binding upon and inure to the benefit of the Parties and their respective successors and permitted assigns.

14.7. All notices, requests, demands, claims and other communications hereunder shall be in writing. Any notice, request, demand, claim or other communication hereunder shall be deemed duly delivered four Business Days after it is sent by registered or certified mail, return receipt requested, postage prepaid, or one Business Day after it is sent by overnight delivery via a reputable national courier service, in each case to the intended recipient as set forth below:

If to Savient:

Savient Pharmaceuticals Inc.
One Tower Center, 14th Floor
East Brunswick, New Jersey 08816, USA
Telexcopy: +1-732-418-9065
Attention: Philip K. Yachmetz, Esq.

If to BTG:

Bio-Technology General (Israel) Ltd.
Kiryat Weizmann
Building 17
Rehovot 76326, Israel
Telexcopy: +972-8-9409041
Attention: Dr. Dov Kanner

A “Business Day” shall be any day other than (i) a Saturday or Sunday or (ii) a day on which banking institutions located in New York, New York, United States of America or in Israel are permitted or required by law, executive order or governmental decree to remain closed.

Any Party may give any notice, request, demand, claim, or other communication hereunder using any other means (including personal delivery, expedited courier, messenger service, telecopy,
telex, ordinary mail, or electronic mail), but no such notice, request, demand, claim or other communication shall be deemed to have been duly given unless and until it actually is received by the Party for whom it is intended. Any Party may change the address to which notices, requests, demands, claims and other communications hereunder are to be delivered by giving the other Party notice in the manner herein set forth.

14.8. Savient and BTG may mutually amend or waive any provision of this Agreement at any time. No amendment or waiver of any provision of this Agreement shall be valid unless the same shall be in writing and signed by both of the Parties.

14.9. Any term or provision of this Agreement that is invalid or unenforceable in any situation in any jurisdiction shall not affect the validity or enforceability of the remaining terms and provisions hereof or the validity or enforceability of the offending term or provision in any other situation or in any other jurisdiction. If the final judgment of a court of competent jurisdiction declares that any term or provision hereof is invalid or unenforceable, the Parties agree that the body making the determination of invalidity or unenforceability shall have the power to reduce the scope, duration or area of the term or provision, to delete specific words or phrases, or to replace any invalid or unenforceable term or provision with a term or provision that is valid and enforceable and that comes closest to expressing the intention of the invalid or unenforceable term or provision, and this Agreement shall be enforceable as so modified.

14.10. Except as otherwise specifically provided to the contrary in this Agreement, each of the Parties shall bear its own costs and expenses (including legal fees and expenses) incurred in connection with this Agreement and the transactions contemplated hereby.

14.11. This Agreement may be executed in one or more counterparts, each of which shall be deemed an original; but such counterparts shall together constitute but one and the same instrument.

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IN WITNESS WHEREOF the Parties hereto have set their signatures as of the date first mentioned above.

/s/ Christopher Clement  
SAVIENT PHARMAECUTICLAS, INC.  
By: Christopher Clement  
Title: President and Chief Executive Officer

/s/ Philip K. Yachmetz  
BIO-TECHNOLOGY GENERAL (ISRAEL) LTD.  
By: Philip K. Yachmetz  
Title: Director

List of Annexes:

Annex “A” OCS letter  
Annex “B” Puricase Patents  
Annex “C” Development and Regulatory Work - Puricase  
Annex “D” Term Sheet for Manufacture of Puricase  
Annex “E” Term Sheet for Technology Transfer  
Annex “F” Expert Procedures  
Annex “G” BTG-271 Patents  
Annex “H” List of osmB promoter patents/patent applications  
Annex “I” List of HA Patents, Trademarks and Domain Names
Annex A

OCS letter
July 15, 2003

Mr. Avi Feldman, Esq.
General Counsel to the
Office of the Chief Scientist
Ministry of Industry, Trade and Labor
4 Mevo Hamatmid Street
Jerusalem 91021

Dear Mr. Feldman,

Re: Bio-Technology General (Israel) Ltd. (“BTG Israel”)

We have been informed of the meeting that took place in Jerusalem on June 15, 2003 with the participation of representatives of the Chief Scientist (the “CS”) and BTG Israel.

We understand that during the course of the meeting, the parties resolved certain issues that arose in relation to CS-approved R & D programs at BTG Israel (the “Approved Programs”) as follows:

1. BTG Israel will have title to all future Approved Programs, relating to new projects.

2. BTG Israel will have an exclusive irrevocable and perpetual right from us to conduct R&D with technology developed in the course of Approved Programs which are completed or ongoing, excluding clinical trials that BTG Israel is not in a position to monitor from Israel; and

3. Except as otherwise approved by the CS, BTG Israel will have an exclusive right from us to manufacture in Israel products developed through Approved Programs.

We understand that the CS will not unreasonably withhold its consent to the conduct of such R&D activities outside of Israel if BTG Israel is finable to carry out such activities, or the manufacture of such products outside of Israel, if commercially unfeasible or if BTG Israel is unable to carry out such activities.

We also understand it was agreed that upon receipt of our agreement to the foregoing, funds withheld by the CSO upon the 2002 audit as well as funds that would otherwise have been payable in 2002 (if properly spent and reported) will be immediately released to BTG Israel.
On the basis of such understandings, and without waiving any rights that we may have from time to time under the Law for the Encouragement of Research and Development in Industry, we hereby confirm our agreement to the understandings set out above.

Respectfully yours,

/s/ Sim Fass

Savient Pharmaceuticals, Inc.
By: Sim Fass
Title: Chairman & CEO

cc: Mr. Amos Efrati
    Mr. Shaul Freilich
    Deputies to the Chief Scientist

    Y. Baratz
    D. Kanner
    R. Shaw
Annex B

Puricase Patents

1. New Applications

1.1. Puricase

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1.2. Protein Purification

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The following outline summarizes the key elements of ongoing development work and regulatory services relating to Puricase which will be required from BTG as from the Closing, certain elements of which are required under agreement with the OCS. This outline will form the basis of a detailed work plan covering these activities, which will be concluded prior to the Closing. It is anticipated that the detailed work plan when completed, will include a specific list of deliverables and a timetable for performance and delivery.

While every effort has been utilized to make this outline as comprehensive as possible, certain activities shown here may need to be expanded to include normal and customary related activities.

1. **Project Timeline**

   Puricase is currently completing Phase 2 clinical testing and Savient expects to initiate Phase 3 testing in late 2005. Assuming FDA agreement with the proposed clinical plan and a successful clinical trial, the Puricase Biologics License Application ("BLA") filing is expected to take place in Q1 2007. Services to be provided by BTG (with the exception of certain ongoing stability studies) are to be planned for completion by 1 Jan 07.

2. **Scope of Work**

   2.1. **R & D Services**

      The R & D services to be provided involve completion of needed elements in the Chemistry/Manufacturing/Controls (CMC) section of the Puricase BLA. These elements are listed in Table 1, along with an indication of which tasks will be performed for Phase 3 and which tasks will be completed by BLA filing.

   2.2. **Regulatory Services**

      The Regulatory services involve elements needed to complete the relevant sections of the BLA as well as other documentation, and appropriate support for the various filings. This includes, but is not limited to:

      2.2.1. preparation of the CMC update for the Phase 3 FDA package including a Rehovot-Beer Tuvia bridging document;

      2.2.2. development and preparation of the requisite assays;

      2.2.3. analytical method validation;
2.2.4. preparation of process validation documents;

2.2.5. annual report preparation (CMC, stability, process updates);

2.2.6. preparation of the CMC chapter of the BLA (process, methods, validations, specifications);

2.2.7. participation in meetings and calls with Savient (e.g. preparation for the end of Phase 2 [EOP21 meeting); 

2.2.8. participation in meetings with regulatory authorities (e.g. the EOP2 meeting); and

2.2.9. support for any and all regulatory activities required for worldwide registrations.

2.3. Reporting - BTG shall provide Savient with the necessary development reports to support the methods, specifications and in-process controls that are chosen, in a form acceptable to FDA inspectors and reviewers.

3. Financial provisions

3.1. Services will be provided at (i) 115% of BTG’s fully loaded cost including only the proportional share of overhead related to this project, as compared to maximum facility utilization, and not including raw Materials or equipment and (ii) 103% of the out-of-pocket cost to BTG of purchasing raw materials for manufacturing Product and equipment used primarily or exclusively to provide the ongoing development work and regulatory services contemplated by this Annex C.

3.2. Reporting and audit rights

3.3. Payment terms

4. Miscellaneous Terms

4.1. Services will be carried out in a professional and workmanlike manner.

4.2. Ownership of results and in any inventions to vest in Savient

4.3. Patents to be filed and maintained by Savient

4.4. Indemnification of BTG from and against any claims in relation to Savient’s use of the results/inventions

4.5. Confidentiality

4.6. No assignment of rights or obligations other than to a party acquiring rights in the Product.
Annex D

Term Sheet
Manufacturing Services

The following outline summarizes the key elements of manufacturing services that will be required from BTG as contract manufacturer with respect to the manufacturing Puricase (the “Product”), as required from BTG as from the Closing. This outline will form the basis of a detailed work plan covering these activities, which will be concluded prior to the Closing. It is anticipated that the detailed work plan when completed, will include a specific list of deliverables and a timetable for performance and delivery.

While every effort has been utilized to make this outline as comprehensive as possible, certain activities shown here may need to be expanded to include normal and customary related activities.

BTG has to date performed all Product manufacture at its Kiryat Weizmann facility. For Phase 3 material, the new Biologics GMP-compliant Beer Tuvia facility will be used. BTG will transfer the production process to Beer Tuvia and validate the process by producing three Product batches which will serve as clinical supply and, if Product stability and timing of BLA approval permit, as initial commercial launch material. Filling (vialling) of finished Product will take place at Dr. Madaus, EITG’s contract filling facility.

These terms and conditions shall be binding upon the Parties, unless and until superseded by a definitive Manufacturing Services Agreement and/or a detailed work plan:

General Obligations of BTG

A. Transfer of production to Beer Tuvia and manufacture of one batch of Product in Beer Tuvia (by Sep 05), to be finished into a Phase 3 clinical lot of Product at Madaus (Sep 05);

B. Completion of process validation by production of two additional batches (H1 06);

C. Filling of two additional lots in order to complete production validation (H2 06).

D. BTG and Savient will work together in good faith to prepare prior to Closing a definitive Manufacturing Services Agreement memorializing the terms and conditions of this Annex D with respect to the Phase 3 and initial commercial supply of the Product and related activities. In addition, BTG and Savient will negotiate in good faith prior to the Closing with the goal of reaching a long-term exclusive supply agreement for Product on commercially competitive terms, provided that any such agreement would permit the technology transfer, as outlined in Annex E, and qualification of an alternative supplier chosen by
E. In the event that no such long-term exclusive supply agreement is reached between BTG and Savient prior to the Closing, (i) BTG shall remain available as commercial scale manufacturer of Product until successor manufacturer is selected, technology transfer, as outlined in Annex E, has been successfully completed and successor manufacturer has been qualified and validated; and thereafter BTG shall remain available as a “back-up” supplier of Product upon reasonable notice and other terms and conditions and (ii) BTG and Savient will use commercially reasonable efforts to complete the technology transfer as outlined on Annex E within 36 months of its commencement, upon which completion of such technology transfer BTG’s obligation to supply Product will termination; provided, however, that if such technology transfer will not or cannot reasonably be successfully completed within such 36-month period, BTG and Savient will enter into good faith discussions to determine an alternative arrangement for continued supply of Product on reasonable terms to be mutually agreed.

1. Clinical Grade Peguricase for Phase 3 clinical trials

1.1. BTG to set up capabilities for manufacturing in Be’er Tuvia

1.1.1. Product specifications

1.1.2. production capacity and quantities to be produced

1.1.3. cost of setting up production facilities

1.1.4. timetable for setting up production facilities

1.1.5. cost of FDA inspections

1.2. Savient to acquire all Product so manufactured.

1.2.1. Placement of orders

1.2.2. Delivery terms - The risk of loss will pass to Savient upon delivery of Product and confirmation that it meets the specifications.

1.2.3. Price – (i) 115% of BTG’s fully loaded cost including only the proportional share of overhead related to this project, as compared to maximum facility utilization, and not including raw materials or equipment and (ii) 103% of the out-of-pocket cost to BTG of purchasing raw materials for manufacturing Product and equipment used primarily or exclusively to manufacture Product.

1.2.4. Reporting and audit rights

1.2.5. Payment terms

2. Supply of Commercial Quantities

2.1. Lead time - Savient will advise BTG if and when it requires
commercial quantities of the Product, at least 12 months in advance.

2.2. BTG to set up capabilities for manufacturing in Be’er Tuvia

2.2.1. Product specifications

2.2.2. capacity and quantities to be produced

2.2.3. cost of setting up production facilities

2.2.4. timetable for setting up production facilities and validation:

2.2.5. cost of FDA inspections

2.3. Purchase of Product

2.3.1. Minimum orders over ..X years

2.3.2. Placement of orders

2.3.3. Price — (i) 115% of BTG’s fully loaded cost including only the proportional share of overhead related to this project, as compared to maximum facility utilization, and not including raw materials or equipment and (ii) 103% of the out-of-pocket cost to BTG of purchasing raw materials for manufacturing Product and equipment used primarily or exclusively to manufacture Product.

2.3.4. Reporting and audit rights

2.3.5. Delivery terms

2.3.6. Payment terms


3.1. Grant of license by Savient to BTG to utilize the Technology required to manufacture the Product, solely for such purpose.

3.2. BTG to set up the production line and manufacture Product in compliance with Good Manufacturing Practices (“GMPs”) and other applicable regulatory requirements. The production line and facility requirements will be subject to a technical annex to the agreement that will detail the requirements for the establishment of the production line and operational and performance criteria, without limitation.

3.3. If BTG terminates on or prior to December 31, 2005 the employment of any of the 12 employees of BTG who were employed by BIG on a temporary basis as of March 21, 2005 for the purposes of assisting with activities related to the product transfer to BTG’s Be’er Tuvia facility including the transfer and manufacture of Product, and any such employee is entitled to any severance payment pursuant to Israel law as a result of such termination, then Savient shall reimburse BTG for the actual amount of such severance payment (without, for the avoidance of doubt, increasing such payment by 15% pursuant to Section 1.2.3 above).
3.4. In the event of failed batches manufactured strictly in adherence with the specifications of the manufacturing process, the cost of batch failures will be borne equally between Savient and BTG based on the actual labor and raw materials cost with no mark-up or increase in such costs pursuant to Section 1.2.3; provided however that any batch failure that results from negligence or misconduct by BTG will be borne solely by BTG.

3.5. BTG to obtain and maintain all permits, approvals and licenses required to manufacture the Product.

3.6. The definitive Manufacturing Agreement or work plan shall include agreed upon success criteria for all manufacturing lots, including those for consistency and stability testing and validation criteria for aseptic filling processes which shall be designed to meet all required worldwide regulatory requirements.

3.7. Savient shall be entitled, but not obliged, to receive and to test samples of the Product.

3.8. BTG shall keep true and complete records on all production and shipment of Product in sufficient detail to enable Savient to determine the quantity of Product produced and the disposition of such Product, and shall grant Savient access during normal business hours following prior written notice.

3.9. BTG shall prepare a batch file for each batch of Product demonstrating compliance with the Specifications and provide same to Savient. BTG will retain copies for its records.

3.10. BIG shall perform all analytical activities required by the Technology or as may be requested by Savient from time to time.

3.11. BTG shall store representative samples of Product for the minimum legal period provided by applicable laws or as reasonably requested by Savient.

3.12. BTG shall inform Savient in writing of any significant modification in the manufacturing process.

3.13. BTG shall permit Savient to inspect the production line and to verify the method and quality of production and the relative documentation.

3.14. Risk of loss will pass to Savient upon delivery of Product and confirmation that it meets the Specifications. Savient shall analyze or have Product analyzed within 30 days of delivery. Any Product not meeting the Specifications shall be destroyed and replaced by BTG at its sole cost and expense. In the event that BTG disputes Savient’s evaluation of non-compliance, the disputed Products will be analyzed by an independent laboratory chosen by mutual consent. If the laboratory confirms non-compliance with the Specifications, BTG shall reimburse Savient for the expense of the analysis and associated expenses.
Packaging and labeling of commercial Product shall be carried out in accordance with Savient’s instructions and applicable laws.

BTG shall be responsible for obtaining any export license required under applicable laws.

Insurance requirements in respect of both parties.

Term

Termination for breach and effect of termination

Breach by BTG failure to meet the timetable during various phases/failure to produce Product meeting the Specifications/ any other material breach - Savient shall have the right to direct BTG to (i) stop production of Product; (ii) discontinue the use of the Technology.

No Assignment - None of the rights, duties or obligations hereunder shall be assignable, except that Savient may assign the same to any party acquiring rights to the Product.

Governing law

Arbitration

Should BTG be unwilling or unable to supply at any time:

3.24.1. BTG shall collaborate with Savient in requesting the OCS for permission to manufacture through a third party;

3.24.2. BTG shall assist Savient in transferring the technology as per the provisions of Exhibit E of the Residual Rights Agreement.
Annex E

Term Sheet
Technology Transfer

The following outline summarizes the key elements of the technology transfer relating to Puricase which may be required from BTG, after the Closing. This outline will form the basis of a detailed work plan covering these activities, which will be concluded prior to the Closing. It is anticipated that the detailed work plan when completed, will include a specific list of deliverables and a timetable for performance and delivery.

While every effort has been utilized to make this outline as comprehensive as possible, certain activities shown here may need to be expanded to include normal and customary related activities.

These terms and conditions shall be binding upon the Parties, unless and until superseded by a definitive Technology Transfer Agreement and/or a detailed work plan:

1. **Scope of Work**
   1.1. Detailed Description
   1.2. List of deliverables
   1.3. Timetable for performance and delivery

2. **Financial Provisions**

   Services will be rendered at the rate of $400 per 8 hours man day, pro rata per partial day. payment terms

3. **General Provisions**

   3.1. Services shall be carried out by BTG in a professional and workmanlike manner.
   3.2. Technical assistance to be provided in an advisory capacity.
   3.3. Indemnification of BTG from and against any claims in relation to Savient’s use of the Technology.
ANNEX F
Expert Procedures

Pursuant to Sections 2.5 and 6.2 of the Residual Rights Agreement:

1. Either Party may serve on the other Party notice (a “Referral Notice”) that it wishes to refer to a single expert (the “Expert”) any dispute relating to the royalties due and payable by BTG to Savient and any other terms and conditions of the License Agreement or the CPC License Agreement.

2. The Expert shall be an independent and impartial person residing in the US or Israel, having significant experience in the pharmaceutical industry, who shall be agreed upon by the Parties or, and in the absence of such agreement between the Parties, within 30 (thirty) days of the service of a Referral Notice, be appointed by the London Court of International Arbitration.

3. Thirty (30) days after the appointment of the Expert pursuant to Paragraph 2, both Parties shall provide the Expert with any information that the Expert may request in relation to the subject matter, with a copy to the other Party.

4. There shall be no hearing except that the Expert may call for a one day hearing if such Expert considers the same to be desirable and appropriate. The Expert shall issue his/her reasoned decision in writing to the Parties within 30 days after review of all evidence deemed necessary by him/her has been completed.

5. The seat of the dispute resolution shall be the normal place of business or residence of the Expert.

6. The language of the dispute resolution shall be English.

7. The Expert shall not have power to alter, amend or add to the provisions of the Agreement.

8. The Expert shall have the power to request copies of any documents in the possession and/or control of the Parties which may be relevant to the dispute. The Parties shall forthwith provide to the Expert and the other Parties copies of any documents so requested by the Expert.

9. The Expert shall decide the dispute as an expert and not as an arbitrator. The Expert shall decide which party or parties shall bear the costs involved for the Expert procedure and in what proportion.

10. The decision of the Expert shall be final and binding upon all of the Parties except in the case of manifest error. The Parties hereby exclude any rights of application or appeal to any court, and in particular in connection with any question of law arising in the course of these procedures.
Annex G

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Annex I

List of HA Patents, Trademarks and Domain Names

1. **Patents**
   
   Refer to attached list

2. **Design Right Registrations**
   
   
   2.2. Israel: Design 23832 - Filed January 22, 1995, Granted June 20, 1995; Expiration date January 22, 2010.

3. **Trademarks**
   
   Refer to attached list

4. **Domain Names**

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Exhibit G

Product Specifications
# Summary of Release Testing of Bulk Uricase Intermediate

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<th>Provisional Acceptance Criteria</th>
<th>Revision</th>
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<td>Appearance</td>
<td>Visual inspection</td>
<td>Clear colorless solution, free of visible particles</td>
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<td>General</td>
<td>pH</td>
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<td>Protein Content</td>
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<td>Potency</td>
<td>Enzymatic activity</td>
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<td>Identification</td>
<td>N-terminal amino acid sequence</td>
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<td>Identification</td>
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<td>Electrophoretogram similar to reference standard</td>
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<td>Identification</td>
<td>Peptide Mapping</td>
<td>Profile of the chromatogram of test solution corresponds to that of reference solution</td>
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<td>Identification</td>
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<td>Revision to indicate specific molecular weight</td>
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<td>Purity/Impurities</td>
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<td>E. coli Proteins by Slot Blot</td>
<td>≤ 25 ppm (≤ 25 ng/mg)</td>
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<td>Lysozyme by ELISA</td>
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<td>Microbial Limit</td>
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## Summary of Release Testing of PEG-uricase API

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<td>Free Uricase by ELISA</td>
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<td>Xanthine by RP-HPLC</td>
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FIRST AMENDMENT TO COMMERCIAL SUPPLY AGREEMENT

THIS AMENDMENT is made and entered into this 24th day of September, 2007, (hereinafter the “Effective Date”).

BETWEEN:

SAVIENT PHARMACEFUTICALS, INC.
a Delaware corporation, (hereinafter “Savient”)

AND

BIO-TECHNOLOGY GENERAL (ISRAEL) Ltd.
an Israeli corporation, (hereinafter “BTG”)

WHEREAS:

Savient and BTG are parties to a Commercial Supply Agreement with an effective date of March 20, 2007, (hereinafter, the “Agreement”) pursuant to which BTG agreed to manufacture and supply a certain Bulk Product, as defined in the Agreement, to Savient, and Savient agreed to purchase such Bulk Product from BTG; and

Savient and BTG have held discussions relating to the modification and amendment of the Agreement to clarify a certain provision relating to the adjustment of Bulk Product Forecasts.

