UNITED STATES SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

AMENDMENT NO. 3
TO
FORM S-1
REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933

HORIZON PHARMA, INC.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of incorporation or organization)

2834
(Primary Standard Industrial Classification Code Number)

27-2179987
(I.R.S. Employer Identification Number)

1033 Skokie Boulevard, Suite 355 Northbrook, Illinois 60062
(224) 383-3000
(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Timothy P. Walbert
Chairman, President and Chief Executive Officer
Horizon Pharma, Inc.
1033 Skokie Boulevard, Suite 355 Northbrook, Illinois 60062
(224) 383-3000
(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:
Lynda Kay Chandler, Esq.
Barbara L. Borden, Esq.
Cooley LLP
4401 Eastgate Mall
San Diego, California 92121
(858) 550-6000

Cheston J. Larson, Esq.
Divakar Gupta, Esq.
Matthew T. Bush, Esq.
Latham & Watkins LLP
12636 High Bluff Drive Suite 400
San Diego, California 92130
(858) 523-5400

Approximate date of commencement of proposed sale to the public:
As soon as practicable after the effective date of this registration statement.

If any of the securities being registered on this form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, as amended (the “Securities Act”), check the following box. ☐

If this form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of “large accelerated filer,” “accelerated filer” and “smaller reporting company” in Rule 12b-2 of the Exchange Act. (Check one):
Large accelerated filer ☐ Accelerated filer ☐ Non-accelerated filer ☐ Smaller reporting company ☐
(Do not check if a smaller reporting company)

CALCULATION OF REGISTRATION FEE

<table>
<thead>
<tr>
<th>Title of each class of securities to be registered</th>
<th>Proposed maximum aggregate offering price(1)</th>
<th>Amount of registration fee</th>
</tr>
</thead>
<tbody>
<tr>
<td>Common Stock, $0.0001 par value per share</td>
<td>$86,250,000</td>
<td>$6,149.63(2)</td>
</tr>
</tbody>
</table>

(1) Estimated solely for the purpose of calculating the amount of the registration fee in accordance with Rule 457(o) under the Securities Act of 1933, as amended. Includes the offering price of shares that the underwriters have the option to purchase to cover overallocations, if any.

(2) Previously paid.

The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment that specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, as amended, or until the registration statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.
Horizon Pharma, Inc. has prepared this Amendment No. 3 to the Registration Statement on Form S-1 (File No. 333-168504) for the purpose of filing Exhibit 3.5 and re-filing Exhibits 10.7, 10.8, 10.10, 10.11, 10.12, 10.14, 10.16, 10.17, 10.19, 10.21, 10.25 and 10.26 to the Registration Statement and updating Item 16 of the Registration Statement and the Exhibit Index accordingly. This Amendment No. 3 does not modify any provision of the Prospectus that forms a part of the Registration Statement and accordingly such Prospectus has not been included herein.
Information not Required in Prospectus

Item 13. Other expenses of issuance and distribution.

The following table sets forth all costs and expenses, other than underwriting discounts and commissions, paid or payable by us in connection with the sale of the common stock being registered. All amounts shown are estimates except for the Securities and Exchange Commission, or SEC, registration fee, the Financial Industry Regulatory Authority, Inc., or FINRA, filing fee and the listing fee for The NASDAQ Global Market.

<table>
<thead>
<tr>
<th>Amount Paid or to be Paid</th>
<th>Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>SEC registration fee</td>
<td>$6,150</td>
</tr>
<tr>
<td>FINRA filing fee</td>
<td>$9,125</td>
</tr>
<tr>
<td>The NASDAQ Global Market listing fee</td>
<td>$125,000</td>
</tr>
<tr>
<td>Blue sky qualification fees and expenses</td>
<td>*</td>
</tr>
<tr>
<td>Printing and engraving expenses</td>
<td>*</td>
</tr>
<tr>
<td>Legal fees and expenses</td>
<td>*</td>
</tr>
<tr>
<td>Accounting fees and expenses</td>
<td>*</td>
</tr>
<tr>
<td>Transfer agent and registrar fees and expenses</td>
<td>*</td>
</tr>
<tr>
<td>Miscellaneous expenses</td>
<td>*</td>
</tr>
<tr>
<td>Total</td>
<td>*</td>
</tr>
</tbody>
</table>

* to be provided by amendment


We are incorporated under the laws of the State of Delaware. Section 145 of the Delaware General Corporation Law provides that a Delaware corporation may indemnify any persons who are, or are threatened to be made, parties to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative (other than an action by or in the right of such corporation), by reason of the fact that such person was an officer, director, employee or agent of such corporation, or is or was serving at the request of such corporation as an officer, director, employee or agent of another corporation or enterprise. The indemnity may include expenses (including attorneys’ fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by such person in connection with such action, suit or proceeding, provided that such person acted in good faith and in a manner he or she reasonably believed to be in or not opposed to the corporation’s best interests and, with respect to any criminal action or proceeding, had no reasonable cause to believe that his or her conduct was illegal. A Delaware corporation may indemnify any persons who are, or are threatened to be made, a party to any threatened, pending or completed action or suit by or in the right of the corporation by reason of the fact that such person was a director, officer, employee or agent of such corporation, or is or was serving at the request of such corporation as a director, officer, employee or agent of another corporation or enterprise. The indemnity may include expenses (including attorneys’ fees) actually and reasonably incurred by such person in connection with the defense or settlement of such action or suit provided such person acted in good faith and in a manner he or she reasonably believed to be in or not opposed to the corporation’s best interests except that no indemnification is permitted without judicial approval if the officer or director is adjudged to be liable to the corporation. Where an officer or director is successful on the merits or otherwise in the defense of any action referred to above, the corporation must indemnify him or her against the expenses which such officer or director has actually and reasonably incurred. Our amended and restated certificate of incorporation and amended and restated bylaws, each of which will become effective upon the completion of this offering, provide for the indemnification of our directors and officers to the fullest extent permitted under the Delaware General Corporation Law.
Section 102(b)(7) of the Delaware General Corporation Law permits a corporation to provide in its certificate of incorporation that a director of the corporation shall not be personally liable to the corporation or its stockholders for monetary damages for breach of fiduciary duties as a director, except for liability for any:

- transaction from which the director derives an improper personal benefit;
- act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- unlawful payment of dividends or redemption of shares; or
- breach of a director’s duty of loyalty to the corporation or its stockholders.

Our amended and restated certificate of incorporation and amended and restated bylaws include such a provision. Expenses incurred by any officer or director in defending any such action, suit or proceeding in advance of its final disposition shall be paid by us upon delivery to us of an undertaking, by or on behalf of such director or officer, to repay all amounts so advanced if it shall ultimately be determined that such director or officer is not entitled to be indemnified by us.

Section 174 of the Delaware General Corporation Law provides, among other things, that a director who willfully or negligently approves of an unlawful payment of dividends or an unlawful stock purchase or redemption may be held liable for such actions. A director who was either absent when the unlawful actions were approved, or dissented at the time, may avoid liability by causing his or her dissent to such actions to be entered in the books containing minutes of the meetings of the board of directors at the time such action occurred or immediately after such absent director receives notice of the unlawful acts.

As permitted by the Delaware General Corporation Law, we have entered into indemnity agreements with each of our directors and executive officers, that require us to indemnify such persons against any and all expenses (including attorneys’ fees), witness fees, damages, judgments, fines, settlements and other amounts incurred (including expenses of a derivative action) in connection with any action, suit or proceeding, whether actual or threatened, whether or not such a claim is covered by insurance obtained by us, to which any such person may be made a party by reason of the fact that such person is or was a director, an officer or an employee of Horizon or any of its affiliated enterprises, provided that such person acted in good faith and in a manner such person reasonably believed to be in or not opposed to our best interests and, with respect to any criminal proceeding, had no reasonable cause to believe his or her conduct was unlawful. The indemnification agreements also set forth certain procedures that will apply in the event of a claim for indemnification thereunder.

At present, there is no pending litigation or proceeding involving any of our directors or executive officers as to which indemnification is required or permitted, and we are not aware of any threatened litigation or proceeding that may result in a claim for indemnification.

We have an insurance policy covering our officers and directors with respect to certain liabilities, including liabilities arising under the Securities Act of 1933, as amended, or the Securities Act, or otherwise.

We have entered into an underwriting agreement which provides that the underwriters are obligated, under some circumstances, to indemnify our directors, officers and controlling persons against specified liabilities, including liabilities under the Securities Act.

Reference is made to the following documents filed as exhibits to this registration statement regarding relevant indemnification provisions described above and elsewhere herein:

<table>
<thead>
<tr>
<th>Exhibit Document</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Form of Underwriting Agreement.</td>
<td>1.1</td>
</tr>
<tr>
<td>Form of Amended and Restated Certificate of Incorporation to be effective upon completion of this offering.</td>
<td>3.3</td>
</tr>
<tr>
<td>Form of Amended and Restated Bylaws to be effective upon completion of this offering.</td>
<td>3.5</td>
</tr>
<tr>
<td>Form of Indemnity Agreement.</td>
<td>10.1</td>
</tr>
</tbody>
</table>
Item 15. Recent sales of unregistered securities.

The following list sets forth information regarding all securities sold by us in the three years preceding the filing of this Registration Statement:

(1) In December 2007, Horizon Pharma USA, Inc. entered into a loan and security agreement with Comerica Bank, or Comerica, and Hercules Technology Growth Capital, Inc., or Hercules, pursuant to which it issued warrants to purchase 38,959 shares of its Series C preferred stock, with an initial exercise price of $14.22 per share. In April 2010, in connection with our recapitalization, these warrants became exercisable for 51,813 shares of our Series A preferred stock at an exercise price of $10.692 per share. Upon completion of this offering, these warrants will become exercisable for 51,813 shares of common stock at an exercise price of $10.692 per share.

(2) In July 2007, Horizon Pharma USA entered into a Series C Preferred Stock Purchase Agreement pursuant to which it issued and sold to accredited investors an aggregate of 2,109,706 shares of Series C preferred stock at a purchase price of $14.22 per share, for net proceeds of approximately $29.9 million. Of these 2,109,706 shares of Series C preferred stock issued, 17,580 shares were converted into Special preferred stock of Horizon Pharma USA in connection with the Series D financing described below. The remaining 2,092,126 shares of Series C preferred stock were converted into 2,782,448 shares of our Series A preferred stock, 555,080 shares of which are currently held in escrow, in connection with our recapitalization. Upon completion of this offering, those shares of Series A preferred stock will convert into an equal number of shares of our common stock. All of the 17,580 shares of Special preferred stock were converted into an equal number of shares of our common stock in connection with the recapitalization.

(3) Between October 2008 and November 2009, Horizon Pharma USA sold $17.0 million in aggregate principal amount of convertible promissory notes, or the bridge notes, and issued warrants, or the bridge warrants, exercisable for shares of Horizon Pharma USA’s capital stock to accredited investors in four tranches. The bridge notes accrued interest at 8% per year and were convertible into shares of Horizon Pharma USA’s preferred stock in the event Horizon Pharma USA completed a preferred stock financing of at least $25.0 million, or convertible in the event of the sale of Horizon Pharma USA or in certain other circumstances. The bridge warrants were exercisable for a number of shares of capital stock of Horizon Pharma USA determined based on the number and type of shares into which the bridge notes were to be converted, with an initial exercise price of $5.201 per share. In connection with the Series D financing described below, the bridge notes converted into an aggregate of 3,440,463 shares of Series D preferred stock of Horizon Pharma USA and the bridge warrants became exercisable for an aggregate of 490,290 shares of Series D preferred stock of Horizon Pharma USA. These shares were converted into 3,440,463 shares of our Series A preferred stock, 686,349 shares of which are currently held in escrow, in connection with the recapitalization. In April 2010, in connection with our recapitalization, the bridge warrants became exercisable for 490,290 shares of our Series A preferred stock at an exercise price of $5.201 per share. Upon completion of this offering, these warrants will become exercisable for 490,290 shares of common stock at an exercise price of $10.692 per share.

(4) In November 2008, as consideration for increasing the loan amount under the loan and security agreement with Comerica and Hercules, Horizon Pharma USA issued warrants to purchase shares of its Series C preferred stock, with an initial exercise price of $14.22 per share. In April 2010, in connection with our recapitalization, these warrants became exercisable for an aggregate of 10,363 shares of our Series A preferred stock at an exercise price of $10.692 per share. Upon completion of this offering, these warrants will become exercisable for 10,363 shares of common stock at an exercise price of $10.692 per share.

(5) In December 2009, Horizon Pharma USA entered into a Series D Preferred Stock Purchase Agreement pursuant to which it issued and sold to accredited investors, in a series of closings between December 2009 and January 2010, an aggregate of 4,978,674 shares of Series D preferred stock at a purchase price of $5.201 per share, for net proceeds of approximately $25.8 million. Of these 4,978,674 shares of Series D preferred stock issued, 3,440,463 shares were issued pursuant to the conversion of the bridge notes. All of the 4,978,674 shares of Series D preferred stock were converted into an equal number of shares of our Series A preferred stock, 993,211 shares of which are currently held in escrow, in connection with our recapitalization. Upon completion of this offering, these shares will convert into 4,978,674 shares of common stock.

(6) In April 2010, we completed our recapitalization and acquired Nitec Pharma AG, or Nitec (now Horizon Pharma AG), pursuant to a Share Exchange Agreement with Nitec, Horizon Pharma USA, Horizon MergerSub, Inc., the
shareholders of Nitec and their representative and certain stockholders of Horizon Pharma USA and their representative. In connection with the Nitec acquisition, we issued an aggregate of 2,035,494 shares of our common stock and an aggregate of 11,211,413 shares of our Series A preferred stock to Nitec shareholders in exchange for all of the capital stock of Nitec. In connection with our recapitalization, we issued an aggregate of 1,593,089 shares of our common stock and an aggregate of 11,239,887 shares of our Series A preferred stock to Horizon Pharma USA stockholders upon conversion of all outstanding shares of capital stock of Horizon Pharma USA. Upon completion of this offering, these shares will represent 25,989,883 shares of common stock.

(7) In April 2010, and concurrently with the recapitalization and Nitec acquisition, we entered into a Series B Preferred Stock and Subordinated Convertible Note Purchase Agreement pursuant to which we issued and sold to accredited investors, in a first closing, an aggregate of 2,510,040 shares of our Series B preferred stock at a purchase price of $7.968 per share, for aggregate consideration of approximately $20.0 million. Upon completion of this offering, these shares will convert into 2,510,040 shares of common stock.

(8) In April 2010, we issued a warrant to Kreos Capital III (UK) Limited, or Kreos, to purchase 118,496 shares of our Series A preferred stock at an initial exercise price of $0.01 per share, pursuant to a loan facility Nitec originally entered into with Kreos and which was subsequently amended in connection with the recapitalization and Nitec acquisition. Upon completion of this offering, the warrant will become exercisable for an aggregate of 118,496 shares of our common stock at an exercise price equal to $0.01 per share.

(9) In April 2010, in connection with a loan and security agreement we entered into with Silicon Valley Bank, Kreos, Horizon Pharma USA and Horizon Pharma AG, we issued a warrant to each of Silicon Valley Bank and Kreos to purchase 75,301 shares of our Series B preferred stock at an initial exercise price of $0.01 per share. Upon completion of this offering, the warrants will become exercisable for an aggregate of 150,602 shares of our common stock at an exercise price equal to $0.01 per share.

(10) In July 2010, pursuant to the Series B Preferred Stock and Subordinated Convertible Note Purchase Agreement we issued $10.0 million in aggregate principal amount of convertible promissory notes, or the 2010 notes, to accredited investors. The 2010 notes accrue interest at 10% per year. In the event the 2010 notes are not converted into shares of our Series B preferred stock or new equity securities prior to the completion of this offering, then the 2010 notes may be converted into 1,271,520 shares of common stock upon completion of this offering at the lesser of (i) the price per share to the public of our common stock sold in this offering or (ii) $7.968.

(11) From January 1, 2007 to June 30, 2010, we, along with Horizon Pharma USA, granted stock options under our 2005 Stock Plan to purchase 3,145,866 shares of common stock (net of expirations and cancellations) to our employees, directors and consultants, having exercise prices ranging from $2.19 to $12.14 per share. Of these, no options to purchase shares of common stock have been exercised through June 30, 2010. The offers, sales and issuances of the securities described in paragraphs (1), (2), (3), (4), (5), (7), (8), (9) and (10) were deemed to be exempt from registration under the Securities Act in reliance on Rule 506 of Regulation D in that the issuance of securities to the accredited investors did not involve a public offering. The recipients of securities in each of these transactions acquired the securities for investment only and not with a view to or for sale in connection with any distribution thereof and appropriate legends were affixed to the securities issued in these transactions. Each of the recipients of securities in these transactions was an accredited investor under Rule 501 of Regulation D.

The offers, sales and issuances of the securities described in the first closing of the Series B Preferred Stock and Subordinated Convertible Note Purchase Agreement were deemed to be exempt from registration under the Securities Act in reliance on Rule 506 of Regulation D in that the issuance of securities to the accredited investors did not involve a public offering and Regulation S in that the issuance of securities to non-U.S. persons were made pursuant to an offshore transaction, and no directed selling efforts were made in the United States. Each of the recipients of securities in these transactions was an accredited investor under Rule 501 of Regulation D who acquired the securities for investment only and not with a view to or for sale in connection with any distribution thereof, or a non-U.S. person under Rule 902 of Regulation S. Appropriate legends were affixed to the securities issued in the transaction.

The offers, sales and issuances of the securities described in paragraph (11) were deemed to be exempt from registration under the Securities Act in reliance on Rule 701 in that the transactions were under compensatory benefit plans and contracts relating to compensation as provided under Rule 701. The recipients of such securities were our employees, directors or bona fide consultants and received the securities under our 2005 Stock Plan. Appropriate legends were affixed to the securities issued in these transactions. Each of the recipients of securities in these transactions had adequate access, through employment, business or other relationships, to information about us.
**Item 16. Exhibits and financial statement schedules.**

**(a) Exhibits.**

<table>
<thead>
<tr>
<th>Exhibit Number</th>
<th>Description of Document</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.1†</td>
<td>Form of Underwriting Agreement.</td>
</tr>
<tr>
<td>3.1(1)</td>
<td>Amended and Restated Certificate of Incorporation, as currently in effect.</td>
</tr>
<tr>
<td>3.2(1)</td>
<td>Certificate of Amendment to Amended and Restated Certificate of Incorporation, as currently in effect.</td>
</tr>
<tr>
<td>3.3†</td>
<td>Form of Amended and Restated Certificate of Incorporation to be effective upon completion of this offering.</td>
</tr>
<tr>
<td>3.4(1)</td>
<td>Bylaws, as currently in effect.</td>
</tr>
<tr>
<td>3.5</td>
<td>Form of Amended and Restated Bylaws to be effective upon completion of this offering.</td>
</tr>
<tr>
<td>4.1†</td>
<td>Form of Common Stock Certificate.</td>
</tr>
<tr>
<td>4.2(1)</td>
<td>Form of Warrant issued by Registrant to bridge financing investors.</td>
</tr>
<tr>
<td>4.3(1)</td>
<td>Warrant issued by Registrant on December 18, 2007 to Comerica Bank.</td>
</tr>
<tr>
<td>4.4(1)</td>
<td>Warrant issued by Registrant on December 18, 2007 to Hercules Technology Growth Capital, Inc.</td>
</tr>
<tr>
<td>4.6(1)</td>
<td>Warrant issued by Registrant on November 21, 2008 to Hercules Technology Growth Capital, Inc.</td>
</tr>
<tr>
<td>4.7(1)</td>
<td>Warrant issued by Registrant on April 1, 2010 to Kreos Capital III Limited.</td>
</tr>
<tr>
<td>4.8(1)</td>
<td>Warrant issued by Registrant on April 1, 2010 to Kreos Capital III Limited.</td>
</tr>
<tr>
<td>4.9(1)</td>
<td>Warrant issued by Registrant on April 1, 2010 to Silicon Valley Bank.</td>
</tr>
<tr>
<td>4.10(1)</td>
<td>Investors’ Rights Agreement, dated April 1, 2010, by and among the Registrant and certain of its stockholders.</td>
</tr>
<tr>
<td>5.1†</td>
<td>Opinion of Cooley LLP.</td>
</tr>
<tr>
<td>10.1(1)</td>
<td>Form of Indemnity Agreement.</td>
</tr>
<tr>
<td>10.2+(1)</td>
<td>2005 Stock Plan and Form of Stock Option Agreement thereunder.</td>
</tr>
<tr>
<td>10.3+†</td>
<td>2010 Equity Incentive Plan and Form of Stock Option Agreement thereunder.</td>
</tr>
<tr>
<td>10.4+†</td>
<td>2010 Employee Stock Purchase Plan and Form of Offering Document thereunder.</td>
</tr>
<tr>
<td>10.5(1)</td>
<td>Loan and Security Agreement, dated April 1, 2010, among the Registrant, Horizon Pharma AG, Kreos Capital III (UK) Limited and Silicon Valley Bank.</td>
</tr>
<tr>
<td>10.6(1)</td>
<td>Agreement for the Provision of a Loan Facility of up to Euro 7,500,000, dated August 15, 2008, by and between Horizon Pharma AG and Kreos Capital III (UK) Limited.</td>
</tr>
<tr>
<td>10.7</td>
<td>First Amendment to Agreement for the Provision of a Loan Facility of up to Euro 7,500,000, dated April 1, 2010, by and between Horizon Pharma AG and Kreos Capital III (UK) Limited.</td>
</tr>
<tr>
<td>10.8*</td>
<td>Development and License Agreement, dated August 20, 2004, by and among Horizon Pharma AG, Jagotec AG and SkyePharma AG.</td>
</tr>
<tr>
<td>10.9*(1)</td>
<td>Amendment to Development and License Agreement, dated August 3, 2007, by and among Horizon Pharma AG, Jagotec AG and SkyePharma AG.</td>
</tr>
<tr>
<td>10.10*</td>
<td>Manufacturing and Supply Agreement, dated August 3, 2007, by and between Horizon Pharma AG and Jagotec AG.</td>
</tr>
</tbody>
</table>

II-5
<table>
<thead>
<tr>
<th>Exhibit Number</th>
<th>Description of Document</th>
</tr>
</thead>
<tbody>
<tr>
<td>10.11*</td>
<td>Technology Transfer Agreement, dated August 2, 2004, by and among Horizon Pharma AG, Horizon Pharma GmbH and Merck KgaA.</td>
</tr>
<tr>
<td>10.12*</td>
<td>Transfer, License and Supply Agreement, dated December 19, 2006, by and among Horizon Pharma AG, Horizon Pharma GmbH and Merck Serono GmbH.</td>
</tr>
<tr>
<td>10.13*(1)</td>
<td>Amendment to Transfer, License and Supply Agreement, dated December 17, 2008, by and among Horizon Pharma AG, Horizon Pharma GmbH and Merck Serono GmbH.</td>
</tr>
<tr>
<td>10.14*</td>
<td>Transfer, License and Supply Agreement, dated March 26, 2009, by and among Horizon Pharma AG, Horizon Pharma GmbH and Merck GesmbH.</td>
</tr>
<tr>
<td>10.15+(1)</td>
<td>Form of Employee Proprietary Information and Inventions Agreement.</td>
</tr>
<tr>
<td>10.16*</td>
<td>Manufacturing and Supply Agreement, dated March 24, 2009, by and between Horizon Pharma AG and Mundipharma Medical Company.</td>
</tr>
<tr>
<td>10.18(1)</td>
<td>Amendment to Exclusive Distribution Agreement, dated July 7, 2009 by and between Horizon Pharma AG and Mundipharma International Corporation Limited.</td>
</tr>
<tr>
<td>10.19*</td>
<td>Technical Transfer Agreement, dated November 9, 2009, by and between Horizon Pharma USA, Inc. and sanofi-aventis U.S. LLC.</td>
</tr>
<tr>
<td>10.20*(1)</td>
<td>Sublease, dated April 21, 2009, by and between Horizon Pharma USA, Inc. and Advanced Personnel, Inc., as amended.</td>
</tr>
<tr>
<td>10.24+(1)</td>
<td>Amended and Restated Executive Employment Agreement, dated July 27, 2010, by and between Horizon Pharma, Inc., Horizon Pharma USA, Inc. and Jeffrey W. Sherman, M.D. FACP.</td>
</tr>
<tr>
<td>10.25*</td>
<td>Packaging and Supply Agreement, dated September 29, 2008, by and between Horizon Pharma AG and Catalent Schorndorf GmbH.</td>
</tr>
<tr>
<td>10.26*</td>
<td>Master Services Agreement, dated September 11, 2008, by and between Horizon Pharma USA, Inc. and Pharmaceutics International, Inc.</td>
</tr>
<tr>
<td>10.27+(1)</td>
<td>Severance Benefit Plan.</td>
</tr>
<tr>
<td>10.28+†</td>
<td>Non-Employee Director Compensation Policy.</td>
</tr>
<tr>
<td>10.29*(1)</td>
<td>Sales Contract, dated July 1, 2010, by and between Horizon Pharma USA, Inc. and BASF Corporation.</td>
</tr>
<tr>
<td>21.1(1)</td>
<td>Subsidiaries of the Registrant.</td>
</tr>
<tr>
<td>23.1(1)</td>
<td>Consent of PricewaterhouseCoopers LLP, independent registered public accounting firm.</td>
</tr>
<tr>
<td>23.2(1)</td>
<td>Consent of Ernst &amp; Young Ltd, independent registered public accounting firm.</td>
</tr>
<tr>
<td>23.3</td>
<td>Consent of Cooley LLP. Reference is made to Exhibit 5.1.</td>
</tr>
<tr>
<td>24.2(1)</td>
<td>Power of Attorney.</td>
</tr>
</tbody>
</table>

† To be filed by amendment.
+ Indicates management contract or compensatory plan.
* 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.
(1) Previously filed.
(b) Financial statement schedule.

No financial statement schedules are provided because the information called for is not required or is shown either in the consolidated financial statements or notes.

Item 17. Undertakings.

The undersigned Registrant hereby undertakes to provide to the underwriter at the closing specified in the underwriting agreement certificates in such denominations and registered in such names as required by the underwriter to permit prompt delivery to each purchaser.

Insofar as indemnification for liabilities arising under the Securities Act of 1933, as amended, or Securities Act, may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the Registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the Registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

The undersigned Registrant hereby undertakes that:

(1) For purposes of determining any liability under the Securities Act, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this Registration Statement as of the time it was declared effective.

(2) For the purpose of determining any liability under the Securities Act, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.
Signatures

Pursuant to the requirements of the Securities Act of 1933, as amended, or the Securities Act, the Registrant has duly caused this Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of San Diego, State of California, on the 21st day of October, 2010.

HORIZON PHARMA, INC.

By: /s/ TIMOTHY P. WALBERT
    Timothy P. Walbert
    Chief Executive Officer

Pursuant to the requirements of the Securities Act this Registration Statement has been signed by the following persons in the capacities and on the dates indicated.

<table>
<thead>
<tr>
<th>Signature</th>
<th>Title</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>/s/ TIMOTHY P. WALBERT</td>
<td>Chairman, President and Chief Executive Officer (Principal Executive Officer)</td>
<td>October 21, 2010</td>
</tr>
<tr>
<td>Timothy P. Walbert</td>
<td></td>
<td></td>
</tr>
<tr>
<td>/s/ ROBERT J. DE VAERE</td>
<td>Executive Vice President and Chief Financial Officer (Principal Financial and Accounting Officer)</td>
<td>October 21, 2010</td>
</tr>
<tr>
<td>Robert J. De Vaere</td>
<td></td>
<td></td>
</tr>
<tr>
<td>/s/ JEFFREY BIRD, M.D., PH.D.*</td>
<td>Director</td>
<td>October 21, 2010</td>
</tr>
<tr>
<td>Jeffrey Bird, M.D., Ph.D.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>/s/ HUBERT BIRNER, PH.D.*</td>
<td>Director</td>
<td>October 21, 2010</td>
</tr>
<tr>
<td>Hubert Birner, Ph.D.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>/s/ LOUIS C. BOCK*</td>
<td>Director</td>
<td>October 21, 2010</td>
</tr>
<tr>
<td>Louis C. Bock</td>
<td></td>
<td></td>
</tr>
<tr>
<td>/s/ JEAN-FRANÇOIS FORMELA, M.D.*</td>
<td>Director</td>
<td>October 21, 2010</td>
</tr>
<tr>
<td>Jean-François Formela, M.D.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>/s/ JEFF HIMAWAN, PH.D.*</td>
<td>Director</td>
<td>October 21, 2010</td>
</tr>
<tr>
<td>Jeff Himawan, Ph.D.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>/s/ PETER JOHANN*</td>
<td>Director</td>
<td>October 21, 2010</td>
</tr>
<tr>
<td>Peter Johann, Ph.D.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
* Pursuant to Power of Attorney

BY: ___________________________ /s/ TIMOTHY P. WALBERT
    Timothy P. Walbert
    Attorney-in-Fact
<table>
<thead>
<tr>
<th>Exhibit Number</th>
<th>Description of Document</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.1†</td>
<td>Form of Underwriting Agreement.</td>
</tr>
<tr>
<td>3.1(1)</td>
<td>Amended and Restated Certificate of Incorporation, as currently in effect.</td>
</tr>
<tr>
<td>3.2(1)</td>
<td>Certificate of Amendment to Amended and Restated Certificate of Incorporation, as currently in effect.</td>
</tr>
<tr>
<td>3.3†</td>
<td>Form of Amended and Restated Certificate of Incorporation to be effective upon completion of this offering.</td>
</tr>
<tr>
<td>3.4(1)</td>
<td>Bylaws, as currently in effect.</td>
</tr>
<tr>
<td>3.5</td>
<td>Form of Amended and Restated Bylaws to be effective upon completion of this offering.</td>
</tr>
<tr>
<td>4.1†</td>
<td>Form of Common Stock Certificate.</td>
</tr>
<tr>
<td>4.2(1)</td>
<td>Form of Warrant issued by Registrant to bridge financing investors.</td>
</tr>
<tr>
<td>4.3(1)</td>
<td>Warrant issued by Registrant on December 18, 2007 to Comerica Bank.</td>
</tr>
<tr>
<td>4.4(1)</td>
<td>Warrant issued by Registrant on December 18, 2007 to Hercules Technology Growth Capital, Inc.</td>
</tr>
<tr>
<td>4.6(1)</td>
<td>Warrant issued by Registrant on November 21, 2008 to Hercules Technology Growth Capital, Inc.</td>
</tr>
<tr>
<td>4.7(1)</td>
<td>Warrant issued by Registrant on April 1, 2010 to Kreos Capital III Limited.</td>
</tr>
<tr>
<td>4.8(1)</td>
<td>Warrant issued by Registrant on April 1, 2010 to Kreos Capital III Limited.</td>
</tr>
<tr>
<td>4.9(1)</td>
<td>Warrant issued by Registrant on April 1, 2010 to Silicon Valley Bank.</td>
</tr>
<tr>
<td>4.10(1)</td>
<td>Investors’ Rights Agreement, dated April 1, 2010, by and among the Registrant and certain of its stockholders.</td>
</tr>
<tr>
<td>5.1†</td>
<td>Opinion of Cooley LLP.</td>
</tr>
<tr>
<td>10.1(1)</td>
<td>Form of Indemnity Agreement.</td>
</tr>
<tr>
<td>10.2+(1)</td>
<td>2005 Stock Plan and Form of Stock Option Agreement thereunder.</td>
</tr>
<tr>
<td>10.3†</td>
<td>2010 Equity Incentive Plan and Form of Stock Option Agreement thereunder.</td>
</tr>
<tr>
<td>10.4†</td>
<td>2010 Employee Stock Purchase Plan and Form of Offering Document thereunder.</td>
</tr>
<tr>
<td>10.5(1)</td>
<td>Loan and Security Agreement, dated April 1, 2010, among the Registrant, Horizon Pharma AG, Kreos Capital III (UK) Limited and Silicon Valley Bank.</td>
</tr>
<tr>
<td>10.6(1)</td>
<td>Agreement for the Provision of a Loan Facility of up to Euro 7,500,000, dated August 15, 2008, by and between Horizon Pharma AG and Kreos Capital III (UK) Limited.</td>
</tr>
<tr>
<td>10.7</td>
<td>First Amendment to Agreement for the Provision of a Loan Facility of up to Euro 7,500,000, dated April 1, 2010, by and between Horizon Pharma AG and Kreos Capital III (UK) Limited.</td>
</tr>
<tr>
<td>10.8*</td>
<td>Development and License Agreement, dated August 20, 2004, by and among Horizon Pharma AG, Jagotec AG and SkyePharma AG.</td>
</tr>
<tr>
<td>10.9*(1)</td>
<td>Amendment to Development and License Agreement, dated August 3, 2007, by and among Horizon Pharma AG, Jagotec AG and SkyePharma AG.</td>
</tr>
<tr>
<td>Exhibit Number</td>
<td>Description of Document</td>
</tr>
<tr>
<td>---------------</td>
<td>-------------------------</td>
</tr>
<tr>
<td>10.10*</td>
<td>Manufacturing and Supply Agreement, dated August 3, 2007, by and between Horizon Pharma AG and Jagotec AG.</td>
</tr>
<tr>
<td>10.11*</td>
<td>Technology Transfer Agreement, dated August 2, 2004, by and among Horizon Pharma AG, Horizon Pharma GmbH and Merck KgaA.</td>
</tr>
<tr>
<td>10.12*</td>
<td>Transfer, License and Supply Agreement, dated December 19, 2006, by and among Horizon Pharma AG, Horizon Pharma GmbH and Merck Serono GmbH.</td>
</tr>
<tr>
<td>10.13*(1)</td>
<td>Amendment to Transfer, License and Supply Agreement, dated December 17, 2008, by and among Horizon Pharma AG, Horizon Pharma GmbH and Merck Serono GmbH.</td>
</tr>
<tr>
<td>10.14*</td>
<td>Transfer, License and Supply Agreement, dated March 26, 2009, by and among Horizon Pharma AG, Horizon Pharma GmbH and Merck GesmbH.</td>
</tr>
<tr>
<td>10.15+(1)</td>
<td>Form of Employee Proprietary Information and Inventions Agreement.</td>
</tr>
<tr>
<td>10.16*</td>
<td>Manufacturing and Supply Agreement, dated March 24, 2009, by and between Horizon Pharma AG and Mundipharma Medical Company.</td>
</tr>
<tr>
<td>10.18(1)</td>
<td>Amendment to Exclusive Distribution Agreement, dated July 7, 2009 by and between Horizon Pharma AG and Mundipharma International Corporation Limited.</td>
</tr>
<tr>
<td>10.19*</td>
<td>Technical Transfer Agreement, dated November 9, 2009, by and between Horizon Pharma USA, Inc. and sanofi-aventis U.S. LLC.</td>
</tr>
<tr>
<td>10.20*(1)</td>
<td>Sublease, dated April 21, 2009, by and between Horizon Pharma USA, Inc. and Advanced Personnel, Inc., as amended.</td>
</tr>
<tr>
<td>10.24+(1)</td>
<td>Amended and Restated Executive Employment Agreement, dated July 27, 2010, by and between Horizon Pharma, Inc., Horizon Pharma USA, Inc. and Jeffrey W. Sherman, M.D. FACP.</td>
</tr>
<tr>
<td>10.25*</td>
<td>Packaging and Supply Agreement, dated September 29, 2008, by and between Horizon Pharma AG and Catalent Schorndorf GmbH.</td>
</tr>
<tr>
<td>10.26*</td>
<td>Master Services Agreement, dated September 11, 2008, by and between Horizon Pharma USA, Inc. and Pharmaceutics International, Inc.</td>
</tr>
<tr>
<td>10.27+(1)</td>
<td>Severance Benefit Plan.</td>
</tr>
<tr>
<td>10.28†</td>
<td>Non-Employee Director Compensation Policy.</td>
</tr>
<tr>
<td>10.29*(1)</td>
<td>Sales Contract, dated July 1, 2010, by and between Horizon Pharma USA, Inc. and BASF Corporation.</td>
</tr>
<tr>
<td>21.1(1)</td>
<td>Subsidiaries of the Registrant.</td>
</tr>
<tr>
<td>23.1(1)</td>
<td>Consent of PricewaterhouseCoopers LLP, independent registered public accounting firm.</td>
</tr>
<tr>
<td>23.2(1)</td>
<td>Consent of Ernst &amp; Young Ltd, independent registered public accounting firm.</td>
</tr>
<tr>
<td>23.3</td>
<td>Consent of Cooley LLP. Reference is made to Exhibit 5.1.</td>
</tr>
<tr>
<td>24.2(1)</td>
<td>Power of Attorney.</td>
</tr>
</tbody>
</table>

† To be filed by amendment.
+ Indicates management contract or compensatory plan.
* 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.
(1) Previously filed.
AMENDED AND RESTATED BYLAWS
OF
HORIZON PHARMA, INC.
(A DELAWARE CORPORATION)
**TABLE OF CONTENTS**

<table>
<thead>
<tr>
<th>ARTICLE I</th>
<th>OFFICES</th>
<th>PAGE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Section 1.</td>
<td>Registered Office</td>
<td>1</td>
</tr>
<tr>
<td>Section 2.</td>
<td>Other Offices</td>
<td>1</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>ARTICLE II</th>
<th>CORPORATE SEAL</th>
<th>PAGE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Section 3.</td>
<td>Corporate Seal</td>
<td>1</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>ARTICLE III</th>
<th>STOCKHOLDERS’ MEETINGS</th>
<th>PAGE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Section 4.</td>
<td>Place Of Meetings</td>
<td>1</td>
</tr>
<tr>
<td>Section 5.</td>
<td>Annual Meetings</td>
<td>1</td>
</tr>
<tr>
<td>Section 6.</td>
<td>Special Meetings</td>
<td>6</td>
</tr>
<tr>
<td>Section 7.</td>
<td>Notice Of Meetings</td>
<td>7</td>
</tr>
<tr>
<td>Section 8.</td>
<td>Quorum</td>
<td>8</td>
</tr>
<tr>
<td>Section 9.</td>
<td>Adjournment And Notice Of Adjourned Meetings</td>
<td>8</td>
</tr>
<tr>
<td>Section 10.</td>
<td>Voting Rights</td>
<td>8</td>
</tr>
<tr>
<td>Section 11.</td>
<td>Joint Owners Of Stock</td>
<td>9</td>
</tr>
<tr>
<td>Section 12.</td>
<td>List Of Stockholders</td>
<td>9</td>
</tr>
<tr>
<td>Section 13.</td>
<td>Action Without Meeting</td>
<td>9</td>
</tr>
<tr>
<td>Section 14.</td>
<td>Organization</td>
<td>9</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>ARTICLE IV</th>
<th>DIRECTORS</th>
<th>PAGE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Section 15.</td>
<td>Number And Term Of Office</td>
<td>10</td>
</tr>
<tr>
<td>Section 16.</td>
<td>Powers</td>
<td>10</td>
</tr>
<tr>
<td>Section 17.</td>
<td>Classes of Directors</td>
<td>10</td>
</tr>
<tr>
<td>Section 18.</td>
<td>Vacancies</td>
<td>11</td>
</tr>
<tr>
<td>Section 19.</td>
<td>Resignation</td>
<td>11</td>
</tr>
<tr>
<td>Section 20.</td>
<td>Removal</td>
<td>11</td>
</tr>
<tr>
<td>Section 21.</td>
<td>Meetings</td>
<td>11</td>
</tr>
<tr>
<td>Section 22.</td>
<td>Quorum And Voting</td>
<td>12</td>
</tr>
<tr>
<td>Section 23.</td>
<td>Action Without Meeting</td>
<td>13</td>
</tr>
<tr>
<td>Section 24.</td>
<td>Fees And Compensation</td>
<td>13</td>
</tr>
<tr>
<td>Section 25.</td>
<td>Committees</td>
<td>13</td>
</tr>
<tr>
<td>Section 26.</td>
<td>Duties of Chairman of the Board of Directors</td>
<td>14</td>
</tr>
<tr>
<td>Section 27.</td>
<td>Organization</td>
<td>14</td>
</tr>
</tbody>
</table>
# Table of Contents

## Article V: Officers
- Section 28. Officers Designated  
- Section 29. Tenure And Duties Of Officers  
- Section 30. Delegation Of Authority  
- Section 31. Resignations  
- Section 32. Removal  

## Article VI: Execution of Corporate Instruments and Voting of Securities Owned by the Corporation
- Section 33. Execution Of Corporate Instruments  
- Section 34. Voting Of Securities Owned By The Corporation  

## Article VII: Shares of Stock
- Section 35. Form And Execution Of Certificates  
- Section 36. Lost Certificates  
- Section 37. Transfers  
- Section 38. Fixing Record Dates  
- Section 39. Registered Stockholders  

## Article VIII: Other Securities of the Corporation
- Section 40. Execution Of Other Securities  

## Article IX: Dividends
- Section 41. Declaration Of Dividends  
- Section 42. Dividend Reserve  

## Article X: Fiscal Year
- Section 43. Fiscal Year  

## Article XI: Indemnification
- Section 44. Indemnification of Directors, Officers, Employees and Other Agents  

## Article XII: Notices
- Section 45. Notices  

## Article XIII: Amendments
- Section 46. Amendments  

## Article XIV: Loans to Officers
- Section 47. Loans To Officers  

---

ii.
AMENDED AND RESTATED BYLAWS
OF
HORIZON PHARMA, INC.
(A DELAWARE CORPORATION)

ARTICLE I
OFFICES

Section 1. Registered Office. The registered office of Horizon Pharma, Inc. (the “Corporation”) in the State of Delaware shall be in the City of Wilmington, County of New Castle.

Section 2. Other Offices. The Corporation shall also have and maintain an office or principal place of business at such place as may be fixed by the Board of Directors of the Corporation (the “Board of Directors”), and may also have offices at such other places, both within and without the State of Delaware as the Board of Directors may from time to time determine or the business of the Corporation may require.

ARTICLE II
CORPORATE SEAL

Section 3. Corporate Seal. The Board of Directors may adopt a corporate seal. Said seal may be used by causing it or a facsimile thereof to be impressed or affixed or reproduced or otherwise.

ARTICLE III
STOCKHOLDERS’ MEETINGS

Section 4. Place Of Meetings. Meetings of the stockholders of the Corporation may be held at such place, either within or without the State of Delaware, as may be determined from time to time by the Board of Directors. The Board of Directors may, in its sole discretion, determine that the meeting shall not be held at any place, but may instead be held solely by means of remote communication as provided under the Delaware General Corporation Law (“DGCL”).

Section 5. Annual Meetings.

(a) The annual meeting of the stockholders of the Corporation, for the purpose of election of directors and for such other business as may lawfully come before it, shall be held on such date and at such time as may be designated from time to time by the Board of Directors. Nominations of persons for election to the Board of Directors of the Corporation and the
proposed other business to be considered by the stockholders may be made at an annual meeting of stockholders only: (i) pursuant to the Corporation’s notice of meeting of stockholders (with respect to business other than nominations); (ii) brought specifically by or at the direction of the Board of Directors; or (iii) by any stockholder of the Corporation who was a stockholder of record at the time of giving the stockholder’s notice provided for in Section 5(b) below, who is entitled to vote at the meeting and who complied with the notice procedures set forth in Section 5. For the avoidance of doubt, clause (iii) above shall be the exclusive means for a stockholder to make nominations and submit other business (other than matters properly included in the Corporation’s notice of meeting of stockholders and proxy statement under Rule 14a-8 under the Securities Exchange Act of 1934, as amended, and the rules and regulations thereunder (the “1934 Act”)) before an annual meeting of stockholders.

(b) At an annual meeting of the stockholders, only such business shall be conducted as shall have been properly brought before the meeting. For nominations or other business to be properly brought before an annual meeting by a stockholder pursuant to clause (iii) of Section 5(a) of these Bylaws, (i) the stockholder must have given timely notice thereof in writing and in proper form to the Secretary of the Corporation, (ii) such other business must be a proper matter for stockholder action under Delaware law and (iii) the stockholder of record and the beneficial owner, if any, on whose behalf any such proposal or nomination is made, must have acted in accordance with the representations set forth in the Solicitation Statement required by these Bylaws. To be timely, a stockholder’s notice shall be delivered to the Secretary at the principal executive offices of the Corporation not later than the close of business on the ninety (90th) day prior to the first anniversary of the preceding year’s annual meeting; provided, however, that in the event that the date of the annual meeting is advanced more than thirty (30) days prior to or delayed by more than thirty (30) days after the anniversary of the preceding year’s annual meeting, notice by the stockholder to be timely must be so delivered not later than the close of business on the later of the ninetieth (90th) day prior to such annual meeting or the tenth (10th) day following the day on which public announcement of the date of such meeting is first made by the Corporation. In no event shall the public announcement of an adjournment or postponement of an annual meeting commence a new time period for the giving of a stockholder’s notice as described in this Section 5(b). To be in proper form, such stockholder’s notice shall:

(A) as to each person whom the stockholder proposes to nominate for election as a director (1) set forth the name, age, business address and residence address of such nominee, (2) set forth the principal occupation or employment of such nominee, (3) set forth the class and number of shares of each class of capital stock of the Corporation which are owned of record and beneficially by such nominee, (4) set forth the date or dates on which such shares were acquired and the investment intent of such acquisition, (5) with respect to each proposed nominee, include a completed and signed questionnaire, representation and agreement required by Section 5(c), (6) set forth such other information concerning such nominee as would be required to be disclosed in a proxy statement soliciting proxies for the election of such nominee as a director in an election contest (even if an election contest is not involved), or that is otherwise required pursuant to Regulation 14A under the 1934 Act and the rules and regulations promulgated thereunder (including such proposed nominee’s written consent to being named as a nominee and to serving as a director if elected) and (7) set forth the information required by Section 5(b)(C). The Corporation may require any proposed nominee to furnish such other
information as it may reasonably require to determine the eligibility of such proposed nominee to serve as an independent director of the Corporation or that could be material to a reasonable stockholder’s understanding of the independence, or lack thereof, of such proposed nominee, and the impact that such service would have on the ability of the Corporation to satisfy the requirements of laws, rules, regulations and listing standards applicable to the Corporation or its directors;

(B) as to any other business that the stockholder proposes to bring before the meeting, set forth (1) a brief description of the business desired to be brought before the meeting, (2) the text of the proposal or business (including the text of any resolutions proposed for consideration and if such business includes a proposal to amend these Bylaws, the text of the proposed amendment), (3) the reasons for conducting such business at the meeting, (4) any material interest (including any anticipated benefit of such business to any Proponent (as defined below) other than solely as a result of its ownership of the Corporation’s capital stock, that is material to any Proponent individually, or to the Proponents in the aggregate) in such business of any Proponent and (5) the information required by Section 5(b)(C); and

(C) as to the stockholder giving the notice and the beneficial owner, if any, on whose behalf the nomination or proposal is made (each, a “Proponent” and collectively, the “Proponents”) (1) the name and address of each Proponent (including, if applicable, the name and address that appear on the Corporation’s books), (2) the class or series and number of shares of the Corporation that are owned beneficially and of record by each Proponent, (3) a description of any agreement, arrangement or understanding (whether oral or in writing) with respect to the nomination or proposal between or among any Proponent and any of its affiliates or associates, and any others (including their names) acting in concert, or otherwise under the agreement, arrangement or understanding, with any of the foregoing, (4) a representation that the Proponents are holders of record or beneficial owners, as the case may be, of shares of the Corporation entitled to vote at the meeting and intend to appear in person or by proxy at the meeting to nominate the person or persons specified in the notice, (5) a representation as to whether the Proponents intend to deliver a proxy statement and form of proxy to holders of a sufficient number of the Corporation’s voting shares to elect such nominee or nominees or to carry such proposal, (6) to the extent known by any Proponent, the name and address of any other stockholder supporting the proposal on the date of such stockholder’s notice and (7) a description of all Derivative Transactions (as defined below) by each Proponent during the previous twelve (12) month period, including the date of any such Derivative Transaction and the class, series and number of securities involved in, and the material economic terms of, any such Derivative Transaction.

For purposes of this Section 5, a “Derivative Transaction” means any agreement, arrangement, interest or understanding entered into by, on behalf or for the benefit of, any Proponent or any of its affiliates or associates, whether record or beneficial:

(i) the value of which is derived in whole or in part from the value of any class or series of shares or other securities of the Corporation,

(ii) which otherwise provides any direct or indirect opportunity to gain or share in any gain derived from a change in the value of securities of the Corporation,
(iii) the effect or intent of which is to mitigate loss, manage risk or benefit of security value or price changes, or

(iv) which provides the right to vote or increase or decrease the voting power of, such Proponent, or any of its affiliates or associates, with respect to any securities of the Corporation, which agreement, arrangement, interest or understanding may include, without limitation, any option, warrant, debt position, note, bond, convertible security, swap, stock appreciation right, short position (for purposes hereof, a person or entity shall be deemed to have a short position in a security of the Corporation if such person or entity, directly or indirectly, through any contract, arrangement, relationship, understanding or otherwise, has the opportunity to profit or share in any profit derived from any decrease in the value of such security), profit interest, hedge, right to dividends, voting agreement, performance-related fee or arrangement to borrow or lend shares (whether or not subject to payment, settlement, exercise or conversion in any such class or series), and any proportionate interest of such Proponent in the securities of the Corporation held, directly or indirectly, by any general or limited partnership, or any limited liability company, of which such Proponent is a general partner or managing member or, directly or indirectly, beneficially owns an interest in such general partner or managing member.

To be eligible to be a nominee for election as a director of the Corporation, such nominee or a person on his or her behalf must deliver (in the case of a nomination under clause (iii) of Section 5(a), in accordance with the time periods prescribed for delivery of notice under Section 5(b)) to the Secretary at the principal executive offices of the Corporation a written questionnaire with respect to the background and qualification of such nominee (and in the case of a nomination under clause (iii) of Section 5(a), the background of any other person or entity on whose behalf the nomination is being made), which questionnaire shall be provided by the Secretary promptly upon written request, and a written representation and agreement, in the form provided by the Secretary promptly upon written request, that such person (A) is not and will not become a party to (1) any agreement, arrangement or understanding with, and has not given any commitment or assurance to, any person or entity as to how such person, if elected as a director of the Corporation, will act or vote on any issue or question (a “Voting Commitment”) that has not been disclosed to the Corporation in the questionnaire or (2) any Voting Commitment that could limit or interfere with such person’s ability to comply, if elected as a director of the Corporation, with such person’s fiduciary duties under applicable law; (B) is not and will not become a party to any agreement, arrangement or understanding with any person or entity other than the Corporation with respect to any direct or indirect compensation, reimbursement or indemnification in connection with service or action as a director of the Corporation that has not been disclosed therein; and (C) except as otherwise disclosed in the questionnaire, would be in compliance, if elected as a director of the Corporation, and will comply with, all applicable publicly disclosed corporate governance, conflict of interest, confidentiality and stock ownership and trading policies and guidelines of the Corporation.

A stockholder providing the written notice required by Section 5(b) shall update and supplement such notice in writing, if necessary, so that the information provided or required to be provided in such notice is true and correct in all material respects as of (A) the record date for the meeting and (B) as of the date that is five (5) business days prior to the date of the meeting and, in the event of any adjournment or postponement thereof, five (5) business days
prior to the date to which such meeting is adjourned or postponed (or such lesser number of days prior to the date of such adjourned or postponed meeting as is reasonably practicable under the circumstances). In the case of an update and supplement pursuant to clause (A) of this Section 5(d), such update and supplement shall be received by the Secretary at the principal executive offices of the Corporation not later than five (5) business days after the record date for the meeting. In the case of an update and supplement pursuant to clause (B) of this Section 5(d), such update and supplement shall be delivered to, or mailed and received by, the Secretary at the principal executive offices of the Corporation not later than two (2) business days prior to the date of the meeting, and, in the event of any adjournment or postponement thereof, two (2) business days prior to the date to which such meeting is adjourned or postponed (or such lesser number of days prior to the date of such adjourned or postponed meeting as is reasonably practicable under the circumstances).

(e) Notwithstanding anything in the third sentence of Section 5(b) to the contrary, if the number of directors in an Expiring Class is increased effective at the annual meeting and the public announcement by the Corporation naming the nominees for the additional directorships is not made by the close of business on the one hundredth (100th) day prior to the first anniversary of the preceding year’s annual meeting, a stockholder’s notice required by this Section 5 shall also be considered timely, but only with respect to nominees for any new positions in such Expiring Class created by such increase, if it shall be delivered to the Secretary at the principal executive offices of the Corporation not later than the close of business on the tenth (10th) day following the day on which such public announcement is first made by the Corporation. For purposes of this Bylaw, an “Expanding Class” shall mean a class of directors whose term shall expire at the next annual meeting of stockholders.

(f) General.

(i) Only persons who are nominated in accordance with the procedures set forth in these Bylaws shall be eligible to be elected as directors at an annual or special meeting of stockholders and only such business shall be conducted at a meeting of stockholders as shall have been brought before the meeting in accordance with the procedures set forth in this Section 5 or Section 6, as applicable. Except as otherwise provided by law, the Certificate of Incorporation or these Bylaws, the chairman of the meeting shall have the power and duty to determine whether a nomination or any business proposed to be brought before the meeting was made, or proposed, as the case may be, in accordance with the procedures set forth in these Bylaws and, if any proposed nomination or business is not in compliance with these Bylaws, to declare that such defective proposal or nomination shall not be presented for stockholder action at the meeting and shall be disregarded. Notwithstanding anything in these Bylaws to the contrary, unless otherwise required by law (including without limitation Rule 14a-8 of the 1934 Act), if a stockholder intending to make a nomination for the election to the Board of Directors or to propose business at a meeting pursuant to Section 5 does not provide the information in the stockholder’s notice required under Section 5(b), as applicable, within the applicable time periods specified in this Section 5 (including any update and supplement required under Section 5(d)), or the stockholder (or a qualified representative of the stockholder) does not appear at the annual or special meeting of stockholders of the Corporation to present a nomination or proposed business, such nomination shall be disregarded and such proposed
business shall not be transacted, notwithstanding that proxies in respect of such nominations or such business may have been solicited or
received by the Corporation.

(ii) For purposes of Section 5 and Section 6, to be considered a qualified representative of the stockholder, a person must be a duly
authorized officer, manager or partner of such stockholder or must be authorized by a writing executed by such stockholder or an electronic
transmission delivered by such stockholder to act for such stockholder as proxy at the meeting of stockholders and such person must produce
such writing or electronic transmission, or a reliable reproduction of the writing or electronic transmission, at the meeting of stockholders.

(iii) Notwithstanding the foregoing provisions of this Section 5, a stockholder who seeks to have any proposal included in the
Corporation’s proxy materials shall also comply with all applicable requirements of the 1934 Act and the rules and regulations thereunder with
respect to the matters set forth in this Section 5. Nothing in these Bylaws shall be deemed to affect any rights of stockholders to request inclusion
of proposals in the Corporation’s proxy statement pursuant to applicable rules and regulations under the 1934 Act, including without limitation
Rule 14a-11; provided, however, that any references in these Bylaws to the 1934 Act or the rules and regulations thereunder are not intended to
and shall not limit the requirements applicable to proposals and/or nominations to be considered pursuant to Section 5(a)(iii) of these Bylaws.

(iv) For purposes of Sections 5 and 6, “public announcement” shall mean disclosure in a press release reported by the Dow Jones News
Service, Associated Press or comparable national news service or in a document publicly filed by the corporation with the Securities and
Exchange Commission pursuant to Section 13, 14 or 15(d) of the 1934 Act.

Section 6. Special Meetings.

(a) Special meetings of the stockholders of the Corporation may be called, for any purpose as is a proper matter for stockholder action under
Delaware law, by only (i) the Chairman of the Board of Directors, (ii) the Chief Executive Officer, or (iii) the Board of Directors pursuant to a resolution
adopted by a majority of the total number of authorized directors (whether or not there exist any vacancies in previously authorized directorships at the
time any such resolution is presented to the Board of Directors for adoption).

(b) The Board of Directors shall determine the time and place, if any, of such special meeting. Upon determination of the time and place, if any,
of the meeting, the Secretary shall cause a notice of meeting to be given to the stockholders entitled to vote, in accordance with the provisions of
Section 7 of these Bylaws. No business may be transacted at such special meeting otherwise than specified in the Corporation’s notice of meeting.

(c) Only such business shall be conducted at a special meeting of stockholders as shall have been set forth in the Corporation’s notice of
meeting. Nominations of persons for election to the Board of Directors may be made at a special meeting of stockholders at which directors are to be
elected pursuant to the Corporation’s notice of meeting (i) by or at the direction of the Board of Directors or (ii) provided that the Board of Directors
has determined

6.
that directors shall be elected at such meeting, by any stockholder of the Corporation who is entitled to vote at the meeting, who complies with the notice procedures set forth in Section 6(c) and who is a stockholder of record at the time such written notice is delivered to the Secretary of the Corporation setting forth the information required by Section 5(b). In the event the Corporation calls a special meeting of stockholders for the purpose of electing one or more directors to the Board of Directors, any stockholder entitled to vote in such election may nominate such number of persons for election to such position(s) as are specified in the Corporation’s notice of meeting, if the stockholder’s notice as required by this Section 6(c) shall be delivered to the Secretary at the principal executive offices of the Corporation not later than the close of business on the later of the ninetieth (90th) day prior to such special meeting or the tenth (10th) day following the day on which public announcement of the date of the special meeting and of the nominees proposed by the Board of Directors to be elected at such meeting is first made by the Corporation. The stockholder shall also update and supplement such information on a timely basis as set forth in Section 5(d). In no event shall the public announcement of an adjournment or a postponement of a special meeting commence a new time period (or extend any time period) for the giving of a stockholder’s notice as described above.

(d) Notwithstanding the foregoing provisions of this Section 6, a stockholder who seeks to have any proposal included in the Corporation’s proxy materials shall also comply with all applicable requirements of the 1934 Act and the rules and regulations thereunder with respect to the matters set forth in this Section 6. Nothing in these Bylaws shall be deemed to affect any rights of stockholders to request inclusion of proposals in the Corporation’s proxy statement pursuant to applicable rules and regulations under the 1934 Act, including without limitation Rule 14a-11; provided, however, that any references in these Bylaws to the 1934 Act or the rules and regulations thereunder are not intended to and shall not limit the requirements applicable to nominations for the election to the Board of Directors to be considered pursuant to Section 6(c) of these Bylaws.

Section 7. Notice Of Meetings. Except as otherwise provided by law, notice, given in writing or by electronic transmission, of each meeting of stockholders shall be given not less than ten (10) nor more than sixty (60) days before the date of the meeting to each stockholder entitled to vote at such meeting, such notice to specify the place, if any, date and hour, in the case of special meetings, the purpose or purposes of the meeting, and the means of remote communications, if any, by which stockholders and proxy holders may be deemed to be present in person and vote at any such meeting. If mailed, notice is deemed given when deposited in the United States mail, postage prepaid, directed to the stockholder at such stockholder’s address as it appears on the records of the corporation. If sent via electronic transmission, notice is deemed given as of the sending time recorded at the time of transmission. Notice of the time, place, if any, and purpose of any meeting of stockholders may be waived in writing, signed by the person entitled to notice thereof, or by electronic transmission by such person, either before or after such meeting, and will be waived by any stockholder by his attendance thereat in person, by remote communication, if applicable, or by proxy, except when the stockholder attends a meeting for the express purpose of objecting, at the beginning of the meeting, to the transaction of any business because the meeting is not lawfully called or convened. Any stockholder so waiving notice of such meeting shall be bound by the proceedings of any such meeting in all respects as if due notice thereof had been given.

7.
Section 8. Quorum. At all meetings of stockholders, except where otherwise provided by statute or by the Certificate of Incorporation, or by these Bylaws, the presence, in person, by remote communication, if applicable, or by proxy duly authorized, of the holders of a majority of the outstanding shares of stock entitled to vote shall constitute a quorum for the transaction of business. In the absence of a quorum, any meeting of stockholders may be adjourned, from time to time, either by the chairman of the meeting or by vote of the holders of a majority of the shares represented thereat, but no other business shall be transacted at such meeting. The stockholders present at a duly called or convened meeting, at which a quorum is present, may continue to transact business until adjournment, notwithstanding the withdrawal of enough stockholders to leave less than a quorum. Except as otherwise provided by statute or by applicable stock exchange rules, or by the Certificate of Incorporation or these Bylaws, in all matters other than the election of directors, the affirmative vote of a majority of shares present in person, by remote communication, if applicable, or represented by proxy at the meeting and entitled to vote generally on the subject matter shall be the act of the stockholders. Except as otherwise provided by statute, the Certificate of Incorporation or these Bylaws, directors shall be elected by a plurality of the votes of the shares present in person, by remote communication, if applicable, or represented by proxy at the meeting and entitled to vote generally on the election of directors. Where a separate vote by a class or classes or series is required, except where otherwise provided by the statute or by the Certificate of Incorporation or these Bylaws, a majority of the outstanding shares of such class or classes or series, present in person, by remote communication, if applicable, or represented by proxy duly authorized, shall constitute a quorum entitled to take action with respect to that vote on that matter. Except where otherwise provided by statute or by the Certificate of Incorporation or these Bylaws, the affirmative vote of the majority (plurality, in the case of the election of directors) of shares of such class or classes or series present in person, by remote communication, if applicable, or represented by proxy at the meeting shall be the act of such class or classes or series.

Section 9. Adjournment And Notice Of Adjourned Meetings. Any meeting of stockholders, whether annual or special, may be adjourned from time to time either by the chairman of the meeting or by the vote of a majority of the shares present in person, by remote communication, if applicable, or represented by proxy at the meeting. When a meeting is adjourned to another time or place, if any, notice need not be given of the adjourned meeting if the time and place, if any, thereof are announced at the meeting at which the adjournment is taken. At the adjourned meeting, the Corporation may transact any business which might have been transacted at the original meeting. If the adjournment is for more than thirty (30) days or if after the adjournment a new record date is fixed for the adjourned meeting, a notice of the adjourned meeting shall be given to each stockholder of record entitled to vote at the meeting.

Section 10. Voting Rights. For the purpose of determining those stockholders entitled to vote at any meeting of the stockholders, except as otherwise provided by law, only persons in whose names shares stand on the stock records of the Corporation on the record date, as provided in Section 12 of these Bylaws, shall be entitled to vote at any meeting of stockholders. Every person entitled to vote shall have the right to do so either in person, by remote communication, if applicable, or by an agent or agents authorized by a proxy granted in accordance with Delaware law. An agent so appointed need not be a stockholder. No proxy shall be voted after three (3) years from its date of creation unless the proxy provides for a longer period.
Section 11. Joint Owners Of Stock. If shares or other securities having voting power stand of record in the names of two (2) or more persons, whether
fiduciaries, members of a partnership, joint tenants, tenants in common, tenants by the entirety, or otherwise, or if two (2) or more persons have the same
fiduciary relationship respecting the same shares, unless the Secretary is given written notice to the contrary and is furnished with a copy of the instrument or
order appointing them or creating the relationship wherein it is so provided, their acts with respect to voting shall have the following effect: (a) if only one
(1) votes, his act binds all; (b) if more than one (1) votes, the act of the majority so voting binds all; (c) if more than one (1) votes, but the vote is evenly split
on any particular matter, each faction may vote the securities in question proportionally, or may apply to the Delaware Court of Chancery for relief as
provided in the DGCL, Section 217(b). If the instrument filed with the Secretary shows that any such tenancy is held in unequal interests, a majority or even-
split for the purpose of subsection (c) shall be a majority or even-split in interest.

Section 12. List Of Stockholders. The Secretary shall prepare and make, at least ten (10) days before every meeting of stockholders, a complete list of
the stockholders entitled to vote at said meeting, arranged in alphabetical order, showing the address of each stockholder and the number of shares registered
in the name of each stockholder. Such list shall be open to the examination of any stockholder, for any purpose germane to the meeting, (a) on a reasonably
accessible electronic network, provided that the information required to gain access to such list is provided with the notice of the meeting, or (b) during
ordinary business hours, at the principal place of business of the Corporation. In the event that the Corporation determines to make the list available on an
electronic network, the Corporation may take reasonable steps to ensure that such information is available only to stockholders of the Corporation. The list
shall be open to examination of any stockholder during the time of the meeting as provided by law.

Section 13. Action Without Meeting. No action shall be taken by the stockholders except at an annual or special meeting of stockholders called in
accordance with these Bylaws, and no action shall be taken by the stockholders by written consent or by electronic transmission.

Section 14. Organization.

(a) At every meeting of stockholders, the Chairman of the Board of Directors, or, if a Chairman has not been appointed or is absent, the President,
or, if the President is absent, a chairman of the meeting chosen by a majority in interest of the stockholders entitled to vote, present in person or by
proxy, shall act as chairman. The Secretary, or, in his or her absence, an Assistant Secretary directed to do so by the President, shall act as secretary of
the meeting.

(b) The Board of Directors of the Corporation shall be entitled to make such rules or regulations for the conduct of meetings of stockholders as it
shall deem necessary, appropriate or convenient. Subject to such rules and regulations of the Board of Directors, if any, the chairman of the meeting
shall have the right and authority to prescribe such rules, regulations and procedures and to do all such acts as, in the judgment of such chairman, are
necessary, appropriate or convenient for the proper conduct of the meeting, including, without limitation, establishing an agenda or order of business
for the meeting, rules and procedures for maintaining order at the meeting and the safety of those present, limitations on participation in

9.
such meeting to stockholders of record of the Corporation and their duly authorized and constituted proxies and such other persons as the chairman
shall permit, restrictions on entry to the meeting after the time fixed for the commencement thereof, limitations on the time allotted to questions or
comments by participants and regulation of the opening and closing of the polls for balloting on matters which are to be voted on by ballot. The date
and time of the opening and closing of the polls for each matter upon which the stockholders will vote at the meeting shall be announced at the
meeting. Unless and to the extent determined by the Board of Directors or the chairman of the meeting, meetings of stockholders shall not be required
to be held in accordance with rules of parliamentary procedure.

ARTICLE IV
DIRECTORS

Section 15. Number And Term Of Office. The authorized number of directors of the Corporation shall be fixed in accordance with the Certificate of
Incorporation. Directors need not be stockholders unless so required by the Certificate of Incorporation. If for any cause, the directors shall not have been
elected at an annual meeting, they may be elected as soon thereafter as convenient at a special meeting of the stockholders called for that purpose in the
manner provided in these Bylaws.

Section 16. Powers. The powers of the Corporation shall be exercised, its business conducted and its property controlled by the Board of Directors,
except as may be otherwise provided by statute or by the Certificate of Incorporation.

Section 17. Classes of Directors. Subject to the rights of the holders of any series of Preferred Stock to elect additional directors under specified
circumstances, the directors shall be divided into three classes designated as Class I, Class II and Class III, respectively. The Board of Directors is authorized
to assign members of the Board of Directors already in office to such classes at the time the classification becomes effective. At the first annual meeting of
stockholders following the initial classification of the Board of Directors, the term of office of the Class I directors shall expire and Class I directors shall be
elected for a full term of three years. At the second annual meeting of stockholders following such initial classification, the term of office of the Class II
directors shall expire and Class II directors shall be elected for a full term of three years. At the third annual meeting of stockholders following such initial
classification, the term of office of the Class III directors shall expire and Class III directors shall be elected for a full term of three years. At each succeeding
annual meeting of stockholders, directors shall be elected for a full term of three years to succeed the directors of the class whose terms expire at such annual
meeting.

Notwithstanding the foregoing provisions of this Bylaw, each director shall serve until his successor is duly elected and qualified or until his earlier
death, resignation or removal. No decrease in the number of directors constituting the Board of Directors shall shorten the term of any incumbent director.
Section 18. Vacancies.

(a) Unless otherwise provided in the Certificate of Incorporation, and subject to the rights of the holders of any series of Preferred Stock, any vacancies on the Board of Directors resulting from death, resignation, disqualification, removal or other causes and any newly created directorships resulting from any increase in the number of directors shall, unless the Board of Directors determines by resolution that any such vacancies or newly created directorships shall be filled by stockholders, be filled only by the affirmative vote of a majority of the directors then in office, even though less than a quorum of the Board of Directors, or by a sole remaining director, and not by the stockholders, provided, however, that whenever the holders of any class or classes of stock or series thereof are entitled to elect one or more directors by the provisions of the Certificate of Incorporation, vacancies and newly created directorships of such class or classes or series shall, unless the Board of Directors determines by resolution that any such vacancies or newly created directorships shall be filled by stockholders, be filled by a majority of the directors elected by such class or classes or series thereof then in office, or by a sole remaining director so elected, and not by the stockholders. Any director elected in accordance with the preceding sentence shall hold office for the remainder of the full term of the director for which the vacancy was created or occurred and until such director’s successor shall have been elected and qualified. A vacancy in the Board of Directors shall be deemed to exist under this Bylaw in the case of the death, removal or resignation of any director.

Section 19. Resignation. Any director may resign at any time by delivering his or her notice in writing or by electronic transmission to the Secretary, such resignation to specify whether it will be effective at a particular time, upon receipt by the Secretary or at the pleasure of the Board of Directors. If no such specification is made, it shall be deemed effective at the pleasure of the Board of Directors. When one or more directors shall resign from the Board of Directors, effective at a future date, a majority of the directors then in office, including those who have so resigned, shall have power to fill such vacancy or vacancies, the vote thereon to take effect when such resignation or resignations shall become effective, and each Director so chosen shall hold office for the unexpired portion of the term of the Director whose place shall be vacated and until his successor shall have been duly elected and qualified.

Section 20. Removal.

(a) Subject to the rights of any series of Preferred Stock to elect additional directors under specified circumstances, neither the Board of Directors nor any individual director may be removed without cause.