NOW THEREFORE in consideration of the mutual promises and agreements and covenants contained herein, the adequacy of such consideration has been agreed and acknowledged by each party, and in accordance with the provisions of Section 14.08 of the Agreement, the parties hereto agree as follows:

1. Definitions. All of the Definitions contained in Article 1 of the Agreement shall have the same meanings herein unless specifically stated otherwise. Any capitalized terms not specifically defined herein, shall have the same meaning ascribed to them as set forth in the Agreement.

2. Modification of Bulk Product Forecasts. Section 5.06 of the Agreement is hereby repealed in its entirety and is replaced with the following,

“Any Bulk Product Forecast that is not a Firm Order is to be considered a forecast or estimate to be used for planning purposes, and shall not be construed as a firm commitment by Savient to BTG and thus can be increased or reduced by Savient from time to time. Savient shall be entitled at any time up until and including the time that a Firm Forecast or Estimated Forecast becomes a Firm Order, to increase or decrease such monthly Firm Forecast or Estimated Forecast for Bulk Product, provided, however, such increases or decreases on a monthly basis shall not be greater than twenty-five percent (25%) of the originally forecasted quantity for such month, provided, however, (a) each month may not be increased and
decreased more than one time, and, (b) any such monthly increase or decrease as contemplated herein shall be expressed in whole batch quantities of not less than one (1) batch. As a request by Savient to increase the quantity of Bulk Product in a Firm Forecast prior to its becoming a Firm Order may require longer lead times for delivery than requested by Savient, both Parties shall agree jointly on a new delivery date as close as possible to the requested date having due regard for BTG’s commercial commitments to Third Parties and its own production needs, such agreement to not be unreasonably withheld, conditioned or delayed. Once a Firm Forecast becomes a Firm Order, Savient may not reduce it, but may request that BTG increase the quantity of Bulk Product subject to a Firm Order and BTG shall use commercially reasonable efforts to fill the increased order.”

3. **No Modification.** Except as expressly provided for herein, the Agreement shall remain in full force and effect without amendment. If there is any conflict or inconsistency between this Amendment and the Agreement, this Amendment shall prevail. This Amendment contains the entire agreement between the parties hereto with respect to the subject matter contemplated herein and shall not be modified or amended except by a written instrument signed by both parties hereto.

**IN WITNESS WHEREOF,** the parties have caused this Amendment to be executed by their respective duly authorized officers as of the date first written above.

SAVIENT PHARMACEUTICALS, INC.  

By: /s/Philip K. Yachmetz  
Philip K. Yachmetz  
Executive Vice President &  
Chief Business Officer

BIO-TECHNOLOGY GENERAL (ISRAEL) Ltd.  

By: /s/Dov Kanner  
Dov Kanner  
Managing Director
SECOND AMENDMENT TO COMMERCIAL SUPPLY AGREEMENT

THIS SECOND AMENDMENT is made and entered into this 24th day of January, 2009, (hereinafter the “Effective Date”).

BETWEEN: SAVIENT PHARMACEUTICALS, INC.

a Delaware corporation, (hereinafter “Savient”)

AND

BIO-TECHNOLOGY GENERAL (ISRAEL) Ltd.

an Israeli corporation, (hereinafter “BTG”)

WHEREAS:

Savient and BTG are parties to a Commercial Supply Agreement with an effective date of March 20, 2007, (hereinafter, the “Agreement”) pursuant to which BTG agreed to manufacture and supply a certain Bulk Product, as defined in the Agreement, to Savient, and Savient agreed to purchase such Bulk Product from BTG; and

Savient and BTG have subsequently amended the Agreement on September 24, 2007, (the “First Amendment”) and have issued a Letter Agreement dated July 30, 2008, (the “Letter Agreement”) pertaining to the Agreement; and

Savient and BTG desire to further amend the Agreement in accordance with the terms and conditions of this Second Amendment.

NOW THEREFORE in consideration of the mutual promises and agreements and covenants contained herein, the adequacy of such consideration has been agreed and acknowledged by each party, and in accordance with the provisions of Section 14.08 of the Agreement, the parties hereto agree as follows:

1. Definitions. All of the Definitions contained in Article 1 of the Agreement shall have the same meanings herein unless specifically stated otherwise. Any capitalized terms not specifically defined herein, shall have the same meaning ascribed to them as set forth in the Agreement.

2. Replacement of Exhibits to Agreement. The parties agree that the exhibits which are appended to this Second Amendment shall supersede and replace their counterparts as previously executed by and between the parties. For purposes of clarity the following exhibits to the Agreement are hereby repealed and replaced with the attached exhibits:

   i) Exhibit C, “Current Provisional Bulk Product Specifications”
   ii) Exhibit D, “Quality Agreement”
   iii) Exhibit G, “Product Specifications”
3. **No Modification.** Except as expressly provided for herein, the Agreement shall remain in full force and effect without amendment. If there is any conflict or inconsistency between this Amendment and the Agreement, this Amendment shall prevail. This Amendment contains the entire agreement between the parties hereto with respect to the subject matter contemplated herein and shall not be modified or amended except by a written instrument signed by both parties hereto.

IN WITNESS WHEREOF, the parties have caused this Amendment to be executed by their respective duly authorized officers as of the date first written above.

**SAVIENT PHARMACEUTICALS, INC.**

By: /s/Philip K. Yachmetz
Philip K. Yachmetz
Senior Vice President &
General Counsel

**BIO-TECHNOLOGY GENERAL (ISRAEL) Ltd.**

By: /s/Dov Kanner
Dov Kanner
Managing Director
Exhibit C

Current Provisional Bulk Product Specifications
Table 1. Tests Performed on […***…]

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***Confidential Treatment Requested

C-1
## Table 2. Tests Performed on […***…]

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***Confidential Treatment Requested***

C-2
QUALITY ASSURANCE RESPONSIBILITY AGREEMENT

BETWEEN

SAVIENT PHARMACEUTICALS, INC.

AND

BIO-TECHNOLOGY GENERAL (ISRAEL) LTD.

(COMMERCIAL PHASE)

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ARTICLE 1
PURPOSE AND SCOPE:

1.01 Savient Pharmaceuticals, Inc. (“SAVIENT”) and Bio-Technology General (Israel) Ltd. (“BTG”) have entered into a Supply Agreement of (event date) herewith (the “Supply Agreement”).

This document (the “Quality Agreement”) defines the quality assurance responsibilities between SAVIENT and BTG. This Quality Agreement applies only to the manufacture and supply by BTG to SAVIENT of the Product (as defined in the Supply Agreement).

ARTICLE 2
DEFINITIONS:

2.01 Capitalized terms used but not otherwise defined in this Quality Agreement will have the meanings ascribed thereto in the Supply Agreement. For ease of reference, the following definitions from the Supply Agreement which are used in this Quality Agreement are copied in full below, amended where appropriate for the purposes of this Quality Agreement:

(i) “BLA” means a Biologics License Application filed with the FDA and/or any other application required for the purpose of marketing or selling or using a therapeutic or prophylactic product to be filed with a governmental agency in a non-U.S. country or group of countries, including, without limitation, a Product License Application or Marketing Authorization in the European Union.

(ii) “Bulk Product” shall mean the bulk solution of polyethylene glycol (PEG) conjugate of uricase ordered by Savient from BTG pursuant to the Supply Agreement.

(iii) “Bulk Product Specifications” shall mean the manufacturing and quality specifications for the Bulk Product, including, without limitation, unit descriptions established from time to time in accordance with section 3.01 of the Supply Agreement.

(iv) “Business Day” shall mean any day other than (i) Friday, Saturday or Sunday or (ii) a day on which banking institutions located in New York, New York, United States of America or in Israel are permitted or required by law, executive order or governmental decree to remain closed.

(v) “cGMP” shall mean current good manufacturing practices as set forth in Title 21, Parts 210 and 211 of the C.F.R. and 21 C.F.R. Part 312 (IND) and Part 314 (NDA), and 21 C.F.R. Part 600 (Biological Products), as established and amended by the FDA.
“FDA” shall mean the United States Food and Drug Administration or, where applicable, its regulatory equivalent in a foreign jurisdiction.

“Facility” shall mean, as applicable, the Be’er Tuvia manufacturing facility located at Beer Tuvia Industrial Zone, POB 571, Kiryat Malachi 83104, Israel

“IND” shall mean an Investigational New Drug application, as defined in 21 C.F.R. 312.3, and filed with the FDA or any equivalent foreign Regulatory Agency.

“Legal Requirements” shall mean (i) any present and future national, state, local or similar laws (whether under statute, rule, regulation or otherwise), (ii) requirements under permits, orders, decrees, judgments or directives, and requirements of applicable Regulatory Agencies (including, without limitation, cGMP) and (iii) regulations pertaining to BLAs (with respect to each of the foregoing, as amended or revised from time to time).

“Process” or “Processing” shall mean the act of purification, preparation, filling, testing and any other pharmaceutical manufacturing procedures, or any part thereof (including, but not limited to, product or process specifications, testing or test methods, raw material specifications or suppliers, equipment, etc.), relating to, as applicable, Bulk Product and Product.

“Product” shall mean pharmaceutical products containing Bulk Product ordered by Savient pursuant to the Supply Agreement.

“Regulatory Agency” shall mean with respect to the United States, the FDA, or, in the case of a country in the Territory other than the United States, such other appropriate regulatory agency with similar responsibilities.

In addition, the following definitions apply to this Quality Agreement:

(i) “Bulk Product” shall mean bulk solution of polyethylene glycol (PEG) conjugate of uricase in its final formulation which is in Process, and has been produced for sterilization, filling or other finishing activities.

(ii) “Filled Product” shall mean sterile Product that is in Process and has been filled into its final primary packaging for further labeling or packaging activities.

(iii) “Final Product” shall mean finished Product in its final packaged and labeled form which is ready for distribution to the marketplace or third party distributors for sale or clinical use.

(iv) “Release” shall mean control, approval and authorization of shipment.
ARTICLE 3

NOTIFICATION OF PROCESS DEVIATIONS AND DOCUMENTATION OF CHANGES:

3.01  BTG shall provide to SAVIENT, within two Business Days of BTG’s discovery of its occurrence, written notification of (i) any deviation from the Process as set forth in the Bulk Product Specifications and the BLA and any deviation from cGMP requirements, regulations and standards, and any event that represents an unexpected or unforeseeable event that may affect safety, purity or potency of Bulk Product; and (ii) any deviation in the quality (purity, physical and chemical properties) of the Bulk Product from the Bulk Product Specifications. Appendix I sets forth a list of examples of deviations from the Process, for purposes of illustration only, and is not intended to be comprehensive or definitive.

(i)  BTG shall not conduct any retesting or reprocessing as the result of deviations described above without prior written authorization from SAVIENT Quality Assurance unless a delay of retesting or reprocessing would result in increased risk to the safety, purity or potency of the Bulk Product or Product.

3.02  Any changes to be made to this Quality Agreement in accordance with the provisions set out in this section 3 must be documented as an addendum to this Quality Agreement, and must be signed by authorized representatives from each of the BTG QA department and the SAVIENT QA department, in addition to authorized representatives from any other departments as may be specified in relation to the matters set forth in section 3.3 below. This Quality Agreement will be reviewed by BTG and SAVIENT on a periodic basis (approximately once per year) and revised as appropriate.

3.03  Change Control

(i)  Specifications that control the Process for the manufacture, including packaging, holding, and test of Bulk Product and Product, must be signed by authorized representatives from BTG and SAVIENT Quality Assurance, SAVIENT Regulatory Affairs, and SAVIENT Manufacturing. Such documents include, but are not limited to Bulk Product Specifications (including specifications for intermediate), Product Specifications (including specifications for product, component and packaging). Changes to such documents must be signed by authorized representatives from SAVIENT Quality Assurance, SAVIENT Manufacturing and SAVIENT Regulatory Affairs.

(ii) Changes to additional documents that control the Process for the manufacture of Bulk Product and Product (including test methods, manufacturing procedures and batch records) must be assessed according to the BTG change control process described in section 3.4. Any change that would have an impact on the Process, Bulk Product or Product, or require submissions to or approvals from any Regulatory Agency must receive prior written approval by authorized representatives from SAVIENT Quality Assurance, SAVIENT Manufacturing and SAVIENT Regulatory Affairs. If there is no such impact, BTG may proceed with the change, but must notify SAVIENT Quality
Assurance no later than 5 days from the initiation of the BTG change control process. If SAVIENT does not agree with BTG’s assessment of impact, SAVIENT must respond to BTG no later than within 5 days of receipt of notification.

(iii) The stability protocol as well as any changes to the stability protocol must be approved by SAVIENT QA and SAVIENT Regulatory Affairs.

(iv) Critical Raw Materials. The current specifications for Critical Raw Materials are attached as Appendix III. The Parties acknowledge and agree that these specifications may be amended from time to time by the supplier of the material. With respect to such amendments:

BTG shall notify SAVIENT as soon as reasonable practicable, but no later than within 5 days of receipt of notification by BTG.

The Parties will meet and agree as to suitability of the material produced according to the amended specification for manufacture of the Bulk Product.

3.04 BTG will utilize a documented system of written procedures for the control of changes to documents relating to raw materials, packaging materials, labeling, suppliers, equipment, manufacturing methods, batch size, product, intermediates and raw materials specifications, sampling, analytical test methods and Release requirements and any other Processing by BTG, relating to the Bulk Product.

3.05 Any changes to any matter relating to the manufacture and supply of Bulk Product by BTG shall be governed by the procedures set out in the Supply Agreement at Article 3 in relation to changes to the Bulk Product Specifications, and Article 6 in relation to changes to the Process.

3.06 SAVIENT Regulatory Affairs will have responsibility for determining the regulatory impact of any proposed change. SAVIENT Regulatory Affairs will determine the classification and requirements for notification to, or approval by FDA. SAVIENT is responsible for communication of any changes to FDA. SAVIENT Regulatory Affairs will have responsibility to advise BTG of any changes to the BLA prior to submission.

BTG will ensure that changes are evaluated and qualified in accordance with all applicable ICH (International Conference on Harmonization) requirements in addition to all Legal Requirements, including but not limited to:

ICH Guideline Q5E Comparability of Biotechnological/Biological Products Subject to Changes in Their Manufacturing Process.

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ARTICLE 4
MATERIALS

4.01 Procurement of Components
BTG will procure all the components described in the Bulk Product Specifications in such quantities as may be necessary to meet Purchase Orders placed by SAVIENT pursuant to the Supply Agreement, and store the components in appropriate storage conditions under quarantine until tested.

4.02 Inspection and Testing of Materials

Upon receipt, BTG shall sample in accordance with acceptable statistical methods, inspect and test containers of all materials to be used in the Process or in connection with the supply and manufacture of Bulk Product on a batch-by-batch basis, in accordance with the Bulk Product Specifications.

4.03 Bulk Product

BTG will be responsible for ensuring that Bulk Product is manufactured, tested and stored in compliance with all applicable ICH guidance documents (including, without limitation, the guidance contained therein for master and working cell banks) in addition to all Legal Requirements. ICH Guidance includes, but is not limited to:

Q5D Quality of Biotechnological Products: Derivation and Characterization of Cell Substrates Used for Production of Biotechnological/Biological Products.

Q7A, Good Manufacturing Practices Guidance for Active Pharmaceutical Ingredients

4.04 Retention, Storage and Handling of Materials and Product Samples

BTG shall sample and retain such amounts of Bulk Product and of all materials to be used in the Process or in connection with the supply and manufacture of Bulk Product (“Retains”) except water, compressed gasses and any highly volatile compounds as set forth in Appendix II or as otherwise required in accordance with applicable Legal Requirements. BTG will store for five years, or such longer period as may be required in accordance with Appendix II or by Legal Requirement, sample Product and Retains for each batch or lot of intermediates and raw materials. Reasonably prior to the expiry of such retention period, or upon termination of this Quality Agreement, BTG shall offer all such materials to SAVIENT. Any labor costs of BTG employees and/or Third Party expenses incurred by BTG related to the transfer of such materials shall be reimbursed by SAVIENT in the manner and at the rates set forth on Exhibit B to the Supply Agreement.

A schedule of specific Retains, storage conditions and retention periods for Puricase® is listed in Appendix II.

4.05 Transmissible Spongiform Encephalopathy (TSE)

BTG will provide a written TSE declaration that all materials (including non-dedicated equipment) used in the manufacturing process are free from animal derived material. In addition, BTG must have available, on site, written TSE declarations from the supplier, where appropriate, of raw material used in the manufacturing process verifying exclusion
of animal derived material. If BTG is unable to provide the above declarations, BTG will comply with applicable TSE laws and regulations and will obtain all associated TSE documentation as requested by SAVIENT. This documentation may include a TSE Certificate of Suitability in accordance with European directive 75/318/EEC as amended by directive 1999/82/EEC, the note for guidance EMEA/410/01 rev2 as amended and AP-CSP(99)4, Appendix 2, as amended.

4.06 Supplier Audits

BTG and SAVIENT will provide each other with copies of supplier audit reports for materials used in the Process or manufacture of the Product.

ARTICLE 5

MANUFACTURING, PACKAGING, INSPECTION AND TEST:

5.01 The Processing, packaging, and labeling of Bulk Product will be performed and documented by BTG. BTG will not subcontract any of the Processing, packaging, and labeling functions except as may be permitted in accordance with the Bulk Product Specifications, and if so permitted, in accordance with the provision set forth in Section 2.05 of the Supply Agreement.

5.02 BTG shall not Process or store Bulk Product in the same building in which BTG manufactures, stores or processes potentially hazardous substances (including, without limitation, certain antibiotics such as beta-lactam and cephalosporins, cytotoxic compounds, toxins or poisons such as pesticides or herbicides, (collectively, “Potential Contaminants”) unless the Potential Contaminants are stored or manufactured in contained environments and in compliance with all Legal Requirements and the Bulk Product is Processed and stored in compliance with building, cleaning, validation and changeover requirements of all cGMPs and all Legal Requirements. BTG shall promptly notify SAVIENT if any of the Potential Contaminants are manufactured, processed or stored in any portion of the Facility which may result in the introduction of Potential Contaminants into the areas of such facilities where the Bulk Product is Processed. Savient is aware that other products are processed in the Facility, the nature of those other products existing today and that certain equipment (multi-use equipment) is used in the processing of both the Bulk Product and these other existing products. Savient has also had the opportunity to assess the risk to the Processing of Bulk Product of the use of such certain multi-use equipment with respect to the other existing products. However, in the instance where BTG intends to introduce a new product or substance to its Facility which is out of the matrix of existing products and use such multi-use equipment in the processing or handling of such new product or substance, Savient will need to reassess the risks to the Processing of Bulk Product with this new product or substance utilizing the multi-use equipment. Therefore, whenever BTG plans to introduce a new product or molecular entity which is out of the matrix of existing products to equipment shared with Puricase production, BTG will provide no less than 30 days prior notice of its intent, and will contemporaneously make supporting cleaning validation data/rationale available to Savient. Savient will make its assessment of the risk potential for adulteration of its own product through examination of cleaning validation.

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documentation prior to any further Puricase production and will respond to BTG within 5 days of its receipt of cleaning validation data/rationale as to its conclusion(s) about the introduction.

5.03 BTG will provide to SAVIENT: a copy of all master batch record documents and production and control records, a Certificate of Analysis (PEG-uricase API and uricase), executed batch records and associated batch documentation, which shall include, without limitation: formulation records, label records, manufacturing records, environmental monitoring data, microbiological data, in-process and final analytical data, including lab control results, sterility data, deviations/out-of-specification reports and cleaning records for any critical product contact equipment (for example, fermentors or any other non-dedicated product contact equipment).

   (i) Translation: BTG will provide an English translation of all such documents, including, without limitation, all reports, notes or comments on records that are not part of the master batch record but if any of the foregoing documents are only available in a language other than English, the Parties shall agree upon an English language template for such document(s), and BTG shall provide to Savient an English language translation of any deviations from the template(s). When required by SAVIENT, translations shall be performed by an independent, translation firm. Translations by a third party firm must be verified by BTG to ensure translation of company or process specific language. Any labor costs of BTG employees and/or Third Party expenses incurred by BTG in relation thereto shall be reimbursed by SAVIENT in the manner and at the rates set forth on Exhibit B to the Supply Agreement.

5.04 Upon request by SAVIENT, BTG will provide access to additional records that are not normally part of the batch record but which bear a reasonable relation to the Bulk Product for SAVIENT to review, which may include, without limitation, maintenance and use records, water testing data, training records, raw material release records, log books, receiving and shipping records, inventory records and vendor qualification records Any labor costs of BTG employees and/or Third Party expenses incurred by BTG in relation thereto shall be reimbursed by SAVIENT in the manner and at the rates set forth on Exhibit B to the Supply Agreement.

5.05 BTG will retain copies of all completed batch records for a minimum of five years, or such longer period as may be required by Legal Requirement. Reasonably prior to the expiry of such retention period, or upon termination of this Quality Agreement, BTG shall offer such completed batch records to SAVIENT. Any labor costs of BTG employees and/or Third Party expenses incurred by BTG related to the transfer of such materials shall be reimbursed by SAVIENT in the manner and at the rates set forth on Exhibit B to the Supply Agreement.

5.06 Use of BTG Manufacturing Space for Bulk Product

   BTG has allotted an amount of manufacturing floor space at the Facility for the Processing of Bulk Product (Purification Area in the Agreement). This space may be used for the production of other products subject to the following limitations:

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(i) BTG may use the Purification Area for alternate product manufacturing only during periods when the Purification Area is not used for the Processing of Bulk Product.
(ii) BTG adheres to all relevant cGMPs including, without limitation, procedures for prevention of mix-ups, prevention of contamination, labeling requirements, cleaning requirements and changeover requirements
(iii) BTG, shall not, under any circumstances utilize any equipment dedicated to the Processing of Bulk Product for such alternate product manufacturing
(iv) BTG adheres to limits and procedures described in section 5.2 for Potential Contaminants.

ARTICLE 6

RELEASE AND SHIPMENT OF PRODUCT(S):

6.01 Bulk Product shall be Released in accordance with the procedures set forth in the Supply Agreement, together with the additional obligations described in this section of the Quality Agreement. BTG QA will review the records described in section 5.3 above. Following review and acceptance by BTG QA, BTG will send copies of these documents to SAVIENT QA. SAVIENT QA and Manufacturing will then review the documentation and notify BTG whether or not documentation is acceptable. If such documentation is not reasonably acceptable to SAVIENT, BTG will cooperate in taking such steps as SAVIENT may reasonably require to ensure that the documentation, and any Processing described therein complies with the Bulk Product Specifications and all Legal Requirements.