(b) Subject to any limitation imposed by law, any individual director or directors may be removed with cause by the affirmative vote of the holders of at least 66-2/3% of the voting power of all then outstanding shares of capital stock of the Corporation entitled to vote generally at an election of directors.

Section 21. Meetings.

(a) Regular Meetings. Unless otherwise restricted by the Certificate of Incorporation, regular meetings of the Board of Directors may be held at any time or date and at
any place within or without the State of Delaware which has been designated by the Board of Directors and publicized among all directors, either orally or in writing, by telephone, including a voice-messaging system or other system designed to record and communicate messages, facsimile, telegraph or telex, or by electronic mail or other electronic means. No further notice shall be required for regular meetings of the Board of Directors.

(b) Special Meetings. Unless otherwise restricted by the Certificate of Incorporation, special meetings of the Board of Directors may be held at any time and place within or without the State of Delaware whenever called by the Chairman of the Board, the Chief Executive Officer or a majority of the directors then in office.

(c) Meetings by Electronic Communications Equipment. Any member of the Board of Directors, or of any committee thereof, may participate in a meeting by means of conference telephone or other communications equipment by means of which all persons participating in the meeting can hear each other, and participation in a meeting by such means shall constitute presence in person at such meeting.

(d) Notice of Special Meetings. Notice of the time and place of all special meetings of the Board of Directors shall be orally or in writing, by telephone, including a voice messaging system or other system or technology designed to record and communicate messages, facsimile, telegraph or telex, or by electronic mail or other electronic means, during normal business hours, at least twenty-four (24) hours before the date and time of the meeting. If notice is sent by United States mail, it shall be sent by first class mail, charges prepaid, at least three (3) days before the date of the meeting. Notice of any meeting may be waived in writing, or by electronic transmission, at any time before or after the meeting and will be waived by any director by attendance thereat, except when the director attends the meeting for the express purpose of objecting, at the beginning of the meeting, to the transaction of any business because the meeting is not lawfully called or convened.

(e) Waiver of Notice. The transaction of all business at any meeting of the Board of Directors, or any committee thereof, however called or noticed, or wherever held, shall be as valid as though it had been transacted at a meeting duly held after regular call and notice, if a quorum be present and if, either before or after the meeting, each of the directors not present who did not receive notice shall sign a written waiver of notice or shall waive notice by electronic transmission. All such waivers shall be filed with the corporate records or made a part of the minutes of the meeting.

Section 22. Quorum And Voting.

(a) Unless the Certificate of Incorporation requires a greater number, and except with respect to questions related to indemnification arising under Section 44 for which a quorum shall be one-third of the exact number of directors fixed from time to time, a quorum of the Board of Directors shall consist of a majority of the exact number of directors fixed from time to time by the Board of Directors in accordance with the Certificate of Incorporation; provided, however, at any meeting whether a quorum be present or otherwise, a majority of the directors present may adjourn from time to time until the time fixed for the next regular meeting of the Board of Directors, without notice other than by announcement at the meeting.
(b) At each meeting of the Board of Directors at which a quorum is present, all questions and business shall be determined by the affirmative vote of a majority of the directors present, unless a different vote be required by law, the Certificate of Incorporation or these Bylaws.

Section 23. Action Without Meeting. Unless otherwise restricted by the Certificate of Incorporation or these Bylaws, any action required or permitted to be taken at any meeting of the Board of Directors or of any committee thereof may be taken without a meeting, if all members of the Board of Directors or committee, as the case may be, consent thereto in writing or by electronic transmission, and such writing or writings or transmission or transmissions are filed with the minutes of proceedings of the Board of Directors or committee. Such filing shall be in paper form if the minutes are maintained in paper form and shall be in electronic form if the minutes are maintained in electronic form.

Section 24. Fees And Compensation. Directors shall be entitled to such compensation for their services as may be approved by the Board of Directors, including, if so approved, by resolution of the Board of Directors, a fixed sum and expenses of attendance, if any, for attendance at each regular or special meeting of the Board of Directors and at any meeting of a committee of the Board of Directors. Nothing herein contained shall be construed to preclude any director from serving the Corporation in any other capacity as an officer, agent, employee, or otherwise and receiving compensation therefor.

Section 25. Committees.

(a) Executive Committee. The Board of Directors may appoint an Executive Committee to consist of one (1) or more members of the Board of Directors. The Executive Committee, to the extent permitted by law and provided in the resolution of the Board of Directors shall have and may exercise all the powers and authority of the Board of Directors in the management of the business and affairs of the Corporation, and may authorize the seal of the Corporation to be affixed to all papers which may require it; but no such committee shall have the power or authority in reference to (i) approving or adopting, or recommending to the stockholders, any action or matter (other than the election or removal of directors) expressly required by the DGCL to be submitted to stockholders for approval, or (ii) adopting, amending or repealing any Bylaw of the Corporation.

(b) Other Committees. The Board of Directors may, from time to time, appoint such other committees as may be permitted by law. Such other committees appointed by the Board of Directors shall consist of one (1) or more members of the Board of Directors and shall have such powers and perform such duties as may be prescribed by the resolution or resolutions creating such committees, but in no event shall any such committee have the powers denied to the Executive Committee in these Bylaws.

(c) Term. The Board of Directors, subject to any requirements of any outstanding series of Preferred Stock and the provisions of subsections (a) or (b) of this Section 25, may at any time increase or decrease the number of members of a committee or terminate the existence of a committee. The membership of a committee member shall terminate on the date of his death or voluntary resignation from the committee or from the Board of
Directors. The Board of Directors may at any time for any reason remove any individual committee member and the Board of Directors may fill any committee vacancy created by death, resignation, removal or increase in the number of members of the committee. The Board of Directors may designate one or more directors as alternate members of any committee, who may replace any absent or disqualified member at any meeting of the committee, and, in addition, in the absence or disqualification of any member of a committee, the member or members thereof present at any meeting and not disqualified from voting, whether or not he or they constitute a quorum, may unanimously appoint another member of the Board of Directors to act at the meeting in the place of any such absent or disqualified member.

(d) **Meetings.** Unless the Board of Directors shall otherwise provide, regular meetings of the Executive Committee or any other committee appointed pursuant to this Section 25 shall be held at such times and places as are determined by the Board of Directors, or by any such committee, and when notice thereof has been given to each member of such committee, no further notice of such regular meetings need be given thereafter. Special meetings of any such committee may be held at any place which has been determined from time to time by such committee, and may be called by any director who is a member of such committee, upon notice to the members of such committee of the time and place of such special meeting given in the manner provided for the giving of notice to members of the Board of Directors of the time and place of special meetings of the Board of Directors. Notice of any special meeting of any committee may be waived in writing or by electronic transmission at any time before or after the meeting and will be waived by any director by attendance thereat, except when the director attends such special meeting for the express purpose of objecting, at the beginning of the meeting, to the transaction of any business because the meeting is not lawfully called or convened. Unless otherwise provided by the Board of Directors in the resolutions authorizing the creation of the committee, a majority of the authorized number of members of any such committee shall constitute a quorum for the transaction of business, and the act of a majority of those present at any meeting at which a quorum is present shall be the act of such committee.

**Section 26. Duties of Chairman of the Board of Directors.** The Chairman of the Board of Directors, when present, shall preside at all meetings of the stockholders and the Board of Directors. The Chairman of the Board of Directors shall perform other duties commonly incident to the office and shall also perform such other duties and have such other powers, as the Board of Directors shall designate from time to time.

**Section 27. Organization.** At every meeting of the directors, the Chairman of the Board of Directors, or, if a Chairman has not been appointed or is absent, the Chief Executive Officer (if a director), or, if a Chief Executive Officer is absent, the President (if a director), or if the President is absent, the most senior Vice President (if a director), or, in the absence of any such person, a chairman of the meeting chosen by a majority of the directors present, shall preside over the meeting. The Secretary, or in his absence, any Assistant Secretary or other officer or director directed to do so by the President, shall act as secretary of the meeting.
ARTICLE V

OFFICERS

Section 28. Officers Designated. The officers of the Corporation shall include, if and when designated by the Board of Directors, the Chairman of the Board of Directors, the Chief Executive Officer, the President, one or more Vice Presidents, the Secretary, the Chief Financial Officer, the Treasurer and the Controller. The Board of Directors may also appoint one or more Assistant Secretaries, Assistant Treasurers, Assistant Controllers and such other officers and agents with such powers and duties as it shall deem necessary. The Board of Directors may assign such additional titles to one or more of the officers as it shall deem appropriate. Any one person may hold any number of offices of the Corporation at any one time unless specifically prohibited therefrom by law. The salaries and other compensation of the officers of the Corporation shall be fixed by or in the manner designated by the Board of Directors.

Section 29. Tenure And Duties Of Officers.

(a) General. All officers shall hold office at the pleasure of the Board of Directors and until their successors shall have been duly elected and qualified, unless sooner removed. Any officer elected or appointed by the Board of Directors may be removed at any time by the Board of Directors. If the office of any officer becomes vacant for any reason, the vacancy may be filled by the Board of Directors.

(b) Duties of Chief Executive Officer. The Chief Executive Officer shall preside at all meetings of the stockholders and at all meetings of the Board of Directors, unless the Chairman of the Board of Directors has been appointed and is present. Unless some other officer has been appointed Chief Executive Officer of the Corporation, the President shall be the chief executive officer of the Corporation and shall, subject to the control of the Board of Directors, have general supervision, direction and control of the business and officers of the Corporation. To the extent that a Chief Executive Officer has been appointed and no President has been appointed, all references in these Bylaws to the President shall be deemed references to the Chief Executive Officer. The Chief Executive Officer shall perform other duties commonly incident to the office and shall also perform such other duties and have such other powers, as the Board of Directors shall designate from time to time.

(c) Duties of President. The President shall preside at all meetings of the stockholders and at all meetings of the Board of Directors, unless the Chairman of the Board of Directors or the Chief Executive Officer has been appointed and is present. Unless another officer has been appointed Chief Executive Officer of the Corporation, the President shall be the chief executive officer of the Corporation and shall, subject to the control of the Board of Directors, have general supervision, direction and control of the business and officers of the Corporation. The President shall perform other duties commonly incident to the office and shall also perform such other duties and have such other powers, as the Board of Directors shall designate from time to time.
(d) Duties of Vice Presidents. The Vice Presidents may assume and perform the duties of the President in the absence or disability of the President or whenever the office of President is vacant. The Vice Presidents shall perform other duties commonly incident to their office and shall also perform such other duties and have such other powers as the Board of Directors or the Chief Executive Officer, or, if the Chief Executive Officer has not been appointed or is absent, the President shall designate from time to time.

(e) Duties of Secretary. The Secretary shall attend all meetings of the stockholders and of the Board of Directors and shall record all acts and proceedings thereof in the minute book of the Corporation. The Secretary shall give notice in conformity with these Bylaws of all meetings of the stockholders and of all meetings of the Board of Directors and any committee thereof requiring notice. The Secretary shall perform all other duties provided for in these Bylaws and other duties commonly incident to the office and shall also perform such other duties and have such other powers, as the Board of Directors shall designate from time to time. The President may direct any Assistant Secretary or other officer to assume and perform the duties of the Secretary in the absence or disability of the Secretary, and each Assistant Secretary shall perform other duties commonly incident to the office and shall also perform such other duties and have such other powers as the Board of Directors or the President shall designate from time to time.

(f) Duties of Chief Financial Officer. The Chief Financial Officer shall keep or cause to be kept the books of account of the Corporation in a thorough and proper manner and shall render statements of the financial affairs of the Corporation in such form and as often as required by the Board of Directors or the President. The Chief Financial Officer, subject to the order of the Board of Directors, shall have the custody of all funds and securities of the Corporation. The Chief Financial Officer shall perform other duties commonly incident to the office and shall also perform such other duties and have such other powers as the Board of Directors or the President shall designate from time to time. To the extent that a Chief Financial Officer has been appointed and no Treasurer has been appointed, all references in these Bylaws to the Treasurer shall be deemed references to the Chief Financial Officer. The President may direct the Treasurer, if any, or any Assistant Treasurer, or the Controller or any Assistant Controller to assume and perform the duties of the Chief Financial Officer in the absence or disability of the Chief Financial Officer, and each Treasurer and Assistant Treasurer and each Controller and Assistant Controller shall perform other duties commonly incident to the office and shall also perform such other duties and have such other powers as the Board of Directors or the President shall designate from time to time.

(g) Duties of Treasurer. Unless another officer has been appointed Chief Financial Officer of the Corporation, the Treasurer shall be the chief financial officer of the Corporation and shall keep or cause to be kept the books of account of the Corporation in a thorough and proper manner and shall render statements of the financial affairs of the Corporation in such form and as often as required by the Board of Directors or the President, and, subject to the order of the Board of Directors, shall have the custody of all funds and securities of the Corporation. The Treasurer shall perform other duties commonly incident to the office and shall also perform such other duties and have such other powers as the Board of Directors or the President shall designate from time to time.
Section 30. Delegation Of Authority. The Board of Directors may from time to time delegate the powers or duties of any officer to any other officer or agent, notwithstanding any provision hereof.

Section 31. Resignations. Any officer may resign at any time by giving notice in writing or by electronic transmission to the Board of Directors or to the President or to the Secretary. Any such resignation shall be effective when received by the person or persons to whom such notice is given, unless a later time is specified therein, in which event the resignation shall become effective at such later time. Unless otherwise specified in such notice, the acceptance of any such resignation shall not be necessary to make it effective. Any resignation shall be without prejudice to the rights, if any, of the Corporation under any contract with the resigning officer.

Section 32. Removal. Any officer may be removed from office at any time, either with or without cause, by the affirmative vote of a majority of the directors in office at the time, or by the unanimous written consent of the directors in office at the time, or by any committee or by the Chief Executive Officer or by other superior officers upon whom such power of removal may have been conferred by the Board of Directors.

ARTICLE VI
EXECUTION OF CORPORATE INSTRUMENTS AND VOTING OF SECURITIES OWNED BY THE CORPORATION

Section 33. Execution Of Corporate Instruments. The Board of Directors may, in its discretion, determine the method and designate the signatory officer or officers, or other person or persons, to execute on behalf of the Corporation any corporate instrument or document, or to sign on behalf of the Corporation the corporate name without limitation, or to enter into contracts on behalf of the Corporation, except where otherwise provided by law or these Bylaws, and such execution or signature shall be binding upon the Corporation.

All checks and drafts drawn on banks or other depositaries on funds to the credit of the Corporation or in special accounts of the Corporation shall be signed by such person or persons as the Board of Directors shall authorize so to do.

Unless authorized or ratified by the Board of Directors or within the agency power of an officer, no officer, agent or employee shall have any power or authority to bind the Corporation by any contract or engagement or to pledge its credit or to render it liable for any purpose or for any amount.

Section 34. Voting Of Securities Owned By The Corporation. All stock and other securities of other corporations owned or held by the Corporation for itself, or for other parties in any capacity, shall be voted, and all proxies with respect thereto shall be executed, by the person authorized so to do by resolution of the Board of Directors, or, in the absence of such authorization, by the Chairman of the Board of Directors, the Chief Executive Officer, the President, or any Vice President.
ARTICLE VII
SHARES OF STOCK

Section 35. Form And Execution Of Certificates. The shares of the Corporation shall be represented by certificates, or shall be uncertificated if so provided by resolution or resolutions of the Board of Directors. Certificates for the shares of stock of the Corporation, if any, shall be in such form as is consistent with the Certificate of Incorporation and applicable law. Every holder of stock represented by certificate in the Corporation shall be entitled to have a certificate signed by or in the name of the Corporation by the Chairman of the Board of Directors, the Chief Executive Officer or the President or any Vice President and by the Chief Financial Officer, Treasurer or Assistant Treasurer or the Secretary or Assistant Secretary, certifying the number of shares owned by him in the Corporation. Any or all of the signatures on the certificate may be facsimiles. In case any officer, transfer agent, or registrar who has signed or whose facsimile signature has been placed upon a certificate shall have ceased to be such officer, transfer agent, or registrar before such certificate is issued, it may be issued with the same effect as if he were such officer, transfer agent, or registrar at the date of issue.

Section 36. Lost Certificates. A new certificate or certificates shall be issued in place of any certificate or certificates theretofore issued by the Corporation alleged to have been lost, stolen, or destroyed, upon the making of an affidavit of that fact by the person claiming the certificate of stock to be lost, stolen, or destroyed. The Corporation may require, as a condition precedent to the issuance of a new certificate or certificates, the owner of such lost, stolen, or destroyed certificate or certificates, or the owner’s legal representative, to agree to indemnify the Corporation in such manner as it shall require or to give the Corporation a surety bond in such form and amount as it may direct as indemnity against any claim that may be made against the Corporation with respect to the certificate alleged to have been lost, stolen, or destroyed.

Section 37. Transfers.

(a) Transfers of record of shares of stock of the Corporation shall be made only upon its books by the holders thereof, in person or by attorney duly authorized, and, in the case of stock represented by certificate, upon the surrender of a properly endorsed certificate or certificates for a like number of shares.

(b) The Corporation shall have power to enter into and perform any agreement with any number of stockholders of any one or more classes of stock of the Corporation to restrict the transfer of shares of stock of the Corporation of any one or more classes owned by such stockholders in any manner not prohibited by the DGCL.

Section 38. Fixing Record Dates.

(a) In order that the Corporation may determine the stockholders entitled to notice of or to vote at any meeting of stockholders or any adjournment thereof, the Board of Directors may fix a record date, which record date shall not precede the date upon which the resolution fixing the record date is adopted by the Board of Directors, and which record date
shall, subject to applicable law, not be more than sixty (60) nor less than ten (10) days before the date of such meeting. If no record date is fixed by the Board of Directors, the record date for determining stockholders entitled to notice of or to vote at a meeting of stockholders shall be at the close of business on the day next preceding the day on which notice is given, or if notice is waived, at the close of business on the day next preceding the day on which the meeting is held. A determination of stockholders of record entitled to notice of or to vote at a meeting of stockholders shall apply to any adjournment of the meeting; provided, however, that the Board of Directors may fix a new record date for the adjourned meeting.

(b) In order that the Corporation may determine the stockholders entitled to receive payment of any dividend or other distribution or allotment of any rights or the stockholders entitled to exercise any rights in respect of any change, conversion or exchange of stock, or for the purpose of any other lawful action, the Board of Directors may fix, in advance, a record date, which record date shall not precede the date upon which the resolution fixing the record date is adopted, and which record date shall be not more than sixty (60) days prior to such action. If no record date is fixed, the record date for determining stockholders for any such purpose shall be at the close of business on the day on which the Board of Directors adopts the resolution relating thereto.

Section 39. Registered Stockholders. The Corporation shall be entitled to recognize the exclusive right of a person registered on its books as the owner of shares to receive dividends, and to vote as such owner, and shall not be bound to recognize any equitable or other claim to or interest in such share or shares on the part of any other person whether or not it shall have express or other notice thereof, except as otherwise provided by the laws of Delaware.

ARTICLE VIII

OTHER SECURITIES OF THE CORPORATION

Section 40. Execution Of Other Securities. All bonds, debentures and other corporate securities of the Corporation, other than stock certificates (covered in Section 35), may be signed by the Chairman of the Board of Directors, the Chief Executive Officer, the President or any Vice President, or such other person as may be authorized by the Board of Directors, and the corporate seal impressed thereon or a facsimile of such seal imprinted thereon and attested by the signature of the Secretary or an Assistant Secretary, or the Chief Financial Officer or Treasurer or an Assistant Treasurer; provided, however, that where any such bond, debenture or other corporate security shall be authenticated by the manual signature, or where permissible facsimile signature, of a trustee under an indenture pursuant to which such bond, debenture or other corporate security shall be issued, the signatures of the persons signing and attesting the corporate seal on such bond, debenture or other corporate security shall be issued, the signatures of the persons signing and attesting the corporate seal on such bond, debenture or other corporate security may be the imprinted facsimile of the signatures of such persons. Interest coupons appertaining to any such bond, debenture or other corporate security, authenticated by a trustee as aforesaid, shall be signed by the Treasurer or an Assistant Treasurer of the Corporation or such other person as may be authorized by the Board of Directors, or bear imprinted thereon the facsimile signature of such person. In case any officer who shall have signed or attested any bond, debenture or other corporate security, or whose facsimile signature shall appear thereon or on any such interest coupon, shall have ceased to be such officer before the bond, debenture or other corporate

19.
security so signed or attested shall have been delivered, such bond, debenture or other corporate security nevertheless may be adopted by the Corporation and issued and delivered as though the person who signed the same or whose facsimile signature shall have been used thereon had not ceased to be such officer of the Corporation.

ARTICLE IX
DIVIDENDS

Section 41. Declaration Of Dividends. Dividends upon the capital stock of the Corporation, subject to the provisions of the Certificate of Incorporation and applicable law, if any, may be declared by the Board of Directors pursuant to law at any regular or special meeting. Dividends may be paid in cash, in property, or in shares of the capital stock, subject to the provisions of the Certificate of Incorporation and applicable law.

Section 42. Dividend Reserve. Before payment of any dividend, there may be set aside out of any funds of the Corporation available for dividends such sum or sums as the Board of Directors from time to time, in their absolute discretion, think proper as a reserve or reserves to meet contingencies, or for equalizing dividends, or for repairing or maintaining any property of the Corporation, or for such other purpose as the Board of Directors shall think conducive to the interests of the Corporation, and the Board of Directors may modify or abolish any such reserve in the manner in which it was created.

ARTICLE X
FISCAL YEAR

Section 43. Fiscal Year. The fiscal year of the Corporation shall be fixed by resolution of the Board of Directors.

ARTICLE XI
INDEMNIFICATION

Section 44. Indemnification of Directors, Officers, Employees and Other Agents.

(a) Directors and Officers. The Corporation shall indemnify its directors and officers to the extent not prohibited by the DGCL or any other applicable law; provided, however, that the Corporation may modify the extent of such indemnification by individual contracts with its directors and officers; and, provided, further, that the Corporation shall not be required to indemnify any director or officer in connection with any proceeding (or part thereof) initiated by such person unless (i) such indemnification is expressly required to be made by law, (ii) the proceeding was authorized by the Board of Directors of the Corporation, (iii) such indemnification is provided by the Corporation, in its sole discretion, pursuant to the powers vested in the Corporation under the DGCL or any other applicable law or (iv) such indemnification is required to be made under subsection (d).
(b) Employees and Other Agents. The Corporation shall have power to indemnify its employees and other agents as set forth in the DGCL or any other applicable law. The Board of Directors shall have the power to delegate the determination of whether indemnification shall be given to any such person to such officers or other persons as the Board of Directors shall determine.

(c) Expenses. The Corporation shall advance to any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative, by reason of the fact that he is or was a director or officer, of the Corporation, or is or was serving at the request of the Corporation as a director or officer of another corporation, partnership, joint venture, trust or other enterprise, prior to the final disposition of the proceeding, promptly following request therefor, all expenses incurred by any director or officer in connection with such proceeding provided, however, that if the DGCL requires, an advancement of expenses incurred by a director or officer in his or her capacity as a director or officer (and not in any other capacity in which service was or is rendered by such indemnitee, including, without limitation, service to an employee benefit plan) shall be made only upon delivery to the Corporation of an undertaking (hereinafter an "undertaking"), by or on behalf of such indemnitee, to repay all amounts so advanced if it shall ultimately be determined by final judicial decision from which there is no further right to appeal (hereinafter a "final adjudication") that such indemnitee is not entitled to be indemnified for such expenses under this Bylaw or otherwise.

Notwithstanding the foregoing, unless otherwise determined pursuant to paragraph (e) of this Bylaw, no advance shall be made by the Corporation to an officer of the Corporation (except by reason of the fact that such officer is or was a director of the Corporation in which event this paragraph shall not apply) in any action, suit or proceeding, whether civil, criminal, administrative or investigative, if a determination is reasonably and promptly made (i) by a majority vote of directors who were not parties to the proceeding, even if not a quorum, or (ii) by a committee of such directors designated by a majority vote of such directors, even though less than a quorum, or (iii) if there are no such directors, or such directors so direct, by independent legal counsel in a written opinion, that the facts known to the decision-making party at the time such determination is made demonstrate clearly and convincingly that such person acted in bad faith or in a manner that such person did not believe to be in or not opposed to the best interests of the Corporation.

(d) Enforcement. Without the necessity of entering into an express contract, all rights to indemnification and advances to directors or officers under this Bylaw shall be deemed to be contractual rights and be effective to the same extent and as if provided for in a contract between the Corporation and the director or officer. Any right to indemnification or advances granted by this Bylaw to a director or officer shall be enforceable by or on behalf of the person holding such right in any court of competent jurisdiction if (i) the claim for indemnification or advances is denied, in whole or in part, or (ii) no disposition of such claim is made within ninety (90) days of request therefor. To the extent permitted by law, the claimant in such enforcement action, if successful in whole or in part, shall be entitled to be paid also the expense of prosecuting the claim. In connection with any claim for indemnification, the Corporation shall be entitled to raise as a defense to any such action that the claimant has not met the standards of conduct that make it permissible under the DGCL or any other applicable law.
for the Corporation to indemnify the claimant for the amount claimed. In connection with any claim by an officer of the Corporation (except in any action, suit or proceeding, whether civil, criminal, administrative or investigative, by reason of the fact that such officer is or was a director of the Corporation) for advances, the Corporation shall be entitled to raise a defense as to any such action clear and convincing evidence that such person acted in bad faith or in a manner that such person did not believe to be in or not opposed to the best interests of the Corporation, or with respect to any criminal action or proceeding that such person acted without reasonable cause to believe that his conduct was lawful. Neither the failure of the Corporation (including its Board of Directors, independent legal counsel or its stockholders) to have made a determination prior to the commencement of such action that indemnification of the claimant is proper in the circumstances because the director or officer has met the applicable standard of conduct set forth in the DGCL or any other applicable law, nor an actual determination by the Corporation (including its Board of Directors, independent legal counsel or its stockholders) that the claimant has not met such applicable standard of conduct, shall be a defense to the action or create a presumption that claimant has not met the applicable standard of conduct. In any suit brought by a director or officer to enforce a right to indemnification or to an advancement of expenses hereunder, the burden of proving that the director or officer is not entitled to be indemnified, or to such advancement of expenses, under this Bylaw or otherwise shall be on the Corporation.

(e) **Non-Exclusivity of Rights.** The rights conferred on any person by this Bylaw shall not be exclusive of any other right which such person may have or hereafter acquire under any applicable statute, provision of the Certificate of Incorporation, Bylaws, agreement, vote of stockholders or disinterested directors or otherwise, both as to action in such person’s official capacity and as to action in another capacity while holding office. The Corporation is specifically authorized to enter into individual contracts with any or all of its directors, officers, employees or agents respecting indemnification and advances, to the fullest extent not prohibited by the DGCL, or by any other applicable law.

(f) **Survival of Rights.** The rights conferred on any person by this Bylaw shall continue as to a person who has ceased to be a director or officer, employee or other agent and shall inure to the benefit of the heirs, executors and administrators of such a person.

(g) **Insurance.** To the fullest extent permitted by the DGCL or any other applicable law, the Corporation, upon approval by the Board of Directors, may purchase insurance on behalf of any person required or permitted to be indemnified pursuant to this Bylaw.

(h) **Amendments.** Any repeal or modification of this Bylaw shall only be prospective and shall not affect the rights under this Bylaw in effect at the time of the alleged occurrence of any action or omission to act that is the cause of any proceeding against any agent of the Corporation.

(i) **Saving Clause.** If this Bylaw or any portion thereof shall be invalidated on any ground by any court of competent jurisdiction, then the Corporation shall nevertheless indemnify each director and officer to the full extent not prohibited by any applicable portion of this Bylaw that shall not have been invalidated, or by any other applicable law. If this Bylaw
shall be invalid due to the application of the indemnification provisions of another jurisdiction, then the Corporation shall indemnify each director and officer to the full extent under any other applicable law.

(j) Certain Definitions. For the purposes of this Bylaw, the following definitions shall apply:

(i) The term “proceeding” shall be broadly construed and shall include, without limitation, the investigation, preparation, prosecution, defense, settlement, arbitration and appeal of, and the giving of testimony in, any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative.

(ii) The term “expenses” shall be broadly construed and shall include, without limitation, court costs, attorneys’ fees, witness fees, fines, amounts paid in settlement or judgment and any other costs and expenses of any nature or kind incurred in connection with any proceeding.

(iii) The term the “corporation” shall include, in addition to the resulting corporation, any constituent corporation (including any constituent of a constituent) absorbed in a consolidation or merger which, if its separate existence had continued, would have had power and authority to indemnify its directors, officers, and employees or agents, so that any person who is or was a director, officer, employee or agent of such constituent corporation, or is or was serving at the request of such constituent corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, shall stand in the same position under the provisions of this Bylaw with respect to the resulting or surviving corporation as he would have with respect to such constituent corporation if its separate existence had continued.

(iv) References to a “director,” “officer,” “employee,” or “agent” of the Corporation shall include, without limitation, situations where such person is serving at the request of the Corporation as, respectively, a director, officer, employee, trustee or agent of another corporation, partnership, joint venture, trust or other enterprise.

(v) References to “other enterprises” shall include employee benefit plans; references to “fines” shall include any excise taxes assessed on a person with respect to an employee benefit plan; and references to “serving at the request of the Corporation” shall include any service as a director, officer, employee or agent of the Corporation which imposes duties on, or involves services by, such director, officer, employee, or agent with respect to an employee benefit plan, its participants, or beneficiaries; and a person who acted in good faith and in a manner such person reasonably believed to be in the interest of the participants and beneficiaries of an employee benefit plan shall be deemed to have acted in a manner “not opposed to the best interests of the Corporation” as referred to in this Bylaw.
ARTICLE XII

NOTICES

Section 45. Notices.

(a) **Notice To Stockholders.** Written notice to stockholders of stockholder meetings shall be given as provided in Section 7 herein. Without limiting the manner by which notice may otherwise be given effectively to stockholders under any agreement or contract with such stockholder, and except as otherwise required by law, written notice to stockholders for purposes other than stockholder meetings may be sent by United States mail or nationally recognized overnight courier, or by facsimile, telegraph or telex or by electronic mail or other electronic means.

(b) **Notice To Directors.** Any notice required to be given to any director may be given by the method stated in subsection (a), as otherwise provided in these Bylaws, or by overnight delivery service, facsimile, telex or telegram, except that such notice other than one which is delivered personally shall be sent to such address as such director shall have filed in writing with the Secretary, or, in the absence of such filing, to the last known post office address of such director.

(c) **Affidavit Of Mailing.** An affidavit of mailing, executed by a duly authorized and competent employee of the Corporation or its transfer agent appointed with respect to the class of stock affected, or other agent, specifying the name and address or the names and addresses of the stockholder or stockholders, or director or directors, to whom any such notice or notices was or were given, and the time and method of giving the same, shall in the absence of fraud, be prima facie evidence of the facts therein contained.

(d) **Methods of Notice.** It shall not be necessary that the same method of giving notice be employed in respect of all recipients of notice, but one permissible method may be employed in respect of any one or more, and any other permissible method or methods may be employed in respect of any other or others.

(e) **Notice To Person With Whom Communication Is Unlawful.** Whenever notice is required to be given, under any provision of law or of the Certificate of Incorporation or Bylaws of the Corporation, to any person with whom communication is unlawful, the giving of such notice to such person shall not be required and there shall be no duty to apply to any governmental authority or agency for a license or permit to give such notice to such person. Any action or meeting which shall be taken or held without notice to any such person with whom communication is unlawful shall have the same force and effect as if such notice had been duly given. In the event that the action taken by the Corporation is such as to require the filing of a certificate under any provision of the DGCL, the certificate shall state, if such is the fact and if notice is required, that notice was given to all persons entitled to receive notice except such persons with whom communication is unlawful.

(f) **Notice to Stockholders Sharing an Address.** Except as otherwise prohibited under the DGCL, any notice given under the provisions of the DGCL, the Certificate
of Incorporation or the Bylaws shall be effective if given by a single written notice to stockholders who share an address if consented to by the stockholders at that address to whom such notice is given. Such consent shall have been deemed to have been given if such stockholder fails to object in writing to the Corporation within sixty (60) days of having been given notice by the Corporation of its intention to send the single notice. Any consent shall be revocable by the stockholder by written notice to the Corporation.

ARTICLE XIII
AMENDMENTS

Section 46. Amendments. Subject to the limitations set forth in Section 44(h) of these Bylaws or the provisions of the Certificate of Incorporation, the Board of Directors is expressly empowered to adopt, amend or repeal the Bylaws of the Corporation. Any adoption, amendment or repeal of the Amended and Restated Bylaws of the corporation by the Board of Directors shall require the approval of a majority of the authorized number of Directors. The stockholders also shall have power to adopt, amend or repeal the Bylaws of the Corporation; provided, however, that, in addition to any vote of the holders of any class or series of stock of the Corporation required by law or by the Certificate of Incorporation, such action by stockholders shall require the affirmative vote of the holders of at least 66-2/3% of the voting power of all of the then-outstanding shares of the capital stock of the Corporation entitled to vote generally in the election of directors, voting together as a single class.

ARTICLE XIV
LOANS TO OFFICERS

Section 47. Loans To Officers. Except as otherwise prohibited by applicable law, the Corporation may lend money to, or guarantee any obligation of, or otherwise assist any officer or other employee of the Corporation or of its subsidiaries, including any officer or employee who is a director of the Corporation or its subsidiaries, whenever, in the judgment of the Board of Directors, such loan, guarantee or assistance may reasonably be expected to benefit the Corporation. The loan, guarantee or other assistance may be with or without interest and may be unsecured, or secured in such manner as the Board of Directors shall approve, including, without limitation, a pledge of shares of stock of the Corporation. Nothing in these Bylaws shall be deemed to deny, limit or restrict the powers of guaranty or warranty of the Corporation at common law or under any statute.
This First Amendment To Agreement For The Provision Of A Loan Facility Of Up To Euro 7,500,000 ("Amendment") is made and entered into as of April 1, 2010, by and between Nitec Pharma AG, a company incorporated in Switzerland with number CH-280.3.007.771-0/ ("Borrower"), and Kreos Capital III (UK) Limited, a company incorporated in England and Wales whose company number is 05981165 ("Lender").

Recitals

A. Borrower and Lender have entered into that certain Agreement for the Provision of a Loan Facility of up to Euro 7,500,000 dated August 15, 2008 (the "Loan Agreement") pursuant to which Lender has agreed to extend and make available to Borrower certain advances of money.

B. Borrower desires that Lender amend the Loan Agreement and the Security Documents (as defined therein) upon the terms and conditions more fully set forth herein.

C. Subject to the representations and warranties of Borrower herein and upon the terms and conditions set forth in this Amendment, Lender is willing to so amend the Loan Agreement and the Security Documents.

Agreement

Now, Therefore, in consideration of the foregoing recitals and the mutual covenants herein set forth and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, and intending to be legally bound, Borrower and Lender hereby agree to amend the Loan Agreement and the Security Documents as follows:

1. Definitions. Unless otherwise defined herein, all terms defined in the Loan Agreement have the same meaning when used herein.

2. Consent to Acquisition of Borrower by Horizon Pharma, Inc. Lender hereby consents to the transactions contemplated under that Share Exchange Agreement dated on or about the date hereof by and among Borrower, Horizon Therapeutics, Inc., a Delaware corporation, Horizon Pharma, Inc., the shareholders of Borrower, certain stockholders of Horizon Therapeutics, Inc., and a representative of the stockholders of Horizon Therapeutics, Inc. pursuant to which immediately following the consummation of such transactions, the existing stockholders of Horizon Therapeutics, Inc. will own approximately 51% of Horizon Pharma, Inc. on a fully-diluted basis and the existing shareholders of Borrower will own approximately 49% of Horizon Pharma, Inc. on a fully-diluted basis, and Horizon Pharma, Inc. will own 100% of the capital stock of Horizon Therapeutics, Inc. and 100% of the capital stock of Borrower. Lender further acknowledges and agrees that such transaction is permitted notwithstanding that it constitutes a “change of control” as defined in Clause 9.1.12 of the Loan Agreement. Without limiting the foregoing, Lender agrees that the completion of such transaction shall not constitute an Event of Default under the Loan Agreement or give rise to the consequences set forth in Clauses 9.2.1 and 9.2.2 of the Loan Agreement.

3. Amendments to Loan Agreement.
3.1 Clause 3.7.3 of the Loan Agreement is hereby amended and restated in its entirety to read as follows:

“Upon the loan being discharged in full and the Lender under no further obligation to make any financial accommodation or loan facility to the Borrower under this Loan Agreement or upon the closing of a firmly underwritten public offering pursuant to an effective registration statement under the United States Securities Act of 1933, as amended, covering the offer and sale of common stock of the holding company of the Borrower, for at least US $50,000,000 before deducting underwriting discounts and commissions and other offering expenses (the “Qualified IPO”), the Pledged Assets (as defined in the Pledge Agreement) shall be released to the Borrower or such other Party as designated by the Borrower.”

3.2 Clause 5.2 of the Loan Agreement is hereby amended and restated in its entirety to read as follows:

“The Borrower shall pay accrued interest only on the outstanding principal balance of the Loan on the first Business Day of each calendar month amounting to €50,000 per calendar month, commencing on May 1, 2010 and ending on December 1, 2010. Thereafter, the Borrower shall repay the outstanding principal balance of the Loan in 35 equal monthly payments of principal, each such payment in the amount shown on Schedule 5.2 attached hereto at Exhibit A, together with accrued and unpaid interest thereon, amounting to €184,000 per month to be paid to the Lender on the first Business Day of the 35 calendar months, commencing on January 1, 2011. Any amount repaid or prepaid may not be redrawn.”

3.3 Clause 7.1.12 of the Loan Agreement is hereby amended by deleting the phrase “and each date of repayment” contained therein.

3.4 Clause 8.1.6 of the Loan Agreement is amended (i) by deleting “Company” in the eighth line thereof and substituting “Borrower” therefor and (ii) by deleting “proposed to be” in the fourteenth line thereof.

3.5 Clause 8.1.7 of the Loan Agreement is amended by deleting “each Group Company” in the third line thereof and substituting “its parent holding company on a consolidated basis” therefor.

3.6 Clause 8.1.9 of the Loan Agreement is amended by adding the following language to the end thereof:

“subject to exclusion of access to proprietary information, confidential information relating to employees (including compensation), and other information as reasonably necessary to preserve the attorney-client privilege.”

3.7 Clause 8.1.11 of the Loan Agreement is amended by deleting the second sentence thereof that begins “In addition, upon the occurrence of a default…” and substituting the following therefor:

“In addition, upon the occurrence of an Event of Default and during the continuance thereof, the Lender shall be entitled to have a representative to attend all meetings of the Borrower’s board of directors in a non-voting observer capacity, subject to exclusion of access to proprietary information, confidential information relating to employees (including compensation), and other information as reasonably necessary to preserve the attorney-client privilege.”
3.8 Clause 8.1.15 of the Loan Agreement is hereby amended (i) by deleting “or” at the end of clause 8.1.15.2 and (ii) by adding the following new clauses 8.1.15.4 and 8.1.15.5 to read as follows:

“8.1.15.4 under the Loan and Security Agreement dated as of April 1, 2010 by and among Horizon Pharma, Inc., Lender, and Silicon Valley Bank, as the same may be amended or amended and restated from time to time; or

8.1.15.5 those certain subordinated convertible promissory notes, in an aggregate principal amount of up to US $10,000,000 (the “Subordinated Notes”), as may be issued by Horizon Pharma, Inc. from time to time pursuant to the terms of that certain Series B Preferred Stock and Subordinated Convertible Note Purchase Agreement dated on or about April 1, 2010 by and among Horizon Pharma, Inc. and the Purchasers listed on the Schedule of Purchasers thereto (the “Purchase Agreement”), as the Subordinated Notes and Purchase Agreement may be amended from time to time;”

3.9 Clause 8.1.19 of the Loan Agreement is hereby amended and restated in its entirety to read as follows:

“8.1.19 Clauses 8.1.3, 8.1.4, 8.1.17 and 8.1.18 do not apply to:

8.1.19.1 Security provided to the Lender under the Loan Agreement or any Security Document;

8.1.19.2 Security provided to Lender and Silicon Valley Bank under the Loan and Security Agreement referred to in clause 8.1.15.4;

8.1.19.3 any netting or set-off arrangement entered into by any Group Company in the ordinary course of its banking arrangements for the purpose of netting debit and credit balances;

8.1.19.4 any lien arising by operation of law and in the ordinary course of trading, including liens of carriers, warehousemen, suppliers, or other persons that are possessory in nature and liens to secure payment of workers’ compensation, employment insurance, old-age pensions, social security and other like obligations;

8.1.19.5 any lien for taxes, fees, assessments or other government charges or levies, either not due and payable or being contested in good faith and for which the Borrower or other Group Company (as the case may be) maintains adequate reserves on its books; provided that no notice of any such lien has been filed or recorded by any government authority; and

8.1.19.6 liens arising solely by virtue of any statutory or common law provision relating to banker’s liens, rights of setoff or similar rights and remedies as to deposit accounts or other funds maintained with a creditor depository institution;

8.1.19.7 Clauses 8.1.3, 8.1.4, 8.1.17, 8.1.18, and 8.1.22 do not apply to non-exclusive or exclusive licenses granted by the Borrower or any Group Company to Borrower or a Group Company or a third party over any of its Intellectual Property rights provided that (i) such licenses are granted for full market value and (ii) such licenses are granted in arms’ length transactions in the ordinary course of business for the development, manufacture, marketing, distribution and/or commercialization of DUEXA and/or LODOTRA. In addition, clauses 8.1.3, 8.1.4, 8.1.17, 8.1.18, and 8.1.22, insofar as they apply to the Pledged Assets (as such term is defined in the Pledge Agreement), shall no longer have any force and effect, and shall be deemed to be automatically deleted from this Loan Agreement, upon the later of the completion by the holding company of the
3.10 Clause 9.1.12 of the Loan Agreement is hereby amended (i) until the later of the completion by the holding company of the Borrower of a Qualified IPO or the issuance by the FDA of marketing approval for either DUEXA or LODOTRA, by inserting the phrase “except for exclusive licenses permitted by the first sentence of clause 8.1.19.7” immediately before the words “the exclusive license” in the thirteenth line thereof and (ii) upon the later of the completion by the holding company of the Borrower of a Qualified IPO or the issuance by the FDA of marketing approval for either DUEXA or LODOTRA, by deleting the phrase “or the exclusive license of all or a material portion of the Borrower’s intellectual property, to any other entity or person, other than a wholly-owned subsidiary of the Borrower”.

4. Amendment to Pledge Agreement.

4.1 Clause 3.2 of the Pledge Agreement is hereby amended by adding the following language to the end thereof:

“or such licenses are granted in arms’ length transactions in the ordinary course of business for the development, manufacture, marketing, distribution and/or commercialization of DUEXA and/or LODOTRA. In addition, this clause 3.2 shall no longer have any force and effect, and shall be deemed to be automatically deleted from this Agreement, upon the later of the completion by the holding company of the Borrower of a Qualified IPO or the issuance by the FDA of marketing approval for either DUEXA or LODOTRA”

4.2 Clause 3.3 of the Pledge Agreement is hereby amended by adding the following language to the end thereof:

“or such licenses are granted in arms’ length transactions in the ordinary course of business for the development, manufacture, marketing, distribution and/or commercialization of DUEXA and/or LODOTRA. In addition, this clause 3.3 shall no longer have any force and effect, and shall be deemed to be automatically deleted from this Agreement, upon the later of the completion by the holding company of the Borrower of a Qualified IPO or the issuance by the FDA of marketing approval for either DUEXA or LODOTRA”

4.3 Clause 5.1 of the Pledge Agreement is hereby amended and restated in its entirety to read as follows:

“Upon the Secured Liabilities being discharged in full and the Pledgee being under no further actual or contingent obligation to make any financial accommodation or loan facility to the Pledgor under the Loan Agreement, or upon the closing of a firmly underwritten public offering pursuant to an effective registration statement under the United States Securities Act of 1933, as amended, covering the offer and sale of common stock of the holding company of the Pledgor, for at least US $50,000,000 before deducting underwriting discounts and commissions and other offering expenses, the Pledged Assets or any remainder thereof shall be released at the request of the Pledgor, to the Pledgor or such other party as designated by the Pledgor.”

5. Amendment to Receivables Assignment Agreement.

5.1 Clause 5.1 of the Receivables Assignment Agreement is hereby amended and restated in its entirety to read as follows:
“Upon the Secured Liabilities being discharged in full and the Assignee being under no further obligation to make any financial accommodation or loan facility to the Assignor under the Loan Agreement, the assigned Receivables shall be released and re-assigned at the request of the Assignor, to the Assignor or such other party as designated by the Assignor.”

6. **Ratification and Reaffirmation of Liens.** Borrower hereby ratifies and reaffirms the validity and enforceability of all of the liens and security interests heretofore granted pursuant to the Security Documents, as collateral security for the Secured Liabilities (as defined therein), and acknowledges that all of such liens and security interests, and all Charged Assets heretofore pledged as security for the Secured Liabilities continue to be and remain subject to the Security Documents from and after the date hereof until released as provided in the Loan Agreement and the Security Documents.

7. **Representations And Warranties.** Borrower represents and warrants that its representations and warranties in the Loan Agreement and the Security Documents continue to be true and complete in all material respects as of the date hereof after giving effect to this Amendment and that the execution, delivery and performance of this Amendment are duly authorized, do not require the consent or approval of any governmental body or regulatory authority and are not in contravention of or in conflict with any law or regulation or any term or provision of any other agreement entered into by Borrower.

8. **Full Force And Effect; Entire Agreement.** Except to the extent expressly provided in this Amendment, the terms and conditions of the Loan Agreement and the Security Documents shall remain in full force and effect. This Amendment, the Security Documents, and the Option Agreement among Borrower, Lender, and Kreos Capital III Limited executed on or about September 9, 2008 constitute and contain the entire agreement of the parties hereto and supersede any and all prior agreements, negotiations, correspondence, understandings and communications between the parties, whether written or oral, respecting the subject matter hereof. The parties hereto further agree that the Loan Agreement, the Security Documents, and said Option Agreement comprise the entire agreement of the parties thereto and supersede any and all prior agreements, negotiations, correspondence, understandings and other communications between the parties thereto, whether written or oral respecting the extension of credit by Lender to Borrower.

9. **Counterparts; Effectiveness.** This Amendment may be executed in any number of counterparts, each of which when so delivered shall be deemed an original, but all such counterparts taken together shall constitute but one and the same instrument. This Amendment shall be deemed effective as of the date first written above.

10. **Option Agreement and Warrant.** In consideration of this Amendment and in connection with the acquisition of the Borrower referenced in Section 2 of this Amendment (the “Acquisition”), Borrower, Lender and Kreos Capital III Limited agree that certain Option Agreement dated September 10, 2008 issued by Borrower to Lender and Kreos Capital III Limited (as may have been amended from time to time, the “Existing Option”) shall, as of the date of this Amendment,
be exchanged for a warrant to purchase Series A Preferred Stock of Horizon Pharma, Inc., the parent of Borrower, in the form attached hereto as Exhibit B (the “Warrant”). Upon the execution and delivery of the Warrant to Lender and to Kreos Capital III Limited, the Existing Option shall be deemed cancelled and terminated effective as of the closing of the Acquisition. Each of Lender and Kreos Capital III Limited hereby waives any right to notice it may have under the Existing Option with respect to the Acquisition and each of Lender and Kreos Capital III Limited hereby releases and forever discharges Borrower, its parent, subsidiaries, affiliates and agents from any and all claims, demands, liabilities and obligations of any kind, known or unknown, arising under or related to the Existing Option.

11. **Governing Law.** This Amendment shall be governed by the laws of England and the parties accept the non-exclusive jurisdiction of the courts of England.

[signature page to follow]
IN WITNESS WHEREOF, each of the parties hereto has caused this Amendment to be executed and delivered by its duly authorized officer as of the date first written above.

BORROWER:

NITEC PHARMA AG

By: /s/ Anders Härstrand
Name: Anders Härstrand
Title: CEO EVP

LENDER:

KREOS CAPITAL III (UK) LIMITED

By: ________________________________
Name: ________________________________
Title: ______________________________

(solely for purposes of Clause 10 of the Amendment:)

KREOS CAPITAL III LIMITED

By: ________________________________
Name: ________________________________
Title: ______________________________
IN WITNESS WHEREOF, each of the parties hereto has caused this Amendment to be executed and delivered by its duly authorized officer as of the date first written above.

BORROWER:

NITEC PHARMA AG

By:  
Name:  
Title:  

LENDER:

KREOS CAPITAL III (UK) LIMITED

By: /s/ Maurizio Petit Bon  
Name: Maurizio Petit Bon  
Title: Director  

(solely for purposes of Clause 10 of the Amendment:)

KREOS CAPITAL III LIMITED

By:  
Name:  
Title:  

IN WITNESS WHEREOF, each of the parties hereto has caused this Amendment to be executed and delivered by its duly authorized officer as of the date first written above.

BORROWER:

NITEC PHARMA AG

By: ________________________________
Name: ______________________________
Title: ______________________________

LENDER:

KREOS CAPITAL III (UK) LIMITED

By: ________________________________
Name: ______________________________
Title: ______________________________

(solely for purposes of Clause 10 of the Amendment:)

KREOS CAPITAL III LIMITED

By: /s/ Ross Ahlgren
Name: Ross Ahlgren
Title: ______________________________
### SCHEDULE 5.2

All amounts stated are in Euros

<table>
<thead>
<tr>
<th>Due Date</th>
<th>Repayment Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>01-May-10</td>
<td>50,000.00</td>
</tr>
<tr>
<td>01-Jun-10</td>
<td>50,000.00</td>
</tr>
<tr>
<td>01-Jul-10</td>
<td>50,000.00</td>
</tr>
<tr>
<td>01-Aug-10</td>
<td>50,000.00</td>
</tr>
<tr>
<td>01-Sep-10</td>
<td>50,000.00</td>
</tr>
<tr>
<td>01-Oct-10</td>
<td>50,000.00</td>
</tr>
<tr>
<td>01-Nov-10</td>
<td>50,000.00</td>
</tr>
<tr>
<td>01-Dec-10</td>
<td>50,000.00</td>
</tr>
<tr>
<td>01-Jan-11</td>
<td>184,000.00</td>
</tr>
<tr>
<td>01-Feb-11</td>
<td>184,000.00</td>
</tr>
<tr>
<td>01-Mar-11</td>
<td>184,000.00</td>
</tr>
<tr>
<td>01-Apr-11</td>
<td>184,000.00</td>
</tr>
<tr>
<td>01-May-11</td>
<td>184,000.00</td>
</tr>
<tr>
<td>01-Jun-11</td>
<td>184,000.00</td>
</tr>
<tr>
<td>01-Jul-11</td>
<td>184,000.00</td>
</tr>
<tr>
<td>01-Aug-11</td>
<td>184,000.00</td>
</tr>
<tr>
<td>01-Sep-11</td>
<td>184,000.00</td>
</tr>
<tr>
<td>01-Oct-11</td>
<td>184,000.00</td>
</tr>
<tr>
<td>01-Nov-11</td>
<td>184,000.00</td>
</tr>
<tr>
<td>Date</td>
<td>Amount</td>
</tr>
<tr>
<td>------------</td>
<td>----------</td>
</tr>
<tr>
<td>01-Dec-11</td>
<td>184,000.00</td>
</tr>
<tr>
<td>01-Jan-12</td>
<td>184,000.00</td>
</tr>
<tr>
<td>01-Feb-12</td>
<td>184,000.00</td>
</tr>
<tr>
<td>01-Mar-12</td>
<td>184,000.00</td>
</tr>
<tr>
<td>01-Apr-12</td>
<td>184,000.00</td>
</tr>
<tr>
<td>01-May-12</td>
<td>184,000.00</td>
</tr>
<tr>
<td>01-Jun-12</td>
<td>184,000.00</td>
</tr>
<tr>
<td>01-Jul-12</td>
<td>184,000.00</td>
</tr>
<tr>
<td>01-Aug-12</td>
<td>184,000.00</td>
</tr>
<tr>
<td>01-Sep-12</td>
<td>184,000.00</td>
</tr>
<tr>
<td>01-Oct-12</td>
<td>184,000.00</td>
</tr>
<tr>
<td>01-Nov-12</td>
<td>184,000.00</td>
</tr>
<tr>
<td>01-Dec-12</td>
<td>184,000.00</td>
</tr>
<tr>
<td>01-Jan-13</td>
<td>184,000.00</td>
</tr>
<tr>
<td>01-Feb-13</td>
<td>184,000.00</td>
</tr>
<tr>
<td>01-Mar-13</td>
<td>184,000.00</td>
</tr>
<tr>
<td>01-Apr-13</td>
<td>184,000.00</td>
</tr>
<tr>
<td>01-May-13</td>
<td>184,000.00</td>
</tr>
<tr>
<td>01-Jun-13</td>
<td>184,000.00</td>
</tr>
<tr>
<td>01-Jul-13</td>
<td>184,000.00</td>
</tr>
<tr>
<td>01-Aug-13</td>
<td>184,000.00</td>
</tr>
<tr>
<td>01-Sep-13</td>
<td>184,000.00</td>
</tr>
<tr>
<td>01-Oct-13</td>
<td>184,000.00</td>
</tr>
</tbody>
</table>
THE SECURITIES REPRESENTED HEREBY HAVE BEEN ACQUIRED PURSUANT TO REGULATION S OF THE SECURITIES ACT OF 1933, AS AMENDED (THE “ACT”), AND MAY NOT BE SOLD, MORTGAGED, PLEDGED, HYPOTHECATED OR OTHERWISE TRANSFERRED EXCEPT IN ACCORDANCE THEREWITH, PURSUANT TO A REGISTRATION UNDER THE ACT OR PURSUANT TO AN AVAILABLE EXEMPTION FROM REGISTRATION. THE ISSUER OF THESE SECURITIES MAY REQUIRE AN OPINION OF COUNSEL IN FORM AND SUBSTANCE SATISFACTORY TO THE ISSUER TO THE EFFECT THAT ANY PROPOSED TRANSFER OR RESALE IS IN COMPLIANCE WITH THE ACT AND ANY APPLICABLE STATE SECURITIES LAWS. IN ADDITION, NO HEDGING TRANSACTION MAY BE CONDUCTED WITH RESPECT TO THESE SECURITIES UNLESS SUCH TRANSACTIONS ARE IN COMPLIANCE WITH THE ACT.

HORIZON PHARMA, INC.

WARRANT TO PURCHASE SERIES A PREFERRED STOCK [SERIES A FOR THE REPLACEMENT WARRANT; SERIES B FOR THE NEW KREOS AND SVB WARRANTS UNDER THE NEW LOAN]

No. PAW— April __, 2010

Void After April __, 2020

[NOTE: THIS FORM OF WARRANT IS INTENDED TO SERVE TWO PURPOSES: (1) TO BE THE REPLACEMENT WARRANT FOR THE EXISTING KREOS OPTION, FOR WHICH IT WILL BE A SERIES A PREFERRED WARRANT, AND (2) TO BE THE FORM OF SERIES B WARRANT FOR BOTH KREOS AND SVB]

THIS CERTIFIES THAT, for value received, Kreos Capital III Limited, with its principal office at 47 Esplanade, St-Helier, Jersey or assigns (the “Holder”), is entitled to subscribe for and purchase at the Exercise Price (defined below) from HORIZON PHARMA, INC., a Delaware corporation, with its principal office at 1033 Skokie Boulevard, Suite 355, Northbrook, Illinois 60062 (the “Company”), up to [_______] shares of the Series A Preferred Stock of the Company (the “Series A Stock”) or if the outstanding Series A Preferred Stock is converted into Common Stock of the Company, then the number of shares of Common Stock of the Company (the “Common Stock”) into which such Series A Stock would have been converted had the Warrant been exercised immediately prior to the conversion of the outstanding Series A Preferred Stock into Common Stock.

1. DEFINITIONS. As used herein, the following terms shall have the following respective meanings:

(a) “Current Market Price” as of a specified date shall mean: (i) if the Warrant is exercisable for Common Stock and the Common Stock is publicly traded on such date, the average closing price per share over the preceding five trading days (or, if less than five days, the average closing price per share of all trading days since the stock became publicly traded) as reported on the principal stock exchange or quotation system on which the stock is listed or quoted; or (ii) if the Series A Stock (as adjusted herein) is not publicly traded on such
date, the Board of Directors of the Company shall determine Current Market Price in its reasonable good faith judgment.

(b) “Exercise Period” means the period commencing with the date hereof and ending on April __, 2020, unless sooner terminated as provided below.

(c) “Exercise Price” means U.S.$0.01 per share, subject to adjustment pursuant to Section 6 below. If the outstanding Series A Stock converts into Common Stock at a conversion rate that is more or less than one share for one share, then the per share Exercise Price shall be adjusted by dividing the aggregate Exercise Price of all of the Exercise Shares immediately prior to the conversion by the number of Exercise Shares immediately following the conversion.

(d) “Exercise Shares” means as applicable the shares of the Series A Stock or shares of Common Stock issuable upon exercise of this Warrant, subject to adjustment pursuant to the terms herein, including but not limited to adjustment pursuant to Section 6 below.


(f) “U.S. Person” means (i) any natural person resident in the United States, (ii) any partnership or corporation organized or incorporated under the laws of the United States (iii) any estate of which any executor or administrator is a U.S. Person, (iv) any trust of which any trustee is a U.S. Person, (v) any agency or branch of a foreign entity located in the United States, (vi) any non-discretionary account or similar account (other than an estate or trust) held by a dealer or other fiduciary for the benefit or account of a U.S. Person, (vii) any discretionary account or similar account (other than an estate or trust) held by a dealer or other fiduciary organized, incorporated, or (if an individual) resident in the United States, and (viii) any partnership or corporation if: (1) organized or incorporated under the laws of any foreign jurisdiction; and (2) formed by a U.S. Person principally for the purpose of investing in securities not registered under the Act (as defined below), unless it is organized or incorporated, and owned, by accredited investors (as defined in Regulation D under the Act) who are not natural persons, estates or trusts, provided, however, the following are not “U.S. Persons”: (i) any discretionary account or similar account (other than an estate or trust) held for the benefit or account of a non-U.S. Person by a dealer or other professional fiduciary organized, incorporated, or (if an individual) resident in the United States, (ii) any estate of which any professional fiduciary acting as executor or administrator is a U.S. Person if: (1) an executor or administrator of the estate who is not a U.S. Person has sole or shared investment discretion with respect to the assets of the estate; and (2) the estate is governed by foreign law, (iii) any trust of which any professional fiduciary acting as trustee is a U.S. Person, if a trustee who is not a U.S. Person has sole or shared investment discretion with respect to the trust assets, and no beneficiary of the trust (and no settler if the trust is revocable) is a U.S. Person, (iv) an employee benefit plan established and administered in accordance with the law of a country other than the United States and customary practices and documentation of such country, (v) any agency or branch of a U.S. Person located outside the United States if: (1) the agency or branch operates for valid business reasons; and (2) the agency or branch is engaged in the business of insurance or banking and is subject to substantive insurance or banking regulation, respectively, in the jurisdiction where
located; and (vi) the International Monetary Fund, the International Bank for Reconstruction and Development, the Inter-American Development Bank, the
Asian Development Bank, the African Development Bank, the United Nations, and their agencies, affiliates and pension plans, and any other similar
international organizations, their agencies, affiliates and pension plans.

2. EXERCISE OF WARRANT. The rights represented by this Warrant may be exercised in whole or in part at any time during the Exercise Period, by
delivery of the following to the Company at its address set forth above (or at such other address as it may designate by notice in writing to the Holder):

(a) An executed Notice of Exercise in the form attached hereto;

(b) Payment of the Exercise Price either (i) in cash or by check, (ii) by cancellation of indebtedness, or (iii) as provided in Section 2.1; and

(c) This Warrant.

Upon the exercise of the rights represented by this Warrant, a certificate or certificates for the Exercise Shares so purchased, registered in the name of
the Holder or persons affiliated with the Holder, if the Holder so designates, shall be issued and delivered to the Holder within a reasonable time after the
rights represented by this Warrant shall have been so exercised.

The person in whose name any certificate or certificates for Exercise Shares are to be issued upon exercise of this Warrant shall be deemed to have
become the holder of record of such shares on the date on which this Warrant was surrendered and payment of the Exercise Price was made, irrespective of the
date of delivery of such certificate or certificates, except that, if the date of such surrender and payment is a date when the stock transfer books of the
Company are closed, such person shall be deemed to have become the holder of such shares at the close of business on the next succeeding date on which the
stock transfer books are open.

2.1 Net Exercise. Notwithstanding any provisions herein to the contrary, if the fair market value of one share of the Series A Stock (or as
applicable one share of Common Stock) is greater than the Exercise Price (at the date of calculation as set forth below), in lieu of exercising this Warrant by
payment of cash, the Holder may elect to receive shares equal to the value (as determined below) of this Warrant (or the portion thereof being canceled) by
surrender of this Warrant at the principal office of the Company together with the properly endorsed Notice of Exercise in which event the Company shall
issue to the Holder a number of shares of Series A Stock or Common Stock computed using the following formula:

\[
X = \frac{Y (A - B)}{A}
\]

Where

- \(X\) = the number of shares of Series A Stock to be issued to the Holder
- \(Y\) = the number of shares of Series A Stock purchasable under the Warrant or, if only a portion of the Warrant is being exercised, the portion
  of the Warrant being canceled (at the date of such calculation)
\( A = \) Current Market Price (at the date of such calculation)  
\( B = \) Exercise Price (as adjusted to the date of such calculation)

**2.2 Automatic Exercise.** Notwithstanding any provisions herein to the contrary, if the Holder of this Warrant has not elected to exercise this Warrant prior to expiration of this Warrant pursuant to Section 8, then this Warrant shall automatically (without any act on the part of the Holder) be exercised pursuant to Section 2.1 effective immediately prior to the expiration of the Warrant to the extent such net issue exercise would result in the issuance of Exercise Shares unless Holder shall earlier provide written notice to the Company that the Holder desires that this Warrant expire unexercised. If this Warrant is automatically exercised, the Company shall notify the Holder of the automatic exercise as soon as reasonably practicable, and the Holder shall surrender the Warrant to the Company in accordance with the terms hereof.

**3. COVENANTS OF THE COMPANY.**

**3.1 Covenants as to Exercise Shares.** The Company covenants and agrees that all Exercise Shares that may be issued upon the exercise of the rights represented by this Warrant will, upon issuance, be validly issued and outstanding, fully paid and nonassessable, and free from all taxes, liens and charges with respect to the issuance thereof. The Company further covenants and agrees that the Company will at all times during the Exercise Period, have authorized and reserved, free from preemptive rights, a sufficient number of shares of its Series A Stock and Common Stock to provide for the exercise of the rights represented by this Warrant and the conversion of the Series A Stock into Common Stock. If at any time during the Exercise Period the number of authorized but unissued shares of Series A Stock or Common Stock, as applicable, shall not be sufficient to permit exercise of this Warrant, the Company will take such corporate action as may, in the opinion of its counsel, be necessary to increase its authorized but unissued shares of Series A Stock or Common Stock to such number of shares as shall be sufficient for such purposes.

**3.2 Rights under the Investor Rights Agreement.** The Holder shall be entitled to registration rights with respect to the Exercise Shares, or the Common Stock issuable upon conversion thereof, as set forth in that certain Investors’ Rights Agreement, dated as of April 1, 2010, a true and complete copy of which is attached hereto as Appendix I (the “Investor Rights Agreement”), as such may from time to time be amended, for purposes of Sections 1 (with the exception of Section 1.2) and 3 only. The Exercise Shares shall also be deemed “Registrable Securities” as that term is defined in the Investor Rights Agreement, and the Holder shall be deemed a “Holder,” subject to all of the rights and obligations thereunder, in each case only for the purposes of those sections listed above. The Holder shall perform such steps as are required by the Company to make it a party to the Investor Rights Agreement as described in this Section 3.2. The Company agrees that no amendments will be made to the Investor Rights Agreement which would have an adverse impact on Holder’s registration rights thereunder different from the impact on the rights of other Holders (as defined in the Rights Agreement) of the Company’s stock without the consent of Holder. By acceptance of this Warrant, Holder shall be deemed to be a party to the Investor Rights Agreement solely for the purposes of the above-mentioned registration rights.
4. REPRESENTATIONS OF HOLDER.

4.1 Acquisition of Warrant for Personal Account.

(a) The Holder represents and warrants that it is acquiring the Warrant and the Exercise Shares solely for its account for investment, not as a nominee or agent, and not for the account or benefit of, a U.S. Person, and not with a view to or for sale or distribution of said Warrant or Exercise Shares or any part thereof in the United States or to a U.S. Person. The Holder also represents that the entire legal and beneficial interests of the Warrant and Exercise Shares the Holder is acquiring is being acquired for, and will be held for, its account only.

(b) The Holder represents and warrants that it does not have any contract, undertaking, agreement or arrangement with any person to sell, transfer or grant participations to such person or to any third person in the United States or to a U.S. Person, or any hedging transaction with any third person in the United States or to a United States resident, with respect to the Warrant or any of the Exercise Shares.

(c) The Holder is a person or entity that is not a U.S. Person.

(d) The Holder understands that it could lose its entire investment in the Company.

4.2 Securities Are Not Registered.

(a) The Holder understands that the Warrant and the Exercise Shares have not been registered under the Securities Act of 1933, as amended (the “Act”), on the basis that the issuance of the Warrant and the Exercise Shares are exempt from registration under the Act pursuant to Regulation S thereof. The Holder realizes that the basis for the exemption may not be present if, notwithstanding its representations, the Holder has a present intention of acquiring the securities for a fixed or determinable period in the future, selling (in connection with a distribution or otherwise), granting any participation in, or otherwise distributing the securities. The Holder has no such present intention.

(b) The Holder recognizes that the Warrant and the Exercise Shares must be held indefinitely unless they are subsequently registered under the Act in accordance with the provisions of Regulations S, or an exemption from such registration is available. The Holder recognizes that the Company has no obligation to register the Warrant or the Exercise Shares of the Company, or to comply with any exemption from such registration.

(c) The Holder is aware that neither the Warrant nor the Exercise Shares may be sold pursuant to Rule 144 adopted under the Act unless certain conditions are met, including, among other things, the existence of a public market for the shares, the availability of certain current public information about the Company, the resale following the required holding period under Rule 144 and the number of shares being sold during any three month period not exceeding specified limitations. Holder is aware that the conditions for resale set forth in Rule 144 have not been satisfied and that the Company presently has no plans to satisfy these conditions in the foreseeable future.
4.3 Disposition of Warrant and Exercise Shares.

(a) The Holder will not, directly or indirectly, offer, sell, pledge, transfer or otherwise dispose of (or solicit any offers to buy, purchase or otherwise acquire or take a pledge of) this Warrant or any of the Exercise Shares except in compliance with the Act, applicable blue sky laws, and the rules and regulations promulgated thereunder. The Holder further agrees not to engage in hedging transactions with regard to such securities unless in compliance with the Act.

(b) The Holder further agrees not to make any disposition of all or any part of the Warrant or Exercise Shares in any event unless and until:

(i) The Company shall have received a letter secured by the Holder from the Securities and Exchange Commission stating that no action will be recommended to the Commission with respect to the proposed disposition;

(ii) There is then in effect a registration statement under the Act covering such proposed disposition and such disposition is made in accordance with said registration statement, or pursuant to an exemption from registration; or

(iii) The Holder shall have notified the Company of the proposed disposition and shall have furnished the Company with a detailed statement of the circumstances surrounding the proposed disposition, and if reasonably requested by the Company, the Holder shall have furnished the Company with an opinion of counsel, reasonably satisfactory to the Company, for the Holder to the effect that such disposition will not require registration of such Warrant or Exercise Shares under the Act or any applicable state securities laws.

(c) The Holder understands and agrees that all certificates evidencing the shares to be issued to the Holder may bear the following legend (in addition to any legend required under applicable state or foreign securities laws):

THE SHARES REPRESENTED BY THIS CERTIFICATE HAVE BEEN ACQUIRED PURSUANT TO REGULATION S OF THE SECURITIES ACT OF 1933, AS AMENDED (THE “ACT”), AND MAY NOT BE OFFERED, SOLD, MORTGAGED OR OTHERWISE TRANSFERRED, PLEDGED OR HYPOTHECATED EXCEPT IN ACCORDANCE WITH REGULATION S, PURSUANT TO A REGISTRATION UNDER THE ACT, OR PURSUANT TO AN AVAILABLE EXEMPTION FROM REGISTRATION. THE ISSUER OF THESE SECURITIES MAY REQUIRE AN OPINION OF COUNSEL IN FORM AND SUBSTANCE REASONABLY SATISFACTORY TO THE ISSUER TO THE EFFECT THAT ANY PROPOSED TRANSFER OR RESALE IS IN COMPLIANCE WITH THE ACT AND ANY APPLICABLE SECURITIES LAWS.

5. REPRESENTATIONS OF COMPANY. The Company represents and warrants to the Holder that:
5.1 Authorization. All corporate action on the part of the Company, its officers, directors and stockholders necessary for the authorization, execution and delivery of this Warrant, the performance of all obligations of the Company hereunder and the authorization, issuance (or reservation for issuance), sale and delivery of the Exercise Shares has been taken, and this Warrant, when executed and delivered by the Company, shall constitute valid and legally binding obligations of the Company, enforceable against the Company in accordance with its terms except (i) as limited by applicable bankruptcy, insolvency, reorganization, moratorium, fraudulent conveyance, or other laws of general application relating to or affecting the enforcement of creditors’ rights generally or (ii) as limited by laws relating to the availability of specific performance, injunctive relief, or other equitable remedies.