6.02 BTG QA will be responsible for the QC testing of Filled Product until such time as a third party laboratory has been qualified to perform such testing. BTG will provide a Certificate of Analysis and/or stability results for each batch that BTG tests. Savient QA will be responsible for the review of the manufacturing batch record for Filled Product, review of the Certificate of Analysis and Release of the Filled Product.

6.03 SAVIENT QA will be responsible for the Release of the Final Product.

6.04 Product shall be delivered in accordance with the provisions of Article 7 of the Supply Agreement.

6.05 BTG will not ship any SAVIENT products to any destination, as identified by SAVIENT, unless prior approval has been received from SAVIENT.

ARTICLE 7

DEVIATIONS IN PROCESS OR BULK PRODUCT:

In the event of a notification of a deviation by BTG in accordance with section 0 above, BTG shall investigate and fully document in English such deviation within 30 days of its discovery. If BTG cannot resolve the deviation within the 30-day period, BTG will provide
weekly updates of the investigation progress. At SAVIENT’s request, BTG shall conduct such additional or more detailed investigation of the deviation as SAVIENT may reasonably instruct. Investigation documentation will be retained by BTG as part of the batch documentation for the batch affected. When a deviation has occurred, SAVIENT will have the final review and decision making responsibility as to the impact of the deviation on the Bulk Product or Product, which will include the disposition of affected lots.

ARTICLE 8

STORAGE OF PRODUCT(S):

Bulk Product will be stored under appropriate storage conditions and in a secure area to ensure that they comply with the Bulk Product Specifications, including all the label requirements, quality specifications and attributes as well as Legal Requirements.

ARTICLE 9

TRACEABILITY OF PRODUCT(S):

SAVIENT will be responsible for traceability of products to first consignee within the US. BTG will be responsible for traceability from the finished product lot number to raw material and component lots used in manufacture.

ARTICLE 10

CONFLICT OF TERMS:

To the extent that there exists any conflict between the terms of this Quality Agreement and the Supply Agreement, the latter shall prevail. To the extent that there exists any conflict between the terms of this Quality Agreement and any Legal Requirements, the latter shall prevail.

ARTICLE 11

COMPLIANCE WITH LAWS:

BTG will ensure that all of its activities pursuant to this Agreement are performed in accordance with all Legal Requirements (including cGMPs), the respective Bulk Product Specifications, conditions of the BLA, and BTG’s Standard Operating Procedures (SOPs). BTG will ensure that the Bulk Product supplied by it to SAVIENT shall not itself cause the Final Product to be adulterated or misbranded within the meaning of the Federal Food, Drug, and Cosmetic Act and regulations.
ARTICLE 12

INSPECTIONS:

Each party shall advise the other of any governmental communication, inspection or report, including, without limitation, that of any appropriate regulatory agency in any jurisdiction with responsibilities similar to those of the FDA in respect of the United States, any environmental agency, health agency or other governmental or administrative agency having jurisdiction over the Product or the Processing. The notifying party shall promptly notify the other party by fax and telephone, to the person and on the contact numbers set out below:

TO SAVIENT:

- Contact Name: Eric Nickerson, Senior Director Quality Assurance
- Telephone: 732-418-9300
- Fax: 732-418-0766

TO BTG:

- Contact Name: Yosefa Bilman, Senior Director Quality Assurance
- Telephone: 972-8-861-2007
- Fax: 972-8-861-2166

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ARTICLE 13

OBSERVATION BY SAVIENT:

Observation by SAVIENT or its authorized representative shall be governed the following. Observation will be limited to not more than one quality audit every 12 months. One additional quality audit may be conducted within the 12 month period if BTG receives a communication from any regulatory authority threatening license approval or supply of the Product due to compliance deficiencies at BTG facilities or if BTG was found to be in material non-compliance of this Agreement during or since the last quality audit. Person-in-Plant visits may be conducted at the discretion of SAVIENT during the manufacture of Bulk Product at BTG facilities. The frequency and duration of any additional visits must be agreed to by SAVIENT and BTG.

ARTICLE 14

ADVERSE EVENTS:

14.1 BTG will provide to SAVIENT within 48 hours of becoming aware, any information from any source that suggests an adverse event or serious adverse event has occurred. This information will include any adverse drug experience or reaction reports or any other information indicating that the product has any toxicity, sensitivity reactions or is otherwise alleged to cause illness or injury due to a possible product quality problem, adulteration or misbranding.

14.2 Quality Assurance Investigations. Upon notification to BTG that SAVIENT has received an SAE, AE, product complaint or inquiry regarding a Product supplied or incorporating a Bulk Product supplied, BTG shall conduct a quality assurance investigation to determine if any process or testing deviations or events may have contributed to the SAE, AE, product complaint or inquiry. BTG shall provide a written report on the results of the investigation to SAVIENT in not more than 30 days from Savient’s notification. In cases where a more comprehensive investigation might be required, the Parties will jointly develop an investigation plan. BTG shall reasonably cooperate with SAVIENT and regulatory agencies regarding an investigation or inquiry that may be initiated by a regulatory agency or otherwise required in response to a consumer or healthcare professional. BTG shall further provide SAVIENT with all data or other information that SAVIENT may reasonably require in connection with any reports or correspondence that SAVIENT provides to the regulatory agency, consumer or healthcare professional relative to any such AE, SAE or product complaint. BTG shall make records accessible to SAVIENT for purposes of FDA or other regulatory agency inspection.

14.3 Exchange of Drug Safety Requests. The Parties shall immediately provide each other with copies of all drug safety requests from all governmental and other regulatory health authorities. Proposed answers affecting the Product will be exchanged between the Parties before submission and the Parties shall cooperate with respect to such answers. SAVIENT shall
have the ultimate decision-making authority with respect to the answers relating to the Product. The Parties shall exchange decisions from applicable health authorities immediately.

ARTICLE 15

STABILITY:

BTG will perform the stability testing, data interpretation, reporting and updating of stability information to regulatory documents for the Product and Bulk Product and for Product until such time as a third party laboratory has been qualified to perform such testing. Stability related activities for which BTG is responsible shall be completed in accordance with the timing specified in stability protocols and BTG procedures.

ARTICLE 16

REGULATORY AFFAIRS:

Each Party shall advise the other Party of any regulatory action of which it is aware which would affect the Product in any country of the Territory.

ARTICLE 17

ANNUAL REPORT TO FDA:

BTG will prepare a summary of all changes to the product, production process, quality controls, equipment or facilities that have a potential to affect the identity, strength, quality, purity or potency of the Product. Such data will be prepared and sent to SAVIENT within thirty days of the end of the review period. BTG will also ensure that the results of all stability testing performed within the review period are sent to Savient within thirty days of the end of the review period.

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<td>SAVIENT QA</td>
<td>Eric Nickerson</td>
<td>/s/Eric Nickerson</td>
<td>19-FEB-2009</td>
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<tr>
<td>BTG QA</td>
<td>Yosefa Bilman</td>
<td>/s/Yosefa Bilman</td>
<td>19/02/09</td>
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The following is a non-exclusive list of deviations requiring notification in accordance with Article 3:

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APPENDIX II

Schedule of Retains, Storage Conditions and Retention Periods for Puricase®

The following is a list of the reserve/retention samples that are taken during the manufacturing processes of bulk uricase and PEG-uricase as well as from the final bulk uricase and the final bulk PEG-uricase (Bulk Product).

The document was prepared based on the following BTG QC SOPs:

[...***…]

Table I details the reserve/retention samples that are taken during the manufacturing process of bulk uricase and from the final bulk uricase.

Table 2 details the reserve/retention samples that are taken during the manufacturing process of PEG-uricase and from the final hulk PEG-uricase (Bulk Product).

All IPC samples (including reserve/retention samples) are to be discarded after the Bulk Product is released by BTG QA.

Uricase retention and reserve samples will be kept for one year after manufacturing. PEG-Uricase retention and reserve samples will be kept for six years after manufacturing.

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Table 1. Reserve/Retention Samples for Bulk Uricase (IPC and Final)

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Table 2. Reserve/Retention Samples for PEG-Uricase API (IPC and Final)

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# APPENDIX III

Critical Raw Materials Used in the Production of Recombinant Uricase and PEG-Uricase

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<th>Material</th>
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Exhibit G

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***Confidential Treatment Requested***
THIRD AMENDMENT TO COMMERCIAL SUPPLY AGREEMENT

THIS THIRD AMENDMENT is made and entered into this 1st day of July, 2010, (hereinafter the “Effective Date”).

BETWEEN:

SAlient PHARMACEUTICALS, INC.
a Delaware corporation, (hereinafter “Savient”)

AND

BIO-TECHNOLOGY GENERAL (ISRAEL) LTD.
an Israel corporation, (hereinafter “BTG”)

WHEREAS:

Savient and BTG are parties to a Commercial Supply Agreement with an effective date of March 20, 2007, (hereinafter, the “Agreement”) pursuant to which BTG agreed to manufacture and supply a certain Bulk Product, as defined in the Agreement, to Savient, and Savient agreed to purchase such Bulk Product from BTG; and

Savient and BTG have subsequently amended the Agreement on September 24, 2007, (the “First Amendment”) and on January 24, 2009, (the “Second Amendment”), and have issued a Letter Agreement dated July 30, 2008, (the “Letter Agreement”) pertaining to the Agreement; and

Savient and BTG desire to further amend the Agreement in accordance with the terms and conditions of this Third Amendment.

NOW THEREFORE in consideration of the mutual promises and agreements and covenants contained herein, the adequacy of such consideration has been agreed and acknowledged by each party, and in accordance with the provisions of Section 14.08 of the Agreement, the parties hereto agree as follows:

1. **Definitions.** All of the Definitions contained in Article 1 of the Agreement shall have the same meanings herein unless specifically stated otherwise. Any capitalized terms not specifically defined herein, shall have the same meaning ascribed to them as set forth in the Agreement.

2. **Application of Capacity Reservation Fees.** The parties agree that Section 5.01(ii)(D)(2) of the Agreement is hereby replaced in its entirety as follows:

   “(2) be credited, inclusive of interest, by BTG on a per batch basis by providing a 20% discount on the value of each batch at the time of invoicing for Bulk Product purchased by Savient until it is fully utilized, provided however, except as otherwise provided in Sections 5.01(ii)(F), 5.01(ii)(G) and 5.01(ii)(H), any uncredited Processing Capacity Reservation Fee, inclusive of interest, which is
remaining at the close of business on [...***...] due to a failure by Savient to take delivery of Bulk Product which conforms to the Commercial Bulk Product Specifications and which is ordered pursuant to a Bulk Product Forecast provided pursuant to Section 5.03 or an Amended Bulk Product Forecast provided pursuant to Section 5.06 and which is otherwise properly amended pursuant to Section 5.05 shall be forfeited by Savient to BTG. For purposes of clarity, the credit of the Processing Capacity Reservation Fee shall accrue upon the delivery of the Bulk Product by BTG to Savient and shall be reflected on the invoice which relates to the Bulk Product shipment in question; and”.

3. **No Modification.** Except as expressly provided for herein, the Agreement shall remain in full force and effect without amendment. If there is any conflict or inconsistency between this Amendment and the Agreement, this Amendment shall prevail. This Amendment contains the entire agreement between the parties hereto with respect to the subject matter contemplated herein and shall not be modified or amended except by a written instrument signed by both parties hereto.

**IN WITNESS WHEREOF,** the parties have caused this Amendment to be executed by their respective duly authorized officers as of the date first written above.

**SAVIENT PHARMACEUTICALS, INC.**

By: /s/ Philip K. Yachmetz  
Philip K. Yachmetz  
Senior Vice President &  
General Counsel

**BIO-TECHNOLOGY GENERAL (ISRAEL) LTD.**

By: /s/ Dov Kanner  
Dov Kanner  
Managing Director

***Confidential Treatment Requested***
FOURTH AMENDMENT TO COMMERCIAL SUPPLY AGREEMENT

THIS FOURTH AMENDMENT TO COMMERCIAL SUPPLY AGREEMENT (this “Fourth Amendment”) is made and effective as of this 21st day of March 2012, (hereinafter the “Amendment Effective Date”).

BETWEEN:

SAVIENT PHARMACEUTICALS, INC.
a Delaware corporation, (hereinafter “Savient”)

AND

BIO-TECHNOLOGY GENERAL (ISRAEL) LTD.
an Israel corporation, (hereinafter “BTG”)

WHEREAS:

Savient and BTG are parties to a Commercial Supply Agreement with an effective date of March 20, 2007, (hereinafter, the “Agreement”, modified as provided in the next paragraph) pursuant to which BTG agreed to manufacture and supply a certain Bulk Product, as defined in the Agreement, to Savient, and Savient agreed to purchase such Bulk Product from BTG; and

Savient and BTG have subsequently amended the Agreement on September 24, 2007, (the “First Amendment”), on January 24, 2009, (the “Second Amendment) and on July 1, 2010, (the “Third Amendment”), and have issued a Letter Agreement dated July 30, 2008, (the “Letter Agreement”) pertaining to the Agreement; and

Savient and BTG desire to further amend the Agreement in accordance with the terms and conditions of this Fourth Amendment.

NOW THEREFORE in consideration of the mutual promises, agreements and covenants contained herein, the adequacy of such consideration has been agreed and acknowledged by each Party, and in accordance with the provisions of Section 14.08 of the Agreement, the Parties agree as follows:

1. **Definitions.** All of the Definitions contained in Article 1 of the Agreement shall have the same meanings herein unless specifically stated otherwise. Any capitalized terms not specifically defined herein, shall have the same meaning ascribed to them as set forth in the Agreement.

2. **Addition and Replacement of Exhibits to Agreement.** The Parties agree that the exhibits which are appended to this Fourth Amendment shall, as applicable, be added or supersede and replace their counterparts as previously executed by and between
the Parties. For purposes of clarity, the following exhibits to the Agreement are hereby repealed and replaced with the attached exhibits:

(a) Exhibit C-1, “Current Commercial Bulk Product Specifications” which are the current regulatory acceptance criteria and are added pursuant to Section 3.01(ii) of the Agreement;

(b) Exhibit C-2, “Modified Acceptance Criteria to be Used to Govern the Commercial Supply Agreement” [...***...](the “Modified Acceptance Criteria”); and

(c) Exhibit E, “Product Price” [...***...].

3. **Modified Payment Terms for Bulk Product.** Savient and BTG acknowledge and agree that, due to additions or modifications to the Current Commercial Bulk Product Specifications, additional experience manufacturing Bulk Product may be required in order to provide a higher level of assurance that Bulk Product can be consistently manufactured in a manner that conforms to the Current Commercial Bulk Product Specifications as set forth in Exhibit C-1 hereto. [...***...]. As more fully set forth in clauses (a) through (c) herein below, Savient and BTG agree to share financial responsibility with respect to (x) certain Bulk Product manufactured by BTG under the Agreement [...***...] and (y) Bulk Product manufactured by BTG under the Agreement beginning with the production of [...***...] and ending after the completion of [...***...] batches under this Agreement (the “[...***...] Specification Batches”). After completion of the [...***...] specification batches the Current Commercial Bulk Product Specifications will be reassessed and the Parties will mutually agree on any revisions thereto deemed necessary or appropriate (which agreement shall not be unreasonably withheld, conditioned or delayed) for submission to Regulatory Authorities in whose territories KRYSTEXXA is licensed. After the acceptance by such Regulatory Authorities of any revisions to the Current Commercial Bulk Product Specifications as set forth in Exhibit C-1 hereto, unless the Parties mutually agree otherwise in writing, the risk of failed batches and payment terms set forth in the Agreement (as amended by Section 2(b) above) shall apply, in full force and effect, with respect to all future Bulk Product manufactured by BTG pursuant to the Agreement. During the pendency between the completion of the [...***...] Specification Batches and the acceptance of any revisions to the Current Commercial Bulk Product Specifications by the pertinent Regulatory Authorities in whose territories KRYSTEXXA is licensed, the parties agree that BTG shall continue to manufacture batches of Bulk Product in accordance with the Modified Acceptance Criteria set forth in Exhibit C-2 and

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any nonconformities in any such batches shall be resolved in accordance with Section 3(b) of this Fourth Amendment.

(a) Within [***] business days after the full execution of this Fourth Amendment, Savient shall pay to BTG a one-time payment of [***] Dollars ($[***]), [***].

(b) With respect to any of the [***] Specification Batches of Bulk Product manufactured by BTG under the Agreement (unless extended by mutual written agreement of the Parties):

(i) If any of the [***] Specification Batches is deemed not to conform to the Current Commercial Bulk Product Specifications and (A) such non-conformance does comply with all of the Modified Acceptance Criteria and (B) such non-conformance is not attributable in any way to human error (each such batch a “Modified Acceptance Criteria Conforming Batch”), Savient shall pay BTG for such batch at a rate of [***] Dollars and [***] cents ($[***] per gram (e.g., [***] Dollars and [***] cents ($[***]) on the basis of a [***] batch), rather than the Price. For purposes of clarity, human error may include, but is not limited to, the introduction of foreign material, improper connection of equipment, improper cleaning of equipment, and the failure to follow established SOPs and master batch records.

(ii) If any of the [***] Specification Batches is deemed not to conform to the Current Commercial Bulk Product Specifications and (A) such batch does not conform to the Modified Acceptance Criteria, or (B) such non-conformance is attributable in any way to human error caused by BTG, Savient shall have no liability to BTG with respect to such Bulk Product.

(iii) For any of the [***] Specification Batches deemed to conform to the Current Commercial Bulk Product Specifications, Savient shall pay BTG for such batch in accordance with the terms and conditions of the Agreement, including the then-current Price.

(c) Savient may, in its sole discretion, apply, on a batch-by-batch basis, [***] Dollar ($[***]) of the Processing Capacity Reservation Fee credit (or such greater amount agreed upon as the then current per batch Processing Capacity Reservation Fee credit due to the accrual of interest on the Processing Capacity Reservation Fee amount) toward any payment owed to BTG in accordance with clause (b) above.

In the event either Party determines that a batch of Bulk Product is a Current Commercial Bulk Product Non-Conforming Batch it shall promptly notify the other Party. If the other Party does not agree with such determination, the Parties shall investigate and fully document such non-conformance using typical out-of-specification investigation

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techniques performed to the mutual satisfaction of the Parties (in the case of specifications for which the analyses are not conducted at BTG, Savient shall enable BTG to review all data related to those analyses). If following such investigation the Parties do not agree whether a batch of Bulk Product is a Current Commercial Bulk Product Non-Conforming Batch, the Parties shall promptly appoint an independent specialist (appointed by mutual agreement between the Parties, which agreement shall not be unreasonably withheld, conditioned or delayed) who shall determine whether such batch of Bulk Product is a Current Commercial Bulk Product Non-Conforming Batch. In the absence of manifest error, the independent specialist’s decision shall be conclusive and binding on the Parties.

4. **Suspension of Manufacturing.** Without limiting the provisions of Section 5.08 of the Agreement, in the event that [...] or more of the [...] Specification Batches (unless extended by mutual written agreement of the Parties) are deemed to be Modified Specification Non-Conforming Batches, then Savient may, in its sole discretion and without any penalty under the Agreement, suspend all manufacture of Bulk Product under the Agreement. In the event that manufacture of Bulk Product is suspended in accordance with the preceding sentence, Savient shall be released from its purchase obligations under Section 6.01 of the Agreement and no forecast or estimate shall be considered a Firm Order until such time as BTG demonstrates to Savient’s reasonable satisfaction that the manufacture of Bulk Product may be resumed with a reduced and manageable risk of the manufacture of Modified Specification Non-Conforming Batches.

5. **Remediation Plan.** Prior to the Amendment Effective Date, BTG and Savient (a) [...] and (b) mutually agreed to implement investigations of [...]. Appendix 1 sets forth the proposals for these investigations that have been agreed to by the Parties and BTG shall, after the Amendment Effective Date, promptly pursue such investigations and implement such changes which may be determined to be necessary to the Facility to Savient’s reasonable satisfaction. Savient and BTG shall agree on the terms and conditions for the implementation of the Facility Changes, and the allocation of costs, in accordance with Section 6.03. If Savient and BTG determine that Process Changes or Process development work is needed to prevent Modified Specification Non-Conforming Batches (as distinguished from equipment changes or work of general applicability to BTG’s manufacturing activities), the Parties shall agree on the terms and conditions for such additional Process development work in accordance with Section 6.02(iii).

6. **Submission of Data to the FDA.** BTG acknowledges that in accordance with the post-regulatory approval commitments made by Savient to the FDA with respect to the FDA’s approval of the Product, Savient is required to submit to the FDA revised specifications for Bulk Product and the supporting data therefore after the completion of the manufacture of the [...] Specification Batches. BTG shall provide all information and assistance which is reasonably necessary or useful in the preparation of such submissions in accordance with Section 3.02. All documents to be supplied by BTG pursuant to this ***Confidential Treatment Requested***
Section 6 shall be translated by BTG into the English language as may be necessary. Any labor costs of BTG employees shall be reimbursed by Savient in the manner and at the rates set forth on Exhibit B to the Agreement.

7. **Savient Observation Rights.** During the Term, BTG shall make best efforts to accommodate Savient’s requests to visit the facility where the Bulk Product is manufactured and observe the manufacturing of the Bulk Product in order to ensure that the Process complies with Applicable Law and the Product Specifications. These visits will be at Savient’s sole cost and expense and will take place during normal business hours and upon [...] Business Days notice.

8. **Additional Agreement.** As an additional inducement to Savient for the execution of this Fourth Amendment, BTG and its parent company, Ferring B.V. will cause Ferring International Centre S.A. to execute, contemporaneously with the execution of this Fourth Amendment, the OsmB Promoter License Agreement in the form attached hereto as Appendix 2.

9. **No Modification.** Except as expressly provided for herein, the Agreement shall remain in full force and effect without amendment. If there is any conflict or inconsistency between this Amendment and the Agreement, this Amendment shall prevail. The Agreement, as modified by this Amendment, contains the entire agreement between the parties hereto with respect to the subject matter contemplated herein and shall not be modified or amended except by a written instrument signed by both parties hereto.

**IN WITNESS WHEREOF,** the parties have caused this Amendment to be executed by their respective duly authorized officers as of the date first written above.

**SAVIENT PHARMACEUTICALS, INC.**

By: /s/Philip K. Yachmetz
Philip K. Yachmetz
Senior Vice President &
General Counsel

**BIO-TECHNOLOGY GENERAL (ISRAEL) Ltd.**

By: /s/Dov Kanner
Dov Kanner
Managing Director

***Confidential Treatment Requested***

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Release Tests Performed on […]***…]

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EXHIBIT E to Fourth Amendment

Product Price

As and from [***…], the Price of the Product shall be as follows:

(i) For each gram, [***…] Dollars (USD$[***…]) for any aggregated quantities of the Product up to and including [***…] ordered during any calendar year that commercial batches of Product are shipped, i.e. after the first commercial batch of Product has been shipped.