5.2 Organization. The Company is a corporation duly organized, validly existing and in good standing under the laws of the State of Delaware and has all requisite corporate power and authority to own its properties and assets, to carry on its business as presently conducted or as proposed to be conducted.

6. ADJUSTMENT OF EXERCISE PRICE, ETC.

6.1 Adjustments for Reclassification, Exchange or Substitution, etc. In the event of changes in the outstanding Series A Stock or as applicable the outstanding Common Stock of the Company by reason of stock dividends, split-ups, recapitalizations, reclassifications, combinations or exchanges of shares, separations, reorganizations, liquidations, or the like, the number and class of shares available under the Warrant in the aggregate and the Exercise Price shall be correspondingly adjusted to give the Holder of the Warrant, on exercise for the same aggregate Exercise Price, the total number, class, and kind of shares as the Holder would have owned had the Warrant been exercised prior to the event and had the Holder continued to hold such shares until after the event requiring adjustment; provided, however, that such adjustment shall not be made with respect to, and, except as otherwise provided in Section 2.2 above, this Warrant shall terminate if not exercised prior to, the events set forth in Section 8 below. The form of this Warrant need not be changed because of any adjustment in the number of Exercise Shares subject to this Warrant.

7. FRACTIONAL SHARES. No fractional shares shall be issued upon the exercise of this Warrant as a consequence of any adjustment pursuant hereto. All Exercise Shares (including fractions) issuable upon exercise of this Warrant may be aggregated for purposes of determining whether the exercise would result in the issuance of any fractional share. If, after aggregation, the exercise would result in the issuance of a fractional share, the Company shall, in lieu of issuance of any fractional share, pay the Holder otherwise entitled to such fraction a sum in cash equal to the product resulting from multiplying the then current fair market value of an Exercise Share by such fraction.

8. EARLY TERMINATION. If after the date hereof the Company shall enter into any Reorganization (as hereinafter defined), then, as a condition of such Reorganization, lawful provisions shall be made, and duly executed documents evidencing the same from the Company or its successor shall be delivered to the Holder, so that the Holder shall thereafter have the right to purchase, at a total price not to exceed that payable upon the exercise of this Warrant in full, the kind and amount of shares of stock and other securities and property receivable upon such
Reorganization by a holder of the number of shares of Series A Stock which might have been purchased by the Holder immediately prior to such
Reorganization, and in any such case appropriate provisions shall be made with respect to the rights and interest of the Holder to the end that the provisions
hereof (including without limitation, provisions for the adjustment of the Exercise Price and the number of shares issuable hereunder and the provisions
relating to the net issue election) shall thereafter be applicable in relation to any shares of stock or other securities and property thereafter deliverable upon
exercise hereof. For the purposes of this Section 8, the term "Reorganization" shall include without limitation any reclassification, capital reorganization or
change of the Series A Stock (other than by reason of stock dividends, split-ups, recapitalizations, reclassifications, combinations or exchanges of shares,
separations, reorganizations, liquidations, or the like provided for in Section 6 hereof), or any consolidation of the Company with, or merger of the Company
into, another corporation or other business organization (other than a merger in which the Company is the surviving corporation and which does not result in
any reclassification or change of the outstanding Series A Stock), or any sale or conveyance to another corporation or other business organization of all or
substantially all of the assets of the Company.

9. **MARKET STANDOFF.** [FOR KREOS’ SERIES A REPLACEMENT WARRANT AND KREOS’ SERIES B WARRANT:]
Holder agrees, in connection with the Company’s sale of its Common Stock in a firm underwritten public offering pursuant to a registration statement under the Act, Holder
agrees to consider a request by the Company and its underwriters that (i) the Holder enter into an agreement that it shall not sell, make any short sale of, loan,
grant any option for the purchase of, enter into any hedging or similar transaction with the same economic effect as a sale, or otherwise dispose of any of the
Company’s capital stock (or any securities convertible into the Company’s capital stock) held by Holder, however or whenever acquired (other than those
included in the registration or purchased subsequent to the initial public offering) without the prior written consent of Company or such underwriters, as the
case may be, for such period of time (not to exceed one hundred and eighty (180) days, but subject to such extension or extensions as may be required by the
underwriters in order to publish research reports while complying with the Rule 2711 of the National Association of Securities Dealers, Inc., such extension or
extensions not to exceed thirty-four (34) days after the expiration of such 180-day period) from the effective date of such registration statement as may be
requested by the Company or such managing underwriters and to execute an agreement reflecting the foregoing as may be requested by the underwriters at
the time of the Company’s initial public offering and (ii) that Holder provide such information as may be required by the Company or such representative in
connection with the completion of any public offering of the Company’s securities pursuant to a registration statement filed under the Act.

[FOR THE SVB SERIES B WARRANT:
Holder shall not sell, make any short sale of, loan, grant any option for the purchase of, enter into any
hedging or similar transaction with the same economic effect as a sale, or otherwise dispose of any of the Company’s capital stock (or any securities
convertible into the Company’s capital stock) held by Holder, however or whenever acquired (other than those included in the registration or purchased
subsequent to the initial public offering) without the prior written consent of Company or such underwriters, as the case may be, for such period of time (not
to exceed one hundred and eighty (180) days, but subject to such extension or extensions as may be required by the underwriters in order to publish research
reports while complying with the Rule 2711 of the National Association of

8.
Securities Dealers, Inc., such extension or extensions not to exceed thirty-four (34) days after the expiration of such 180-day period) from the effective date of such registration statement as may be requested by the Company or such managing underwriters and to execute an agreement reflecting the foregoing as may be requested by the underwriters at the time of the Company’s initial public offering. Holder agrees to execute and deliver such other agreements as may be reasonably requested by the Company or the underwriter that are consistent with the Holder’s obligations under this Section 9 or that are necessary to give further effect thereto. In addition, if requested by the Company or the representative of the underwriters of the Company’s capital stock (or other securities) of the Company, Holder shall provide, within ten (10) days of such request, such information as may be required by the Company or such representative in connection with the completion of any public offering of the Company’s securities pursuant to a registration statement filed under the Securities Act. In order to enforce the foregoing covenants, the Company may impose stop-transfer instructions with respect to such capital stock (or other securities) until the end of such period. The underwriters of the Company’s stock are intended third party beneficiaries of this Section 9 and shall have the right, power and authority to enforce the provisions hereof as though they were a party hereto.]

10. **NOTIFICATION OF CERTAIN EVENTS.** Prior to the expiration of this Warrant pursuant to Section 8, in the event that the Company shall authorize:

(a) the issuance of any dividend or other distribution on the capital stock of the Company (other than (i) dividends or distributions otherwise provided for in Section 6, (ii) repurchases of common stock issued to or held by employees, officers, directors or consultants of the Company or its subsidiaries upon termination of their employment or services pursuant to agreements providing for the right of said repurchase; (iii) repurchases of common stock issued to or held by employees, officers, directors or consultants of the Company or its subsidiaries pursuant to rights of first refusal or first offer contained in agreements providing for such rights; or (iv) repurchases of capital stock of the Company in connection with the settlement of disputes with any stockholder), whether in cash, property, stock or other securities;

(b) the voluntary liquidation, dissolution or winding up of the Company;

(c) any transaction resulting in the expiration of this Warrant pursuant to Section 8; or

(d) receipt by the Company of any request for registration made pursuant to Section 1.2 or 1.4 of the Investor Rights Agreement;

the Company shall send to the Holder of this Warrant at least ten (10) days prior written notice of the date on which a record shall be taken for any such dividend or distribution specified in clause (a) or the expected effective date of any such other event specified in clause (b), (c) or (d), as applicable. The notice provisions set forth in this section may be shortened or waived prospectively or retrospectively with the consent of the Holder. In addition, the Company shall deliver to the Holder copies of any proxy or information statements or other communications delivered to shareholders generally.

9.
11. NO STOCKHOLDER RIGHTS. This Warrant in and of itself shall not entitle the Holder to any voting rights or other rights as a stockholder of the Company.

12. TRANSFER OF WARRANT. Subject to applicable laws and the restriction on transfer set forth on the first page of this Warrant, this Warrant and all rights hereunder are transferable, by the Holder in person or by duly authorized attorney, upon delivery of this Warrant and the form of assignment attached hereto to any transferee designated by Holder. The transferee shall sign an investment letter in form and substance satisfactory to the Company.

13. LOST, STOLEN, MUTILATED OR DESTROYED WARRANT. If this Warrant is lost, stolen, mutilated or destroyed, the Company may, on such terms as to indemnity or otherwise as it may reasonably impose (which shall, in the case of a mutilated Warrant, include the surrender thereof), issue a new Warrant of like denomination and tenor as the Warrant so lost, stolen, mutilated or destroyed. Any such new Warrant shall constitute an original contractual obligation of the Company, whether or not the allegedly lost, stolen, mutilated or destroyed Warrant shall be at any time enforceable by anyone.

14. NOTICES, ETC. All notices required or permitted hereunder shall be in writing and shall be deemed effectively given: (a) upon personal delivery to the party to be notified, (b) when sent by confirmed telex or facsimile if sent during normal business hours of the recipient, if not, then on the next business day, (c) five (5) days after having been sent by registered or certified mail, return receipt requested, postage prepaid, or (d) one (1) day after deposit with a nationally recognized overnight courier, specifying next day delivery, with written verification of receipt. All communications shall be sent to the Company at the address listed on the signature page and to Holder at the addresses listed for Holder above or at such other address as the Company or Holder may designate by ten (10) days advance written notice to the other parties hereto.

15. ACCEPTANCE. Receipt of this Warrant by the Holder shall constitute acceptance of and agreement to all of the terms and conditions contained herein.

16. GOVERNING LAW. This Warrant and all rights, obligations and liabilities hereunder shall be governed by the laws of the State of Delaware.
IN WITNESS WHEREOF, the Company has caused this Warrant to be executed by its duly authorized officer as of _____, 2010.

HORIZON PHARMA, INC.

By: ________________________________
Name: ______________________________
Title: ______________________________
Address: ____________________________
NOTICE OF EXERCISE

TO: HORIZON PHARMA, INC.

(1) ☐ The undersigned hereby elects to purchase _____ shares of the Series A Preferred Stock of Horizon Pharma, Inc. (the "Company") pursuant to the terms of the attached Warrant, and tenders herewith payment of the exercise price in full, together with all applicable transfer taxes, if any.

☐ The undersigned hereby elects to purchase _____ shares of the Series A Preferred Stock of the Company pursuant to the terms of the net exercise provisions set forth in Section 2.1 of the attached Warrant, and shall tender payment of all applicable transfer taxes, if any.

(2) Please issue a certificate or certificates representing said shares of Series A Preferred Stock in the name of the undersigned or in such other name as is specified below:

________________________________________
(Name)

________________________________________
(Address)

(3) The undersigned hereby restates and reaffirms the representations and covenants in Section 4 of the Warrant with respect to the Exercise Shares to be received pursuant to this Notice of Exercise.

________________________________________
(Date)

________________________________________
(Signature)

________________________________________
(Print name)

________________________________________
(Date)

________________________________________
(Signature)

________________________________________
(Print name)
ASSIGNMENT FORM

(To assign the foregoing Warrant, execute this form and supply required information. Do not use this form to purchase shares.)

FOR VALUE RECEIVED, the foregoing Warrant and all rights evidenced thereby are hereby assigned to

Name: ____________________________________________
   (Please Print)

Address: __________________________________________
   (Please Print)

Dated: _____, 20___

Holder’s
Signature: ______________________________

Holder’s
Address: ________________________________

Holder’s
Signature: ______________________________

Holder’s
Address: ________________________________

NOTE: The signature to this Assignment Form must correspond with the name as it appears on the face of the Warrant, without alteration or enlargement or any change whatever. Officers of corporations and those acting in a fiduciary or other representative capacity should file proper evidence of authority to assign the foregoing Warrant.
DATED 20 AUGUST 2004

JAGOTEC AG

and

SKYEPHARMA AG

and

NITEC PHARMA AG

DEVELOPMENT & LICENCE AGREEMENT
THIS DEVELOPMENT and LICENCE AGREEMENT (this “Agreement”) is made on 20 August 2004 by and between:

(1) JAGOTEC AG, a Swiss corporation having its place of business at Eptingerstrasse 51, CH-4132 Muttenz, Switzerland (hereinafter referred to as “Jagotec”);

(2) SKYEPHARMA AG, a Swiss corporation having its place of business at Eptingerstrasse 51, CH-4132 Muttenz, Switzerland (hereinafter referred to as “SkyePharma”); and SkyePharma and Jagotec hereinafter sometimes collectively referred to as “Skye”), and

(3) NITEC PHARMA AG, a Swiss corporation, having a place of business at Röschenzerstrasse 9, CH-4153 Reinach, Switzerland (hereinafter referred to as “Nitec”).

WITNESSES AS FOLLOWS:

A. By an agreement effective as of 18th day of August 1998, Skye and Merck KGaA, a German corporation, having a place of business Frankfurterstrasse 250, D-64271 Darmstadt, Germany (hereinafter referred to as “Merck”) entered into an agreement relating to the development of the product, Prednisone using certain proprietary technology and know-how owned by Jagotec relating to pharmaceutical systems for the controlled and/or modified release of active substances, including but not limited to, Jagotec’s patented GEOMATRIX® Technology (as defined below) (hereinafter called the “Merck Agreement”).

B. By an agreement between Merck and Nitec signed by Merck on 14 July 2004 and by Nitec on 2 August 2004 (the “Technology Transfer Agreement”), Merck assigned the Merck Agreement to Nitec, effective as of the Effective Date of this Agreement.

C. Skye has consented to the assignment of the Merck Agreement pursuant to the Technology Transfer Agreement, provided that certain modifications agreed between the Parties (as defined below) are made to the contractual arrangements under the Merck Agreement.
D. On signature of this Agreement, the provisions of the Merck Agreement shall be terminated and replaced in their entirety with the terms and conditions set out below.

NOW, THEREFORE, in consideration of the premises, mutual covenants and agreements contained in this Agreement and intending to be legally bound by it, the Parties hereby agree as follows:

1 Definitions

For purposes of this Agreement, the terms defined in this Section 1 shall have the following meanings:

1.1 “Active Drug” shall mean each of the substances Prednisone, Prednisolone and Methylprednisolone of a quality suitable for the manufacture of Product meeting the Specifications;

1.2 “Affiliate” shall mean any corporation, partnership or other entity controlled by, controlling or under common control with, either Party, with “control” meaning (i) with respect to either Party direct or indirect beneficial ownership of more than 50% of the voting power of, or more than 50% of ownership interest in, such corporation, partnership or other entity and for the avoidance of doubt, Jagotec and SkyePharma shall be regarded as Affiliates;

1.3 “Background IP” shall mean any intellectual property owned by the respective Parties on the Effective Date of this Agreement in respect of the Nitec Know-How or the Skye Know-How which is or may be used under this Agreement and in the case of Nitec shall include all relevant rights intellectual property owned or used by Merck under the Merck Agreement necessary or desirable for use under this Agreement;

1.4 “Commercially Reasonable Efforts” means those efforts and resources that would be used by an established pharmaceutical company were it developing, manufacturing, promoting and detailing its own pharmaceutical products which are of similar market potential as the Product, taking into account product labelling, market potential, past performance, economic return, the regulatory
environment and competitive market conditions in the therapeutic area, all as measured by the facts and circumstances at the time such efforts are due.

1.5 “Confidential Information” shall mean any and all of the Skye Know-How and the Nitec Know-How, as well as any and all information developed during the course of this Agreement, including, but not limited to, materials and techniques, analytical and testing methods, chemical formulae and specifications, product design criteria and test data, and technical information relating to product production and commercial plans;

1.6 “Development Costs” shall mean all reasonable out-of-pocket costs (except those resulting from any breach by Skye hereunder) of the Development Programme performed by Jagotec hereunder;

1.7 “Development Programme” shall mean the programme of work to be carried out by the Parties attached hereto as Exhibit C as may be amended by the Parties in writing acting in good faith within thirty (30) days of the signature of this Agreement and thereafter as may be amended in writing by the Parties from time to time and “Development” shall be construed accordingly;

1.8 “Dose Strength” shall mean with respect to Product each of the formulations containing 1, 2, 5 and 10 mg of Active Drug, respectively;

1.9 “Effective Date” shall mean the date of signature of this Agreement;

1.10 “FDA” shall mean the U.S. Federal Food and Drug Administration and any successor agency thereof;

1.11 “First Launch” shall mean the first commercial sale of the Product in any country of the Territory to any unaffiliated third party in commercial quantities following receipt of all applicable pricing and reimbursement approvals;

1.12 “Foreground IP” shall mean any intellectual property that arises or is developed by either party arising out of this Agreement;

1.13 “GEOMATRIX® Technology” shall mean all of Skye’s oral controlled and/or modified drug release delivery and related technologies together with all improvements thereon and thereto;

1.14 “Intellectual Property” shall mean any patent, including patent applications, divisional, continuation or continuation-in-part applications, re-issues, registered

3.
1.15 “Jagotec Manufacturing Agreement” shall mean the Manufacturing and Supply Agreement to be negotiated in good faith at the appropriate time by and between Jagotec or any of its Affiliates and Nitec or any of its Affiliates on the manufacturing and supply of Product;

1.16 “Licence” shall mean the licence granted to Nitec as set out in Section 5.1;

1.17 “Mutual Recognition Procedure” shall mean the decentralized procedure to obtain a marketing authorisation for prescription drugs in EU countries;

1.18 “Net Sales” shall mean, with respect to any Product, the invoiced sales price of such Product in finished package form invoiced by Nitec and/or its Affiliates and/or its sub-licensee(s) to any independent customer other than Nitec Affiliates or sub-licensee(s), less only (a) sales, use, value added and other direct taxes (but excluding any income tax) actually incurred and paid by Nitec and/or its Affiliates and/or its sub-licensee(s); and (b) customs duties, surcharges and other governmental charges incurred by Nitec and/or its Affiliates and/or its sub-licensee(s) in connection with the exportation or importation of such Product in final form, and (c) a lump sum deduction of [...] for all trade discounts, rebates, commissions, retroactive price reductions, amounts repaid or credited by reason of rejections, returns, and the like;

1.19 “Nitec Know-How” shall mean all of Nitec’s and/or its Affiliates’ information and data (including, without limitation, information and data of Merck under the Merck Agreement), which are not generally known including, but not limited to, patent claims and related information not yet disclosed to the public, formulae, procedures, protocols, techniques and results of experimentation and testing which relate to Active Drug, and/or are useful and/or necessary to develop, make, use or sell any product containing Active Drug;

1.20 “Nitec Manufacturing Licence” shall mean the licence to Nitec granted pursuant to the option set out in Section 5.2;

1.21 “Party” or “Parties” shall mean SkyePharma, Jagotec and Nitec or any of them;
1.22 “Patents” shall mean all patents and patent applications heretofore or hereafter filed or having legal force in any country owned by or licensed to Skye and/or its Affiliates relating to the Product, which claim the GEOMATRIX® Technology or the process of manufacture by use of, or the use of, the GEOMATRIX® Technology and are set out in the attached Exhibit A. Exhibit A is hereby deemed to be amended to include any and all patent applications relating to the subject matter of this Agreement eventually to be filed by or owned by or licensed to Skye or its Affiliates after the Effective Date, together with any and all corresponding foreign patents and patent applications which issue therefrom, and all divisionals, continuations, continuations-in-part, reissues, renewals, extensions, substitutions, confirmations or additions to any such patents or patent applications;

1.23 “Phase III Clinical Study” shall mean a large scale clinical trial in patients suffering from rheumatoid arthritis, the primary goal of which is to establish Product efficacy (and chronic safety) according to Regulatory Authority registration rules or regulations;

1.24 “Product” shall mean the pharmaceutical orally-administered controlled-release formulation (intended to exhibit a lag phase of at least one hour, with substantially all of the drug release immediately thereafter) containing Prednisone, Prednisolone and/or Methylprednisolone, presented as a compressed tablet developed pursuant to this Agreement and using the GEOMATRIX® Technology, and shall include all Dose Strengths unless otherwise explicitly stated;

1.25 “Registration” shall mean the granting of any and all approvals and registrations of Product by any Regulatory Authority, including without limitation price approval, which are required and/or necessary under any applicable law, rule, regulation or other governmental order to manufacture, market, distribute and sell Product in any country of the Territory;

1.26 “Regulatory Authority” shall mean the FDA and any equivalent competent regulatory authority in the other countries of the Territory;

1.27 “Skye Know-How” shall mean all of Skye’s and/or its Affiliates’ information and data, which are not generally known including, but not limited to, patent
claims and related information not yet disclosed to the public, formulae, procedures, protocols, techniques and results of experimentation and testing, which relate to the GEOMATRIX® Technology and/or are useful and/or necessary to develop, make, use or sell Products using the GEOMATRIX® Technology;

1.28 “Specifications” shall mean the preliminary specifications of the Product set forth in Exhibit B attached hereto to be updated from time to time by mutual agreement of the Parties;

1.29 “Technical Agreement” shall mean the additional contract to be entered into by Nitec as contract giver and Jagotec as contract acceptor, allocating the respective pharmaceutical responsibilities relating to the manufacture and control of Products;

1.30 “Territory” shall mean all countries and territories in the world.

2 Development Preamble and further Development Programme

2.1 Jagotec has, prior to the execution of this Agreement, developed the Product under the Development and Licence Agreement with Merck, which shows some promising results. In particular, the Parties have agreed to use the results as the basis of further development under this Agreement, the terms of which are hereby incorporated into this Agreement as set out below.

2.2 Jagotec and Nitec undertake to conduct the further development of the Product in rheumatoid arthritis (and such other indications (e.g. asthma, IBD) as may be agreed between the Parties in writing from time to time) in accordance with the Development Programme in an efficient and professional manner, and shall apply generally accepted Good Laboratory, Good Clinical and Good Manufacturing Practices (each as applicable to pharmaceutical products for human use in the European Union and similar regulations applicable in other territories). The Development shall also comply with the current guidelines of the European Union (e.g. Note for guidance on quality of modified release products). Nitec shall actively support Jagotec regarding the development and studies to be executed by Jagotec under this Agreement as may be reasonably required by Jagotec from time to time. In particular, Nitec shall provide information
reasonably requested by Jagotec relating to the Active Drug for the purposes of carrying out this development, including, but not limited to physico-chemical characteristics, safe-handling instructions, in-vitro analytical methods, degradation products and standards and analytical methods therefore, all to the extent that any such information has not been delivered to Jagotec under the development and Licence Agreement with Merck. Any costs and expenses incurred by Nitec in connection with such support shall be borne by Nitec.

2.3 Jagotec shall use all Active Drug supplied to it by Nitec hereunder solely and exclusively in connection with the Development.

2.4 Due to the nature and complexity of the development and the respective studies as set forth in this Agreement, the Parties recognize and acknowledge that problems and delays might render the timeframe of the development difficult or impossible to accomplish. The Parties agree that they shall immediately inform each other in writing in the event that significant problems or delays are encountered or envisaged during the course of the development and shall discuss such problems and delays in order to mutually agree on Commercially Reasonable Efforts to resolve such problems or delays. Nothing under this Section 2.4 shall affect the timelines set out in Section 3 except to the extent of delays resulting directly from the breach of its obligations under this Agreement by Jagotec.

2.5 Nitec acknowledges and agrees that Jagotec’s obligations under this Agreement shall be strictly limited to the development steps and tasks explicitly listed and described in the Development Programme, and that any amendment, change and alteration to, or extension of, any such development steps and tasks shall require the mutual agreement by the Parties.

2.6 Nitec shall bear all Development Costs. Nitec and Jagotec shall have the right to approve any additional activities not listed in Exhibit C which are proposed by Jagotec or Nitec.

2.7 Nitec shall reimburse Jagotec on a quarterly basis any and all Development Cost incurred by Jagotec hereunder upon receipt of the respective invoices pursuant to Section 2.9 below.

7.
2.8 During the term of this Agreement, Jagotec shall provide Nitec on a quarterly basis with an overview of the work intended by Jagotec to be performed according to the Development Programme during the following three (3) months (hereinafter the “Quarterly Workplan”). Each such Quarterly Workplan shall contain information regarding the steps to be performed by Jagotec hereunder together with an estimate of the man-hours expected to be spent on such steps and the anticipated Development Costs. Upon receipt of any such Quarterly Workplan, Nitec may comment thereon or disapprove certain steps included therein by written notice within five (5) business days after receipt of each such Quarterly Workplan, provided that each Quarterly Workplan shall be deemed approved by Nitec if no such written notice is received by Jagotec within such five (5) business days, and provided further that Jagotec shall have no responsibility for any delay in the Development Programme caused by or resulting from any such notice from Nitec.

2.9 Jagotec shall issue quarterly a report (“Quarterly Report”) reasonably detailing all development steps performed during the preceding three (3) month period, and Jagotec shall, simultaneously with each such Quarterly Report, issue an invoice covering all cost and expenses incurred by Jagotec hereunder in accordance with the terms of this Agreement including any Development Costs over the period covered by such Quarterly Report applying a rate of [...***...] per man-hour spent. Any excess of the aggregate amount of development fees paid by Nitec over the aggregate amount(s) invoiced by Jagotec shall be credited by Jagotec against future invoices hereunder.

2.10 Nitec undertakes to settle each invoice so issued, which shows a balance in favour of Jagotec, within [...***...] as of the respective invoice date.

3 Responsibilities

3.1 Nitec will use all Commercially Reasonable Efforts to perform at its sole cost and expense, the following:

(a) all clinical studies, including without limitation:

***Confidential Treatment Requested
(i) commence the Phase III Clinical Study in Rheumatoid Arthritis as agreed with the German authority February, 17\textsuperscript{a} 2004 within [...***…] of the Effective Date;

(ii) complete the above mentioned (3.1(a)(i) Phase III Clinical Study within [...***…] of commencing the Phase III Clinical Study, and;

(iii) other development steps and tasks (other than those which are assigned to Jagotec as may be agreed between the parties from time to time) which are required and/or necessary and/or deemed reasonable to be performed pursuant to all applicable law, statute or regulation, in order to apply for, and subsequently receive, Registrations for Product in at least one major European market and eventually other countries of the Territory;

(b) apply for and diligently pursue, in Nitec’s (or its Affiliates’) own name; Registrations for Product in Rheumatoid Arthritis with the Regulatory Authorities in at least one major European market within [...***…] of the completion of the Phase III clinical studies, and eventually other countries of the Territory;

(c) apply for and diligently pursue (except where the primary obligation for doing so is placed on Jagotec under relevant legislation) any and all approvals required by any applicable law, statute or regulation to manufacture Product at the manufacturing site as set forth in the Jagotec Manufacturing Agreement or any other facility to subsequently manufacture Product;

(d) within [...***…] of the receipt of first Registration for Product in the reference member state, being such country referred to in Section 3.1(b), to start and thereafter diligently pursue the Mutual Recognition Procedure or other procedure to obtain Registration in at least three other countries of the Territory; and

(e) launch or have launched the Product in at least three European Union countries within [...***…] following receipt of Registration in those countries of the European Union.

***Confidential Treatment Requested
3.2 Nitec may decide at its own discretion and according to its business strategy, in which country of the Territory to first apply for Registration of Product and initiate and pursue the steps required to be performed for successful Registration of Product.

3.3 In the event that Nitec does not in any material respect meet any of its obligations pursuant to Section 3.1 above, Skye may thereafter call a meeting with Nitec at which Skye will determine, at Jago’s sole option, either to (i) allow Nitec a further [...] to complete such obligation, or (ii) Skye to terminate the Agreement in which case the terms of Section 10.4 (c) shall apply.

3.4 Jagotec agrees to provide such technical assistance and consultation in addition to the tasks assigned to Jagotec pursuant to this Agreement as may be reasonably required by Nitec in connection with the development, testing, performance of clinical studies, applications for Registrations or similar services, provided that Nitec shall pay to Jagotec an amount of [...] spent by Jagotec personnel in providing such additional assistance and consultation. In addition to such fee, Nitec undertakes to reimburse Jagotec for all cost and expenses incurred in connection with travel and accommodation of Jagotec personnel providing upon specific request by Nitec any such assistance and consultation at locations remote from their usual working location to the extent separately agreed upon.

3.5 Jagotec shall have no responsibility whatsoever in respect of the availability or quality of the results of the development steps to be performed by Nitec pursuant to Section 3.1 above, unless otherwise agreed upon by the Parties in writing with respect to any specified development step or part thereof to be performed by Jagotec in accordance with Section 3.4 above.

3.6 Nitec undertakes to provide to Jagotec upon availability with all information on any of the development steps performed by Nitec under Section 2.1 above in reasonable detail or as reasonably required by Jagotec to perform its obligation under this Agreement. In particular, but without limitation, Nitec shall provide Jagotec upon availability with results, data, reports and similar information obtained by any of the studies, testing, Registration procedures or the like performed by Nitec under this Agreement. Any and all such information provided by Nitec to Jagotec shall be treated by Jagotec as Confidential Information and

***Confidential Treatment Requested
3.7 In the event that the Parties shall deem the results of any of the development steps to be performed by Nitec under this Section 3, including without limitation, the results of any clinical study (including Phase III Clinical Study) performed hereunder, to be unsatisfactory for any reason, the Parties may mutually agree to abandon the development of the Product under this Agreement and terminate this Agreement with immediate effect.

3.8 The allocation of all technical and pharmaceutical responsibilities shall be included in the Technical Agreement which the Parties shall negotiate in good faith within thirty (30) days of the Effective Date.

4 Proprietary Rights and Patents

4.1 Rights to Foreground IP

(a) Any Foreground IP relating specifically and exclusively to the GEOMATRIX® Technology or the process of manufacture by use of, or the use of the GEOMATRIX® Technology, including the formulation of any compound (including Active Drug) with GEOMATRIX® Technology shall vest in and be owned absolutely by Jagotec, irrespective which party has created or developed such Foreground IP or its contribution to it (hereinafter referred to as “Skye IPR”).

(b) Any Foreground IP relating specifically and exclusively to the Product containing Active Drug, any use of the Active Drug, or any attribute or property of the Active Drug, shall vest in and be owned absolutely by Nitec, irrespective which party has created or developed such Foreground IP or its contribution to it (hereinafter referred to as “Nitec IPR”).

(c) All Foreground IP other than that set out in Section 4.1(a) and (b) will be owned (i) by the Party developing or discovering it; or (ii) if jointly developed or discovered, shall be owned jointly (together, “Other IP”) all as determined in accordance with the legislation applying in the country or jurisdiction where such development or discovery shall take place.
4.2 Rights to Background IP

(a) All Background IP is and shall remain the exclusive property of the party owning it (or if applicable from the third party from whom its rights to use the Background IP has derived).

(b) In case the Foreground IP of either party is dependent on any or all Background IP of the other party, the parties agree to the following:

(i) in case Skye IPR or Other IP is dependent on any or all Background IP of Nitec (hereinafter referred to as “Dependent Skye IPR”), Nitec shall grant to Jagotec a non-exclusive, perpetual, royalty-free right to use such Background IP with a right to grant sublicenses to the extent necessary for Jagotec and its licensees and sublicensees to make unrestricted use of its Foreground IP;

(ii) in case Nitec IPR or Other IP is dependent on any or all Background IP of Jagotec (hereinafter referred to as “Dependent Nitec IPR”), Jagotec shall grant to Nitec a non-exclusive, perpetual, royalty-free right to use such Background IP with a right to grant sublicenses to the extent necessary for Nitec and its licensees and sublicensees to make unrestricted use of its Foreground IP.

4.3 Confirmation by Jagotec

Jagotec hereby confirms that neither it nor any of its Affiliates currently own any patent or patent application not included in the term “Patents”, which is reasonably necessary or useful to develop, manufacture, sell or otherwise dispose of a Product under this Agreement. Future Skye IPR which may be necessary to develop, manufacture, sell or otherwise dispose of a Product under this Agreement will be deemed added to Exhibit A on filing.

4.4 Prosecution of Patent Applications

(a) During the term of this Agreement, Jagotec shall use all Commercially Reasonable Efforts, at its own cost, to prepare, prosecute and maintain all patent applications and patents constituting Patents, and shall keep Nitec fully and promptly informed on any developments or changes relating thereto. If Jagotec decides not to further prosecute or not to maintain any patent application constituting Patents, Jagotec shall promptly inform Nitec of such decision in writing, and the Parties shall, upon Nitec’s written request, meet to discuss any
appropriate action taking into due consideration Nitec’s interests under this Agreement.

(b) Nitec shall be responsible for and shall use all Commercially Reasonable Efforts to control, at its own cost, the preparation, prosecution and maintenance of all Nitec IPR and shall keep Jagotec fully and promptly informed on any developments or changes relating thereto. During the term of this Agreement, Nitec shall, at its sole cost, take all steps necessary to prosecute and maintain all Nitec IPR to the extent Nitec deems commercially reasonable. If Nitec intends not to further prosecute and/or maintain any of the Nitec IPR, Nitec shall promptly inform Jagotec of such intention in writing, and Jagotec shall meet with Nitec to discuss any appropriate action taking into due consideration Jagotec’s interests under this Agreement.

4.5 Notification of Infringement

(a) If Nitec becomes aware of (i) any product or activity of any kind that involves or may involve an infringement or violation of Skye IPR, or (ii) any third-party action, claim or dispute (including, but not limited to, actions for declaratory judgment alleging the invalidity or non-infringement) based upon or arising out of Skye IPR, then Nitec shall promptly notify Jagotec in writing of any such infringement, violation, action, claim or dispute.

(b) If Jagotec becomes aware of (i) any product or activity of any kind that involves or may involve an infringement or violation of Skye IPR with respect to Product or of Nitec IPR, or (ii) any third-party action, claim or dispute (including, but not limited to, actions for declaratory judgment alleging the invalidity or non-infringement) based upon or arising out of Skye IPR with respect to Product or of Nitec IPR, then Jagotec shall promptly notify Nitec in writing of any such infringement, violation, action, claim or dispute.

4.6 Enforcement of Skye IPR

(a) Jagotec, at its sole expense, shall have the right, but not the obligation, (1) to determine the appropriate course of action to enforce, or otherwise abate the infringement of, or defend third-party actions regarding, Skye IPR and its Background IP to the extent necessary for the Dependent Nitec IPR (hereinafter referred to as “Skye IPR plus Background”), (ii) to take, or refrain from taking,
appropriate action to enforce, or defend third-party actions regarding, Skye IPR plus Background, (iii) to control any litigation or other enforcement action regarding Skye IPR plus Background, and (iv) to enter into, or permit, the settlement of any such litigation or other enforcement action regarding Skye IPR plus Background. Notwithstanding anything contained in the preceding sentence, Jagotec shall not settle any suit or action or otherwise consent to an adverse judgement in such suit or action without Nitec’s prior written consent, which consent shall not be withheld unreasonably. Jagotec shall keep Nitec informed on a regular basis on its taking or refraining from taking, and the development of, any of the foregoing actions, and shall consider, in good faith, the interests of Nitec under this Agreement when taking any of the foregoing actions. Nitec shall, at its own cost, fully cooperate with Jagotec in the planning and execution of any suit or other action to enforce, or defend third-party actions regarding, Skye IPR plus Background to the extent affecting Product and as reasonably required by Jagotec.