(ii) For each gram, [***…] Dollars (USD$[***…]) for any aggregated quantities of the Product between [***…] and [***…] ordered during any calendar year as above; and

(iii) For each gram, [***…] United States Dollars (USD$[***…]) for any aggregated quantities of the Product equal to or greater than [***…] ordered during any calendar year as above.

The Parties agree that Savient will enter into a supply agreement with [***…], the supplier of [***…], and will order and pay for [***…] needed in Product manufacture on an ongoing basis. In the event that BTG purchases [***…] directly from [***…] or any other manufacturer, the cost of the [***…] will be invoiced to Savient.

Beginning on the [***…] anniversary of the date of receipt of the first commercial batch of Product by Savient, and on each successive [***…] thereafter, the Price of the Product shall increase by an amount equal to the average increase in the United States Consumer Pricing Index (CPI) over the immediately preceding [***…] period; such percentage increase shall be applied to each amount specified in (i) through (iii) above.

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APPENDIX 1

[...***...]
This OsmB Promoter License Agreement (the “Agreement”) is entered into as of this 21st day of March, 2012, with a retroactive effective date of July 18, 2005 (“Effective Date”), between Savient Pharmaceuticals, Inc., a Delaware corporation (“Savient”) and Ferring International Centre S.A., a Swiss corporation (“FIC”).

Introduction

WHEREAS on March 23, 2005, Ferring B.V., FIC and Savient executed a Share Purchase Agreement and an Asset Purchase Agreement, and associated documents, which accomplished the sale of Savient's global biologics manufacturing business comprising the transfer of all outstanding shares in Bio-Technology General (Israel), Ltd. (“BTG”) and certain defined assets from Savient to Ferring B.V. and FIC (the “BTG Divestiture”). Part of the BTG Divestiture included the transfer of certain intellectual property rights from Savient and BTG to FIC;

WHEREAS Savient and BTG entered into an Amended and Restated Residual Rights Agreement dated July 17, 2005, pursuant to which BTG performed certain manufacturing development and bulk product manufacturing activities pending the finalization of more definitive agreement relating to those activities and wherein the parties stated their intention to license certain intellectual property rights in certain patents from BTG to Savient in order to assure Savient’s rights and liabilities to manufacture the Puricase product, now known as pegloticase (the “RRA”);

WHEREAS, pursuant to the terms and conditions of the RRA, Savient and BTG entered into a Development Agreement (the “DA”) and Commercial Supply Agreement (the “CSA”), each dated March 20, 2007, both of which agreements upon their execution superseded and replaced, in relevant part, the RRA;

WHEREAS pursuant to the terms and conditions of the DA and CSA, in Sections 2.02 (iii) and 2.01(iii) respectively, BTG has granted, and has undertaken to cause its Affiliates to grant, to Savient a fully paid-up, royalty-free, non-exclusive license in the Territory (defined in each of the DA and CSA as meaning, collectively, each country of the world) to manufacture, have manufactured, produce, have produced, develop, have developed, use, have used, offer for sale, have offered for sale, sell, have sold, export, and have exported Bulk Product under the BTG Licensed Improvements and BTG Know-How, as each term is defined in the DA and CSA (collectively the “Pegloticase Licenses”);

WHEREAS the Closing of the transactions effectuating the BTG Divestiture occurred on July 18, 2005, upon which all right, title and interest in and to all intellectual property related to the global biologics manufacturing business of BTG, including the intellectual property defined in the DA and CSA as BTG Licensed Improvements and BTG Know-How transferred to and was vested in FIC (the “BTG IP”); and
WHEREAS, in view of FIC’s ownership of the BTG IP, Savient and FIC desire to execute this Agreement in order to effectuate and perfect the Pegloticase Licenses granted by BTG on and in accordance with the terms and conditions as follows.

NOW THEREFORE in consideration of the recitals in the Introduction above, the covenants and agreements herein, and other good and valuable consideration, the receipt and sufficiency of which the parties acknowledge, the parties agree as follows:

ARTICLE 1

As used herein, the following terms shall have the meanings ascribed to them as follows:

1.1 “Affiliate” shall mean any person or entity controlling, controlled by or under common control with a party to this Agreement.

1.2 “Patents” shall mean those patents listed in Exhibit 1, all foreign counterparts thereto, and any disclosures, continuations, continuations-in-part, divisionals, provisional, PCT applications, reissuances, revisions, substitutions, conversions, renewals, extensions, prolongations, and reexaminations thereof, any technology and inventions covered thereby, and any corresponding international, regional and national applications, whether existing at present or in the future.

1.3 “Pegloticase” shall mean […***…].

1.4 “Territory” shall mean, collectively, each country in the world.

1.5 Capitalized terms used but not specifically defined herein shall have the meaning ascribed to them in the DA and CSA.

ARTICLE 2

2.1 Grant of License. FIC hereby grants to Savient a fully paid-up, royalty-free, non-exclusive license in the Territory to manufacture, have manufactured, produce, have produced, develop, have developed, use, have used, offer for sale, have offered for sale, sell, have sold, export, and have exported Pegloticase bulk product under the intellectual property owned by FIC which embodies the BTG Licensed Improvements and BTG Know-How, as each term is defined in the DA and CSA, including, without limitation the Patents. Such license includes the right to sublicense solely for the purposes of effectuating the rights granted to Savient hereunder. To the extent necessary or required, upon request by Savient, FIC shall execute, and shall cause its Affiliates to execute, any such additional documentation as may be necessary in order to give effect to this license grant.

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ARTICLE 3

This Agreement shall commence as of the Effective Date, and continue in full force and effect until the expiration date of the last to expire of the Patents or other patents which embody BTG Licensed Improvements or BTG Know-How.

ARTICLE 4

4.1 Entire Agreement. This Agreement constitutes the entire agreement between the parties with respect to the subject matter hereof, and supersedes any prior agreements or understandings, whether oral or written, between the parties and their respective Affiliates with respect to such matters.

4.2 Modification. No modification of the terms hereof shall be effective except by a written instrument signed by both parties.

4.3 Severability. The invalidity or unenforceability of any term or provision of this Agreement shall not effect the other terms and provisions, and such invalid or unenforceable term or provision will, in all events be construed and enforced to the fullest extent permissible under applicable law.

4.4 Assignment. Either party may assign this Agreement and its rights and obligations hereunder, provided that any such assignee agrees to be bound by the terms, conditions and covenants of such assigning party hereunder. The Agreement shall be binding upon and inure to the benefit of the parties, and their respective successors and permitted assigns.

4.5 Dispute Resolution. Any dispute arising between the parties with respect to any provision of this Agreement or any matter relating to the performance of either party hereunder shall first attempt to be resolved if reasonably possible by good faith negotiation between designated executives of each party. In the event of such dispute, the parties shall promptly designate respective executives who shall then confer in good faith in an attempt to resolve the dispute before any further action is commenced. In the event no mutual resolution is possible using the foregoing method, either party may require the other party to submit to non-binding mediation using a recognized dispute resolution entity before court litigation is commenced.

4.6 Order of Precedence. In the event of a conflict or inconsistency that relates to the subject matter hereof between any terms of this Agreement and the DA, CSA or RRA, and in each such instance the Exhibits thereto, the terms of this Agreement shall take precedence over any conflicting terms in the earlier agreements.

4.7 Governing Law. This Agreement shall be deemed to have been made in the State of New York, and will be construed and enforced and under and governed by the internal laws of such state, without giving effect to conflicts of laws principles.
4.8 Counterparts. This Agreement may be signed in any number of counterparts, any of which shall constitute an original and all of which when taken together shall constitute one and the same instrument.

IN WITNESS WHEREOF, each party has caused it duly authorized representative to execute this Agreement on the date first written above, effective as of the Effective Date.

Savient Pharmaceuticals, Inc.

/s/ Philip K. Yachmetz
By: Philip K. Yachmetz
Title: SVP & General Counsel

Ferring International Centre S.A.

/s/ Lars Peter Brunse
By: Lars Peter Brunse
Title: EVP Technical Operations
### EXHIBIT 1 to OsmB Promoter License Agreement

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<th>Expiry Date</th>
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***Confidential Treatment Requested

-7-
COMMERCIAL SUPPLY AGREEMENT

This Commercial Supply Agreement (this “Agreement”) is entered into as of October 16, 2008, (the “Effective Date”) by and between Enzon Pharmaceuticals, Inc., a Delaware corporation with an address of 685 Route 202-206, Bridgewater, New Jersey 08807 (“Enzon”), and Savient Pharmaceuticals, Inc., a Delaware corporation, having its principal place of business at One Tower Center, 14th Floor, East Brunswick, New Jersey 08816 (“Savient”). Enzon and Savient may be referred to individually as a “Party” or collectively as “Parties.”

RECITALS

WHEREAS, Savient is engaged in the development and research of certain biologic products and requires manufacture of such a product for commercial distribution;

WHEREAS, Enzon is a contract manufacturer that possesses the necessary technical capabilities and operates facilities for the manufacture of pharmaceutical and biological products for commercial distribution;

WHEREAS, Savient desires Enzon to supply to it the Product on the terms and conditions set forth herein; and

WHEREAS, Enzon is willing to supply the Product to Savient on the terms and conditions set forth below.

NOW, THEREFORE, in consideration of the mutual promises contained herein, and for other good and valuable consideration, the receipt and adequacy of which each of the Parties does hereby acknowledge, the Parties, intending to be legally bound, agree as follows:

Section 1. DEFINITIONS

1.1 As used herein, the following terms shall have the following meanings:

1.2 “Affiliate” shall mean any business entity which directly or indirectly controls, is controlled by, or is under common control with any Party to this Agreement. A business entity shall be deemed to “control” another business entity if (i) it owns, directly or indirectly, at least fifty percent (50%) of the issued and outstanding voting securities, capital stock, or other comparable equity or ownership interest of such business entity, or (ii) it has the de facto ability to control or direct the management of such business entity.

1.3 “Applicable Laws” means all relevant federal, state and local laws, statutes, rules, and regulations which are applicable to a Party’s activities hereunder, including, without limitation, the applicable regulations of the Regulatory Authority, European Medicines Agency (EMEA) and United States and European Union cGMPs. The Parties may amend this section in writing to include additional countries.

Commercial Supply Agreement
Execution Copy
Page 1 of 44
1.4 “BLA” means a regulatory application filed with a governmental agency in the United States, the European Union, or any other country that the Parties mutually agree upon in writing (e.g. FDA and EMEA) for the purpose of lawfully marketing, selling, distributing, importing, exporting, manufacturing, developing or using a therapeutic or prophylactic product for the treatment or prevention of a disease or physical condition. As used herein, BLA shall include, without limitation, a Marketing Authorization Application in the European Union, a Biologics License Application in the United States.

1.5 “Bulk Product” shall mean the bulk solution of methoxy-polyethylene glycol (m-PEG) conjugate of uricase supplied by Savient to Enzon pursuant to this Agreement.

1.6 “Commercially Reasonable Efforts” shall mean efforts in accordance with the standards of care and diligence Enzon practices with respect to its own products.

1.7 “cGMPs” shall mean current good manufacturing practices as promulgated by the FDA under the United States Food, Drug and Cosmetic Act, 21 C.F.R. Part 210 et seq., as amended from time to time, and the European Union.

1.8 “Field Alerts” shall have the definition of field alerts used by the FDA irrespective of the jurisdiction in which the acts or circumstances giving rise to such field alerts occur.

1.9 “Process Consumables” means media, resins, raw materials, filters, membranes, product contact materials or surfaces, disposable lab supplies and similar materials used in the manufacture of Product. Provided, however, that Process Consumables shall not include components of manufacture supplied by third parties such as labels (hereinafter referred to as “Manufacture Components”).

1.10 “Product” means pegloticase, a PEGylated recombinant mammalian uricase formulation in final drug product form ready for commercial sale.

1.11 “Quality Agreement” shall mean that certain Quality Agreement by and between the Parties hereto, dated as of the date hereof and attached to this Agreement.

1.12 “Regulatory Authority” shall mean any governmental agency with jurisdiction over the regulation of drug and biological agents for use in man, including, but not limited to, the United States Food and Drug Administration and any foreign equivalents thereto.

1.13 “Savient-supplied Materials” shall mean those materials including, but not limited to Bulk Product, supplied by Savient for use in connection with the manufacture of the Product, as set forth in the Work Plan which is attached hereto as Exhibit A or any subsequent Work Plan signed by both parties.

1.14 “Savient Intellectual Property” shall mean (i) all valid patent claims owned or licensed by Savient and all converted provisionals, divisions, continuations, continuations-in-part, reissues, reexaminations or extensions thereof, as well as any corresponding foreign
counterparts and equivalents thereof, whether issued or pending as of the Effective Date or thereafter; (ii) trademarks which are owned, licensed or sublicensed by Savient and which are registered in the United States and, where applicable, foreign jurisdictions for use in association with the Product; and (iii) any Savient Know-How developed by Savient or any of its Affiliates during the Term relating to (a) the Bulk Product or the Product (including, without limitation, its pharmaceutical utility) or (b) the Services provided hereunder.

1.15 "Savient Know-How" shall mean all technical information, data (including, without limitation, regulatory data) patentable and unpatentable inventions, developments, discoveries, methods and processes that are, in each case, not disclosed in a published patent application or patent or otherwise publicly available, which are developed or conceived of by Savient or any of its Affiliates or which is licensed to Savient or any of its Affiliates.

1.16 "Service" means those services described in any Work Plan which is made a part of this Agreement and those services described in any Quality Agreement pertaining to such services.

1.17 "Specifications" means the written specifications for the Product and Savient-supplied Materials attached hereto as Exhibit B, which may be amended from time to time by the mutual written agreement of the parties.

1.18 "Work Plan" means the schedule and detailed plans used to prepare formulated Bulk Product, fill Bulk Product into vials and package the resulting drug product thereby resulting in the ultimate deliverable which is the Product. The definition of Work Plan shall also include subsequent change orders to any Work Plan (as described in Section 3.3). The first Work Plan is attached hereto as Exhibit A.

Section 2. SERVICES

2.1 Enzon shall perform the Services described in this Agreement and in the exhibits hereto, which are made part of this Agreement, or as described in any Work Plan, the Specifications, or change order pursuant to Section 3.3. Savient shall provide such Savient-supplied Materials and make such payments as are set forth therein. The Parties mutually acknowledge and agree that nothing contained in this Agreement or any Work Plan executed hereunder shall create an exclusive manufacture or supply arrangement between the Parties.

2.2 To the extent necessary to enable Enzon to provide the Services, Savient hereby grants to Enzon a royalty-free, non-exclusive license and, where appropriate, sublicense, to use the Savient Intellectual Property which pertains to the Product or the Services hereunder; provided, however, that any license, or sublicense, granted herein as the case may be, shall be used by Enzon or any permitted sublicensee solely for the purposes of carrying out the Services and no rights or title in or to the Savient Intellectual Property shall vest in Enzon. Upon the expiration or earlier termination of this Agreement the license or sublicense granted to Enzon to
use Savient Intellectual Property shall immediately cease and Enzon shall make no further use thereof and shall cause any permitted sublicensee to make no further use thereof.

2.3 Enzon agrees to provide the Services outlined in the Work Plan attached hereto as Exhibit A which is incorporated and made a part of this Agreement and any other Services that may be described in any future Work Plan or change order, or Quality Agreement which addresses the Services described in this Section 2, which shall be incorporated into this Agreement upon execution by both parties. Such Services shall be performed in accordance with Applicable Laws. Savient agrees to make payments in accordance with this Agreement and all Work Plans. In the event of a conflict between this Agreement and any Work Plan, this Agreement shall control.

2.4 Enzon shall provide Savient, at no additional charge, product support services, at Savient’s reasonable request, for the activities listed below:

• Meetings with Regulatory Authorities, whether in person or by phone
• Routine documentation provided to Regulatory Authorities on behalf of Savient
• Annual product reviews for commercial products, as required by Regulatory Authorities.
• All audit correspondence including Savient-requested revisions to Enzon’s audit response.

Savient may request from Enzon other product support services at its customary rate, as set forth on Exhibit C, including but not limited to:

• Preparation of documents in anticipation of a Pre-Approval Inspection.
• Letters of reference from Enzon or Enzon’s vendors that are requested by Savient (e.g., Master file reference letters, rubber or glass vendor letters).
• Documentation provided to Regulatory Authorities on behalf of Savient, other than routine documentation.
• All time used for collecting and photocopying Savient documentation. One copy of a batch record is exempted from support charges.
• Changes and revisions to artwork mandated by Regulatory Authorities or requested by Savient.
• Any additional validation work requested by Savient beyond original Work Plan or outside current validation requirements.
• Any analytical development and/or analyses beyond original Work Plan.

For all requests under this Section 2.4, Savient shall provide Enzon a written request for product support services that describes the required services and/or documents/work product required. Enzon shall provide Savient an estimate based on its customary rate. Upon acceptance of such estimate by Savient, Savient shall issue a purchase order to Enzon and Enzon shall perform such services in accordance with the terms hereof.
2.5 Enzon shall prepare and effect the Product shipment in accordance with explicit written instructions issued by Savient, which shall include the packaging instructions and Savient’s selected mode of transportation. All transportation costs shall be borne by Savient in accordance with the terms contained herein.

Section 3. MANAGEMENT/FORECASTING/MATERIALS

3.1 Account Management. Each party will appoint an account manager who will be the party responsible for overseeing the activities hereunder.

3.2 Content of Work Plans. Each Work Plan shall include a reasonably detailed description of the Services to be provided, relevant Specifications, a schedule for completion of the Work Plan, a fee and payment schedule, and such other information as is necessary for Enzon to perform the relevant Services.

3.3 Change Orders. In the event that Enzon is requested to perform services that are outside the scope of agreed-upon Work Plans such changes must be mutually agreed upon by the parties in a written change order prior to the provision of said services. Each such change order constitutes an amendment to the applicable Work Plan (which shall be explicitly referenced in such change order) and the services set forth therein shall be deemed to be part of such Work Plan. After receipt of the reasonably detailed description of the additional services from Savient, Enzon shall provide Savient with a cost estimate for performing the changed or additional services. Each change order shall be governed by the terms and conditions of this Agreement and by such supplementary written amendments of this Agreement or Work Plans as may be, from time to time, executed between the parties.

3.4 Forecasting And Savient-supplied Materials

(a) Upon execution of this Agreement and on the first day of each calendar quarter thereafter, Savient shall deliver to Enzon’s account manager an updated rolling forecast of Product requirements (in full-batch quantities) for the twenty four (24) month period commencing on the first day of the immediately following calendar month. Enzon shall, within ten (10) days of receipt of a forecast from Savient, confirm its receipt thereof in writing and shall advise Savient of whether such forecast is accepted in whole or in part; in the event that any part of the forecast is not accepted by Enzon then Enzon shall detail in writing the rationale for such non-acceptance. Within thirty (30) days of accepting each forecast, Enzon will provide Savient a projected manufacturing schedule indicating approximate dates of manufacturing which shall conform with the delivery dates specified in the forecast supplied by Savient. The foregoing notwithstanding, once a forecast (or any portion thereof) has been accepted by Enzon it shall be binding on both parties except as otherwise may be explicitly set forth herein; in the event that Enzon neither accepts or rejects any forecast submitted by Savient within ten (10) days of receipt from Savient then the entire forecast as submitted by Savient shall be deemed accepted by Enzon. If accepted, the forecast for the first six (6) calendar months of each forecast (“Firm Forecast”) shall be 100% binding on both parties and the forecast for the next twelve (12) calendar months (“Planning Forecast”) shall be binding on both parties as set forth in the
following sentence. Product requirements within the Planning Forecast shall not be increased or decreased by Savient by more than one (1) batch per three month period, per forecast, provided that no month may be reduced to zero (0) batches unless the initial Planning Forecast for that particular month was initially set as one or zero batches; for purposes of clarification only, the parties agree that the intention of this provision is to allow Savient, in each subsequent forecast, to modify each three month period of the most recently supplied Planning Forecast by one (1) batch as follows: the first three month period of the most recently provided Planning Forecast (which becomes the final three month period of the Firm Forecast) may be modified by one batch, the second three month period of the Planning Forecast may be modified by one batch, the third three month period of the most recently provided Planning Forecast may be modified by one batch and the fourth three month period of the most recently provided Planning Forecast may be modified by one batch. Savient shall forecast Product requirements for the six (6) months following the Planning Forecast, and the forecast for those six months are non-binding (“Non-Binding Forecast”) on Savient. Savient shall place firm purchase orders for its requirement of the Product in full-batch quantities at least ninety (90) days prior to the requested date of delivery. Each firm written purchase order, signed by Savient’s duly authorized representative, shall authorize Enzon to manufacture the number of batches of the Product as are set forth therein. The number of purchase orders submitted by Savient shall not exceed one (1) per calendar month, unless otherwise agreed to by the parties in writing. Enzon shall have completed any and all activities which are required by the applicable Work Plan and all Applicable Laws so as to be able to deliver the Product on or before the delivery dates specified by Savient in the subject purchase order but in any event the Product shall not be delivered by Enzon more than one (1) month in advance of any specified delivery date. Provided, however, that Enzon shall use Commercially Reasonable Efforts to minimize the amount of time elapsing between the completion of manufacturing activities and delivery of the completed Product to Savient.

(b) Starting from inception of the manufacture of the Product, Savient shall supply to Enzon, and use Commercially Reasonable Efforts to ensure that Enzon has on hand, a sufficient stock of Savient-supplied Materials as is necessary to provide the Services. Enzon shall have no liability for any failure to supply Product to Savient in accordance with the delivery terms contained in a Savient purchase order if sufficient quantities of Savient-supplied Materials in light of the forecasting described above have not been supplied to Enzon at least four (4) weeks prior to the scheduled manufacture date, as communicated to Savient pursuant to Section 3.4(a). In such case, manufacture of Product may be delayed until receipt of adequate supplies of Savient-supplied Materials and the availability of an appropriate manufacturing slot; provided, however, that Enzon shall use Commercially Reasonable Efforts to schedule the manufacture of the Product as soon as is possible subsequent to receiving the Savient-supplied Materials. If Savient provides Enzon with insufficient Savient-supplied Materials to produce the amount of Product requested in a particular purchase order, both sides may nonetheless agree in writing to have Enzon produce a lesser amount based on the amount of Savient-supplied Materials provided to Enzon, and all such batches shall be subject to the pricing listed in Exhibit C, including the minimum batch price, if applicable. Provided, however, that the Parties agree that any shortfall on the part of Enzon to produce at least ten thousand five hundred (10,500) vials of Product when provided with at least fifteen kilograms (15kg) of Bulk Product by Savient shall...
not constitute a breach of this Agreement and that the pricing for such shortfall below ten thousand five hundred (10,500 vials) shall be computed as set forth in Section 6.2(e) herein. Additionally, in the event that any scheduled manufacture of the Product is delayed due to the unavailability of adequate stores of Savient-supplied Materials, then any Firm Forecast then in effect shall be carried forward until such a time as the manufacture and delivery of the Product in accordance with the most recently supplied firm purchase order have been completed. Savient shall be responsible for verifying that all Savient-supplied Materials meet relevant Specifications. Title to Savient-supplied Materials shall not be transferred to Enzon. Savient will provide a signed, abbreviated Certificate of Analysis ("CofA") which shall, at minimum, certify that Savient-supplied Materials meet the Specifications for such Savient-supplied Materials as defined on Exhibit B prior to the processing of Savient-supplied Materials by Enzon. Enzon shall store all Savient-supplied Materials and finished Product in accordance with instructions provided by Savient in the Quality Agreement.

(c) All costs associated with the selection and/or qualification of alternative suppliers for any materials required to perform the Services shall be borne by Savient. Any such activities will be defined by Savient in writing an accompanied by an appropriate purchase order to Enzon.

(d) Upon execution of this Agreement and along with every quarterly forecast, Savient shall pay Enzon a rolling, non-refundable reservation fee equal to 25% of the minimum batch (specified on Exhibit C) price for batches included in the Firm Forecast to secure manufacturing capacity slots corresponding to the forecast provided. Savient shall pay such reservation fee to Enzon within ten (10) days of Enzon’s provision to Savient of the manufacturing schedule, as set forth in Section 3.4(a), which schedule sets forth the approximate dates of manufacturing for the Product. Such reservation fee shall be credited towards Product produced by Enzon on a batch-by-batch basis in a prorated amount. Additionally, upon payment of the reservation fee by Savient, Enzon warrants that manufacture of the Product shall occur on or before the dates specified in the manufacturing schedule which conforms to the Firm Forecast for which the reservation fee is paid. Upon shipment of each completed batch, Enzon will invoice Savient at a rate equivalent to the applicable unit price multiplied by the total number of vials produced less the applicable portion of any reservation fees paid. No less than two weeks prior to each quarterly update of the Firm Forecast, Enzon and Savient will reconcile the invoices against the above-mentioned reservation fee. In the event that Savient cancels any batch within the Firm Forecast, Enzon will charge Savient, and Savient agrees to pay to Enzon, a cancellation fee as set forth in the following sentence. For each batch canceled by Savient, Savient will pay Enzon an amount equal to the minimum batch price set forth on Exhibit C (less nineteen thousand eight hundred ninety dollars ($19,890) representing unused Process Consumables and Manufacturing Components), which amount shall represent liquidated damages resulting from unused manufacturing capacity. In the event that Savient postpones the manufacture of any batch scheduled during the Firm Forecast period for a period of more than thirty (30) days, then Enzon will charge Savient, and Savient agrees to pay to Enzon, a postponement fee as set forth in the following sentence. For each batch postponed by Savient, Savient will pay Enzon an amount equal to the minimum batch price set forth on Exhibit C (less nineteen thousand eight hundred ninety dollars ($19,890) representing unused Process Consumables and Manufacturing Components).
Components) which amount shall represent liquidated damages resulting from unused manufacturing capacity. Only with respect to batches which are postponed beyond the Firm Forecast, Savient will remit to Enzon the amount drawn within 30 days, and that amount will be credited back to the reservation fee. Enzon will draw the cancellation and postponement fee amounts described above from the amounts previously remitted to Enzon as reservation fees. In the event that any amounts owing to Enzon pursuant to this Section exceed the amounts previously remitted to Enzon as reservation fees, Enzon shall submit an invoice to Savient for the difference and Savient shall submit payment for such invoiced amounts in accordance with the terms of this Agreement.

Section 4. COMPENSATION AND EXPENSES

4.1 As compensation for rendering the Services hereunder, Savient shall pay Enzon the amounts specified in Exhibit C and any subsequent additional Work Plans executed in writing by both parties. Except as otherwise specifically provided in the attached Work Plan or any subsequent additional Work Plan, all payments by Savient shall be made within thirty (30) days of the date of its receipt of the appropriate invoice from Enzon. Enzon will charge a late payment fee of 1/2% per month, or the maximum amount permitted by law if less than 1/2% per month, for any payment not received within thirty (30) days of the date of Savient’s receipt of the appropriate invoice from Enzon. Failure to invoice for interest due shall not be a waiver of Enzon’s right to charge interest. Savient will pay any sales, use, gross receipts or other taxes, licenses, or fees (excluding tax based on Enzon’s net income) required to be paid by Enzon to any state or tax jurisdiction in connection with the Services performed hereunder.

4.2 All invoices and/or other requests for payment shall be itemized with a reasonable degree of specificity to ensure accuracy in accounting for services and/or goods provided and invoiced for. All invoices and/or other requests for payment shall be sent to:

Accounts Payable
Savient Pharmaceuticals, Inc.
One Tower Center, 14th Floor
East Brunswick, New Jersey 08816

4.3 Enzon will adjust prices not more often than annually, commencing on January 1, 2010, based on normal and customary increases in costs, not greater than the pharmaceutical Producer Price Index (as published by Bureau of Labor Statistics, Industry Code 325412). Additionally, Enzon may revise the prices provided in an attached Work Plan either upward or downward with Savient’s prior written consent, such consent not to be unreasonably withheld, if (i) any information which the parties reasonably agree is material to the performance of the Services proves to be incomplete or inaccurate (including but not limited to a material reduction in volume or a material change in prices of Enzon’s raw materials), (ii) Savient revises Enzon’s manufacturing or packaging responsibilities, procedures, or assumptions in a way that would impact the cost of the Services, or (iii) unforeseen circumstances, which both parties reasonably agree were unforeseeable at the time of contracting and which are not directly attributable to Enzon, affect the activities required to complete the Work Plan. Enzon will notify Savient
immediately if the costs to complete Services materially differ, either positively or negatively, from the prices stated in the attached Work Plan. Enzon will not commence work involving charges in excess of those stated in the attached Work Plan without Savient’s written approval unless such advance notice was not possible due to the circumstances. Savient shall be responsible for all non-cancelable costs incurred by Enzon as a direct result of any change order or other variation in Services requested by Savient, including but not limited to, inventory rendered unusable under the Work Plan; provided, however, that Enzon shall use Commercially Reasonable Efforts to minimize any non-cancelable costs contemplated herein including, but not limited to, by maintaining on hand only such Manufacture Components which are reasonably required to manufacture such quantities of Product as are specified in the Firm Forecast.

4.4 Savient’s failure to pay for the amounts due under this Agreement (including but not limited to payments under 3.4(d)) shall constitute a material breach of this Agreement. Savient shall have 45 days from Enzon’s written notice to cure such breach; provided, however, that Savient’s failure to pay any amounts otherwise owing hereunder due to a good faith dispute relating to such amounts shall not constitute a material breach only with respect to such amounts. Upon the expiration of the stated cure period, Enzon shall have the right to suspend any Services under this Agreement. Any batch cancellations resulting from such actions will be billed to Savient in accordance with Section 3.4(d).

Section 5. CERTAIN REPRESENTATIONS, WARRANTIES, AND COVENANTS

OF ENZON:

5.1 **Authority.** Enzon represents and warrants that it has full authority to enter into this Agreement.

5.2 **Material/Supplies.** Enzon shall use Savient-supplied Materials only to perform the Services hereunder.

5.3 **Savient Intellectual Property.** Enzon warrants that it shall use Savient Intellectual Property only for the purpose of manufacturing the Product on behalf of Savient in accordance with the terms of this Agreement.

5.4 **MVP Confidential Information.** Enzon hereby represents and warrants that, during the Term of this Agreement, it has not taken any action, nor failed to take any action, which would violate or cause to be violated the terms and conditions contained in the attached Exhibit E, which is incorporated herein by reference. The warranty contained herein shall survive the termination or expiration of the Agreement in accordance with the terms contained in the attached Exhibit E. Anything to the contrary contained in this Agreement notwithstanding, Enzon agrees that there shall be no limitation on the amount of liability for which Enzon may be liable to either Savient or Mountain View Pharmaceuticals, Inc., for breach of this Section 5.4.
5.5 **Books and Records.** Enzon shall maintain true and accurate books, records, test and laboratory data, reports and all other information relating to manufacture of Product as required by regulation and in accord with current good manufacturing practices (“cGMP”) and as set forth in the Quality Agreement.

5.6 **Regulatory Inspections.** Enzon shall make its facilities and all records relating to the Product manufacture available to the Regulatory Authorities at times agreed with such authorities and shall notify Savient if the Regulatory Authority begins or schedules an inspection of Enzon’s records, facilities, or manufacturing processes related to the manufacture of Product and provide Savient access to any documentation related to or resulting from the inspection as described in the Quality Agreement.

5.7 **Debarment.** Enzon hereby certifies it does not and shall not employ, contract with or retain any person directly or indirectly to perform services under this Agreement if such person is debarred under 21 U.S.C. 335a (a) or (b) or other equivalent laws, rules, regulations or standards of any other relevant jurisdiction.

5.8 **Regulatory Filings.** Enzon will cooperate in providing to Savient any non-confidential information in its control relating to this Agreement or the Product that Savient may reasonably require in connection with its regulatory or governmental filings, provided that such information shall be provided in whatever form held by Enzon. If applicable, Enzon will provide a letter permitting applicable Regulatory Authority to reference its relevant drug master file.

5.9 **Product and Process.** Enzon provides services to its customers on a contractual fee-for-service basis. Enzon warrants that it will perform the Services with due care and in accordance with agreed upon protocols and/or specifications, the terms of this Agreement and any Work Plan hereunder, generally prevailing industry standards and Applicable Laws. Enzon warrants that its fill/finish process does not and will not infringe on the rights of any third parties.

**OF SAVIENT:**

5.10 **Authority.** Savient represents and warrants that it has full authority to enter into this Agreement.

5.11 **Savient-supplied Materials.** Savient represents, warrants and covenants as follows: (i) all Savient-supplied Materials will be supplied not later than four (4) weeks prior to a scheduled manufacturing date, as communicated to Savient pursuant to Section 3.4(a), so as to enable Enzon to complete manufacture and delivery of the Product in accordance with all forecasts and firm purchase orders submitted by Savient and accepted by Enzon; (ii) all Savient-supplied Materials shall meet all relevant specifications, (iii) Savient shall take sole and exclusive responsibility for the quality and sufficient supply of all such Savient-supplied Materials, including responsibility for all testing and inspection of the same except to the extent (if any) that Savient and Enzon agree that Enzon shall perform any such testing and/or inspections in any Work Plan to this Agreement, and (iv) Enzon shall have no liability for a loss of Savient-supplied Materials except as set forth in Section 11.4.
5.12  **IP Rights.** Savient represents, warrants and covenants that Savient has all the rights necessary, including the rights to the Savient Trademarks, to permit Enzon to perform the Services hereunder without infringing the intellectual property rights of any third party.

5.13  **Debarment.** Savient hereby certifies it does not and shall not employ, contract with or retain any person directly or indirectly to perform services under this Agreement if such person is debarred under 21 U.S.C. 335a (a) or (b) or other equivalent laws, rules, regulations or standards of any other relevant jurisdiction.

**Section 6. ADDITIONAL PRODUCT SUPPLY TERMS**

6.1  **Delivery.** Delivery terms shall be FCA (Incoterms 2000) Enzon’s manufacturing facility in Indianapolis, Indiana (or such other facility as the Parties may agree upon); Product shall be delivered in accordance with the timeframe set forth in the applicable purchase order. Title to Product and Savient-supplied Materials shall remain vested with Savient at all times.

6.2  **Rejected Goods; Failure of Supply.**

(a) Except as provided for in Section 11.4, Savient’s sole remedy for breach of Enzon’s warranty in Section 5.9 shall be to require Enzon to re-perform the relevant services at Enzon’s cost.

(b) Concurrent with Enzon’s delivery to Savient of any Product contemplated hereunder, Enzon shall provide to Savient a written, executed CofA demonstrating compliance of Product with all relevant Specifications; such CofA may be transmitted to Savient via facsimile or electronic mail. Promptly following receipt of Product, Savient shall have the right but not the obligation to test such Product to determine compliance with the Specifications. Savient shall notify Enzon in writing of any rejection of Product based on any claim that the Product fails to meet Specifications within thirty (30) days of delivery, after which point all unrejected Product shall be deemed accepted. Any rightly rejected Product that does not meet the Specifications shall, at Enzon’s sole discretion and expense, either (i) be returned to Enzon within a reasonable period of time and relabeled or reworked as permitted in the Marketing Authorizations and Specifications, if permitted by the Applicable Laws, or (ii) be destroyed in accordance with Applicable Laws.

(c) In the event that Enzon believes that Product has been incorrectly rejected, Enzon may require that Savient provide to it Product samples for testing. Enzon may retain and test the samples of Product retained by it. In the event of a discrepancy between Savient’s and Enzon’s test results such that one Party’s test results fall within relevant Specifications and the other Party’s test results fall outside the relevant Specifications, or there exists a dispute between the Parties over the extent to which such failure is attributable to a given Party, the Parties shall cause an independent laboratory or appropriate expert promptly to review records, test data and perform comparative tests and/or analyses on samples of the alleged defective Product. Such independent laboratory or expert shall be mutually agreed upon by the Parties, and shall be of such national repute as to allow both Parties to reasonably agree that the independent laboratory...
or expert is sufficiently qualified to perform such analyses. The independent laboratory’s results shall be in writing and shall be final and binding save for manifest error. Unless otherwise agreed to by the Parties in writing, the costs associated with such testing and review shall be borne by the Party against whom the independent laboratory rules.

(d) Enzon shall replace any rightly rejected Product as promptly as practicable, using Commercially Reasonable Efforts to make available manufacturing capacity, after the notice of such rejection, and in any case as soon as reasonably possible after receiving such notice, provided that Savient shall provide to Enzon sufficient quantities of Savient-supplied Materials at no additional cost to Enzon. However, if the failure to meet Specifications is due to defects in the Savient-supplied Materials (where such defects are not due to any failure on the part of Enzon), or any other cause except Enzon’s failure to perform the Services in accordance with this Agreement, Savient will pay the full cost of the rejected batch.

(e) The Parties agree that Savient shall supply variable amounts of Bulk Product to Enzon for purposes of allowing Enzon to provide Services to fill and finish such Bulk Product into Product; the Parties further agree that if Savient supplies to Enzon fifteen kilograms (15kg) or more of Bulk Product for a single filling run that Enzon shall produce not less than ten thousand five hundred (10,500) vials of Product; if Enzon should fail to produce at least ten thousand five hundred (10,500) vials of Product as indicated herein, then Savient shall pay to Enzon an amount equal to the per-vial price indicated on the attached Exhibit C multiplied by the actual number of vials produced. In the event that Savient supplies less than fifteen kilograms (15kg) of Bulk Product to Enzon for a single filling run, then Savient shall pay to Enzon the minimum batch price indicated on Exhibit C attached hereto.

6.3 Recall; Withdrawal; Modification; Complaints. Savient shall be responsible for the cost of and all losses associated with any recall or product withdrawal or modification; provided, however, that to the extent that any such recall or product withdrawal is due to the gross negligence or willful misconduct on the part of Enzon, then Enzon shall reimburse Savient for all direct costs associated with such recall or withdrawal, in addition to any other rights or remedies Savient may have, but in any case only to the extent attributable to Enzon. Enzon shall reasonably cooperate with Savient in connection with any recall, withdrawal, or modification, at the expense of Savient except as otherwise provided for herein. Savient shall share with Enzon all relevant information relating to any such recall, withdrawal, or modification. In addition, Savient shall also promptly and fully detail for Enzon any Product complaints or Field Alerts it receives insofar as any such complaints relate to the Services rendered by Enzon hereunder. Enzon shall cooperate with Savient to report any adverse events of which it becomes aware in accordance with the terms of the Quality Agreement. Enzon shall only be responsible for the testing and protocols set forth in the Work Plan and Exhibits A and B, as applicable, and Savient is responsible for all other testing and protocols.

Section 7. TERM AND TERMINATION

7.1 Term. This Agreement shall commence on the Effective Date and shall remain in full force and effect unless terminated as provided herein.
7.2 **Termination.** Subsequent to the first (1st) anniversary of the Effective Date of this Agreement, this Agreement may be terminated by either party at any time by giving at least twenty-four (24) months prior written notice to the other party as follows: either party may give notice to the other party thirty (30) days prior to every such anniversary date. During the 24-month period between the notice of termination and the effectiveness of such termination, the Parties shall continue to cooperate with each other in good faith to effectuate the purpose of this Agreement; specifically, and without limitation, Savient may place, and Enzon shall accept and fulfill, forecasts and purchase orders for the manufacture of Product, all in accordance with the terms and conditions of this Agreement. During the pendency of the effective date of the termination notice, Savient shall not reduce the final six (6) months of any previously submitted forecast to zero (0) batches except if Enzon is the party which is terminating this Agreement. For the purposes of clarification only, the prohibition contained in the immediately preceding sentence shall not apply where the final six (6) months of the most recently supplied forecast were identified as having zero (0) batches at the time that the notice of termination was provided. Except as provided for herein, if, at any time subsequent to the tendering of a notice of termination pursuant to the terms herein, Savient reduces any of the final six months of the forecast to zero (0) batches, Savient shall pay Enzon a termination fee of $55,000 per batch. Enzon shall use Commercially Reasonable Efforts to minimize the incurrence of any additional charges, fees or expenses which will not be utilized in the manufacture of the Product on behalf of Savient prior to the effective date of termination of this Agreement. Within thirty (30) days of the effective date of the termination of this Agreement, Enzon shall provide to Savient any case reports, analyses and other deliverables which were prepared by Enzon, if any, prior to the date of termination and Enzon shall also provide Savient with a written itemized statement of all Services performed by it hereunder and all costs incurred or for which Enzon is obligated. In the event of termination pursuant to this Section 7.2, Enzon shall be entitled to full payment for the Services actually rendered by it hereunder and all non-cancelable costs incurred through the date of termination. In addition to the foregoing, if Savient terminates this Agreement or any Work Plan pursuant to this Section 7.2, Savient shall pay any cancellation or postponement amounts set forth in Section 3.4(d); provided, however, that Enzon shall use Commercially Reasonable Efforts to mitigate any such cancellation or postponement amounts by scheduling, to the extent practicable, additional third party manufacturing activities, with any such mitigation accruing to the benefit of Savient and proportionately reducing any cancellation or postponement amounts otherwise owing. If the amount already paid by Savient to Enzon exceeds such amounts payable hereunder, Enzon shall refund such excess to Savient and if such amounts payable are greater than the amounts already paid by Savient to Enzon, then Savient shall pay the amount of such shortfall to Enzon.

7.3 This Agreement may also be terminated by either party upon material default in performance of the other party, provided that any defaulting party shall be given not less than ninety (90) days’ prior written notice of default and the opportunity to cure the default during such period. In the event this Agreement is terminated pursuant to this Section 7.3, Enzon shall be entitled to full payment for the services provided by it hereunder (as set forth in any Work Plan(s) made a part hereof) and all costs incurred through the date of termination or for which Enzon is obligated as of the date of termination; provided, however, that if Savient terminates this Agreement pursuant to this Section 7.3 then, anything to the contrary notwithstanding,
Enzon shall be entitled only to payment for such Services which it actually rendered on behalf of Savient through the effective date of termination. In addition to the foregoing, if Enzon terminates this Agreement or any Work Plan pursuant to this Section 7.3, Savient shall pay any applicable cancellation or postponement amounts set forth in Section 3.4(d); provided, however, that Enzon shall use Commercially Reasonable Efforts to mitigate any such cancellation or postponement amounts by scheduling, to the extent practicable, additional third party manufacturing activities, with any such mitigation accruing to the benefit of Savient and proportionately reducing any cancellation or postponement amounts otherwise owing. If the amount previously paid by Savient exceeds such amount payable hereunder, the excess shall be refunded to Savient and if such amounts payable are greater than the amounts already paid by Savient to Enzon, then Savient shall pay the amount of such shortfall to Enzon.

7.4 In the event that Savient’s BLA for the Product is not approved by the FDA, and where such disapproval is final or otherwise not appealed by Savient, then either Party shall have the right, but not the obligation, to terminate this Agreement upon the provision of thirty (30) days notice to the other Party. In the event this Agreement is terminated pursuant to this Section 7.4, Savient shall pay Enzon for packaging and labeling materials, any unpaid amounts for manufactured batches, and any reservation fees or other applicable cancellation or termination fees, provided that Enzon shall use Commercially Reasonable Efforts to mitigate such fees.

7.5 In the event that Savient’s BLA for the Product has not been approved by April 2009, then this Agreement shall continue in force and effect but any deliverables and obligations of the parties shall be held in abeyance for up to 18 months so as to allow Savient to address any findings in such approvable letter issued by the FDA and resubmit the subject BLA. Savient shall pay any cancellation or postponement amounts set forth in Section 3; provided, however, that Enzon shall use Commercially Reasonable Efforts to mitigate any such postponement amounts by scheduling, to the extent practicable, additional third party manufacturing activities, with any such mitigation accruing to the benefit of Savient and proportionately reducing any cancellation or postponement amounts otherwise owing. Savient shall provide to Enzon notice of its receipt of an approvable letter from the FDA within five (5) business days of its receipt of same. After said 18 months lapses, Enzon shall have the right to terminate this agreement immediately and with no penalty, and Savient shall pay all applicable cancellation and postponement amounts as set forth.

7.6 This Agreement may be terminated immediately, upon written notice, upon either party’s bankruptcy (voluntary or involuntary), insolvency, or placing of either party’s business in the hands of a receiver.