(b) If Jagotec does not within [...] or any shorter delay imposed by any applicable law or regulation or court or authority having jurisdiction, after receiving notice of any infringement or violation of Skye IPR plus Background which may adversely affect Product, or of any third-party action, claim or dispute based upon or arising out of Skye IPR plus Background which may adversely affect Product, commence or take an action to enforce, or otherwise abate such infringement, or defend against such third-party action, then the Parties shall, upon Nitec’s written request, promptly meet to discuss any appropriate action with regard to such enforcement of Skye IPR plus Background which may adversely affect Product.

(c) Nitec, upon its written request and at its sole expense, shall be made an additional, not controlling party in any such suit or other action where necessary to obtain complete relief regarding the subject infringement or violation.

4.7 Enforcement of Nitec IPR

(a) Nitec, at its sole expense, shall have the right, but not the obligation, (i) to determine the appropriate course of action to enforce, or otherwise abate the infringement of, or defend third-party actions regarding, Nitec IPR and its ***Confidential Treatment Requested

14.
Background IP to the extent necessary for the Dependent Skye IPR (hereinafter referred to as “Nitec IPR plus Background”), (ii) to take, or refrain from taking, appropriate action to enforce, or defend third-party actions regarding, Nitec IPR plus Background, (iii) to control any litigation or other enforcement action regarding Nitec IPR plus Background, and (iv) to enter into, or permit, the settlement of any such litigation or other enforcement action regarding Nitec IPR plus Background. Notwithstanding anything contained in the preceding sentence, Nitec shall not settle any suit or action or otherwise consent to an adverse judgment in such suit or action without the prior written consent of Jagotec, which consent shall not be withheld unreasonably. Nitec shall keep Jagotec informed on a regular basis on its taking or refraining from taking, and the development of, any of the foregoing actions, and shall consider, in good faith, the interests of Jagotec under this Agreement and in Skye IPR, when taking any of the foregoing actions. Jagotec shall, at its own cost, fully cooperate with Nitec in the planning and execution of any suit or other action to enforce, or defend third-party actions regarding, Nitec IPR plus Background to the extent affecting Product and as reasonably required by Nitec.

(b) If Nitec does not, within [...***...], or any shorter delay imposed by any applicable law or regulation or court or authority having jurisdiction, after receiving notice of any infringement or violation of Nitec IPR plus Background, or of any third-party action, claim or dispute based upon or arising out of Nitec IPR plus Background, commence or take an action to enforce, or otherwise abate such infringement, or defend against such third-party action, then the Parties shall, upon Jagotec’s written request, promptly meet to discuss any appropriate action with regard to such enforcement of Nitec IPR plus Background which may adversely affect Product.

(c) Jagotec, upon its written request and at its sole expense, shall be made an additional, not controlling party in any such suit or other action where necessary to obtain complete relief regarding the subject infringement or violation.

4.8 Application of Monies Recovered

All monies recovered upon the final judgment or settlement of any suit or other action under these Sections 3.6 or 3.7 above shall be applied as follows:

***Confidential Treatment Requested
(i) firstly, to cover any and all costs and expenses (including attorney’s fees) incurred by the Party controlling such suit or other action;
(ii) secondly, to cover any and all costs and expenses (including attorney’s fees) reasonably, or upon request of the controlling Party, incurred by the other Party in connection with such suit or other action, if any;
(iii) finally, the remainder, if any, to the Party controlling any such suit or other action.

5 Licence Grant

5.1 Jagotec hereby grants to Nitec the royalty bearing exclusive and sub-licensable right and licence to market, distribute, sell, offer for sale and use the Product in the Territory and to use the Patents, GEOMATRIX® Technology and Skye Know How exclusively for that purpose.

5.2 Furthermore, subject to the provisions of Section 6.2, Jagotec hereby grants to Nitec the option (the “Option”) to acquire the exclusive and sublicenseable right and licence (hereinafter referred to as the “Nitec Manufacturing Licence”) to make or have made Product in the Territory and to use the Patents, GEOMATRIX® Technology and Skye Know How exclusively for that purpose at any time on twenty four month notice to expire no earlier than five years after the First Launch of the Product in the Territory. The Option may be exercised in accordance with Section 6.2 below. For the avoidance of doubt, no royalty in addition to that set out in Section 7 shall be payable by Nitec to Jagotec in respect of the Nitec Manufacturing Licence. The Nitec Manufacturing Licence shall be co-terminus with the licence granted under Section 5.1.

5.3 Subject to the provisions of Section 5.5, the rights of Nitec to grant any sub-license under the Licence and/or the Nitec Manufacturing Licence, as the case may be, in any part of the Territory shall not require Nitec to receive the written approval of Jagotec.

5.4 In any event, Nitec shall be responsible for any and all acts, deeds and undertakings of its sub-licensee(s) and shall continue to be bound by all terms and provisions under this Agreement throughout its term. In case that Nitec sub-
licenses rights and/or the Licence and/or the Nitec Manufacturing Licence, as the case may be, to any sub-licensee(s), such sub-licensee(s) shall agree in writing to any and all of Nitec’s obligations and undertakings under this Agreement, including but not limited to its confidentiality obligations set out below. Furthermore, Nitec undertakes that any and all sub-licence agreements shall provide for inspection and audit provisions identical to the provisions set forth below in order to enable Jagotec to control and audit and receive any and all Royalties due as provided in this Agreement. Nitec shall provide Jagotec promptly with appropriate information on its sub-licensee(s) and, subject to applicable confidentiality restrictions, copies of all agreements with such sub-licensee(s).

6  Manufacturing and Product Liability

6.1  Subject to the exercise by Nitec of its rights under Section 6.2, Jagotec shall exclusively manufacture, package and supply, or have manufactured, packaged and supplied by an Affiliate, Product in bulk in accordance with the terms and conditions to be agreed upon in the Jagotec Manufacturing Agreement, which Jagotec Manufacturing Agreement shall contain provisions (i) that Nitec shall supply to Jagotec or its Affiliate free of charge all Active Drug in quantities required for such manufacturing of Product, and (ii) on manufacture and packaging of Product in bulk and reimbursement of cost at [***] of Jago’s fully allocated manufacturing cost therefore (calculated in substantially the same manner as Jago’s other manufactured products of similar production process, run and complexity) as required by the Parties. If Jagotec wants to have the product manufactured, packed and supplied by an affiliate other than SkyePharma SAS, the costs of the manufacturing site change to such an affiliate (including but not limited to technical transfer, process validation, bioequivalence study and regulatory expenses) shall be borne by Skye. Furthermore, the Jagotec Manufacturing Agreement shall contain provisions on lead times, order quantity and supply and purchase obligations of such quantities ordered (or part thereof), as may be mutually agreed upon by the Parties and in the event of a failure by the Parties to agree by 31 March, 2005, each Party shall submit the matter to be resolved by an expert, to be appointed by

***Confidential Treatment Requested

17.
a single arbitrator appointed under ICC Rules. With the exception of the principles applied in calculating the fully allocated manufacturing cost referred to above, in relation to any particular proposed clause of the Jagotec Manufacturing Agreement on which the Parties are unable to agree, each Party shall propose terms, only one of which, subject to such amendments specified by the expert as shall be required to ensure that the Jagotec Manufacturing Agreement operates as a whole, shall be selected by the expert as the relevant clause of the Jagotec Manufacturing Agreement binding on the Parties. In the case of the principles applied in calculating the fully allocated manufacturing cost referred to above, the expert shall not be bound only to select terms proposed by one Party or the other as described above but shall be free to make such amendments to proposed terms as the expert shall think fit.

6.2 In the event that Nitec wishes to manufacture the Product under the Nitec Manufacturing Licence rather than having Jagotec manufacture the Product under the Jagotec Manufacturing Agreement, then Nitec shall exercise its Option under Section 5.2 above by serving notice on Jagotec to that effect in writing. Subject to the proviso to this sentence, the right of Nitec under Section 5.2 shall not take effect for a period of [...] from the date of notice and during such period, (i) all pending orders for Product shall be satisfied by Jagotec in accordance with the Jagotec Manufacturing Agreement, and (ii) the Parties will agree the terms of the royalty free Manufacturing Licence to include such provisions as are customary in the circumstances, failing which either Party may refer the matter to an expert for determination. Jagotec agrees that it shall provide technical assistance in connection with such transfer to a third party manufacturer as set out in Section 3.4. The costs of the manufacturing site change (including but not limited to technical transfer, process validation, bioequivalence study and regulatory expenses) shall be born by Nitec. Notwithstanding anything to the contrary contained herein, following exercise of the Option, the Manufacturing License shall be an irrevocable worldwide, fully paid-up, royalty-free license, pursuant to which Nitec and its licensees shall have a right of sublicense.

6.3 Nitec shall indemnify, defend and hold Jagotec and its Affiliates, directors, officers and shareholders harmless from and against any losses, claims, liabilities,

***Confidential Treatment Requested

18.
costs and expenses (including reasonable attorney’s fees) that may be imposed upon or asserted against Jagotec and/or its Affiliates, directors, officers and shareholders as a result of the manufacture of Product under the Manufacturing License, or the marketing, distribution, use or sale of Product under the License by or on behalf of Nitec, its Affiliates, agents or sub-licensee(s), except for those claims, liabilities, costs and expenses arising from negligence or intentional misconduct on the part of Jagotec or its Affiliates and except for claims to the extent any relate to the Patents, GEOMATRIX Technology and Skye Know How.

6.4 In the event that Jagotec wishes to cease to manufacture the Product under the Jagotec Manufacturing Agreement, Jagotec shall be permitted to do so by serving notice on Nitec to that effect in writing. The termination under this Section 6.4 shall not take effect for a period of twenty four (24) months from the date of notice and in any event no earlier than five years after the First Launch of the Product in the Territory and during such period all pending orders for Product shall be satisfied by Jagotec in accordance with the Jagotec Manufacturing Agreement. Jagotec agrees that it shall provide technical assistance in connection with transfer of manufacturing rights to a third party manufacturer as set out in Section 3.4. The costs of the manufacturing site change (including but not limited to technical transfer, process validation, bioequivalence study and regulatory expenses) shall be born by Nitec.

7 Royalties

7.1 In consideration of the License granted by Jagotec to Nitec hereunder, the royalty (the “Royalty”) payable by Nitec to Jagotec shall be:

7.1.1 in the case of all countries of the Territory (other than North America):

(a) [...***…] of Net Sales of Product in the Territory (other than North America), and

(b) [...***…] of sublicensing income in the Territory (other than North America) being any payment not calculated based on Net Sales (to include, without limitation, licence fees, lump sums and milestone payments.).

***Confidential Treatment Requested

19.
7.1.2 in the case of North America:

(a) […]***[…] of Net Sales of Product in North America, and

(b) […]***[…] of sublicensing income in North America being any payment not calculated based on Net Sales (to include, without limitation, licence fees, lump sums and milestone payments).

7.2 All Royalties shall be payable on a quarterly basis. Nitec shall remit to Jagotec within […]***[…] days after the end of each calendar quarter the amount of Royalties, if any, due in respect of the preceding quarter, beginning with the calendar quarter in which the First Launch takes place. Nitec shall deliver to Jagotec, along with such remittance of Royalty payments a detailed statement (hereinafter referred to as the “Royalty Report”) of Net Sales of Product and sublicensing income received on a country-by-country basis to which the Royalty payment relates.

7.3 All Royalty Reports shall be prepared in accordance with generally accepted accounting principles consistently applied from applicable period to period and shall be certified by an officer of Nitec as being so prepared, true, accurate and correct.

7.4 Unless otherwise agreed by the Parties in writing, all payments of Royalties shall be made in EURO and to such place or account as Jagotec reasonably requests from time to time in writing. Any conversions into EURO from the currency in which the corresponding Net Sales for such Royalties and sublicensing income were made, are to be calculated by using the average closing buying rate for such currency quoted in the continental terms method of quoting exchange rates (local currency per EURO 1) published by the Financial Times on the last business day of the applicable reporting period covered by such Royalty Report.

7.5 In the event that Nitec is required to withhold any tax to the tax or revenue authorities in the Territory regarding any payment to Jagotec, such amount shall be deducted from the payment to be made by Nitec, and Nitec shall promptly notify Jagotec of such withholding and, within a reasonable amount of time after making such deduction, furnish Jagotec with copies of any tax certificate or other documentation evidencing such withholding. Each Party agrees to cooperate

***Confidential Treatment Requested
with the other Party in claiming exemptions from such deductions or withholdings under any agreement or treaty from time to time in effect.

8 Inspection and Audit

8.1 During the term of this Agreement and during a period of twelve (12) months after its expiration or termination for any reason, upon the written request of Jagotec and not more than once each calendar year, Nitec shall permit an independent certified public accountant of internationally recognized standing selected by Jagotec, to have access during regular business hours to such of the records of Nitec and its Affiliates and sub-licensee(s), if any, as may be reasonably necessary to verify the accuracy of the Royalty Reports for any year ending not more than twenty-four (24) months prior to the date of such request. The accounting firm shall disclose to Jagotec only whether the Royalty Reports and records of Nitec and its Affiliates and sub-licensee(s), if any, and the amount of Royalties, if any, actually paid are correct or not and the specific details concerning any discrepancies; no other information shall be shared. The Parties agree to accept such written audit report as final and binding upon them.

8.2 If such independent accounting firm correctly concludes that additional Royalties were owed during any such period audited, Nitec shall pay such additional Royalties within thirty (30) days of the date Jagotec delivers to Nitec such accounting firm’s written report so concluding. The fees and expenses charged by such accounting firm with respect to such audit shall be paid by Jagotec, provided however, if any such audit discloses that Royalties payable by Nitec for the audited period are more than [...] of the Royalties actually paid for such period, then Nitec shall pay all reasonable fees and expenses charged by such accounting firm with respect to such audit.

8.3 Jagotec shall treat all financial information subject to review under this Section 7 as confidential and subject to the confidentiality obligations in Article 8 below.

***Confidential Treatment Requested
9 **Confidentiality**

9.1 During the term of this Agreement and in the course of the development work by Jagotec, it may be necessary for each Party to disclose to the other Party, orally or in writing, certain of its Confidential Information, which each Party considers to be confidential and proprietary. Each Party agrees to hold in strict confidence and not to use, except for purposes of this Agreement, all Confidential Information obtained from the other Party during the term of this Agreement.

9.2 The obligations of confidentiality and non-use contained in this Section 8 shall not extend and apply to Confidential Information that:

(i) is in or enters the public domain without breach of this Agreement; or

(ii) can be shown to have been known to the receiving Party prior to disclosure under this Agreement; or

(iii) is disclosed to the receiving Party, without restriction, by a third party having the right to disclose the same; or

(iv) is required to be disclosed by a judicial or administrative authority of competent jurisdiction or by law after maximum practical notice to the originally disclosing Party.

9.3 Confidential Information of the other Party shall be disclosed or made available by the receiving Party only to those employees of the receiving Party who have a need to know such Confidential Information for the purposes of this Agreement. Furthermore, the Parties may also disclose Confidential Information to consultants hired by one or both of the Parties, provided the receiving Party’s consultant has a need to know such Confidential Information for purposes of this Agreement and has previously signed a written confidentiality agreement or has otherwise agreed to such confidentiality obligation with the receiving Party which contains substantially the same obligations of confidentiality and non-use as set forth in this Section 8, and which is broad enough to cover disclosures of Confidential Information from the originally disclosing Party.

9.4 In the event of termination or expiration of this Agreement for whatsoever reason, each Party shall immediately return to the other all of the other Party’s Confidential Information furnished in connection with this Agreement, including

22.
every and all copies made thereof save for one copy of each item of Confidential Information, which may be retained in the legal department or lodged with the legal advisers of the receiving Party exclusively in order to provide a record of Confidential Information disclosed and to so determine each receiving Party’s continuing obligations hereunder.

9.5 The obligations of confidentiality and non-use contained in this Section 8 shall survive the expiration or termination of this Agreement for any reason for a period of five (5) years commencing upon the effective date of such termination or expiration.

10 Term and Termination

10.1 Term and Expiration

(a) This Agreement shall terminate on the later of ten (10) years from the Effective Date or on the expiry on a country-by-country basis upon the expiration of the last to expire of the Patents in each country of the Territory, unless earlier terminated in accordance with Sections 10.2 and 10.3 below.

(b) Upon the expiration of this Agreement in each country of the Territory pursuant to Section 10.1 (a) above and payment of all Royalties and Manufacturing Royalties, if any, due under this Agreement, the License and the Manufacturing License, if applicable, shall be deemed to be a perpetual, fully paid-up and royalty-free license for Product in each such country of the Territory.

10.2 Termination for Cause

During the entire term of this Agreement either Party may terminate this Agreement by giving to the other Party written notice to that effect, if any of the following events occur:

(a) the other Party is in default or in breach of a term or provision hereof and such default or breach is material and continues and is not remedied within [...***…] upon the other Party’s written request to remedy such default or breach;

(b) the other Party shall commit a material breach of any of the confidentiality provisions of Section 9 above; or

***Confidential Treatment Requested
10.3 Termination prior to Registration

In addition and not in limitation to Section 3.7 above, as from the Effective Date throughout the term until the first Registration for Product is granted by any Regulatory Authority in any country of the Territory, this Agreement may be terminated as follows:

(a) by either Party, if such Party reasonably considers based on a determination, in accordance with sound scientific, pharmaceutical and medical judgment, of the results achieved with respect to the Product during the development phase, and that Party can demonstrate that there is a technical, pharmaceutical or medical problem regarding the Product, which would make the Product unapprovable in all of the following countries, USA, UK and Germany, with […] prior notice, provided that such terminating Party, prior to having the right to terminate this Agreement in accordance herewith, has in all detail disclosed such determination and the underlying reasons to the other Party and has taken in due consideration any comments of the other Party on such determination; and

(b) by Nitec, if the first application for Registration of Product or any material part thereof is finally rejected or denied, or if any Regulatory Authority in the country, where the first Registration of Product is applied for, imposes restrictions on or conditions for the commercialization of the Product which have a material negative impact on the marketability of the Product, or if all Registrations of Product in all countries are withdrawn or cancelled by the competent Regulatory Authorities, with […] prior written notice.

10.4 Effect of Termination

(a) The termination of this Agreement shall be without prejudice to any rights and obligations of either Party accrued prior to the effective date of such termination. Nitec shall forthwith make all payments due and outstanding to Jagotec at the date of termination. Except as explicitly otherwise stated in this Agreement,
Jagotec shall not be obliged to refund upon termination of this Agreement to Nitec any payments made by Nitec to Jagotec prior to such termination pursuant to the provisions of this Agreement.

(b) In the event of termination of this Agreement pursuant to Sections 10.2 and 10.3 above, then this Agreement (and any agreements entered into in connection with it) shall immediately be terminated and, except as provided herein, Nitec shall immediately refrain from using directly or indirectly in any way the Patents, GEOMATRIX® Technology and Skye Know-How. Upon termination of this Agreement, except as provided herein, Jagotec shall immediately refrain from using directly or indirectly in any way all Nitec IPR as well as Nitec Know-How. Furthermore, each Party shall return to the other Party all Confidential Information (other than that relating to the Foreground IP of the other) received from or belonging to the other Party, together with all copies thereof in such other Party’s possession or under its control, all free of any charge. Either Party shall have the right, but not the obligation, to use, at its sole discretion, any and all such material for its own purposes.

(c) Subject to any rights of Merck under the Technology Transfer Agreement, in the event of termination by Jagotec under the terms of Section 3.3, the terms of Section 10.4 (b) shall not apply and the Agreement (and any agreements entered into in connection with it) shall immediately be terminated and Nitec shall immediately refrain from using directly or indirectly in any way the Patents, GEOMATRIX® Technology and Skye Know-How. At the same time, subject to any rights of Merck under the Technology Transfer Agreement, Nitec shall grant to Jagotec the exclusive royalty free and, sublicenseable right and license to the Nitec IPR and the Nitec Know-How and any confidential information necessary or desirable for use with the Product in the Territory and shall provide at no additional cost to Jagotec such information and documentation as shall be reasonably requested by Jagotec in that regard.

(d) The termination for cause of this Agreement pursuant to Section 10.2 above by either Party shall not limit remedies which are or may be otherwise available in law or equity to either Party.

25.
Representations and Warranties

11.1 Jagotec represents and warrants that it shall carry out and undertake the development work until approval of the Product in the Territory in a careful and diligent manner. Jagotec agrees to carefully choose, instruct and supervise any employees, officers, Affiliates or third parties to be chosen by it pursuant to this Agreement, who are involved in the Development of the Product. Nothing in this Agreement shall be construed as a representation made, or warranty given, by Jagotec that any development performed by or for Jagotec under this Agreement will be successful in whole or in part, or that any product, including Product, which may be developed, will be successful in the commercial marketplace. Furthermore, except as provided herein, Jagotec makes no representation or warranty, express or implied, with respect to GEOMATRIX® Technology and/or Skye Know-How, including without limitation, any warranty of completeness, accuracy, merchantability or fitness for a particular purpose.

11.2 Jagotec represents and warrants that it has all rights regarding Patents, GEOMATRIX® Technology and Skye Know-How necessary to grant the Licence and the Option and the Nitec Manufacturing Licence hereunder. Notwithstanding the preceding sentence but subject to the following sentence, Jagotec does not assume any responsibility and makes no warranty that the performance of this Agreement and any product developed hereunder, including the Product, do not infringe any third party’s patents, patent applications or other intellectual property rights. Notwithstanding the preceding sentence, Jagotec represents and warrants that, as of the Effective Date, it is not aware and has no knowledge of any such infringement of any third party rights. If however, during the course of this Agreement either Party discovers that the Product infringes or may infringe any third party’s intellectual property rights, it shall promptly inform the other Party thereof and the Parties shall meet to discuss the course of action to be taken with regard thereto.

11.3 Nothing in this Agreement shall be construed as a representation made, or warranty given by Jagotec that any patent will issue based upon any pending patent application encompassed by the term Patents, and that any patent encompassed by the term Patents which issues will be valid or enforceable.
11.4 Except as provided for in the Jagotec Manufacturing Agreement to be agreed upon in due time as referred to in Section 5.1 above, Jagotec assumes no liability or responsibility for any damages caused to Nitec, third parties, and/or the environment by the manufacturing, marketing, distribution, sale or use of the Product or the Active Drug contained therein, except to the extent that any of the above are attributable to the negligence or wilful misconduct of Jagotec in performing its obligations hereunder.

11.5 Nitec represents and warrants to strictly adhere at all times in all material respects to any and all laws, rules, regulations and conditions imposed by any competent authority on the marketing, distribution and sale of Product, and Nitec shall during the entire term of this Agreement be solely and fully responsible for the compliance with all such laws, rules, regulations and conditions when marketing, distributing and selling Product under the Licence.

11.6 Subject to the specific representations and warranties given and specific disclaimers of representations and warranties included in this Article 10, and further subject to anything to the contrary contained in this Agreement, either Party shall, as to third parties, be indemnified and held harmless by the other Party from and against any and all losses, liabilities and damages arising from any claim, action or other proceeding by any third party relating to any acts or omissions of the other Party, its directors, officers, employees or agents, or the gross negligence or wilful misconduct of such other Party, its directors, officers, employees or agents in performing any of its obligations under this Agreement.

11.7 Any liability, warranty and undertaking contained herein shall be limited to the payment by either Party for direct damages to the other Party and in any event, neither Party shall be liable to the other Party for any special, indirect, punitive or consequential damages and/or loss of profits or anticipated profits, respectively.

11.8 Nitec shall, at its own expense, purchase from an insurance company of its choice and shall maintain during the entire term of this Agreement and during […] after its expiration or termination an appropriate and customary policy of general liability and product liability insurance covering its responsibilities, including in particular but without any limitation, Nitec’s development responsibilities under Section 2 above, regarding Product developed,

***Confidential Treatment Requested
27.
manufactured, marketed, sold and used under this Agreement and the Active Drug contained therein and the use thereof. Upon request, Nitec shall provide Jagotec with evidence that such insurances are existing and are maintained.

11.9 Nitec represents and warrants that, to the best of its knowledge and belief, having made due and careful investigation, it has acquired from Merck all relevant rights, including but not limited to all relevant intellectual property rights of Merck in connection with the Merck Agreement to allow Nitec to carry out its obligations hereunder. Nitec shall indemnify Jagotec in respect of any breach thereof.

11.10 Without prejudice and subject to the other terms of this Agreement, if Nitec determines that it requires a licence from a third party in order to manufacture, use, sell, offer for sale or import the Product, including, without limitation, avoid infringement of any third party patent or in connection with settlement of any actual or threatened patent infringement claim, or if Nitec shall be subject to an order or ruling of any court of competent jurisdiction requiring the payment of a royalty or other payment to a third party patent holder in respect of the manufacture, use, sale, offer for sale or import of the Product, then all such payments shall be made at Nitec’s sole cost and expense.

12 Miscellaneous Provisions

12.1 Waivers: A waiver of a breach or default under this Agreement shall not be a waiver of any other or subsequent breach or default. The failure or delay by either Party in enforcing compliance with any term or condition of this Agreement shall not constitute waiver of such term or condition, unless such term or condition is expressly waived in writing.

12.2 Headings: The titles and headings used in this Agreement are intended for convenience only and shall not in any way affect the meaning or construction of any provision of this Agreement.

12.3 Force Majeure: Neither Party shall be held in breach of this Agreement by any reason of acts or omissions caused by any Act of God or other causes beyond the reasonable control of the affected Party. The affected Party shall use due
12.4 Assignment: Except as otherwise expressly stated herein, this Agreement and the rights and obligations hereunder shall not be assignable by either Party without the prior written consent of the other Party, provided however, that either Party may, without such consent, assign this Agreement and its rights and obligations hereunder to an Affiliate of such Party, and in connection with the transfer or sale of all or substantially all of its business, or in the event of its merger, consolidation, change in control or similar transaction. Any permitted assignee shall assume all obligations of its assignor under this Agreement so long as such assignee remains liable on a joint and several basis for its obligations.

12.5 Separate Entities: Nothing in this Agreement shall constitute or be deemed to constitute a partnership between the Parties hereto or constitute or be deemed to constitute either Party as an agent of the other for any purpose whatsoever, and neither Party shall have the authority or power to bind the other Party, or to contract in the name of and create a liability against the other Party in any way or for any purpose, unless explicitly instructed in writing to do so.

12.6 Notices: All notices, reports and other writings which are required to be given or submitted pursuant to this Agreement shall be in writing and delivered personally or sent by international courier service, or by confirmed facsimile transmission, to the addresses set forth below or to such other address as Jagotec or Nitec may from time to time notify to the other Party. Any and all notices sent to the other Party in accordance with this Section 11.6 shall become effective as of receipt thereof by the other Party.

If to Skye, SkyePharma or Jagotec:
Jagotec AG
Eptingerstrasse 51
CH-4132 Muttenz, Switzerland
Attn.: CEO
Fax: ++41-61-467-5574

If to Jagotec:
Jagotec AG
Eptingerstrasse 51
CH-4132 Muttenz, Switzerland
Attn.: CEO
Fax: ++41-61-467-5574
12.7 Severability: Each Party hereby acknowledges that it does not intend to violate any public policy, statutory or common laws, rules, regulations, treaty or decision of any government agency or executive body thereof of any country or community or association of countries. Should one or more provisions of this Agreement be or become invalid, the Parties hereto shall substitute, by mutual consent, valid provisions for such invalid provisions which valid provisions in their economic effect are sufficiently similar to the invalid provisions that it can be reasonably assumed that the Parties would have entered into this Agreement with such provisions. In case such provisions cannot be agreed upon, the invalidity of one or several provisions of this Agreement shall not affect the validity of this Agreement as a whole, unless the invalid provisions are of such essential importance to this Agreement that it is to be reasonably assumed that
the Parties would not have entered into this Agreement without the invalid provisions.

12.8 Interest: In the event any amount due and payable under this Agreement is not paid by the due date, then the Party owing such amount shall pay to the creditor, without being requested by the other Party, interest on the total outstanding amount at the rate equal to the London Interbank Offered Rate (LIBOR), as published by the Financial Times on the date that such payment falls due, increased by [...] in EURO and adjusted on the first day of every calendar quarter.

12.9 Entire Agreement: This Agreement, together with the Exhibits referred to herein and attached hereto, represents the entire understanding of the Parties with respect to the subject matter hereof; and supersedes all proposals or agreements, oral or written, and all other communications between the Parties related to the subject matter of this Agreement, including without limitation any representations or warranties made by either Party hereto or its representatives. This Agreement may not be amended or modified except in a writing duly executed by the Parties.

13 Governing Law and Jurisdiction

13.1 The Parties hereto agree that this Agreement, including without limitation, all transactions affected hereunder, its validity and enforceability and all relationships between the Parties in this connection shall be construed under and be governed in all respects by the laws of Switzerland without reference to the principles of conflicts of laws thereof and shall not be governed by the United Nations Convention on Contracts for the International Sale of Goods (the Vienna Convention of April 11, 1980).

13.2 The Parties hereby agree that any and all disputes arising out of or in connection with this Agreement shall exclusively be submitted to and settled by the courts in Zurich, Switzerland and the Parties hereby submit to such exclusive jurisdiction.

***Confidential Treatment Requested
This Agreement has been executed by Nitec and by Skye, by their duly authorized representatives, in three (3) originals effective as of the Effective Date.

SKYPEPHARMA AG
By: /s/ Francesco Patalano
Name: Francesco Patalano
Title: Director

By: /s/ Tessa Chapman
Name: Tessa Chapman
Title: Director

JAGOTEC AG
By: /s/ Francesco Patalano
Name: Francesco Patalano
Title: Director

By: /s/ Tessa Chapman
Name: Tessa Chapman
Title: Director

NITEC PHARMA AG:
By: /s/ Dr. Hubertus Ludwig
Name: Dr. Hubertus Ludwig
Title: Verwaltungsrat
<table>
<thead>
<tr>
<th>Country</th>
<th>Application date</th>
<th>Application no.</th>
<th>Publication no.</th>
<th>Grant date</th>
<th>K &amp; S Ref.</th>
<th>SkypePharma Ref.</th>
</tr>
</thead>
<tbody>
<tr>
<td>[...***...]</td>
<td>[...***...]</td>
<td>[...***...]</td>
<td>[...***...]</td>
<td>[...***...]</td>
<td>[...***...]</td>
<td>[...***...]</td>
</tr>
<tr>
<td>[...***...]</td>
<td>[...***...]</td>
<td>[...***...]</td>
<td>[...***...]</td>
<td>[...***...]</td>
<td>[...***...]</td>
<td>[...***...]</td>
</tr>
<tr>
<td>[...***...]</td>
<td>[...***...]</td>
<td>[...***...]</td>
<td>[...***...]</td>
<td>[...***...]</td>
<td>[...***...]</td>
<td>[...***...]</td>
</tr>
<tr>
<td>[...***...]</td>
<td>[...***...]</td>
<td>[...***...]</td>
<td>[...***...]</td>
<td>[...***...]</td>
<td>[...***...]</td>
<td>[...***...]</td>
</tr>
<tr>
<td>[...***...]</td>
<td>[...***...]</td>
<td>[...***...]</td>
<td>[...***...]</td>
<td>[...***...]</td>
<td>[...***...]</td>
<td>[...***...]</td>
</tr>
<tr>
<td>[...***...]</td>
<td>[...***...]</td>
<td>[...***...]</td>
<td>[...***...]</td>
<td>[...***...]</td>
<td>[...***...]</td>
<td>[...***...]</td>
</tr>
<tr>
<td>[...***...]</td>
<td>[...***...]</td>
<td>[...***...]</td>
<td>[...***...]</td>
<td>[...***...]</td>
<td>[...***...]</td>
<td>[...***...]</td>
</tr>
<tr>
<td>[...***...]</td>
<td>[...***...]</td>
<td>[...***...]</td>
<td>[...***...]</td>
<td>[...***...]</td>
<td>[...***...]</td>
<td>[...***...]</td>
</tr>
<tr>
<td>[...***...]</td>
<td>[...***...]</td>
<td>[...***...]</td>
<td>[...***...]</td>
<td>[...***...]</td>
<td>[...***...]</td>
<td>[...***...]</td>
</tr>
<tr>
<td>[...***...]</td>
<td>[...***...]</td>
<td>[...***...]</td>
<td>[...***...]</td>
<td>[...***...]</td>
<td>[...***...]</td>
<td>[...***...]</td>
</tr>
<tr>
<td>[...***...]</td>
<td>[...***...]</td>
<td>[...***...]</td>
<td>[...***...]</td>
<td>[...***...]</td>
<td>[...***...]</td>
<td>[...***...]</td>
</tr>
</tbody>
</table>

***Confidential Treatment Requested

33.
38.

***Confidential Treatment Requested
40.

***Confidential Treatment Requested
### Exhibit B

**Preliminary Specifications for Product**

[...***...]

<table>
<thead>
<tr>
<th>Test</th>
<th>Specifications and Requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>[...***...]</td>
<td>[...***...]</td>
</tr>
<tr>
<td>[...***...]</td>
<td>[...***...]</td>
</tr>
<tr>
<td>[...***...]</td>
<td>[...***...]</td>
</tr>
<tr>
<td>[...***...]</td>
<td>[...***...]</td>
</tr>
<tr>
<td>[...***...]</td>
<td>[...***...]</td>
</tr>
<tr>
<td>[...***...]</td>
<td>[...***...]</td>
</tr>
<tr>
<td>[...***...]</td>
<td>[...***...]</td>
</tr>
<tr>
<td>[...***...]</td>
<td>[...***...]</td>
</tr>
</tbody>
</table>

### Exhibit C

**Development Programme**

- [...***...]
- [...***...]

***Confidential Treatment Requested***

41.
Exhibit D

[...***...]

42.

***Confidential Treatment Requested
MANUFACTURING & SUPPLY AGREEMENT

This MANUFACTURING & SUPPLY AGREEMENT ("Agreement"), effective as of 3 August 2007, is entered into between NITEC PHARMA AG, a Swiss corporation having a place of business at Kägenstrasse 17, CH-4153 Reinach, Switzerland (hereinafter referred to as "NITEC"), and JAGOTEC AG, a Swiss corporation having a place of business at Eptingerstrasse 51, CH-4132 Muttenz, Switzerland (hereinafter referred to as "JAGOTEC"; (NITEC and JAGOTEC hereinafter sometimes referred to as "Party" or "Parties"). JAGOTEC is a 100% owned subsidiary of SkyePharma plc and SkyePharma AG is a 100% owned subsidiary of SkyePharma plc.