7.7 Survival. The rights and obligations of each Party which by their nature survive the termination or expiration of this Agreement shall survive the termination or expiration of this Agreement, including Sections 4, 6, 7, 8, 9, 10, 11, 14, and 15 (to the extent relevant). In addition, Enzon hereby acknowledges that neither expiration nor termination of this Agreement shall affect in any manner Savient’s right to manufacture and sell, or have manufactured and sold, the Product.
Section 8. INTELLECTUAL PROPERTY

8.1 Subject to Section 8.2, all Savient Intellectual Property supplied to Enzon or developed by Enzon in the course of performing the Services hereunder are owned by Savient. All information developed by Enzon and related to the Bulk Product or the Product shall be disclosed to Savient promptly upon discovery or development by Enzon. Savient shall have the right to make any use of such information and Enzon agrees to execute any documents which may be reasonably required to effectuate any assignment of inventorship contemplated by this provision, at Savient’s expense. Following completion of the Services outlined in any Work Plan, Enzon will insure the return of all client data or other materials furnished to Enzon. Subject to Section 8.2, all intellectual property rights subsisting in or relating to any calculations, data, methods, specifications, papers, documents, and any other items, material or information arising from the performance of the Services by Enzon under this Agreement are vested in and are the sole property of Savient and Enzon shall execute any and all documents reasonably requested by Savient in order to effectuate the intent of this provision, at Savient’s expense.

8.2 Enzon shall own all rights to any invention (whether or not patentable) relating to manufacturing and analytical methods and processes developed by Enzon in connection with Services performed hereunder that have general use in biopharmaceutical manufacturing, to the extent not specific to Savient’s Product, and to the extent not directed to or derived from any pre-existing Savient Intellectual Property or MVP Confidential Information (“Process Invention”); provided that the provisions of this Section 8.2 shall not apply to manufacturing and analytical methods and processes developed by Enzon at the direction of Savient. Except as specifically prohibited with respect to MVP Confidential Information, Enzon reserves the right to use data developed during the course of performing Services hereunder to support applications, assignments or other instruments necessary to apply for and obtain patent or other intellectual property protection with respect to Process Inventions so long as no information which Enzon is required to keep confidential under this Agreement or any other previously executed agreement between the Parties relating to confidentiality of information is disclosed in any such application, assignment, or other instrument without the prior consent of Savient (not to be unreasonably withheld). For Process Inventions developed by Enzon in connection with performing services hereunder, Enzon will grant to Savient a perpetual, world-wide, royalty-free, non-exclusive license for Savient to use such Process Inventions in the development and manufacture of the Savient Products.

Section 9. CONFIDENTIALITY

9.1 For the duration of the Agreement and five (5) years thereafter with respect to Savient Confidential Information (as defined below), or, in the case of MVP Confidential Information (as defined below), for twenty (20) years from the Effective Date of the Agreement, Enzon will not disclose, without Savient’s written permission, any such Savient Confidential Information or MVP Confidential Information, unless such disclosure: (i) is to an Affiliate, agent, employee or consultant of Enzon that is under a similar obligation to keep such information confidential and such disclosure is reasonably necessary for the performance of the Services contemplated herein; (ii) is or becomes publicly available through no fault of Enzon;
(iii) is disclosed by a third party entitled to disclose it; (iv) is already known to Enzon as shown by its prior written records; or, (v) is required by any law, rule, regulation, order, decision, decree, subpoena or other legal process to be disclosed or in response to a request or order from a regulatory agency. If such disclosure is requested by a regulatory agency or legal process, Enzon will make all reasonable efforts to notify Savient of this request promptly prior to any disclosure to permit Savient to oppose such disclosure by appropriate legal action. Enzon shall use reasonable precautions to protect the confidentiality of both Savient Confidential Information and MVP Confidential Information in a manner that is comparable to precautions taken to protect its own proprietary information. As used herein, “MVP Confidential Information” means any Confidential Information that Savient provides, or has provided, to Enzon which is specifically identified in writing as containing Mountain View Pharmaceuticals, Inc.’s proprietary technology for the manufacture of PEGylated uricase (Puricase®/pegloticase), specifically including the documents referenced in Schedule A of the Second Amendment to the Agreement for Services between Savient and Enzon dated October 31, 2006, which the Parties have agreed to in a letter dated September 12, 2007, as containing Confidential Information belonging to Mountain View Pharmaceuticals, Inc; “Savient Confidential Information” means any Confidential Information provided by Savient to Enzon, with the sole exception of MVP Confidential Information provided by Savient to Enzon, with the sole exception of MVP Confidential Information.

9.2 For the duration of the Agreement and five (5) years thereafter with respect to Savient Confidential Information, or in the case of MVP Confidential Information, for twenty (20) years from the Effective Date of the Agreement, Enzon will not use such Confidential Information except in connection with the performance of Services under the Agreement or any other Agreement between Savient and Enzon related to Savient’s PEGylated uricase (Puricase®/pegloticase) product and in particular represents and warrants that it will not utilize such Confidential Information in the manufacturing of any other product.

9.3 For twenty (20) years from the Effective Date of the Agreement, Savient will not disclose, without Enzon’s written permission, any Confidential Information belonging to Enzon which is provided to Savient by Enzon during the Term of the Agreement (“Enzon Confidential Information”) unless such disclosure: (i) is to an affiliate, agent, employee or consultant of Savient that is under a similar obligation to keep such information confidential; (ii) is or becomes publicly available through no fault of Savient; (iii) is disclosed by a third party entitled to disclose it; (iv) is already known to Savient as shown by its prior written records; or, (v) is required by any law, rule, regulation, order decision, decree, subpoena or other legal process to be disclosed or in response to a request or order from a regulatory agency. If such disclosure is requested by a regulatory agency or legal process, Savient will make all reasonable efforts to notify Enzon of this request promptly prior to any disclosure to permit Enzon to oppose such disclosure by appropriate legal action. Savient shall use reasonable precautions to protect the confidentiality of Enzon Confidential Information in a manner that is comparable to precautions taken to protect its own proprietary information.

9.4 If either Party shall be obliged to provide testimony or records pertaining to the Confidential Information provided by the other in any legal or administrative proceeding, then the Party which supplied the Confidential Information shall reimburse the other Party for its out-
of-pocket costs therefore plus an hourly fee for its employees or representatives equal to the internal fully burdened costs of such employee or representative.

9.5 For both Parties, “Confidential Information” shall mean and include, without limitation, such types of information as: inventions, methods, plans, processes, specifications, characteristics, raw data, analyses, equipment design, trade secrets, costs, marketing, sales, and product performance information, including patents and patent applications, grant applications, notes, and memoranda, whether in writing or presented, stored or maintained electronically, magnetically or by other means, which are disclosed by the disclosing Party to the recipient Party in writing or in other tangible form and marked “confidential” or, if disclosed orally (or in some other non-tangible form), are identified as confidential to the recipient Party in writing within sixty (60) days of such disclosure; provided, however, that failure to reduce any verbal disclosure to writing shall not, in and of itself, vitiate the confidential nature of such Confidential Information and provided, further, that for the purposes of this Agreement, Confidential Information shall include any and all such information exchanged between the Parties prior to the Effective Date of this Agreement pursuant to the Confidentiality Agreement between the Parties dated July 24, 2006.”

Section 10. INSURANCE

Each Party shall for the term of this Agreement and for two (2) years after the last Product is delivered, obtain and maintain at its own cost and expense from a qualified insurance company, comprehensive general liability insurance including, but not limited to, contractual liability coverage and standard product liability coverage in an amount commensurate with industry standards. Savient shall for the term of this Agreement and for two (2) years after the last Product is delivered, obtain and maintain at its own cost and expense from a qualified insurance Savient, insurance coverage for losses of inventory at Enzon’s facility prior to, and following manufacture of the Product. At a Party’s request, the other Party shall provide it with proof of such coverage.

Section 11. INDEMNIFICATION AND LIMITS OF LIABILITY

11.1 Without limiting Enzon’s rights under law or in equity, Savient agrees to indemnify and hold harmless Enzon and its employees, directors and agents from and against any loss, damage, cost and expense (including without limitation attorneys’ fees and expenses) incurred in connection with any claims, proceedings or investigations arising directly or indirectly from (a) the manufacture, promotion, marketing, distribution or sale of the Product, (b) use or exposure to Product or any material provided to Enzon by Savient, (c) use of any Savient Intellectual Property provided by Savient to Enzon (but only in cases where Savient has provided such Savient Intellectual Property for Enzon’s use) or any infringement of the intellectual property rights of any third party related to the Product, or (d) any breach of Savient’s representations and/or warranties, except to the extent any such claim is the result of Enzon’s gross negligence or willful misconduct.
11.2 Without limiting Savient’s rights under law or in equity, Enzon agrees to indemnify and hold harmless Savient and its employees, directors and agents from and against any loss, damage, cost and expense (including without limitation attorneys’ fees and expenses) incurred in connection with any claims, proceedings or investigations arising out of or in connection with (a) this Agreement and the Product produced and the Services rendered hereunder to the extent that such claim, proceeding or investigation is based on the gross negligence or willful misconduct of Enzon or its employees, (b) any breach of Section 9.2 of this Agreement with respect to MVP Confidential Information, (c) any breach of the representations made by Enzon in the Letter Agreement between Enzon and Savient dated September 12, 2007, attached hereto as Exhibit E; but in any case only to the extent attributable to Enzon.

11.3 Any party seeking indemnification pursuant to this Section 11 (the “Indemnitee”) shall give notice within five (5) days to the party from whom indemnification is sought (the “Indemnitor”) of any claim, proceeding or investigation; provided, however, that any failure to notify the Indemnitor within such five (5) day period shall not negate the rights of indemnification granted hereunder except to the extent that the Indemnitor is actually prejudiced by such delay in notification. The Indemnitee shall cooperate in the defense of such claim, proceeding or investigation, subject to reimbursement by the Indemnitor for all reasonable out-of-pocket expenses. The Indemnitor shall, at its option, assume control of the defense of any such claim, proceeding or investigation. The indemnities set forth in Sections 11.1 and 11.2 shall include amounts paid in settlement provided, however, that no such settlement shall be entered into without the Indemnitor’s consent, which consent shall not be unreasonably withheld.

11.4 As Savient’s sole remedy, Enzon agrees to reimburse Savient up to a maximum of $25,000 per batch, pro-rated over the usable portion of the batch, if applicable, for any loss of Savient-supplied Materials for each batch that does not meet Specifications or was not manufactured in accordance with the Manufacturing Process or cGMP or the requirements of this Agreement, and therefore cannot be released or otherwise utilized for its intended purpose; provided that the loss of such materials can be shown after investigation to be caused solely and directly by: (a) the failure of Enzon to follow its SOP’s; or (b) Enzon’s negligence, gross negligence, willful misconduct, or breach of this Agreement. In addition to this payment, if due to Enzon’s gross negligence, willful misconduct, or breach of this Agreement, Enzon will re-perform the Services as provided in Section 6.2(a).

11.5 SECTION 11.4 IS SAVIENT’S SOLE AND EXCLUSIVE REMEDY FOR ANY LOSSES OF SAVIENT-SUPPLIED MATERIAL AS A RESULT OF PRODUCT THAT DOES NOT COMPLY WITH THE SPECIFICATIONS OR THE OTHER REQUIREMENTS OF THIS AGREEMENT. UNDER NO CIRCUMSTANCES SHALL ENZON BE LIABLE TO SAVIENT OR ANY THIRD PARTY FOR ANY CONSEQUENTIAL, INDIRECT (INCLUDING LOST REVENUES OR PROFITS), SPECIAL, OR OTHER DAMAGES, AND THE WARRANTY SET FORTH IN SECTION 5.9 IS THE SOLE AND EXCLUSIVE WARRANTY AND IN LIEU OF ANY AND ALL OTHER WARRANTIES RELATING TO THE SERVICES TO BE PERFORMED, EXPRESS OR IMPLIED, INCLUDING, WITHOUT LIMITATION, ANY IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, OR FOR NON-INFRINGEMENT OF INTELLECTUAL
PROPERTY RIGHTS. ENZON’S MAXIMUM LIABILITY FOR DAMAGES IN CONNECTION WITH A CLAIM RELATED TO THIS AGREEMENT, REGARDLESS OF THE CAUSE OF ACTION, WILL NOT EXCEED THE SUM TOTAL OF THE AMOUNTS PAID BY SAVIENT TO ENZON IN THE PRECEDING TWELVE (12) MONTHS.

EXCEPT AS EXPRESSLY STATED HEREIN, NEITHER PARTY PROVIDES TO THE OTHER PARTY HERETO ANY WARRANTIES, EXPRESS OR IMPLIED, WITH RESPECT TO THE SERVICES PROVIDED HEREUNDER, AND ALL SUCH WARRANTIES, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION ANY IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE ARE WAIVED, OTHER THAN AGREED HEREIN. WITHOUT LIMITING THE PROVISIONS OF SECTION 5.9 AND 6.2(e), ENZON MAKES NO WARRANTIES THAT THE EXECUTION OF THIS AGREEMENT WILL RESULT IN ANY SPECIFIC QUANTITY OR QUALITY OF PRODUCT.

Section 12. PUBLICITY AND PUBLICATIONS

Neither Savient nor Enzon shall make any news release or other public statement, whether to the press or otherwise, disclosing the existence of this Agreement, the terms thereof, or of any amendment thereto without the prior written approval of the other Party, except as required by Applicable Laws including, without limitation, those regulations promulgated by the United States Securities and Exchange Commission.

Section 13. FORCE MAJEURE AND CHANGE IN CIRCUMSTANCES

If either Party shall be delayed or hindered in or prevented from the performance of any act required hereunder by reason of strike, lockouts, labor troubles, restrictive governmental or judicial orders or decrees, riots, insurrection, war, terrorist acts, acts of God, inclement weather, or other reason or cause reasonably beyond such Party’s control (each a “Force Majeure”), then performance of such act shall be excused for the period of such Force Majeure. The Party affected by the Force Majeure shall provide notice to the other of the commencement and termination of the Force Majeure. Should a Force Majeure continue for more than three (3) months, the Party unaffected by the Force Majeure may terminate this Agreement upon prior written notice to the affected Party. If the Force Majeure equally affects the ability of each Party to perform under this Agreement, then such termination shall only be by mutual written agreement. In the event of any other type of unforeseen material change in circumstances (that does not qualify as force majeure), both parties agree to negotiate in good faith to find a commercially reasonable solution.

Section 14. NOTICES

14.1 All administrative communications provided for in this Agreement shall be sent via first class mail (subject to Section 14.2 below), postage prepaid, addressed to the respective parties as follows:
Section 15. MISCELLANEOUS

15.1 Amendments; Assignment. This Agreement, including any Work Plans or other attachments, may not be altered, amended or modified except by a written document signed by both Parties. Enzon will not assign this Agreement without the prior written consent of Savient and any purported assignment in contravention of this Section shall be null and void; provided, however, that either Party may assign this Agreement in connection with the sale of all or substantially all of its assets related to this Agreement or the Services to be provided hereunder; provided, further, that any such successor or assignee assumes and accepts in writing all obligations of the purported assigning party hereunder.

15.2 Subcontracting. Enzon may subcontract or delegate any of its rights or obligations under this Agreement with the prior written authorization of Savient, such authorization not to be unreasonably withheld. Enzon shall cause any subcontractor to be subject by contract to the same restrictions, exceptions, obligations, reports, termination provisions and other provisions contained in this Agreement.

15.3 Successors; Assigns. This Agreement shall be binding upon and inure to the benefit of the Parties hereto and each of their respective successors and permitted assigns.

15.4 Severability. All agreements and covenants contained herein are severable, and in the event any of them shall be held to be invalid by any competent court, this Agreement shall be interpreted as if such invalid agreements or covenants were not contained herein.
15.5 **Entire Agreement.** This Agreement, including the attached Work Plans, constitutes the entire agreement between the Parties and supersedes all prior communications, representations, or agreements, either verbal or written between the Parties which are specifically related to the subject matter contemplated herein; anything to the contrary notwithstanding, any previously executed Confidentiality and Nondisclosure Agreement shall remain valid and enforceable in accordance with its terms. Each Party confirms that it is not relying on any representations or warranties of the other Party except as specifically set forth herein.

15.6 **Independent Contractor.** This Agreement shall not be deemed to create any partnership, joint venture, or agency relationship between the Parties. Each Party shall act hereunder as an independent contractor and its agents and employees shall have no right or authority under this Agreement to assume or create any obligation on behalf of, or in the name of, the other Party. All persons employed by a Party shall be employees of such Party and not of the other Party, and all costs and obligations incurred by reason of any such employment shall be for the account and expense of such Party.

15.7 **Waiver.** The waiver by either Party of any right hereunder shall not be deemed a waiver of any other right hereunder.

15.8 **Counterparts.** This Agreement may be executed in two (2) or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

15.9 **Headings.** The headings used in this Agreement are for convenience only and are not a part of this Agreement.

15.10 **Governing Law.** This Agreement shall be construed and enforced in accordance with the laws of the State of New Jersey, without application of its principles of conflict of laws.

15.11 **Audits.** Once each calendar year during the term of this Agreement, Savient and its agents and designees shall have the right to audit Enzon’s facilities, systems, records solely related to this Agreement or the Product. Such audits may be conducted upon reasonable notice during the term of this Agreement, so long as (i) all auditors have entered into confidentiality agreements relating to the materials to be reviewed, (ii) no materials are removed from the premises of Enzon, provided, however, that Savient may make and retain copies of Enzon materials as may be reasonably necessary solely for purposes of completing the contemplated audit and any such materials shall be considered confidential, and (iii) a copy of all findings is provided to Enzon. All costs for such audits shall be paid by Savient. For the avoidance of doubt, pre-approval inspections shall be considered an audit under this Section 15.11. Anything to the contrary notwithstanding, in the event that an audit is required due to batch failures or because the Services are not rendered in accordance with the terms of this Agreement (including any Work Plan), then such for-cause audit shall not count towards the annual audit provided for herein.

15.12 **Nonsolicitation.** For the term of this Agreement, and for twelve (12) months following termination of this Agreement, for any reason, neither Savient nor Enzon nor any of...
their employees or agents shall, directly or indirectly, solicit any employees of the other, who have been involved in the Services, unless otherwise approved by the other party.

IN WITNESS WHEREOF, each of the Parties hereto has caused this Commercial Supply Agreement to be executed by its duly authorized representative as of the date written above.

ENZON PHARMACEUTICALS, INC.

By: /s/ Ralph del Campo
Ralph del Campo
EVP - Operations

SAVIENT PHARMACEUTICALS, INC.

By: /s/ Philip K. Yachmetz
Philip K. Yachmetz
EVP & Chief Business Officer
Exhibit A

Work Plan

Enzon will fill, inspect, package and test the Product using the components defined below and the process as outlined on the following Process Flow Diagram.

**COMPONENTS:**

<table>
<thead>
<tr>
<th>Bulk Product</th>
<th>Supplier</th>
<th>Form</th>
<th>Concentration in Bulk Formulation</th>
<th>Storage Conditions</th>
<th>Special Handling</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bulk Product formulated, prefiltred peg-uricase</td>
<td>Savient through contract manufacturers</td>
<td>0.22 micron filtered liquid</td>
<td>8 mg/mL</td>
<td>2-8°C</td>
<td>Prevent from freezing</td>
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</table>

**CONTAINER CLOSURE COMPONENTS:**

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<tr>
<th>Description</th>
<th>Enzon Part #</th>
<th>Manufacturer/Part #</th>
<th>Height, min</th>
<th>OD, mm</th>
</tr>
</thead>
<tbody>
<tr>
<td>2 mL, 13 mm Vial</td>
<td>530-101</td>
<td>Alcan/2702-B9BA</td>
<td>31.5-32.5 mm</td>
<td>14.5-15.00 mm</td>
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<tr>
<td>13 mm Stopper</td>
<td>520-010</td>
<td>West Pharmaceutical Services/1012-4668</td>
<td>STOPPER, 13MM, 4416/50, GREY, FEP</td>
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<tr>
<td>Seal, 13 mm, FO, AL Purple #0527</td>
<td>510-002</td>
<td>54130024</td>
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</tbody>
</table>

**Packaging Components**

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<th>Enzon Part #</th>
<th>Supplier Part #</th>
</tr>
</thead>
<tbody>
<tr>
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<td>C49011USA</td>
<td>C49011USA</td>
</tr>
<tr>
<td>Carton Label, Puricase USA</td>
<td>CL49011USA</td>
<td>CL49011USA</td>
</tr>
<tr>
<td>Vial Holder, Puricase USA</td>
<td>H49011USA</td>
<td>H49011USA</td>
</tr>
<tr>
<td>Package Insert, Puricase USA</td>
<td>I49011USA</td>
<td>I49011USA</td>
</tr>
<tr>
<td>Packer, Puricase USA</td>
<td>P49011USA</td>
<td>P49011USA</td>
</tr>
<tr>
<td>Vial Label, Puricase USA</td>
<td>V49011USA</td>
<td>V49011USA</td>
</tr>
</tbody>
</table>
### Final Product Release Specifications

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Test Method</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Endotoxin</td>
<td>ACM-0073</td>
<td>≤80 EU/mL</td>
</tr>
<tr>
<td>Sterility</td>
<td>ACM-0071</td>
<td>Sterile</td>
</tr>
</tbody>
</table>
| Particulates    | ACM-0070 (Light Obscuration method) | Size ≤10 µm: ≤6000 particles per vial  
|                 |                      | Size ≤25 µm: ≤600 particles per vial |

### In-Process Product Specifications

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Test Method</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bioburden (in-process only)</td>
<td>ACM-0072</td>
<td>≤10 CFU/100 mL</td>
</tr>
<tr>
<td>Identity</td>
<td>ACM-1900</td>
<td>Positive for Urate Oxidase activity</td>
</tr>
<tr>
<td>Bulk Sterility</td>
<td>ACM-007</td>
<td>Sterile</td>
</tr>
</tbody>
</table>
### Exhibit C

#### Product Price

**Commercial Manufacturing**

<table>
<thead>
<tr>
<th>Activities Included</th>
<th>Price</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Prepare Master Batch Records</td>
<td>$20.80 per vial</td>
</tr>
<tr>
<td>• Materials to be packed with one vial and product insert per carton.</td>
<td></td>
</tr>
<tr>
<td>• Commercial Batch Prices are effective on 1 January 2008, and are effective through 31 December 2009.</td>
<td></td>
</tr>
<tr>
<td>• Enzon reserves the right to increase prices pursuant to the terms of the Supply Agreement.</td>
<td></td>
</tr>
<tr>
<td>• Release testing of batches; provision of CoA</td>
<td></td>
</tr>
<tr>
<td>• Supply temperature recorders to Drug Substance manufacturer for shipping. Download and provide temperature data to Savient.</td>
<td></td>
</tr>
</tbody>
</table>

The minimum price per batch of $218,400.00 shall apply in accordance with the terms of Section 6.2(e) of the Agreement.

<table>
<thead>
<tr>
<th>Puricase Final Drug Product Stability test Schedule at 5°C ±3°C</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Endotoxin and Sterility At Each Pull Point</td>
<td></td>
</tr>
<tr>
<td>Price is per each lot tested</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Setup &amp; initiation Fee</th>
<th>Initial Test</th>
<th>3 Months</th>
<th>6 Months</th>
<th>12 Months</th>
<th>24 Months</th>
<th>36 Months</th>
<th>Total Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>$1,900</td>
<td>$5,150</td>
<td>N/T</td>
<td>N/T</td>
<td>$5,150</td>
<td>$5,150</td>
<td>$5,150</td>
<td>$22,500</td>
</tr>
</tbody>
</table>

Stability studies will be conducted on batches requested in advance by Savient. Prices will be in effect for stability studies initiated on 2008 or 2009 and subject to review at the end of 2009.

<table>
<thead>
<tr>
<th>Puricase Final Drug Product Stability test Schedule at 25°C ±2°C and 70% ±5% Relative Humidity</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Endotoxin and Sterility At Each Pull Point</td>
<td></td>
</tr>
<tr>
<td>Price is per each lot tested</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Setup &amp; initiation Fee</th>
<th>Initial Test</th>
<th>1 Months</th>
<th>2 Months</th>
<th>3 Months</th>
<th>6 Months</th>
<th>Total Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>$1,900</td>
<td>$5,150</td>
<td>$5,150</td>
<td>$5,150</td>
<td>$5,150</td>
<td>$22,500</td>
<td></td>
</tr>
</tbody>
</table>

**Professional Services Fee Structure**

<table>
<thead>
<tr>
<th>Price</th>
</tr>
</thead>
<tbody>
<tr>
<td>$195.00</td>
</tr>
</tbody>
</table>

*Terms: Purchase Orders are required for each scheduled batch.*

- Invoice for vials produced will be sent upon shipment of materials. Payment due net 30 days.
- Delivery terms are FCA Enzon’s manufacturing facility in Indianapolis, IN
- Cancelled and postponed batches shall be billed in accordance with Section 3.4(d).
Exhibit D

Product Forecast

Savient has provided the following forecast for the 28 month period beginning October 2008.

(See following page.)

Commercial Supply Agreement
Execution Copy
Page 28 of 44
<table>
<thead>
<tr>
<th>YEAR</th>
<th>Delivery Month</th>
<th>Drug Product Supply - Batches</th>
<th>Reservation Fees</th>
<th>POs to be Submitted</th>
</tr>
</thead>
<tbody>
<tr>
<td>2008</td>
<td>October</td>
<td>0</td>
<td>$273,000.00</td>
<td></td>
</tr>
<tr>
<td></td>
<td>November</td>
<td>0</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>December</td>
<td>0</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>January</td>
<td>2</td>
<td>Oct-08</td>
<td></td>
</tr>
<tr>
<td></td>
<td>February</td>
<td>2</td>
<td>Nov-08</td>
<td></td>
</tr>
<tr>
<td></td>
<td>March</td>
<td>1</td>
<td>Dec-08</td>
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</tr>
<tr>
<td></td>
<td>April</td>
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<td>May</td>
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<td>June</td>
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<td>July</td>
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<td>August</td>
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<td>2009</td>
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<td></td>
<td>September</td>
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<tr>
<td>2010</td>
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<td>July</td>
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<tr>
<td></td>
<td>August</td>
<td>2</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>September</td>
<td>2</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Re: Second Amendment to Agreement for Services (“Agreement”) between Savient Pharmaceuticals, Inc. (“Savient”) and Enzon Pharmaceuticals, Inc. (“Enzon”) dated October 31, 2006 and as amended on June 15, 2007

Dear Mr. Puskar:

Pursuant to Section 13,01 of the Agreement, Savient and Enzon hereby agree to amend the Agreement by repealing Section 4: Confidentiality and replacing it as follows:

“4.01: For the duration of the Agreement and five (5) years thereafter with respect to Savient Confidential Information (as defined below), or, in the case of MVP Confidential Information (as defined below), for twenty (20) years from the Effective Date of the Agreement, Enzon will not disclose, without Savient’s written permission, any such Savient Confidential Information or MVP Confidential Information, unless such disclosure: (i) is to an affiliate, agent, employee or consultant of Enzon that is under a similar obligation to keep such information confidential and such disclosure is reasonably necessary for the performance of the Services contemplated herein; (ii) is or becomes publicly available through no fault of Enzon; (iii) is disclosed by a third party entitled to disclose it; (iv) is already known to Enzon as shown by its prior written records; or, (v) is required by any law, rule, regulation, order decision, decree, subpoena or other legal process to be disclosed or in response to a request or order from a regulatory agency. If such disclosure is requested by a regulatory agency or legal process, Enzon will make all reasonable efforts to notify Savient of this request promptly prior to any disclosure to permit Savient to oppose such disclosure by appropriate legal action. Enzon shall use reasonable precautions to protect the confidentiality of both Savient Confidential Information and MVP Confidential Information in a manner that is comparable to precautions taken to protect its own proprietary information. As used herein, “MVP Confidential Information” means any Confidential Information that Savient provides, or has provided, to Enzon which is specifically identified in writing as containing Mountain View Pharmaceuticals, Inc.’s proprietary technology for the manufacture of PEGylated uricase

Cont.../…
(Puricase®/pegloticase), specifically including the documents referenced in the attached Schedule A, which the Parties have agreed to in a letter dated September 12, 2007, as containing Confidential Information belonging to Mountain View Pharmaceuticals, Inc; “Savient Confidential Information” means any Confidential Information provided by Savient to Enzon, with the sole exception of MVP Confidential Information, during the Term of the Agreement,

4.02 For the duration of the Agreement and five (5) years thereafter with respect to Savient Confidential Information, or in the case of MVP Confidential Information, for twenty (20) years from the Effective Date of the Agreement, Enzon will not use such Confidential Information except in connection with the performance of Services under the Agreement or any other Agreement between Savient and Enzon related to Savient’s PEGylated uricase (Puricase®/pegloticase) product and in particular represents and warrants that it will not utilize such Confidential Information in the manufacturing of any other product.

4.03 For twenty (20) years from the Effective Date of the Agreement, Savient will not disclose, without Enzon’s written permission, any Confidential Information belonging to Enzon which is provided to Savient by Enzon during the Term of the Agreement (“Enzon Confidential Information”) unless such disclosure: (i) is to an affiliate, agent, employee or consultant of Savient that is under a similar obligation to keep such information confidential; (ii) is or becomes publicly available through no fault of Savient; (iii) is disclosed by a third party entitled to disclose it; (iv) is already known to Savient as shown by its prior written records; or, (v) is required by any law, rule, regulation, order decision, decree, subpoena or other legal process to be disclosed or in response to a request or order from a regulatory agency. If such disclosure is requested by a regulatory agency or legal process, Savient will make all reasonable efforts to notify Enzon of this request promptly prior to any disclosure to permit Enzon to oppose such disclosure by appropriate legal action. Savient shall use reasonable precautions to protect the confidentiality of Enzon Confidential Information in a manner that is comparable to precautions taken to protect its own proprietary information.

4.04 If either Party shall be obliged to provide testimony or records pertaining to the Confidential Information provided by the other in any legal or administrative proceeding, then the Party which supplied the Confidential Information shall reimburse the other Party for its out-of-pocket costs therefore plus an hourly fee for its employees or representatives equal to the internal fully burdened costs of such employee or representative.
4.05. For both Parties, “Confidential Information” shall mean and include, without limitation, such types of information as:
inventions, methods, plans, processes, specifications, characteristics, raw data, analyses, equipment design, trade secrets, costs,
majoring, sales, and product performance information, including patents and patent applications, grant applications, notes, and
memoranda, whether in writing or presented, stored or maintained electronically, magnetically or by other means, which are
disclosed by the disclosing Party to the recipient Party in writing or in other tangible form and marked “confidential” or, if
disclosed orally (or in some other non-tangible form), are identified as confidential to the recipient Party in writing within sixty
(60) days of such disclosure; provided, however, that failure to reduce any verbal disclosure to writing shall not, in and of itself,
vitiate the confidential nature of such Confidential Information and provided, further, that for the purposes of this Agreement,
Confidential Information shall include any and all such information exchanged between the Parties prior to the effective date of this
Agreement pursuant to the Confidentiality Agreement between the Parties dated July 24, 2006.”

To signify your acceptance of this Amendment, kindly countersign and return one copy to my attention.

Should you have any questions, please do not hesitate to contact John Petrolino at (732) 565-4655.

Very truly yours,

/s/ Philip K. Yachmetz

Philip K. Yechmetz
Executive Vice President
Chief Business Officer

I hereby agree to the terms and conditions
contained herein.

Enzon Pharmaceuticals, Inc.

By: /s/ Ralph del Campo

Name: Ralph del Campo

Title: EVP Technical Operations

Date: 9/17/07
SCHEDULE A

List of Confidential Documents identified pursuant to
Section 4.01 of this Agreement in the letter of September 12, 2007

2. 03V715-2.pdf - Report on the validation of the KT Endotoxin method using a plate reader
3. 04-68-500.pdf SOP for the endotoxin method.
4. 04-68-275 - UV Activity Assay.
Quality Technical Agreement for:

PRODUCT:  Puricase® (PEG-Uricase)
DOSAGE/FORM:  8 mg/ml per vial

This Quality Agreement shall be read in conjunction with a commercial Supply Agreement between ENZON and SAVIENT ("Supply Agreement"), dated as of October 16, 2008 and is incorporated into the Supply Agreement. Capitalized terms not defined herein shall have the respective meanings set forth in the Supply Agreement. The effective date of this Quality Agreement shall be the Effective Date of the Supply Agreement.

This Quality Agreement defines the duties of ENZON and SAVIENT for the contract pharmaceutical manufacture of Product. In particular this Quality Agreement clearly states who is responsible for the cGMP aspects of manufacturing and specifies the way in which the Party releasing Product for sale ensures that the Product complies with the approved Product Specifications (defined below) and the Marketing Authorizations (defined below).

This Quality Agreement takes the form of a detailed checklist of all the activities associated with pharmaceutical production, analysis, release, and distribution. Responsibility for each activity is assigned to either ENZON or SAVIENT in the appropriate box in the Delegation Responsibility Checklist which follows.

In order to provide better quality assurance, ENZON will perform the activities defined herein in accordance with its Standard Operating Procedures (defined below) to the extent that a Standard Operating Procedure is applicable to such activity.

This Agreement is subject to the terms of the Supply Agreement. A breach of this Quality Agreement shall be deemed a breach of the Supply Agreement. In the event of a conflict between this Quality Agreement and the Supply Agreement, the Supply Agreement shall control.

This Quality Agreement is intended to comply with the guidance and directives set forth in the current versions and effective amendments of (I) FDA Guidance for Industry, Cooperative Manufacturing Arrangements for Licensed Biologics, August 1999; (ii) 21 CFR 210 & 211 and applicable portions of 21 CFR 600 through 610; and (iii) European Commission Directive 91/356 down the principles and guidelines of good manufacturing practice for medicinal Products for human use. This will be made accessible to relevant regulatory authorities if required by them.

[signature page follows]
The Parties have caused their duly authorized representatives to executed this Quality Agreement, effective as of October 16, 2008.

**SAVIENT PHARMACEUTICALS, Inc.**

<table>
<thead>
<tr>
<th>Signature</th>
<th>/s/ Robert Lamm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Printed Name</td>
<td>Robert Lamm</td>
</tr>
<tr>
<td>Title</td>
<td>SVP, QA, RA</td>
</tr>
<tr>
<td>Date</td>
<td>10/16/08</td>
</tr>
</tbody>
</table>

**ENZON PHARMACEUTICALS, Inc.**

<table>
<thead>
<tr>
<th>Signature</th>
<th>/s/ Christian W. Dreyer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Printed Name</td>
<td>Christian W. Dreyer</td>
</tr>
<tr>
<td>Title</td>
<td>V.P. QOP</td>
</tr>
<tr>
<td>Date</td>
<td>10/21/08</td>
</tr>
</tbody>
</table>
For purposes of this Quality Agreement, the following definitions shall apply:

A. “FDA” shall mean the United States Food and Drug Administration, and any successor entity thereto.

B. “Marketing Application” shall mean an application for Product marketing authorization which has not yet been approved by the FDA or other regulatory authority, including, without limitation, FDA New Drug Application, FDA Biologics License Application, and other similar marketing applications promulgated by regulatory authorities.

C. “Marketing Authorizations” shall mean any approved application for Product marketing authorization, including, without limitation, FDA New Drug Application, FDA Biologics License Application, and other similar marketing authorizations promulgated by international regulatory authorities.

D. “Process” or “Processing” shall mean the sterile compounding, filling, producing and/or packaging of the raw materials into Product in accordance with the Product Specifications and the terms and conditions set forth in the Supply Agreement and this Quality Agreement.

E. “Product Specifications” shall mean the procedures, requirements, specifications, standards, quality control testing, other data and scope of Supply related to the Product, as set forth in the Project Plan and/or attached hereto. ENZON shall not release Product if these parameters are not met and investigation shows the non-complying parameter to be a valid test result.

F. “Standard Operating Procedures” or “SOPS” shall mean the standard operating procedures in effect at ENZON which have been approved by ENZON Quality Assurance department and which are applicable to the Processing; provided that all Standard Operating Procedures applicable to the Processing or the Product shall also be approved by SAVIENT.

G. “Bulk Product” shall mean the bulk solution of methoxy-polyethylene glycol (m-PEG) conjugate of uricase supplied by Savient to Enzon pursuant to this agreement.

H. “Business Day” shall mean Monday through Friday excluding government holidays.

I. “Component” shall mean all packaging materials utilized during manufacture, including all primary and secondary packaging materials.

J. “Deviation” shall mean any planned or unplanned event or result that is different from the expected event or result defined in existing procedures or specifications.
K. “Filled Product” shall mean in-process sterile Product that has been filled into its final primary package for further labeling and packaging.

L. “Product” shall mean sterile Product in its final packaged and labeled form that is ready for disposition.

M. “Manufacture” shall mean finished drug Product pooling, filling, packaging, and associated in-process and stability testing, as applicable.

N. “Master Production Control Record (MPCR)” shall mean a master document that represents a detailed procedure and data record for the batch manufacturing process, pursuant to CFR 21 §211.186.

O. “Out of Specification (OOS)” shall mean any in-process, intermediate, or finished Product test result that is outside of acceptable ranges defined in approved specifications or analytical test methods.

P. “cGMPs” shall mean current good manufacturing practices as promulgated by the FDA under the United States Food, Drug, and Cosmetic Act, 21 C.F.R. Part 210 et seq., as amended from time to time, and the European Union.

The following Facilities shall be used by ENZON for Processing or provision of Supply (“Facilities”):

<table>
<thead>
<tr>
<th>Manufacturing, Packaging, Testing and Storage</th>
</tr>
</thead>
<tbody>
<tr>
<td>6925 Guion Rd.</td>
</tr>
<tr>
<td>Indianapolis, IN 46268</td>
</tr>
<tr>
<td>USA</td>
</tr>
</tbody>
</table>

Section 16. RESPONSIBILITY DELEGATION CHECKLIST

<table>
<thead>
<tr>
<th>RESPONSIBILITIES</th>
<th>SAVIENT</th>
<th>ENZON</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Regulatory Authorizations &amp; cGMP Compliance</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1.1 Maintain all licenses, registrations and other authorizations as are required to operate a cGMP pharmaceutical manufacturing facility under the Applicable Laws.</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>1.2 Maintain and operate the Facility in compliance with the cGMPs, Applicable Laws and all other Product-specific instructions and requirements agreed to by the Parties.</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>RESPONSIBILITIES</td>
<td>SAVIENT</td>
<td>ENZON</td>
</tr>
<tr>
<td>------------------</td>
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<td>-------</td>
</tr>
<tr>
<td>1.3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Process the Product in accordance with the cGMPs, Applicable Laws and all other Product-specific instructions and requirements agreed to by the Parties.</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>1.4</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prepare, maintain and update the Marketing Authorizations in accordance with cGMPs, Applicable Laws and all other Product-specific instructions and requirements agreed to by the Parties.</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>1.5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Provide ENZON with copies of those portions of the Marketing Applications which are applicable to the Processing, prior to submission of such Marketing Applications to the applicable regulatory authorities.</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>1.6</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Provide ENZON with copies of updates of those portions of the Marketing Authorizations which are applicable to the Processing, prior to submission of such Marketing Applications to the applicable regulatory authorities.</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>1.7</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Satisfy all drug listing filing requirements for all Product and packaging configurations processed at the Facilities.</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>1.8</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prepare and submit post-marketing annual reports to the FDA and other applicable regulatory authorities in accordance with cGMPs, Applicable Laws and all other Product-specific instructions and requirements agreed to by the Parties.</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>1.9</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| Provide SAVIENT within 30 business days of their request with the following information to be included in the post-marketing annual reports:  
  • Change control information for all changes implemented during the preceding year relating to the Product.  
  • Applicable Product test data submitted in accordance with the requirements of the Supply Agreement, including any non-conforming data. |         | X     |
| 1.10             |         |       |
| Conduct Annual Product Quality Review for the Product in accordance with cGMP’s, and Applicable Laws. |         | X     |
| 1.11             |         |       |
| Provide SAVIENT with the following information to be included in the Annual Product Quality Review:  
  • All requested data and information required per 21 CFR 211.180(e) |         | X     |
<table>
<thead>
<tr>
<th>RESPONSIBILITIES</th>
<th>SAVIENT</th>
<th>ENZON</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>2. Regulatory Actions &amp; Inspections</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.1 Promptly (within 24 hours of receiving notice) notify SAVIENT of any FDA or other regulatory authority (a) notice of inspection or inspection of the Facilities directly relating to the Product, or (b) inspection or investigation relating to the Product; and promptly (within 3 days) notify SAVIENT of any regulatory authority request for Product samples or Product batch records.</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>2.2 Promptly (within 24 hours of receiving notice) notify ENZON of any FDA or other regulatory authority inspection or investigation relating to the Product; and promptly (within 3 days) notify ENZON of any regulatory authority request for Product samples or Product batch records.</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>2.3 Provide SAVIENT copies of any FDA Form 483’s, warning letters or the like from applicable regulatory authorities within 30 days of receipt and copies of all subsequent response(s) relating to the Product or Quality Systems.</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>2.4 Approve inspection responses to observations relevant to Product.</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>2.5 Other than a request(s) delivered in conjunction with an inspection, notify the other Party of any requests for information, notices of violations or other communications from a regulatory authority relating directly to the Product produced at the Facility.</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td><strong>3. Specifications &amp; Change Control</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.1 Approve Product Specifications.</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>3.2 Assume primary responsibility for ensuring that all Specifications (including Product Specifications) and batch records that specifically relate to the manufacture and release of Product comply with relevant portions of the Marketing Applications and Marketing Authorizations, as amended from time to time.</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td></td>
<td>RESPONSIBILITIES</td>
<td>SAVIENT</td>
</tr>
<tr>
<td>---</td>
<td>------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
<td>---------</td>
</tr>
<tr>
<td>3.3</td>
<td>Assume secondary responsibility for ensuring that all Specifications (including Product Specifications) and batch records that specifically relate to the manufacture and release of Product comply with relevant portions of the Marketing Applications and Marketing Authorizations, as amended from time to time.</td>
<td></td>
</tr>
<tr>
<td>3.4</td>
<td>Submit any proposed changes to the Specifications to SAVIENT for review and approval, prior to the implementation of such changes by ENZON.</td>
<td></td>
</tr>
<tr>
<td>3.5</td>
<td>Submit any proposed changes to the Specifications to ENZON for review and comment, prior to the submission of any such changes by SAVIENT to the regulatory authorities.</td>
<td></td>
</tr>
<tr>
<td>3.6</td>
<td>Discuss and reach agreement with SAVIENT regarding any proposed changes to the Facilities or the Processing that may impact the Product, prior to implementation of such proposed changes.</td>
<td></td>
</tr>
<tr>
<td>3.7</td>
<td>Serve as sole communicator with regulatory authorities for the approval and any revisions of Product Specifications in the Market Applications and Marketing Authorizations.</td>
<td></td>
</tr>
</tbody>
</table>

4. Materials

4.1 | Maintain Bulk Product according to cGMPs and Applicable Laws                                                                                                                                                                                                                                                                                    |         | X     |
4.2 | Retain reference samples of Bulk Product, including samples for periodic re-tests, for 6 years beyond Product expiry date.                                                                                                                                                                                                                         |         | X     |
4.3 | Provide Bulk Product meeting the Specifications and cGMPs for manufacture, as well as a certificate of analysis for Bulk Product.                                                                                                                                                                                                                 |         | X     |
4.4 | Perform identification testing of Bulk Product.                                                                                                                                                                                                                                                                                                   |         | X     |
4.5 | Source and qualify raw materials (excluding Bulk Product) used in Processing.                                                                                                                                                                                                                                                                  |         | X     |
4.6 | Maintain Specifications for Components and procure, store, sample, test and release raw materials.                                                                                                                                                                                                                                            |         | X     |
4.7 | Audit suppliers that provide Components and Process Consumables used in Processing in accordance with applicable SOPs to ensure full compliance with cGMPs and Applicable Laws.                                                                                                                                                                      |         | X     |
| 4.8 | Store Bulk Product and Components in accordance with the Specifications, SOPs, cGMPs and Applicable Laws while at the Facilities. | X |
| 4.9 | Retain reference samples of raw materials in a quantity sufficient to perform periodic re-tests, for 1 year beyond Product expiry date in accordance with Specifications, SOPs, cGMPs and Applicable Laws. | X |
| 4.10 | Notify SAVIENT of intent to dispose of material retains. | X |
| 4.11 | At SAVIENT’s option, ship material retains to SAVIENT (at SAVIENT’s expense) or destroy. | X |
| 4.12 | Dispose of Product waste and any special waste related to the Processing of the Product in accordance with Applicable Laws. | X |

### 5. Production, Investigations & Validations

<p>| 5.1 | Provide personnel with appropriate education, training and/or experience for manufacturing, testing and disposition of Product that is suitable for human use, and for provision of Supply hereunder. | X |
| 5.2 | Provide premises that are maintained and able to meet design and cleanliness requirements in accordance with Applicable Laws and industry standards. | X |
| 5.3 | Test and maintain utilities and environment to the appropriate compendia or environmental standard to assure appropriateness for use in connection with Processing and the Product. | X |
| 5.4 | Maintain, qualify and validate the Facility, equipment, utilities (air and water) and processes associated with Processing the Product in accordance with Applicable Laws and industry standards. | X |
| 5.5 | Manufacture and test the Product at the Facilities in accordance with the Product master Production control record, the SOPs referenced therein, and the Specifications. | X |
| 5.6 | Perform visual inspection of finished Product in accordance with the Product master Production control record, the SOPs referenced therein, and the Specifications. | X |
| 5.7 | Label Product in accordance with the Product master Production control record, the SOPs referenced therein, and the Specifications. | X |</p>
<table>
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<tr>
<th>Section</th>
<th>Description</th>
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<tr>
<td>5.8</td>
<td>Prepare and approve all artwork, inserts, labeling and packaging in connection with the Product.</td>
</tr>
<tr>
<td>5.9</td>
<td>Package the Product in accordance with the Product master Production control record, the SOPs referenced therein, and the Specifications.</td>
</tr>
<tr>
<td><strong>RESPONSIBILITIES</strong></td>
<td><strong>SAVIENT</strong> <strong>ENZON</strong></td>
</tr>
<tr>
<td>5.10</td>
<td>Perform finished Product testing in accordance with the supply agreement and supply a certificate of analysis and a Certificate of Compliance to SAVIENT.</td>
</tr>
<tr>
<td>5.11</td>
<td>Final release Product in accordance with the Product Specifications.</td>
</tr>
<tr>
<td>5.12</td>
<td>Investigate, resolve and document deviations from the Master Production Control Record and OOS test results in accordance with the cGMPs. Investigations should be completed with 30 calendar days. Interim status reports must be provided to SAVIENT periodically in writing for investigations remaining open beyond 30 business days.</td>
</tr>
<tr>
<td>5.13</td>
<td>Obtain Quality Assurance approval of all investigations and corrective and preventive action plans.</td>
</tr>
<tr>
<td>5.14</td>
<td>Provide equipment maintained and able to meet design and cleanliness requirements in accordance with Applicable Laws and industry standards, as applicable.</td>
</tr>
<tr>
<td>5.15</td>
<td>Establish a validation master plan and maintain the validation program in accordance with plan requirements.</td>
</tr>
<tr>
<td>5.16</td>
<td>Prepare and execute all Product related validation protocols, and complete validation reports.</td>
</tr>
<tr>
<td>5.17</td>
<td>Review and approve validation protocols related to Product.</td>
</tr>
<tr>
<td>5.18</td>
<td>Provide Quality Assurance review and approval of all validation packages.</td>
</tr>
<tr>
<td>6.</td>
<td><strong>Audits</strong></td>
</tr>
<tr>
<td>6.1</td>
<td>SAVIENT will schedule and audit ENZON Facilities, records and documentation related to the Product manufactured by ENZON at a time mutually agreed by Enzon with a minimum advanced notice of 3 months and at a frequency of not more than once every 12 months. SAVIENT may request for-cause audits as needed.</td>
</tr>
<tr>
<td>6.2</td>
<td>Conduct internal audits of Facilities, processes and quality systems, in accordance with cGMPs and applicable SOPs.</td>
</tr>
</tbody>
</table>
6.3 SAVIENT shall provide ENZON with a written audit report containing audit observations within 30 business days of the audit.