WHEREAS, the Parties and SkyePharma AG signed a Development and Licence Agreement on 20 August 2004 ("DLA"); and

WHEREAS, NITEC is a company engaged directly or through its affiliate Nitec Pharma GmbH in the manufacture, distribution and licensing of pharmaceutical products, including the Product (as defined below), and is interested in JAGOTEC manufacturing Product for use, marketing, distribution and sale by itself, Nitec Pharma GmbH or a third party in the Territory (as defined below) under the terms and conditions of this Agreement; and

WHEREAS, JAGOTEC is a company engaged and specialised directly or through its affiliate SkyePharma SAS - inter alia - in the manufacturing of pharmaceutical products and is interested to manufacture Product for NITEC for use, marketing, distribution and sale by itself or a third party in the Territory under the terms and conditions of this Agreement.

NOW, THEREFORE, for and in consideration of the premises, mutual covenants and agreements contained herein, and intending to be legally bound hereby, the Parties hereby agree as follows:

1. Definitions

For purposes of this Agreement, the terms defined in this Article 1 shall have the following meanings:

1.1 "Active Ingredient" shall mean prednisone in a form meeting the Specifications and the Quality Agreement and ordered by NITEC from a third party in accordance with Section 5.

1.2 "Affiliate" shall have the meaning given to it in the DLA.

1.3 "Auxiliary Materials" shall mean any and all material, ingredients and components required and/or necessary for the manufacturing of Product under
and pursuant to the Manufacturing Process and procured by JAGOTEC from third parties in accordance with Section 5, but excluding the Active Ingredient.

1.4 “Batch” shall mean a production lot containing theoretically […] units of Product of the same dosage strength (“Theoretical Quantity”) and, at a lower actual limit, the Lower Quantity.

1.5 “Business Day” shall mean a day on which commercial banks are open for business in Lyon, France.

1.6 “Capacity Plan” shall have the meaning given to it in Section 6.1.

1.7 “Commercially Reasonable Efforts” shall have the meaning given to it in the DLA.

1.8 “Committee Members” shall have the meaning given to it in Section 6.1.

1.9 “Contract Year” shall mean each twelve (12) months period from 1st January through 31st December during the term of this Agreement.

1.10 “GMP” shall mean Current Good Manufacturing Practice in accordance with rules governing medicinal products in the European Community and the US good manufacturing practices (CFR 210&211) and/or becoming applicable during the term of this Agreement.

1.11 “Delivery” shall mean delivery of the Product Ex Works (Incoterm 2000) by JAGOTEC to NITEC in accordance with Section 6.9.

1.12 “Delivery Day” shall mean the day when the Product is Delivered to NITEC or its nominee.

1.13 “Effective Date” shall mean the date first written herein above.

1.14 “Euro” shall mean the single currency of participating members states of the EU.

1.15 “Finished Product” shall mean the Product packaged by or on behalf of NITEC for commercial release and sale.

1.16 “First Launch” shall mean the first commercial sale to a third party customer of the Finished Product in a Major Country.

1.17 “Forecast” shall have the meaning given to it in Section 6.2

1.18 “Joint Product Committee” shall mean a committee established and conducted in accordance with the procedures as set forth in Section 6.1.

***Confidential Treatment Requested
1.19 “Launch Period” shall mean the period of manufacturing Product for First Launch and for the next Contract Year after said First Launch.

1.20 “Lower Quantity” shall mean [...] per Batch or if more than one batch is ordered at one time, the average of all such Batches ordered of the same strength.

1.21 “Major Capital Expenditure” shall mean the investment by JAGOTEC at the Manufacturing Site including in equipment, zoning and any utilities, totalling in excess of [...] for the expansion of overall capacity for the manufacture of Product (as opposed to mere replacement).

1.22 “Major Country” shall mean France, Germany, Italy, Spain, the United Kingdom or the United States of America.

1.23 “Manufacturing Costs” shall mean with respect to Product JAGOTEC’s fully allocated manufacturing costs applied by JAGOTEC to the Product calculated in accordance with generally accepted accounting principles in Switzerland, and shall include but not be limited to [...]. Manufacturing Costs shall not include costs for Auxiliary Materials and Active Ingredient.

1.24 “Manufacturing Process” shall mean the process for the manufacturing of Product as submitted in the request for registration of Product to any Regulatory Authority in the Territory attached hereto as part of the Quality Agreement.

1.25 “Manufacturing Site” shall mean the facilities designated by JAGOTEC for manufacturing Product under this Agreement, which facilities are operated by JAGOTEC’s Affiliate SkyePharma Production S.A.S. and which are located at 55 rue de Montmurier, BP 45, 38291 Saint Quentin-Fallavier Cedex, France.

1.26 “Marketing Authorization” shall mean with respect to any country that the applicable health authority has approved Finished Product for marketing in such country.

1.27 “Minimum Commercial Yield” shall mean the minimum yield in % of a Batch manufactured according to the Manufacturing Process for market purposes as set forth in Section 8.

1.28 “Non-Compliant/Non-Compliance” shall have the meaning given to it in 6.14.

1.29 “Quality Agreement” shall mean the agreement dated as of the Effective Date on cGMP which agreement shall be attached hereto as Annex 5.

***Confidential Treatment Requested
1.29 “Price Per Unit” shall mean the price per unit of Product manufactured and supplied hereunder composed of the […]***[…] of the Manufacturing Costs plus […]***[…] of the costs of the Auxiliary Materials. Costs of the Active Ingredient are not included. The Price per Unit shall be as set out in Annex 4 for the period referred to therein.

1.30 “Product” shall mean the pharmaceutical formulation named Lodotra containing the Active Ingredient manufactured and supplied hereunder by JAGOTEC in accordance with the Quality Agreement including the Manufacturing Process and the Specifications, which have been approved for marketing and sale by Regulatory Authorities in the Territory or which are intended to use for commercialisation purposes or clinical trials. Product is offered in the presentation according to Annex 1.

1.31 “Regulatory Approvals” shall mean all approvals, price approvals or approvals for reimbursements, product and/or establishment licenses, registrations, permits, or authorizations (including Marketing Authorizations) of any federal, state or local regulatory agency, department, bureau or other governmental entity or Regulatory Authority, necessary for the manufacture, packaging, distribution, use, storage, importation, export, transport, marketing and sale of the Products and/or Finished Products for therapeutic use in humans in a country of the Territory.

1.32 “Regulatory Authority/(ies)” shall mean any governmental authority in any country or group of countries of the Territory competent to approve pharmaceutical products for manufacturing, marketing, distribution and sale in any country(ies) of the Territory and/or to approve the price for pharmaceutical products to be sold in any country(ies) of the Territory, including without limitation the FDA and EMEA, and any successor agency thereof.

1.33 “Regulatory Standards” shall mean all standards, rules and regulations promulgated by a Regulatory Authority and applicable to the product and the manufacture thereof, including without limitation cGMP.

1.34 “Release” shall mean release of the Product by the Qualified Person pursuant to the Quality Agreement.

1.35 “Shelf Life” shall mean in relation to the Product have the meaning given to it in the Quality Agreement/shall mean in respect of each Batch a defined period of months (“Shelf Life Period”) as per Annex 2a which will be updated from time to time by NITEC) from the date of first contact between the Active Ingredient and Auxiliary Material.

1.36 “Specifications” shall mean the specifications for the Product as contained in Annex 2.

***Confidential Treatment Requested
“Technical Support” shall mean reasonable assistance provided by JAGOTEC to NITEC strictly limited to providing technical support to an alternative supplier of Product in connection with (a) the training of their staff, (b) cross-validation of the analytical methods and its production of three consecutive validation Batches (of one strength only) complying with the Specifications. All other technical support, including but not limited to regulatory support, stability programs and any in vivo study work, is specifically excluded.

“Territory” shall mean collectively each country or group of countries of the world, in which a Regulatory Authority has granted Regulatory Approval.

2. Subject Matter and Grant of License
   NITEC hereby instructs JAGOTEC, and JAGOTEC hereby agrees under the terms and conditions contained in this Agreement, to manufacture at the Manufacturing Site and supply to NITEC Product in bulk form for use in the Finished Product for sale to the pharmaceutical trade. JAGOTEC shall manufacture and deliver Product exclusively to NITEC. JAGOTEC shall delegate its responsibilities hereunder to its Affiliate SkyePharma SAS, provided that JAGOTEC remains solely liable to NITEC for the same. The use, marketing, distribution and sale of the Finished Product may at NITEC’s option also be carried out by NITEC’s affiliate Nitec Pharma GmbH and NITEC may delegate any other responsibilities under this Agreement to Nitec Pharma GmbH so long as NITEC remains solely liable to JAGOTEC for the same.

3. Manufacturing of Product
   3.1 JAGOTEC shall manufacture the Product for marketing and sale by NITEC in the Manufacturing Site in strict compliance with the Specifications and the approved Manufacturing Process and in accordance with the Quality Agreement. Furthermore, JAGOTEC shall only use such equipment and personnel which are appropriate or duly qualified for the manufacturing of Product in accordance with the provisions of this Agreement and the Quality Agreement. It is acknowledged and agreed between the parties that the final dissolution specification for the Product is not approved by the regulatory authorities at signing this contract but will be approved by the regulatory authorities during the approval process. Therefore, JAGOTEC shall only be liable for failing to manufacture the Product in accordance with such preliminary dissolution specification (as per annex 2) until agreement of the Joint Product Committee as set out below. After approval by the regulatory authorities of a final dissolution specification, JAGOTEC shall use Commercially Reasonable Best Efforts to implement such final dissolution specification such that the Product may be manufactured at the Manufacturing Site in accordance therewith. If, having used such efforts, JAGOTEC is able to manufacture in accordance with such final dissolution specification, it shall notify the Joint Product Committee. Upon the unanimous agreement of the Joint Product Committee that such final dissolution specification has been implemented, the Specifications and/or the
Quality Agreement shall be amended to incorporate such final dissolution specification and JAGOTEC agrees that the campaigns following such amendment shall be manufactured in accordance therewith. If, having used Commercially Reasonable Best Efforts to do so, Jagotec is unable to manufacture Product in accordance with such final dissolution specification within a reasonable period of time following approval, it shall continue to manufacture in accordance with the Specifications at the date hereof, shall not be in breach of this Agreement and shall have no liability to NITEC in connection with such failure. In this clause, “Commercially Reasonable Best Efforts” shall mean those efforts and resources that would be used by an established pharmaceutical company in its capacity as a contract manufacturer (taking into all relevant factors including but not limited to product labelling, stage in the relevant product life, market potential, past performance, availability of resource, economic return, the regulatory environment and competitive market conditions in the therapeutic area), utilizing sound and reasonable scientific and business practice and judgment and its manufacturing expertise, in a diligent and timely manner, all as measured by the facts and circumstances at the time such efforts are due; it being understood however for the avoidance of any doubt that such efforts shall not include, nor shall be deemed to include, (a) the commitment by JAGOTEC to any Major Capital Expenditure and (b) any obligation on JAGOTEC to manufacture and supply the Product at less than a reasonable margin.

3.2 JAGOTEC shall permit duly authorized representatives of (a) NITEC or (b) any third party contracted by NITEC to have an official responsibility for the release of the Finished Product to the market according to applicable laws and regulations applying in countries of the Territory (so long as such third party has signed a confidentiality agreement on terms acceptable to JAGOTEC) during Business Days and hours and upon reasonable prior written notice to inspect once a year (or more often if reasonably requested by NITEC on its own behalf or on behalf of its third party contractor) the Manufacturing Site - including but not limited to manufacturing, testing, warehousing and/or storing and generation and/or disposal of waste - used for the manufacturing of Product and to inspect and take reasonable quantities of Active Ingredient, Auxiliary Materials, intermediate product and Product manufactured for examination purposes to verify JAGOTEC’s compliance with the Manufacturing Process, the Specifications and its obligations under this Agreement including the Quality Agreement. Furthermore, JAGOTEC will supply copies to NITEC (on NITEC’s request and at NITEC’s cost) of any and all records relating to manufacturing and testing of the Product. NITEC shall be promptly informed in writing and by fax or email if and when an inspection by a Regulatory Authority occurs or is scheduled to occur at the Manufacturing Site which in any way involves inspection of the production of Product or any other feature of JAGOTEC’s actions in connection with Product of the performance of this Agreement. NITEC shall be entitled to send a representative to attend any such
inspection of the Manufacturing Site. The findings of any such inspection at the Manufacturing Site or of any other inspections including self inspections carried out in relation to production at the Manufacturing Site of JAGOTEC for the Product shall promptly be made known in their entirety in writing to NITEC insofar and to the extent that they may potentially impact the commercialization, manufacture (including but not limited to quality and testing) and Delivery of the Product under this Agreement.

3.3 JAGOTEC undertakes to use any and all Active Ingredient exclusively for the performance of its obligations hereunder and JAGOTEC shall, upon receipt of any supply of Active Ingredient and Auxiliary Materials, promptly perform the quality and quantity control procedures as provided for in the Quality Agreement. In the event that any Active Ingredient and Auxiliary Materials to be used solely in the manufacture of the Product, or any part thereof, do not meet with the Specifications and/or quality requirements as set forth in the Quality Agreement, then JAGOTEC shall reject such materials and shall promptly notify NITEC thereof in writing including a specific description of the deviation from the Specifications—(a) in every case in relation to Active Ingredient and (b) where such rejection is reasonably likely to impact upon the manufacture of the Product in relation to Auxiliary Materials. The cost of any rejected Auxiliary Materials, the quality control and related rejection for Auxiliary Materials shall be borne by Jagotec or its suppliers subject to the terms of existing supply agreements between Jagotec and its suppliers of Auxiliary Materials. The cost of any rejected Active Ingredient, quality control and related rejection for Active Ingredient shall be borne by NITEC or its selected supplier subject to the terms of any existing supply agreement between NITEC and the Active Ingredient supplier unless this failure is caused by a failure of JAGOTEC during the quality control process for the Active Ingredient.

3.4 JAGOTEC shall store all Active Ingredient, Auxiliary Materials, intermediate product and all Product manufactured hereunder, in a suitable warehouse under suitable conditions as set forth in the Quality Agreement preventing the deterioration, theft or damage of Active Ingredient, Auxiliary Materials, intermediate products and Product until the agreed Delivery Day to NITEC, and JAGOTEC shall insure against such risks all Active Ingredient, Auxiliary Materials, intermediate products and all Product manufactured hereunder until Delivery.

The Active Ingredient ordered by NITEC for the purposes of manufacturing of Product shall remain NITEC property but shall be stored by JAGOTEC under JAGOTEC’s sole responsibility.

JAGOTEC shall report to NITEC at least once a month on the level of stocks of Active Ingredient, and Product manufactured, including a differentiation of the status of the Product manufactured, such as “under quarantine”, “released”, “rejected”). The report frequency may be modified by decision of the Joint Product Committee.
Should Auxiliary Materials ordered exclusively for NITEC need to be re-analysed after being stored by JAGOTEC in compliance with the Quality Agreement for a period in excess of its intended shelf-life, NITEC shall cover the cost of such analysis. Should Active Ingredient or Auxiliary Materials require re-analysis due to failure to comply with the storage provisions of the Quality Agreement, or where such re-analysis is carried out by JAGOTEC for its own internal purposes, then JAGOTEC shall cover the cost of such analysis.

3.5 JAGOTEC hereby agrees to guarantee NITEC, upon two week’s prior written notice, free and full access to any know-how relating to the manufacture of the Product necessary to enable NITEC to obtain or maintain any Regulatory Approval in the Territory, to perform the Batch release, to ensure that the finished Product is in line with the Regulatory Approval and all other (local) applicable laws and regulations and to enable qualified NITEC personnel to fulfill NITEC’s legal and regulatory obligations.

Each change in the Product or in the Manufacturing Process proposed by either Party, shall be communicated to the other Party in advance, to enable the other Party to comment on such intended changes before implementation. Any changes proposed by JAGOTEC shall only be implemented with NITEC’s prior written consent, which consent shall not be unreasonably withheld or delayed. The Joint Product Committee shall discuss any benefit generated by the implementation of changes proposed by JAGOTEC and decide which party shall bear which proportion of the costs thereof. NITEC shall bear or reimburse JAGOTEC for all of JAGOTEC’s costs (including without limitation any regulatory costs) associated with any change initiated by NITEC or required by a Regulatory Authority and related specifically to the Product. Further details regarding the change control procedure will be set forth in the separate Quality Agreement.

3.6 Quality control of Product is under the sole responsibility of NITEC. Therefore JAGOTEC will not analyze the Product in order to determine its suitability for quality control under this Agreement or applicable requirements of a Regulatory Authority or with any applicable Regulatory Approval. All in-process controls are under the sole responsibility of JAGOTEC. JAGOTEC will not change the in-process controls as set forth in the Regulatory Approval and the Quality Agreement without the written consent of NITEC.

JAGOTEC shall provide NITEC with the results of the in-process controls after occurrence and with samples of Product to perform the quality control testing within 3 working days of the final press-coating step. NITEC shall inform JAGOTEC on the results of such analysis also within 3 working days of completion.

In the event that JAGOTEC agrees to the implementation of the analytical method (quality control) for Product at JAGOTEC, NITEC shall reimburse...
JAGOTEC for all of JAGOTEC’s reasonable costs associated with such analytical method transfer, to the extent JAGOTEC has notified NITEC in advance of the estimated amount of such costs. Otherwise, each Party shall bear its own costs related to such analytical method transfer.

3.7 Without prejudice to Section 3.6, JAGOTEC shall perform all in-process control tests and confirm the GMP-compliant manufacture of the Product pursuant to the terms of the Quality Agreement.

3.8 JAGOTEC agrees to provide sufficient manufacturing capacity subject to the terms hereof to fulfill NITEC’s requirements for the Product as bulk tablets, to the extent that these requirements of NITEC are reflected in NITEC’s Forecast per Section 6.2 and in JAGOTEC’s Capacity Plan per Section 6.1.

4. Obligations of NITEC

4.1 NITEC shall be responsible, at its own cost and expense, for maintaining and updating from time to time, if needed, any and all Regulatory Approvals.

4.2 NITEC shall appoint a supplier of Active Ingredient and shall ensure that such supplier supplies Active Ingredient in a timely manner which meets with the Specifications and/or quality requirements as set forth in the Quality Agreement. NITEC agrees that for the avoidance of any shortfalls during the Launch Period it will order [...***...] of the Active Ingredient required for the manufacturing of Product (as recommended by JAGOTEC pursuant to clause 5.1, firmly ordered by NITEC).

4.3 NITEC shall be responsible for the qualification of the supplier of the Active Ingredient as set forth in the Quality Agreement.

4.4 NITEC shall contract with such supplier, be responsible for all dealings with, and settle all invoices of such supplier. NITEC shall negotiate with each such qualified supplier prices, annual amounts and lead times for the supply of the Active Ingredient. NITEC shall inform JAGOTEC in writing of the relevant parts of the agreements between NITEC and the suppliers of the Active Ingredient.

4.5 NITEC shall ensure that such supply of Active Ingredient shall be in compliance with the Specifications and the requirements set forth in the Quality Agreement, and shall be delivered DDP (Incoterms 2000 ICC) to the Manufacturing Site.

4.6 NITEC shall notify JAGOTEC of any matter of which it becomes aware which is reasonably likely to impact upon the delivery or quality of the Active Ingredient to JAGOTEC.

***Confidential Treatment Requested
5. **Obligations and Responsibilities of JAGOTEC**

5.1 JAGOTEC undertakes to recommend a supplier of the Auxiliary Materials which JAGOTEC shall contract with and from which JAGOTEC shall order the same for the purposes hereof.

5.2 JAGOTEC shall be responsible for the qualification of the supplier of the Auxiliary Materials as set forth in the Quality Agreement.

5.3 JAGOTEC shall negotiate with each such qualified supplier prices, annual amounts and lead times for the supply of the Auxiliary Materials. JAGOTEC shall inform NITEC in writing of the agreements between JAGOTEC and the suppliers of the Auxiliary Materials.

5.4 JAGOTEC shall be responsible for the keeping of the contract with the supplier and the usage of Auxiliary Materials for manufacturing of Product which meet with the Specifications and/or quality requirements as set forth in the Quality Agreement.

For the avoidance of any shortfalls during the Launch Period JAGOTEC shall order [...] of the Auxiliary Materials required for the manufacturing of Product firmly ordered by NITEC. JAGOTEC shall ensure that such supply of Auxiliary Materials shall be in compliance with the requirements set forth in the Quality Agreement, and shall be delivered DDP (Incoterm 2000 ICC) to the Manufacturing Site.

5.5 Any change in the supplier or the specification of the Auxiliary Materials shall require the prior written consent of NITEC.

5.6 JAGOTEC shall notify NITEC of any matter of which it becomes aware which is reasonably likely to impact upon the Delivery Day or otherwise on JAGOTEC’s ability to fully and timely perform its obligations under this Agreement.

5.7 JAGOTEC may provide support in relation to technology transfer other than Technical Support to NITEC upon agreement by NITEC to the payment of such costs of providing such support as are agreed.

6. **Order and Supply of Product**

6.1 The parties shall establish a “Joint Product Committee” consisting of four (4) individuals (“Committee Members”); two of whom shall be nominated by JAGOTEC and two of whom shall be nominated by NITEC. The Committee Members may be replaced by notice to the other Party and shall be appropriately qualified and experienced in order to make a meaningful contribution to the Joint Product Committee meetings. The Joint Product

***Confidential Treatment Requested***

10.
Committee shall meet at least once per quarter to review NITEC’s Forecast (as defined in Section 6.2) for the Product, which shall reflect NITEC’s realistically anticipated up-side scenario for its requirements for Product. JAGOTEC shall provide to NITEC, at the beginning of each quarter for the following eight quarters with a capacity plan for the Product (“Capacity Plan”). The Joint Production Committee shall compare the Capacity Plan to NITEC’s Forecast. Each member of the Committee shall have one vote in relation to matters discussed by it and save as otherwise set out herein votes shall be carried by a majority. Initial members of the Committee shall be set out in Annex 9.

6.2 NITEC shall issue, for the first time on the date of signature hereof, and thereafter during the term of this Agreement at the beginning of each quarter in accordance with Section 6.3, a rolling forecast (“Forecast”) for the upcoming […] estimating NITEC’s requirements of Product for (a) distribution and sale and (b) for clinical studies in the Territory, which forecasts shall be used by JAGOTEC for production planning purposes. The submission of each Forecast shall constitute a binding order for the quantity of Product set forth in […] for Delivery at the latest […] after the submission thereof save that the quantities set forth in […] of the first Forecast issued on the date of signature of this Agreement shall not be binding on the parties unless agreed between them. In each Forecast, […] shall be (i) within +/- […] of the quantities in the Forecast immediately preceding the most recent Forecast and (ii) within +/- […] of the quantities set out in […] in the forecast immediately preceding the Forecast referred to in (i). Save as set out herein, it is mutually agreed between the Parties that the Forecast is only a non-binding estimate of NITEC’s requirements of the Product and that in particular in case of any foreseeable launches in a Major Country such Forecast may be adequately adjusted by mutual agreement of the parties.

6.3 Any purchase order (to be sent out by NITEC on a monthly basis) shall be confirmed by JAGOTEC within 5 working days and shall be binding upon JAGOTEC, provided that the requested Delivery Day is not earlier than […] after the receipt of such purchase order and provided that such order shall correspond with the binding element of the Forecast for the month in question. It is JAGOTEC’s obligation to negotiate with the Auxiliary Materials supplier lead times for the supply of the Auxiliary Materials in quantities and of quality sufficient for timely manufacturing of Product in accordance with any […] Forecast. JAGOTEC shall recommend to NITEC and its Active Ingredient supplier (a) the quantity of Active Ingredient and (b) the dates of delivery of the same which would, in JAGOTEC’s reasonable opinion based on Forecasts, be required in order for JAGOTEC to timely manufacture Product in accordance with any […] Forecast. Further JAGOTEC shall inform NITEC at the same time about the existing stock of Active Ingredient held by JAGOTEC. JAGOTEC shall not be responsible for any other dealings with such
supplier nor shall it be liable for the failure of such supplier to supply Active Ingredient in a timely manner or that does not meet with the Specifications and/or quality requirements as set forth in the Quality Agreement. JAGOTEC shall inform NITEC immediately in writing of any deviation from the aforementioned [...***…] lead time.

6.4 Notwithstanding anything contained herein, NITEC may always request supply of Product in excess of the quantity set out in Section 6.3 but any such request shall not be considered a firm order binding upon JAGOTEC unless and to the extent confirmed by JAGOTEC in writing, provided that JAGOTEC shall at all times employ its Commercially Reasonable Efforts to comply with any request of NITEC for Product.

6.5 If (a) in any three consecutive Forecasts, the quantity forecast in respect of [...***…] thereof would, in JAGOTEC’s sole opinion, require Major Capital Expenditure in order for JAGOTEC to manufacture such quantity (JAGOTEC basing such opinion upon it deciding in its sole discretion that the quantity forecast exceeds the quantity that it could provide on the date of each such Forecast by [...***…] of the maximum available capacity for NITEC as per Capacity Plan would be required), and (b) in the third such consecutive Forecast, the quantity forecast in respect of [...***…] thereof would so require Major Capital Expenditure, JAGOTEC within [...***…] of receipt of the third such consecutive Forecast shall notify NITEC and decide, whether or not to commence such Major Capital Expenditure. If JAGOTEC commences such Major Capital Expenditure NITEC agrees and acknowledges that such Major Capital Expenditure is likely to take [...***…] to complete.

6.6 If JAGOTEC decides, upon receiving the third such consecutive Forecast as set out in Section 6.5 above, not to commence Major Capital Expenditure it shall notify NITEC of its decision and any subsequent [...***…] Forecast shall only become binding as to the quantity that JAGOTEC is able to manufacture without such Major Capital Expenditure. Upon such decision not to commence Major Capital Expenditure, NITEC may, from the date upon which the third consecutive [...***…] forecast becomes a [...***…] Forecast, use such second manufacturing site to fulfil in any subsequent quarter only such amount of orders as exceed those which JAGOTEC is unable to manufacture as a result of not commencing Major Capital Expenditure. JAGOTEC shall in such circumstance provide Technical Support to NITEC at NITEC’s cost.

6.7 Each order under Section 6.2 above shall consist of not less than [...***…] Batches of Product covering all dosage strengths (save that in the first two years following First Launch Jagotec agrees to accept individual orders of less than [...***…], without prejudice to the minimum order obligation in the following sentence. NITEC shall order the minimum quantities set out and according to Annex 3 (the “Minimum Quantities”). The firm order for launch

***Confidential Treatment Requested
stock is at least 1 Batch of Product per dosage strength. NITEC will place orders of Product in units of whole Batches.

6.8 It is agreed and understood between the parties that the quantities ordered by NITEC shall be based upon the fact that each Batch (or the average of a number of Batches where more than one Batch is ordered at any one time) may contain \[\ldots\] units and such Lower Quantity would be, if Delivered, sufficient to satisfy its requirements and NITEC shall supply Forecasts accordingly.

6.9 JAGOTEC shall supply Product firmly ordered by NITEC in accordance with this Agreement at the applicable and agreed Delivery Day upon the preceding and following conditions; (a) Any Batch (or number of Batches on average as set out in Section 6.8) of Product may not fall short of the Lower Quantity; and (b) All Products shall be Delivered to NITEC Ex Works (Incoterms 2000) the Manufacturing Site. Together with any such shipment of Product, JAGOTEC shall provide NITEC with the documents and samples specified in the Quality Agreement. JAGOTEC shall be responsible for ensuring that each Delivery of Product shall be delivered to NITEC as soon as possible (and in any event within 3 months) after its manufacture.

6.10 Delivery performance and failures. Orders are considered as orders fulfilled on time if the Products meet the standards set out in the Quality Agreement and not properly rejected on the terms hereof and if the Delivery Day set out in an order acceptance is met by \[\ldots\]. In the case that JAGOTEC does not reach the on time targets above, JAGOTEC shall use all Commercially Reasonable Efforts to fulfill such orders and NITEC shall, in addition to any other remedy (including under Section 8 in any case in which the Minimum Commercial Yield is not achieved), be entitled to reduce the Price Per Unit of late batches by \[\ldots\] of delay but to a maximum of \[\ldots\]

If JAGOTEC produces a Batch or Batches (on average as above) containing less than the Lower Quantity JAGOTEC shall immediately inform NITEC in writing. NITEC will thereafter be entitled to place an additional order (not defined as or part of any Minimum Orders) and JAGOTEC agrees to use Commercially Reasonable Efforts to accept and fulfill this order within such a shortened lead time as is reasonably practicable (and to within five days provide NITEC with a Delivery Day therefor) provided that such quantities of Active Ingredient and Auxiliary Materials are on stock in order to do so. To avoid any shortfalls during the Launch Period the Parties hereby agree (in Sections 4.2 and 5.4) to order \[\ldots\] of Active Ingredient and Auxiliary Materials respectively of the amount firmly ordered by NITEC during such Launch Period.

***Confidential Treatment Requested
NITEC shall then be obliged to pay the following amounts in respect of the additionally ordered Batches as set out above;

(a) in respect of units up to the total Minimum Commercial Yield ordered – the Price Per Unit;

(b) in respect of the balance of supplied units (i.e. in excess of the Minimum Commercial Yield ordered) – the Price Per Unit [...***…]

JAGOTEC shall not keep Product on stock except for the purpose of retaining samples as defined in the quality agreement or as required for analysis in case of a dispute pursuant to clause 6.17 or otherwise.

6.11 JAGOTEC shall notify NITEC of the Delivery Date for a Delivery at least five (5) days prior of the same and NITEC undertakes to accept Delivery of all Product Delivered by JAGOTEC on such Delivery Date. JAGOTEC will package and label Product in accordance with the provisions of the Quality Agreement including at least code number, name of product, batch number, order number, quantity of supplied Product per package and date of manufacture.

6.12 If following completion of Major Capital Expenditure NITEC does not order quantities equal to (a) those in the Forecasts which triggered such Major Capital Expenditure [...***…] and (b) that forecast in respect of [...***…] in the subsequent Forecast, the Price Per Unit of quantities actually ordered will be adjusted as follows;

Where the amounts ordered by NITEC are less than [...***…] but more than [...***…], of maximum available capacity: Price Per Unit [...***…]

Where the amounts ordered by NITEC are [...***…] or less, but more than [...***…] of maximum available capacity: Price Per Unit [...***…] [...***…]

Where the amounts ordered by NITEC are [...***…] or less of maximum available capacity: Price Per Unit [...***…]

The maximum available capacity for the purposes of this Section 6.12 shall be that available for NITEC as per Capacity Plan at the date upon which JAGOTEC notified NITEC of the need for Major Capital Expenditure under Section 6.5.

Any amounts in respect of an increase in prices due under this Section 6.12 shall be invoiced at the end of the twelve month period following completion of Major Capital Expenditure. Payment terms shall be as per order to reflect the price adjustment for the previous twelve month; payment term for this invoice will be as per Annex 4.

***Confidential Treatment Requested
6.13 NITEC shall bear the cost of bulk, quality control and rejection of spoiled, damaged, contaminated or defective Active Ingredient provided that such Active Ingredient’s damage, contamination or defect could not have been discovered by JAGOTEC with standard sampling or analytical procedures as defined in the Quality Agreement.

6.14 If any shipment of Product or any portion thereof is spoiled, damaged, contaminated or defective upon Delivery or fails to meet the Specifications or the quality standards set out in the Quality Agreement (together “Non-Compliant”), then NITEC shall have the right to reject such shipment or the portion affected thereby by giving written notice to JAGOTEC within [...] following the Delivery of such shipment of Product, sufficiently specifying the alleged Non-Compliance and the quantities affected. Any shipment or portion thereof so rejected by NITEC shall be held at JAGOTEC’s disposal for examination. JAGOTEC shall investigate such issue and provide a written report to NITEC as soon as possible after notification. JAGOTEC shall not be liable for any Non-Compliance of the Product arising out of the shipment, storage or handling of Product by NITEC or its representatives, agents or customers.

6.15 In the event that any shipment of Product or any portion thereof is rightly rejected by NITEC in accordance with Section 6.14 above, then JAGOTEC undertakes to take back and, at NITEC’s request, destroy such Non-Compliant Product, and to replace such Non-Compliant shipment or portion thereof with an identical quantity of Product as soon as reasonably possible.

6.16 In any case of Non-Compliance, NITEC shall pay for the Non-Compliant Product, provided that such payment shall not be deemed to be a waiver of NITEC of any of its rights on account of such Non-Compliance. Should the Non-Compliance be due to JAGOTEC, such replacement shall be effected at JAGOTEC’s own cost and expense which includes but is not limited the corresponding amount of Active Ingredient and Auxiliary Materials in the Non-Compliant Batch or part thereof and the Manufacturing Costs. The Non-Compliant Product shall, at JAGOTEC’s cost and expense, be returned to JAGOTEC. NITEC shall pay for the replacement of Product in accordance with the payment provisions of this Agreement, provided that Product supplied by JAGOTEC conforms with quality standards as of Annex 5. Should the Non-Compliance be due to NITEC (including for the avoidance of doubt in situations where the Active Ingredient is contaminated and such Active Ingredient contamination could not be discovered by JAGOTEC with standard sampling or analytical procedures as defined in the Quality Agreement), NITEC shall pay for the replacement of Product in accordance with the payment provisions of this Agreement.

***Confidential Treatment Requested

15.
6.17 In the event of any dispute between the Parties regarding the question whether a shipment of Product or any part thereof timely rejected by NITEC was actually Non-Compliant, and/or where responsibility for such Non-Compliance, under the terms hereof, lies the Parties agree to have an independent mutually acceptable (each Party acting reasonably) laboratory or expert perform such tests and analysis on the rejected Product as deemed necessary and/or required to establish the defect alleged by NITEC and the reasons therefore. The result of such independent laboratory or expert shall be binding upon the Parties, and the cost of such examination shall be borne by the losing Party.

6.18 In cases in which the resolution of a dispute or investigations is anticipated to take more than 2 weeks, JAGOTEC shall upon NITEC’s request and as soon as practicable after notification of the rejection deliver replacement Products for the Products under dispute in order to ensure continuity of supply.

6.19 Together with any shipment of Product, JAGOTEC shall issue a respective invoice for such shipment, applying the then valid Price Per Unit, multiplied by the number of units of Product actually supplied. NITEC undertakes to pay any and all such invoices within [...] as of the delivery date of the respective shipment of Product (“Payment Date”). In the event of late payment JAGOTEC may charge interest on the outstanding amount at a rate of [...] and such interest shall be calculated and payable in respect of the period from Payment Date until the date payment in full is received by JAGOTEC.

7. Calculation and Adjustment of Price Per Unit

7.1 The Price per Unit does not include any Value Added Taxes (VAT), turnover taxes or similar charges in any country, which are to be added and paid by NITEC as applicable. The Price Per Unit of this Agreement shall remain applicable for all supplies of Product during the term from the Effective Date until 31 Dec 2007.