6.4 ENZON will respond to Savient audit report in writing within 15 business days.

6.5 SAVIENT is entitled to inspect and audit suppliers, vendors and contractors used by ENZON in connection with the Product.

7. Lot Codes & Expiration Dating

7.1 Establish Product lot code.

7.2 Establish Product expiry dating as per approved Product License/Marketing Authorization.

8. Samples

8.1 Perform Product sampling in accordance with the Supply Agreement, cGMP’s, and as otherwise agreed to by the Parties in the master Production control record for the Product.

8.2 Retain Finished Product samples including Stability samples in accordance with cGMP’s and the Supply Agreement.

9. Testing & Analysis

9.1 Perform all applicable Product testing according to the Supply Agreement.

9.2 Track and investigate all deviations (including DOS’s) associated with the Product, and notify SAVIENT Quality and Manufacturing within 24 hours of discovery of any significant deviations (those that may affect the identity, strength, quality, or purity of the Product).

9.3 Notify ENZON of any Product recall that might be attributed to Processing the Product.

9.4 Notify SAVIENT Quality and Manufacturing via email within the business day followed by signed documents of any confirmed failure of the Product that might be attributed to Processing the Product.

10. Release

10.1 Provide initial QA disposition of Product to SAVIENT.

10.2 Provide final QA disposition of Product.

11. Records
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<th>Review and approve the executed batch records.</th>
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### Responsibilities

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<th>SAVIENT</th>
<th>ENZON</th>
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</table>

11.2 Provide the released, executed batch record documentation for each batch of Product, which shall include the following:
- A statement that the lot was manufactured, packaged and tested in accordance with cGMPs, identifies the master batch Record documents, and lists any incident reports and investigations associated with the batch.
- A certificate of analysis covering all regulatory authority and compendial tests, and a Certificate of Compliance.
- The signature of the QA Representative who released the batch.
- Copies of significant deviations (those that may materially affect the identify, strength, quality or purity of the Product).
- A list of other deviations that may affect the Product.
- A list of change control records that could impact the Product.
- Copies of summary Quality Assurance reviewed release test records.

11.3 Store the master record, batch records, manufacturing documentation and all other documentation related to the Product for the minimum period required by all Applicable Laws.

11.4 Provide copies of all documentation necessary for SAVIENT to respond to inquiries by regulatory authorities.

### Storage

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12.1 Store and ship the Bulk Product in accordance with the Bulk Product Specifications, SOPs, cGMPs and Applicable Laws until manufacture of the Product.

12.2 Receive and store the Bulk Product. Intermediates, and finished Product in accordance with the Specifications, SOPs, cGMPs and Applicable Laws pending release of the Product.

12.3 Provide written instructions for shipping prior to Product release and shipment.

### Safety

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13.1 Maintain safety/hazard and handling data on the Product and Bulk Product.
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<tr>
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<th>RESPONSIBILITIES</th>
<th>SAVIENT</th>
<th>ENZON</th>
</tr>
</thead>
<tbody>
<tr>
<td>13.2</td>
<td>Maintain safety/hazard and handling data on the raw materials.</td>
<td>X</td>
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<tr>
<td>14. Complaints</td>
<td></td>
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<tr>
<td>14.1</td>
<td>Upon request of SAVIENT, assist SAVIENT in investigating and resolving all medical, adverse events, and non-medical Product complaints.</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>14.2</td>
<td>Collect and log all information relating to Product complaints and adverse drug events.</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>14.3</td>
<td>Investigate all Product complaints and adverse drug events.</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>14.4</td>
<td>Issue all reports and conduct follow up corrective action relating to Product complaints and adverse drug events.</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>15. Recall, Field Alerts and Product Withdrawal</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>15.1</td>
<td>Inform the Quality Assurance contact from the other Party within 24 hours upon knowledge of all quality issues which might compromise the other Party’s quality requirements for Products already shipped, or about to be shipped.</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>15.2</td>
<td>Issue any decision to initiate Product recall or Product withdrawal.</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>15.3</td>
<td>Communicate decision to initiate Product recall to ENZON.</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>15.4</td>
<td>Notify appropriate regulatory authorities of any Product recall or Product withdrawal.</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>15.5</td>
<td>Manage any Product recall or Product withdrawal.</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>15.6</td>
<td>Reconcile returned Product following Product recall or Product withdrawal.</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>15.7</td>
<td>Issue and follow up on FDA Field Alerts (or other similar processes of other regulatory authorities).</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>15.8</td>
<td>Perform mock recall and recall effectiveness checks.</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>16. Quality Agreement Review</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>16.1</td>
<td>On an as-needed basis (or once every two years), conduct a review to ensure that the Quality Agreement is in alignment with the current scope of the Project Plan and the then-current Supply Agreement. Update by mutual agreement of the Parties (if necessary).</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>17. Key Contacts</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Commercial Supply Agreement
Execution Copy

Page 42 of 44
Either party may change the following contact information by issuing a memo to the other party. Each party shall attach the memo to this original signed agreement. The updated information shall be incorporated into the next controlled revision of this agreement.

Savient Pharmaceuticals Inc.

**For All Product Concerns:**
Savient Pharmaceutical’s Inc.
One Tower Center
14th Floor
East Brunswick, New Jersey 08816
USA

Enzon Pharmaceuticals, Inc.

**For Manufacturing, Quality Assurance and Quality Control:**
Enzon Pharmaceuticals, Inc.
6925 Guion Road
Indianapolis, Indiana 46268
USA

**For Regulatory Affairs:**
Enzon Pharmaceuticals, Inc.
685 Route 202/206
Bridgewater, New Jersey 08854
USA

**For Operations, Planning & Logistics:**
Enzon Pharmaceuticals, Inc.
685 Route 202/206
Bridgewater, New Jersey 08807
USA

<table>
<thead>
<tr>
<th>Enzon Contact</th>
<th>Name/Title</th>
<th>Phone</th>
<th>Fax</th>
<th>E-mail</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quality Assurance</td>
<td>Chris Dreyer, Vice President</td>
<td>317-347-2857</td>
<td>317-347-2883</td>
<td><a href="mailto:Chris.dreyer@enzon.com">Chris.dreyer@enzon.com</a></td>
</tr>
<tr>
<td></td>
<td>Quality Operations</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>QA – Product Release</td>
<td>Brendan O'Shaughnessy, Associate</td>
<td>317-347-2849</td>
<td>317-290-0075</td>
<td><a href="mailto:Brendan.OShaughnessy@enzon.com">Brendan.OShaughnessy@enzon.com</a></td>
</tr>
<tr>
<td></td>
<td>Director, QA</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Quality Control Lab</td>
<td>Hector Rosa, Director, Quality</td>
<td>317-612-2932</td>
<td>317-290-0075</td>
<td><a href="mailto:Hector.Rosa@enzon.com">Hector.Rosa@enzon.com</a></td>
</tr>
<tr>
<td>Operations</td>
<td>Control</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Regulatory Affairs</td>
<td>Thomas Eckhardt, Vice President, Regulatory Affairs</td>
<td>908-541-8734</td>
<td>732-980-4638</td>
<td><a href="mailto:Thomas.Eckhardt@enzon.com">Thomas.Eckhardt@enzon.com</a></td>
</tr>
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</tr>
<tr>
<td>Operations – Planning</td>
<td>Derek Kalinowski, Director, Planning &amp; Logistics</td>
<td>908-541-8633</td>
<td>908-541-8691</td>
<td><a href="mailto:Derek.Kalinowski@enzon.com">Derek.Kalinowski@enzon.com</a></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Savient Contact</th>
<th>Name/Title</th>
<th>Phone</th>
<th>Fax</th>
<th>E-mail</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quality Assurance</td>
<td>Robert Lamm, Ph.D Senior Vice President, QA</td>
<td>732-565-4667</td>
<td>732-418-1862</td>
<td><a href="mailto:rlarnm@savientpharma.com">rlarnm@savientpharma.com</a></td>
</tr>
<tr>
<td>Quality Assurance</td>
<td>Eric Nickerson Senior Director, QA</td>
<td>732-565-4759</td>
<td>732-418-1862</td>
<td><a href="mailto:enickerson@savientpharma.com">enickerson@savientpharma.com</a></td>
</tr>
<tr>
<td>QA — Product Release</td>
<td>Shelley Mahon Manager, QA</td>
<td>732-565-4657</td>
<td>732-418-1862</td>
<td><a href="mailto:smahon@savientpharma.com">smahon@savientpharma.com</a></td>
</tr>
<tr>
<td>Regulatory Affairs</td>
<td>Murad Husain Vice President Regulatory Affairs</td>
<td>732-565-4676</td>
<td>732-418-1862</td>
<td><a href="mailto:mhusain@savientpharma.com">mhusain@savientpharma.com</a></td>
</tr>
<tr>
<td>Manufacturing</td>
<td>Peter Clarke, Ph.D Vice President, Technical Operations</td>
<td>732-565-4703</td>
<td>732-418-1862</td>
<td><a href="mailto:pclarke@savientpharma.com">pclarke@savientpharma.com</a></td>
</tr>
<tr>
<td>Planning and Logistics</td>
<td>Gary Savvas Manager, Manufacturing and Logistics</td>
<td>732-565-4661</td>
<td>732-418-1862</td>
<td><a href="mailto:qsavvas@savientpharma.com">qsavvas@savientpharma.com</a></td>
</tr>
</tbody>
</table>
AMENDMENT NO. 1
TO
COMMERCIAL SUPPLY AGREEMENT
DATED OCTOBER 16, 2008

THIS AMENDMENT, effective as of Oct. 5, 2009, is entered into by and between SAVIENT PHARMACEUTICALS, INC. (“SAVIENT”), and ENZON PHARMACEUTICALS, INC. (“ENZON”) hereinafter collectively referred to as the “Parties.”

WHEREAS, the Parties have entered into a certain Commercial Supply Agreement (hereinafter referred to as the “Agreement”) with an effective date of October 16, 2008, which sets forth the terms and conditions for services performed by the Parties.

WHEREAS, the Parties wish to amend the payment structure outlined in the Agreement.

NOW, THEREFORE, notwithstanding anything to the contrary within the Agreement, for the duration of this Amendment set forth below, the parties hereby agree as follows:

• All payments under the Agreement are to be made as follows:
  - Savient shall pay the full amount for the Product upon Enzon’s receipt of Bulk Product.
  - Payment in full due “net 15 days” from bulk receipt. Packaging will occur at Savient’s instructions; final batch cost reconciliation will be calculated and billed at shipment (that payment also net 15 days.) Precise filling date will be confirmed by Enzon to accommodate Savient’s timelines.

• Upon FDA approval of a Biologics License Application for the Product, consistent with the original assumption of the Agreement, the Parties shall repeal this Amendment by signed mutual agreement and thereby revert to the original terms of the Agreement in full.

• A cancellation in Purchase Order or specific Product line after the Project is initiated will not result in a refund. All payments are considered final upon receipt.

Where there is any inconsistency between the provisions of the Agreement and the Amendment, the provisions of this Amendment shall prevail.

All remaining terms and conditions of the Statement shall remain unchanged and in full force and effect.

AGREED:

SAVIENT PHARMACEUTICALS, INC.

By: /s/Philip K. Yachmetz
    Philip K. Yachmetz
    EVP & Chief Business Officer
Date: 10/9 __________, 2009.

ENZON PHARMACEUTICALS, INC.

By: /s/Ralph del Campo
    Ralph del Campo
    EV, Technical Ops
Date: 10/5/09 __________, 2009.
<table>
<thead>
<tr>
<th>Service</th>
<th>Price</th>
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***Confidential Treatment Requested***
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***Confidential Treatment Requested***
Terms:
• Terms and conditions of the Commercial Supply Agreement dated October 16, 2008 and subsequent amendments apply (October 5, 2009 – Amendment No 1)
• Delivery terms are FCA Enzon’s Indianapolis, IN facility (Section 6.1)
• Purchase orders are required for all scheduled work
• Canceled or postponed batches will be billed in full. All payment are considered final

The Parties have caused their duly authorized representatives to execute this supplemental Exhibit C to the Commercial Manufacturing Agreement.

SAVIENT PHARMACEUTICALS, Inc.                        ENZON PHARMACEUTICALS, Inc.
/s/ Philip K. Yachmetz                                   /s/ Ralph del Campo
Signature                                                 Signature
Philip K. Yachmetz                                        Ralph del Campo
Printed Name                                              Title
SVP & General Counsel                                     EVP – Tech Ops
Title
10-26-09                                                  10/26/09
Date
This Amendment ("Amendment") is entered into as of July 29, 2014 (the "Effective Date"), by and between Sigma Tau PharmaSource, Inc., with its principal executive offices located at 6925 Guion Road, Indianapolis, IN, 46268 ("STPS") and Crealta Pharmaceuticals LLC with its principal executive offices located at 500 W. Silver Spring Drive, Suite K-200, Glendale, WI 53217 ("Crealta").

WHEREAS, STPS and Crealta are parties to a certain Commercial Supply Agreement dated October 16, 2008, (the "Agreement"); The parties desire to amend the Agreement to expand the scope of the Agreement. In consideration of the promises and of the mutual covenants and agreements set forth, the parties agree as follows:

1. **Recitals**. The following two recitals are hereby added to the RECITALS section of the Agreement:

   WHEREAS, on or about January 29, 2010, Enzon Pharmaceuticals, Inc. assigned its rights under this Agreement to Sigma-Tau PharmaSource, Inc. ("STPS");

   WHEREAS, on or about January 9, 2014, Savient Pharmaceuticals, Inc. assigned its rights under the Agreement to Crealta; and

2. **Terms and Conditions**. Except as herein amended, all other terms and conditions of Agreement shall remain unchanged and in full force and effect. All defined terms used and not otherwise defined in this Amendment have the meanings ascribed to such terms in the Agreement. This Amendment may only be modified by a written document, signed by both parties. This Amendment may be executed in counterparts, each of which is an original, but all of which together constitute one and the same instrument. The terms and conditions of this Amendment and any Exhibits are incorporated into and made a part of the Agreement.

3. Section 2.4 of the Agreement is deleted in its entirety and replaced with the following:

   STPS shall provide Crealta, at no additional charge, product support services, at Crealta’s reasonable request, for the activities listed below:

   - Meetings with Regulatory Authorities, whether in person or by phone
   - Routine documentation provided to Regulatory Authorities on behalf of Crealta
   - Routine validation activities to support commercial production (e.g. Media fills, annual sterilization validations, or vial washing requalifications).
   - Annual product reviews for commercial products, as required by Regulatory Authorities.
   - All audit correspondence including Crealta-requested revisions to STPS’s audit response.
   - Preparation of documents in anticipation of a Pre-Approval Inspection.
   - Letters of reference from STPS or STPS’s vendors that are requested by Crealta (e.g., Master file reference letters, rubber or glass vendor letters).
   - Documentation provided to Regulatory Authorities on behalf of Crealta, other than routine documentation.
   - All time used for collecting and photocopying Crealta documentation.
   - Changes and revisions to artwork mandated by Regulatory Authorities or requested by Crealta.
   - Batch storage.
Crealta may request from STPS other product support services at its customary rate, as set forth on Exhibit C, including but not limited to:

- Any additional validation work requested by Crealta beyond original Work Plan or outside current validation requirements.
- Any analytical development and/or analyses beyond original Work Plan.

For all requests under this Section 2.4, Crealta shall provide STPS a written request for product support services that describes the required services and/or documents/work product required. STPS shall provide Crealta an estimate based on its customary rate. Upon acceptance of such estimate by Crealta, Crealta shall issue a purchase order to STPS and STPS shall perform such services in accordance with the terms hereof.

4. The first 2 sentences of Section 7.2 shall be deleted in their entirety and replaced with the following:

Subsequent to the first (1st) anniversary of the Effective Date of this Agreement, this Agreement may be terminated by either party at any time by giving at least thirty-six (36) months prior written notice to the other party as follows: either party may give notice to the other party thirty (30) days prior to every such anniversary date. During the 36-month period between the notice of termination and the effectiveness of such termination, the Parties shall continue to cooperate with each other in good faith to effectuate the purpose of this Agreement; specifically, and without limitation, Crealta may place, and STPS shall accept and fulfill, forecasts and purchase orders for the manufacture of Product, all in accordance with the terms and conditions of this Agreement.

5. Section 14.1 is deleted in its entirety and replaced with the following:

All administrative communications provided for in this Agreement shall be sent via first class mail (subject to Section 14.2 below), postage prepaid, addressed to the respective parties as follows:

**To STPS:**

Sigma-Tau PharmaSource, Inc.
6925 Guion Rd.
Indianapolis, IN 46268

With a Copy to:
Sigma-Tau Pharmaceuticals, Inc.
Attn: Legal Dept.
9841 Washingtonian Blvd., Suite 500
Gaithersburg, MD 20878

**To Crealta:**

Crealta Pharmaceuticals LLC
Attn: Richard Crowley
150 S. Saunders Rd., Suite 130
Lake Forest, IL 60045

With a Copy to:
Crealta Pharmaceuticals LLC
Attn: Edward Donovan
150 S. Saunders Rd., Suite 130
Lake Forest, IL 60045

6. Exhibit C of the Agreement is deleted in its entirety and replaced with Attachment 1 of this Amendment.

7. Exhibit F is deleted in its entirety and incorporates by reference with the Quality Agreement between the Parties dated October 16, 2008. Such new version is the new Exhibit F, which supersedes all prior versions of such Quality Agreement.
8. The parties acknowledge that the revised pricing reflected herein is reasonable as of the Effective Date of this Amendment and that current business conditions, as of the Effective Date, with respect thereto do not warrant any adjustment to the prices set forth herein pursuant to the second sentence of Section 4.3. Notwithstanding the foregoing, nothing in this Section 8 of this Amendment shall alter, modify, diminish, or otherwise affect any of the Parties’ rights under Section 4.3 of the Agreement.

The parties have executed this Amendment to be effective as of the Effective Date.

Sigma-Tau PharmaSource, Inc.

By: /s/ Dave Lemus
Name: Dave Lemus
Title: President
Date: 9-22-14

Crealta Pharmaceuticals LLC

By: /s/ Richard Crowley
Name: Richard Crowley
Title: Senior VP, Operations & QA
Date: September 9, 2014
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***Confidential Treatment Requested

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Terms: Purchase Orders are required for each scheduled batch.

- Invoice for vials produced will be sent upon shipment of materials. Payment due Net 30 days.
- Delivery terms are FCA STPS’s manufacturing facility in Indianapolis, IN
- Cancelled and postponed batches shall be billed in accordance with Section 3.4(d)

STPS and Crealta agree that the total price (costs, fees, and incentives, if any) for all work provided for under the Agreement, including the work authorized under this Amendment, shall not exceed the new total contract price. All invoices must be presented to Company no later than 120 days after the completion of services.
Certification of Principal Executive Officer

I, Timothy P. Walbert, certify that:

1. I have reviewed this Amendment No. 1 to the annual report on Form 10-K/A of Horizon Pharma plc; and

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report.

Date: May 26, 2017

/s/ Timothy P. Walbert

Timothy P. Walbert
Chairman, President and Chief Executive Officer
(Principal Executive Officer)
Certification of Principal Financial Officer

I, Paul W. Hoelscher, certify that:

1. I have reviewed this Amendment No. 1 to the annual report on Form 10-K/A of Horizon Pharma plc; and

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report.

Date: May 26, 2017

/s/ Paul W. Hoelscher
Paul W. Hoelscher
Executive Vice President, Chief Financial Officer
(Principal Financial Officer)