7.2 Thereafter, the Price per Unit contained in Annex 4 hereto may be adjusted by JAGOTEC once each Contract Year in the month of October calculated as follows:

(a) Adjustments to Manufacturing Costs shall be calculated on the basis of [...] ;

(b) Adjustments to costs of Auxiliary Materials shall be calculated by reference to actual changes to the costs thereof, without any mark up added by JAGOTEC

In no Contract Year may any increase be in excess of [...] of the then current Price Per Unit save by mutual agreement of the parties. Such adjusted Price

***Confidential Treatment Requested

16.
per Unit shall be attached hereto as new Annex 3 each year and shall remain in force for supplies of Product during the next Contract Year.

7.3 NITEC shall have the right, through its employees and/or its independent auditing representatives and upon reasonable notice, to audit, during normal business hours, all records and accounts of JAGOTEC as may under recognised accounting practices contain information bearing upon the Price per Unit. Such audit shall be carried out at NITEC’s expense unless it reveals that a Price Per Unit quoted by JAGOTEC to NITEC prior to the audit exceeded the Price per Unit calculated in accordance with this Agreement by [...***...] or more, in which case JAGOTEC shall, forthwith reimburse NITEC for the cost of audit and an amount equal to the overpayment.

8. Minimum Commercial Yield

JAGOTEC commits itself to attaining the Minimum Commercial Yield of the Product as set out in Annex 6 (or as may otherwise be amended on the terms hereof). The Commercial Yield shall be calculated as follows:

\[
\frac{a + b}{c}
\]

\[
a = \text{number of units delivered by JAGOTEC}
\]

\[
b = \text{number of sample units necessary for control purposes and retaining samples}
\]

\[
c = \text{theoretical quantity of units per Batch of Product in bulk Tablets}
\]

If the actual yield of Product, calculated for a maximum of one (1) year, is below the Minimum Commercial Yield, JAGOTEC shall reimburse NITEC for a proportionate amount of the cost of Active Ingredient.

This Minimum Yield shall be reviewed annually to allow for possible improvements in the Manufacturing Process.

9. Delivery Conditions:

JAGOTEC will deliver Product packaged and labelled in accordance with the Quality Agreement and the defined “Logistics” under Annex 7.

***Confidential Treatment Requested
10. **Term and Termination**

10.1 According to the DLA this Agreement shall commence as of the Effective Date and shall continue in full force and effect until the end of the 5th year after First Launch (“Minimum Term”). It shall be automatically extended on a yearly basis unless terminated by one Party by giving to the other at least (subject to the Section 10.2 below) twenty four (24) months’ written notice to expire not before the end of the Minimum Term.

10.2 In the event of the payment of Major Capital Expenditure the notice period for any termination by either party to occur within [...***...] years of such Major Capital Expenditure shall be [...***...] months.

10.3 Notwithstanding anything contained in Section 10.1 above, and except as otherwise explicitly provided in this Agreement, this Agreement may be terminated at any time with immediate effect by giving written notice to that effect, as follows:

a) by either Party, if the other Party is materially in default or in material breach of a term or provision hereof and such default or breach continues “and” if curable, is not cured or remedied within [...***...] upon the other Party’s written request to cure or remedy such default or breach; or

b) by either Party, if the other Party becomes insolvent or goes into liquidation, voluntarily or otherwise, other than for the sole purpose of reorganisation, or goes into bankruptcy or makes an assignment for the benefit of creditors, or in the event of a receiver being appointed of the other Party’s property or parts thereof.

10.4 Upon the termination or expiry of this Agreement, regardless of the reason therefor, JAGOTEC shall at NITEC’s written request continue the supply of Product to NITEC until such time as NITEC has an alternative manufacturing site approved by appropriate Regulatory Authorities for the supply of Product save that it shall be under no obligation to continue such supply for a period exceeding 24 months from the date of such termination notice. Upon notice of termination or expiry, NITEC shall seek such an alternative manufacturing site with reasonable speed and JAGOTEC shall provide Technical Support to NITEC in relation to technical transfer issues relating to Product to the alternative manufacturing site chosen by NITEC. If this Agreement is terminated by NITEC for JAGOTEC’s breach of this Agreement, the costs of the Technical Support shall be born by JAGOTEC. In all other circumstances the costs of the Technical Support shall be borne by NITEC.

***Confidential Treatment Requested***

18.
11. Effects of Termination

11.1 In the event of termination or expiry of this Agreement by either Party, no compensation or indemnity shall be payable to or may be claimed by either Party from the other Party as a result of such termination other than as set forth in this Agreement. Notwithstanding the preceding sentence, the termination of this Agreement by either Party shall not relieve the Parties of any obligation accruing prior to the effective date of such termination.

11.2 In the event of termination of this Agreement by JAGOTEC under Section 10.2 above, NITEC shall, upon JAGOTEC’s request together with the respective termination notice take also delivery of any and all Auxiliary Materials in stock and firmly ordered by JAGOTEC on the basis NITEC’s Forecast against payment of the net procurement price for such Auxiliary Materials paid by JAGOTEC to third party suppliers (plus Value Added Tax, turnover tax or similar charges, as applicable). All such Auxiliary Material and Active Ingredient shall be collected by NITEC from the Manufacturing Site.

11.3 The Parties agree that in the event of termination of this Agreement for whatsoever reason, Sections 11, 12, 13 and 17 shall remain in full force and effect in accordance with such respective provisions.

11.4 Except as otherwise explicitly provided in this Agreement, nothing contained in this Section 10 shall in any way limit, and shall be without any prejudice to, any other rights or remedies which may be available to either Party.

12. Indemnity and Insurance

12.1 JAGOTEC does not assume any liability or gives any representation or warranty, whether express nor implied, for the merchantability or fitness for a particular purpose of Product or Finished Product manufactured and/or supplied hereunder except to the extent that such liability arise from the gross negligence or wilful misconduct of JAGOTEC, its Affiliates or any of its or their respective employees.

12.2 In no event shall JAGOTEC be liable for any direct, indirect, incidental, commercial or other damage, costs, fees, expenses or costs (“Damages”) caused by Product and/or the Active Ingredient and/or the Auxiliary Materials to NITEC or any third party except to the extent that such Damages arise from the negligence or wilful misconduct of JAGOTEC, its Affiliates or any of its or their respective employees.

12.3 JAGOTEC assumes no liability as vis a vis third parties, including without limitation, product liability, with respect to any and all Product or Finished Product marketed, distributed, sold or used, directly or indirectly, and the
Active Ingredient and Auxiliary Materials contained in any such Product or Finished Product. NITEC shall indemnify JAGOTEC from and against any and all losses, liabilities, damages and expenses (including reasonable attorney’s fees and reasonable costs) that JAGOTEC suffers as a result of any claim, demand, action or other proceeding by any third party arising from or relating to NITEC’s actions regarding the manufacturing, marketing, distribution, safe or use of Product, the Active Ingredient and/or Auxiliary Materials and/or Finished Product, or resulting from any breach of any of NITEC’s obligations and/or responsibilities and/or representations and warranties hereunder, except to the extent that any such losses, liabilities, damages and expenses arise from the gross negligence or wilful misconduct of JAGOTEC.

12.4 Each of NITEC and JAGOTEC shall maintain, during the term of this Agreement and for a period of not less than five (5) years after its termination for what so ever reason, liability insurance, including in the case of NITEC, product liability insurance, with respect to and covering their respective obligations contained in this Section 12, in such amount as is customary for companies undertaking similar activities as the respective Party with products similar to Product.

13. Confidentiality

13.1 Each Party has disclosed to the other party prior to the Effective Date, and will during the term of this Agreement continue to disclose, proprietary, confidential and non-public information, including without limitation the Manufacturing Process, price calculations and other business and trade secrets (hereinafter, all collectively referred to as “Confidential Information”).

13.2 Each Party as recipient (the “Receiving Party”) of Confidential Information of the other Party (the “Disclosing Party”) hereby undertakes to maintain in confidence all Confidential Information of the Disclosing Party and shall not use, disclose or grant or permit the use of any of the Confidential Information of the Disclosing Party except on a need-to-know basis to its directors, officers, employees, agents, consultants, clinical investigators or other permitted contractors, to the extent such disclosure is reasonably necessary in connection with the activities of the Receiving Party as expressly authorized by this Agreement. To the extent that disclosure is authorized by this Agreement, prior to disclosure, the Receiving Party shall obtain agreement in writing of any such person to hold in confidence and not make use of the Confidential Information of the Disclosing Party for any purpose other than authorized by this Agreement. Each Receiving Party shall notify the Disclosing Party promptly upon the discovery of the unauthorized use or disclosure of any such Confidential Information of the Disclosing Party.

13.3 The obligations of confidentiality and non-use contained in Section 13.2 above shall not apply to the extent that (a) a Receiving Party (i) is required to
disclose the Confidential Information by law, regulation or order of a governmental agency or a court of competent jurisdiction, or (ii) is required to disclose Confidential Information of the Disclosing Party to any Regulatory Authority for purposes of obtaining or maintaining registration for Product and/or Finished Product, provided that the Receiving Party shall request confidential treatment thereof (where available), or (b) the Receiving Party can demonstrate by written or other tangible evidence that (i) the disclosed information of the Disclosing Party was public knowledge at the time of such disclosure to it, or thereafter became public knowledge, other than as a result of actions of the Receiving Party, its directors, officers and employees in violation hereof; or (ii) the disclosed information was rightfully known by the Receiving Party (as shown by its written records) prior to the date of disclosure to it by the Disclosing Party; or (iii) the disclosed information was developed or acquired by the Receiving Party independently of any knowledge or use of the Confidential Information of the Disclosing Party (as shown by its written records); or (iv) the Confidential Information was previously legally provided to the Receiving Party by a third party without any obligations of confidentiality to the Disclosing Party.

13.4 The confidentiality obligations under this Section 13 shall be effective during the term of this Agreement and for a period of ten (10) years after the termination hereof for any reason. Each Disclosing Party shall be entitled to injunctive remedies and relief against the Receiving Party and any third parties for any breach or threatened breach of the confidentiality obligations under this Section 13 with respect to any of the Confidential Information of the Disclosing Party.

14. **Exclusivity**

During the term of this Agreement, JAGOTEC undertakes (a) not to engage in any production of Product for or on behalf of any third party and (b) to supply to NITEC all of NITEC requirements for the Product subject to the terms hereof. NITEC agrees to order all its requirements for the Product from JAGOTEC (save as is otherwise provided herein).

15. **Miscellaneous Provisions**

15.1 **Entire Agreement:** The terms, covenants, conditions and provisions contained in this Agreement, including the Annexes referred to herein which are agreed to form an integral part hereof, constitute the total and complete agreement of the Parties regarding the subject matter hereof and supersede all prior understandings and agreements hereto made, and there are no other representations, understandings or agreements relating to the subject matter hereof. The provisions of this Agreement may not be waived, altered, amended
or repealed in whole or in part except by the written consent of both of the Parties to this Agreement.

15.2 **Assignment:** Save as set out below, this Agreement may not be assigned or otherwise transferred, nor may any right or obligation hereunder be assigned or transferred by either Party without the prior written consent of the other Party. Either Party may assign in full all its rights and obligations hereunder to an Affiliate of that party (and only for so long as the assignee remains an Affiliate) and if the assigning party remains fully liable to the other party for the full and timely performance of this Agreement by the party receiving assignment and any of such parties direct or indirect successors in interest.

Any permitted assignee shall assume all obligations of its assignor under this Agreement or under the respective rights or obligations actually assigned.

15.3 **Notices:** Any consent, notice or report required or permitted to be given or made under this Agreement by one Party to the other shall be in English and in writing, delivered personally or by international courier service or by facsimile (promptly confirmed by personal delivery or international courier service) addressed to the other Party at its address indicated below, or to such other address as shall have been notified in writing to the sending Party by the receiving Party from time to time, and shall take effect upon receipt by the addressee.

**If to NITEC:**
NITEC PHARMA AG  
Kägenstrasse 9  
CH4153 Reinach  
Switzerland  
**attn.: Jochen Mattis**  
**Tel:** ++41 61 715.20.40  
**Fax:** ++41 61 715.20.49  
**Email:** jochen.mattis@nitecpharma.com

**If to JAGOTEC:**
JAGOTEC AG  
Eptingerstrasse 51  
CH-4132 Muttenz,  
Switzerland  
**attn.: Francesco Patalano**  
**Fax No:** ++41 61 467 55 74

**With copy to:**
SkyPharma Plc  
105 Piccadilly  
London W1J 7NJ  
Great Britain  
**attn.: Group Counsel**  
**Fax No:** ++44 20 7491 3338

15.4 **Independent Contractors:** It is expressly agreed that the Parties shall be independent contractors and that the relationship between the Parties shall not
constitute a partnership, joint venture or agency. Neither Party shall have the authority to make any statements, representations or commitments of any kind, or to take any action, which shall be binding on the other Party, without the prior written consent of the other Party to do so.

15.5 **NITEC warranty:** NITEC warrants that it owns one hundred percent of the shares of Nitec Pharma GmbH.

15.6 **Severability:** Each Party hereby acknowledges that it does not intend to violate any public policy, statutory or common laws, rules, regulations, treaty or decision of any government agency or executive body thereof of any country or community or association of countries. Should one or more provisions of this Agreement be or become invalid, the Parties hereto shall substitute, by mutual consent, valid provisions for such invalid provisions which valid provisions in their economic effect are sufficiently similar to the invalid provisions that it can be reasonably assumed that the Parties would have entered into this Agreement with such valid provisions.

15.7 **Force Majeure:** Neither Party hereto shall be held liable or responsible to the other Party nor be deemed to have defaulted under or breached this Agreement for failure or delay in fulfilling or performing any term of this Agreement when such failure or delay is caused by or results from causes beyond the reasonable control of the affected Party including but not limited to fire, floods, embargoes, war, acts of war (whether war be declared or not), insurrections, riots, civil commotions, strikes, lockouts or other labour disturbances, acts of God or acts, omissions or delays in acting by any governmental authority or the other Party hereto.

15.8 **Headings:** The titles and headings used in this Agreement are intended for convenience only and shall not in any way affect the meaning or construction of any provision of this Agreement.

15.9 **Waiver:** The waiver by either Party hereto of any right hereunder or the failure to perform or of a breach by the other Party shall 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.

16. **Dispute Resolution and Jurisdiction**

16.1 In the event of any dispute arising between the Parties concerning this Agreement, the Parties agree that in the first place they shall meet for good faith discussions in an attempt to negotiate an amicable solution.

16.2 For any dispute arising between the Parties out of or in connection with this Agreement, or the interpretation, breach or enforcement thereof, which cannot be amicably resolved pursuant to Section 16.1 above within two (2) months as from the first appearance of such dispute, the Parties agree and irrevocably
submit to arbitration under the Rules of Arbitration of the International Chamber of Commerce (the “Rules”) by three (3) arbitrators appointed in accordance with the Rules. The seat of arbitration shall be Basel, Switzerland, and any such arbitration shall be conducted in the English language. Any judgment upon the award rendered by the arbitrators shall be final and binding upon the parties and may be entered in any court having jurisdiction thereof.

16.3 Notwithstanding anything contained in this Section 16, either Party may seek preliminary or injunctive measures or relief in any competent court having jurisdiction.

17. Applicable Law

The Parties hereto agree that this Agreement shall be construed under and be governed by the laws of Switzerland, without reference to the principles of conflict of laws thereof, and shall not be governed by the United Nations Convention on Contracts for the International Sale of Goods (the Vienna Convention of April 11, 1980).

IN WITNESS WHEREOF, the Parties have executed this Agreement effective as of the Effective Date.

For and on behalf of
JAGOTEC AG

/s/ Francesco PATALANO
by: Francesco PATALANO
its: Director, 3 Aug 07

/Illegible Signature/
by: [Illegible Signature]
its: Director 3 Aug 07

For and on behalf of
NITEC PHARMA AG

/s/ Jochen Mattis 3.8.07
by: Jochen Mattis
its: Managing Director

3 Aug 2007 /s/ Dr. Achim Schäffler
by: Dr. Achim Schäffler
its: EVP RD and Manufacturing
List of Annexes:
Annex 1: Presentations
Annex 2: Specifications
Annex 2a: Shelf Life Period
Annex 3: Minimum Orders
Annex 4: Prices
Annex 5: Quality Agreement
Annex 6: Commercial Yield
Annex 7: Logistics
Annex 8: Hygiene, Safety and Working conditions and Protection of the environment
Annex 9: Initial Members of the Committee
Annex 10: Statement of Storage Conditions
PRESENTATION

- Lodotra
- DOSAGE: 1,2,5 mg
- Bulk tablets stored 30 L plastic drum
Shelf Life Period

[***]

***Confidential Treatment Requested

27.
## Specifications

- [...***...]
- [...***...]
- [...***...]
- [...***...]
- [...***...]
- [...***...]
- [...***...]
- [...***...]
- [...***...]
- [...***...]

***Confidential Treatment Requested

28.
MANUFACTURING & SUPPLY AGREEMENT
BETWEEN NITEC and JAGOTEC
Annex 3

**MINIMUM ORDERS- for the 1st calendar year after Product approval and launch in the first Major Country**

[*** ***]

**MINIMUM ORDERS- starting from the second calendar year after Product approval and launch in 3 out of 5 Major Countries**

[*** ***]

***Confidential Treatment Requested***

31.
PRICES

1. The following prices relate to the packaged Product delivered Ex Works by JAGOTEC

   […***…]

2. Payment shall be made in Euros by bank transfer within […***…] of the invoice date, unless otherwise agreed between the parties. Bank transfer shall be made to such account as Jagotec shall notify to Nitec.

   ***Confidential Treatment Requested
QUALITY AGREEMENT

A Quality Agreement will be signed at the latest after manufacturing of the first campaign of the Product.

33.
MINIMUM COMMERCIAL YIELD

For active ingredient ordered by JAGOTEC on behalf of NITEC, the minimum commercial yield is as follows:

[...***...]

composed of yield [...***...]

***Confidential Treatment Requested
LOGISTICS

Introduction:
In order to facilitate transfer, storage, distribution and shipment of products which are the subject of the present contract, the following recommendations must be applied as from delivery of the first batch, failing this, JAGOTEC undertakes to apply these recommendations within a period agreed with NITEC.

1 - Packaging:
Tablets of Product are packed as bulk tablets for shipment in containers of 20(±3) kg in drums with PE in-liner. The packaging material is defined in the Quality Agreement. For printing batch number and the expiration date ink based technique must be used instead of embossing which is less readable.

2 - Grouping cartons:
The quantity shall be defined in the Quality Agreement (see annex 5).
This quantity will be defined by NITEC in agreement with JAGOTEC.
Identification of each drum will be carried out according to the provisions in the Quality Agreement (see annex 5).

3 - Pallets:
Type 1’200 x 800, five tiers, total high including pallet must not exceed 1’250 mm.
Any variation from this norm must be agreed in writing by NITEC.
Consigned pallets are not accepted. NITEC can supply pallets to JAGOTEC if necessary.
It is recommended to identify each pallet with similar label to those stuck on the drums.
Pallets will be wrapped in a transparent film. A cover must be placed on incomplete pallets before wrapping.
4 - Transport:
If product delivery to NITEC is paid by JAGOTEC, it must use a carrier agreed by itself and only use sheet metal trailers. The carrier must be designed for transporting medicines.

Documents necessary for a good reception must be joined: delivery notes, analysis certificates…

JAGOTEC shall inform NITEC and NITEC’s partner for packaging by fax of all details concerning the load as soon as possible before the truck departure.

5 - Modifications:
Any modifications of points one to four above must be agreed by NITEC Distribution. At the very least the NITEC Distribution must be informed at the time of the start up of the first Batch concerned, if it relates to a modification of regulations.

Each pallet of the modified first Batch must undergo a supplementary special identification mentioning the type of modification.

6 - Detailed log book:
NITEC can provide by simple request JAGOTEC a detailed log book.
MANUFACTURING & SUPPLY AGREEMENT
BETWEEN NITEC and JAGOTEC

Annex 8

Hygiene, Safety and Working conditions and Protection of the environment

1. **Hygiene, Safety and Working conditions:**

1.1 JAGOTEC is held to know all the relevant legislative, regulatory or conventional requirements relating to hygiene, safety and working conditions, which it is required to satisfy by reason of its activities hereunder. It undertakes to comply strictly with these at all times with regard to the provisions foreseen in the present contract.

To this effect, JAGOTEC declares that it has received from NITEC the information which the latter has available concerning:

- The particular hazards of the Active Ingredient or preparations thereof which are the subject of the present contract, as well as the procedures necessary for their use or their manufacture
- The provisions to take to provide against these hazards, notably the particular precautions necessary to take with regard to handling, use and, should the case arise, storage
- The rules for packaging and labelling which are applicable to them
- The action to take in case of an accident

This information is founded on existing scientific and technical knowledge, to which NITEC may have had reasonable access.

1.2 JAGOTEC must, with the least delay and by all means at its disposal, keep NITEC informed of:

- All incidents or accidents occurring on the occasion of carrying out the provisions foreseen in the present contract, which causes harm to, or may cause harm to the health and safety of workers
- The emergency measures which, should the case arise, have been taken by itself or by the competent administrative authority

According to the same terms JAGOTEC will bring to the knowledge of NITEC:

All new facts in its actual knowledge concerning:
the hazardous properties of substances or dangerous preparations which are the subject of the present contract, which result from the improvement of scientific or technical understanding, or result from the observation of the effects of these products on the health of workers or the environment;

The possible modification of physicochemical or toxicological properties of these same substances or preparations, by reason notably of a change in the nature or concentration of the impurities which they contain;

in each case having applied reasonable care to become aware of developments and changes to the same.

In a reciprocal fashion NITEC will, with the least delay and by all means at its disposal bring to the knowledge of JAGOTEC all information of the same type of which comes to be in possession.

1.3 The parties will meet as often as necessary to examine together the conditions, and possibly the difficulties in the application of:

- The legislative, regulatory or conventional dispositions relating to hygiene, safety and working conditions to which the provisions of the present contract are subjected

- The procedure for reciprocal exchange of information instituted in section 1.2 above

Furthermore, each party will have the right to request of the other the holding of an ad hoc technical meeting in order to resolve all questions that particularly relate to hygiene or to industrial safety, or to deal with an emergency situation, whatever the cause. The date and duration of this ad hoc technical meeting will be agreed jointly.

2. Protection of the environment

2.1 JAGOTEC recognises expressly that, in order to have been duly authorised by the competent administrative authority or to have been so declared to it, all the installations necessary for the execution of the provisions foreseen in the present contract comply with the legislative or regulatory dispositions to which they are subject with regard to the protection of the environment.

In consequence, it undertakes to maintain this situation during the full duration of the contract and to be in a position to justify this at any time to NITEC.

2.2 JAGOTEC will comply strictly, for all the provisions foreseen in the present contract, with all the legislative or regulatory dispositions relating to the disposal of waste, the term "disposal" describing the operations of collection, transport, storage, sorting and treatment so as to avoid all harm to the environment, including in the long term.

In particular JAGOTEC undertakes that it will ensure or get assurance that the waste which results from the provisions foreseen in the present contract is treated only in installations duly authorised or accepted to this effect by the
competent administrative authority. It will be in a position to justify this at any time to NITEC.

39.
ANNEX 9
INITIAL MEMBERS OF THE COMMITTEE

NITEC
Achim Schäfler
Jochen Mattis

JAGOTEC
Ken Cunningham
Jean-Marc Chevalier

***Confidential Treatment Requested

40.
ANNEX 10

Statement on the storage condition of Lodotra® tablets

This statement clarifies the requirements of temperature-sensitive materials involved in the production of Lodotra bulk tablets (manufacturing site: SkyePharma Production SAS, France), with regard to in-house storage and handling and shall prevail over any contrary provision in this Agreement.

For all batches of Product manufactured up to September 2007, the agreed storage conditions are and shall be at room temperature in accordance with USP.

For all batches of Product manufactured after September 2007, the nominal storage condition of temperature-sensitive materials, i.e.

– [...***...],

including samples of these materials (e.g. batch release samples), shall be between [...*** ...] Compliance with this temperature range (subject to the following) has to be ensured continuously throughout the presence of the above mentioned materials at the manufacturing site (Monitoring). Proof of this compliance has to be provided by SkyePharma (e.g. temperature curves). Deviations from the nominal temperature range always require written documentation.

After September 2007 the nominal storage condition will not be exceeded by more than [...***...]

The exceptions in the foregoing paragraph do not render temperature monitoring and documentation of deviations from the nominal storage condition unnecessary. Correspondingly, Certificates of Compliance have to be supplemented by deviation reports and temperature monitoring data, if deviations occur.

Nitec proposes the following measures to ensure and/or prove appropriate storage of the materials at the manufacturing site:

– attachment of temperature loggers to the temperature-sensitive materials
– use of mobile (validated) temperature container for storage

***Confidential Treatment Requested

41.
Technology Transfer Agreement

between

Merck KGaA ("Merck"),
Frankfurter Strasse 250, 64271 Darmstadt

and

Nitec Pharma AG ("Nitec Pharma")
Switzerland

Preamble

Merck has been marketing corticoids (Fortecortin, Decortin, Decortin H, Solu Decortin H) successfully – primarily in Germany – for many years. In order to support the corticoid business Merck started developing Prednison Night Time Release in 1998, which is a novel galenic formulation using the active agent prednison. For the treatment of rheumatoid arthritis ("RA") the Project (as defined hereinafter) has not yet entered phase 3 of clinical testing.

Merck due to limited resources and its focus on other business areas is unable to develop the Project until it is ready for marketing or to obtain a legal pharmaceutical licence for the Project. Merck therefore internally has decided to discontinue the Project.

It now appears that Nitec Pharma may be able to resume the Project at its own cost and risk, see it through phase III clinical testing and obtain a license to market the Merchandise (as defined below) in Germany, Austria and other countries.

In light of this development Merck is willing to transfer the Project to Nitec Pharma by turning over to Nitec Pharma all know-how acquired within the framework of and in connection with the Project and all pertinent industrial property rights. In particular Merck is willing to grant Nitec Pharma access to all data, which have accrued within the framework of the Project development and which are still to accrue pending the conclusion of the successful "Mutual Recognition Procedure".

As provided herein Nitec Pharma is willing to undertake to use all of its Commercially Reasonable Efforts (as defined below) to continue the clinical and technical development of the Project on its own, in particular using its own financial resources and at its own company risk and to obtain legal pharmaceutical approvals for relevant markets that have been identified by Nitec Pharma as promising markets and to confirm that Merck shall, under the terms specified in greater detail in section 6 hereof retain the right to market the Merchandise on an exclusive or non-exclusive basis in Germany and Austria and that such right shall only pass to Nitec Pharma as set forth in section 6 hereof.

For this purpose the parties stipulate as follows:
1. Definitions

“Technology Transfer Agreement” or “TTA” refers to this Agreement between Merck and Nitec Pharma.

“Clinical Development” refers to the implementation of all clinical trials aimed at obtaining licences to market the Merchandise in Germany, Austria and other countries.

“Commercially Reasonable Efforts” means those efforts and resources that Nitec Pharma would use were it developing, manufacturing, promoting and detailing the Active Agents as its own pharmaceutical products but taking into account clinical development results (including all safety, efficacy and cost issues), product labeling, regulatory review and approval issues, market potential, past performance, market potential, economic return, the general regulatory environment and competitive market conditions in the therapeutic area, all as measured by the facts and circumstances at the time such efforts are due.

“Technical Development” refers to the implementation of all technical activities aimed at obtaining licences to market the Merchandise in Germany, Austria and other countries.

“Approval” refers to the date on which an approval to market the Merchandise is granted in Germany and/or Austria.

“Launch” refers to the day on which the Merchandise is brought onto the market in Germany and/or Austria.

“Access to Data” refers to access to all data within Merck or affiliated enterprises of Merck within the meaning of § 15 of the German Stock Corporation Act (“Merck Group”) concerning the Project as well as concerning the Project periphery (e.g. Decortin, Decortin H), which are required or useful within the framework of Nitec Pharma’s activities described in this Agreement.

“Initial Application” is the date on which the first application for a legal pharmaceutical licence for the Project is filed in a country, which is a member of the European Union.

“Ex-factory Price” is the list price of the product without discounts by Merck Group to each independent customer.

“Production Costs” are all costs incurred by Nitec Pharma in the complete provision of Merchandise to one of Merck’s supply depots.

“Patents” refer to all of Merck Group’s patents and/or applications and utility models with respect to the Project.

“Project” refers to the galenic formulation containing Active Agents and which releases the latter in a delayed manner as more specifically described in Annex I.

“Merchandise” refers to the primary and secondary project packed and released for marketing.

“Bulk-Ware” refers to the galenic formulation approved for marketing, which still needs to undergo primary and secondary packing.
“Packing Instruments” comprises primary and secondary packing for Merchandise.

“Rheumatoid Arthritis” refers to the indication for which Nitec Pharma initially endeavours to obtain Approval.

“Active Agents” refer to Prednison, Prednisolon and Methylprednisolon.

“Skye Pharma” shall mean Skye Pharma AG with its head office in Muttenz, Switzerland, is the company, which has participated in the development of the Project from the technical aspect and which is meant to undertake production of the bulk-ware at its Lyon production site.

“Jagotec” shall mean Jagotec AG, a Swiss corporation having its head office at Eptingerstr. 51 in CH-6052 Hergiswil, Switzerland.

“Option Area” are the national territories of Germany and Austria.

2. Third Party Contracts

2.1. Merck, subject only to the restriction set forth specifically in section 6 hereof, hereby assigns to Nitec Pharma the agreement attached hereto as Appendix 2.1 (“Skye/Jagotec DLA”) between Merck and SkyePharma/Jagotec concerning the development and production of the Project, on the precondition that SkyePharma/Jagotec shall give its required consent thereto. For the purpose of said assignment, Merck shall continue the agreement until then.

2.2. The content of the agreement with SkyePharma/Jagotec is known to Nitec Pharma. All documents pertaining thereto, including correspondence concerning the agreement as well as other documents, which are useful for the implementation and interpretation thereof, shall be delivered to Nitec Pharma following the signing hereof.

3. Transfer of Rights and Know-How

3.1. Merck hereby sells, assigns and promises to otherwise transfer to and Nitec Pharma hereby purchases, accepts assignment and promises to accept delivery and/or transfer of the entire know-how obtained within the framework of the development of the Project to date, including all clinical test and stability patterns, experimental charges and all (also electronic) documents, including the correspondence to date (“Know-How”). Upon conclusion hereof the Know-How becomes the property of Nitec Pharma and shall be transferred promptly to Nitec Pharma after the signature of this Agreement to the extent that such transfer requires action beyond the signature of this Agreement. Insofar as it is set out in documents, on data carriers or represented in another manner (“Represented Know-How”), Merck shall store the Know-How in safe keeping for Nitec Pharma pending delivery thereof to the latter. In addition, Merck shall grant Nitec Pharma access to all of its know-how obtained with respect to the Active Agent.
3.2. Nitec Pharma shall assemble the Represented Know-How by 31st December 2004 at the latest at Merck’s premises, submit such know-how for Merck’s approval, and Merck shall thereupon deliver the same to Nitec Pharma promptly.

3.3. If the results of the development work performed hitherto are protected by copyrights or other industrial property rights, said rights are hereby assigned to Nitec Pharma and Nitec Pharma accepts such assignment. In the same manner, and subject to the condition precedent of the conferral of the required approval pursuant to section 13.4 of the Skye/Jagotec DLA, all of the industrial property rights acquired by Merck from Skye Pharma or from Jagotec on the basis of the Skye/Jagotec DLA within the framework of or in connection with the Skye/Jagotec DLA, are hereby assigned to Nitec Pharma and Nitec Pharma accepts such assignment.

3.4. The purchase price for such Know-How, Represented Know-How and the property rights as defined hereinabove shall be [... *** ...]. Payment shall become due upon signature of this Agreement.

3.5. Should an assignment pursuant to section 3.1 and 3.3 hereof be impossible for legal reasons, Nitec Pharma is hereby granted [... *** ...] a worldwide, exclusive, unlimited and unrestricted perpetual license to use these property rights (with the right to sublicense but subject to the following sentence). Said right of use shall not be transferable in connection with marketing and distributing Merchandise in the Option Area, but shall be transformed into a transferable right of use for such purpose as soon as Nitec Pharma becomes entitled to market and distribute or have marketed and distributed Merchandise in the Option Area in accordance with the provisions set forth in sec. 6 hereof.

3.6. Should the results of the development performed hitherto contain inventions or ideas capable of being protected, Nitec Pharma shall be entitled hereupon to apply for relevant protections in its own name and at its own costs – and where required by law, by naming the inventors pursuant to the statutory provisions in force from time to time - in any countries.

3.7. Should it be reasonably necessary or beneficial for the development and production of the Project to allow access to know-how and/or copyrights and/or industrial property rights from outside the development of the Project, whether owned or licensed or otherwise available to Merck or any other company within the Merck Group, Merck hereby grants Nitec Pharma and undertakes to use its best efforts to procure that Nitec Pharma is granted by any other company within the Merck Group a non-exclusive, [... *** ...] license to use such know-how and/or copyrights and/or industrial property rights. The right to transfer such right shall be limited to affiliates of Nitec Pharma within the meaning of § 15 German Stock Corporation Act. Transfers to any other persons shall be limited to the following purposes:

- Clinical development in RA and other indications
- Technical development and production,
- obtaining and maintaining the Approval in the Option Area and in other countries

***Confidential Treatment Requested
marketing and distributing Merchandise and for contractual / licensing negotiations with other interested pharmaceutical companies and the
subsequent award of licences, insofar as section 6 does not contradict this.

Irrespective of the above limitations, the transfer of rights obtained pursuant to this section 3.7 shall always be permitted to the extent necessary for
fulfilment of Nitec Pharma’s obligations to grant industrial property rights resulting from the Skye/Jagotec DLA, which is to be assigned to Nitec
Pharma, in particular from section 5.3 (b) of the Skye/Jagotec DLA, as such agreement is amended from time to time between Nitec Pharma and
Skye/Jagotec.

3.8. Insofar as it is reasonably necessary or useful in connection with the Project, Merck allows Nitec Pharma to make a reference or cross-reference with
regard to any approvals obtained by Merck.

3.9. Merck warrants to Nitec Pharma (a) with regard to the Know-How and Represented Know-How and other objects sold or transferred hereunder, that
these are free of third party rights and that at the date of transfer no circumstances exist that would enable third parties to establish such rights to the
assigned rights and other objects without Nitec Pharma’s consent, (b) there is no pending, nor has there been overtly threatened any legal action, suit,
proceeding, arbitration, summons or subpoena relating to the transactions contemplated by this Agreement or the Project or Merchandise or Know-
How; and (c) Merck is the owner of the Know-How and, to Merck’s knowledge, no use of the Know-How or the Licensed Know-How will infringe the
rights of, or result in any liability to, any member of the Merck Group or to any third person.

3.10. Except as expressly provided herein, no warranty is made regarding the completeness or the suitability for a specific purpose (e.g. the Project) of the
Know-How and/or Represented Know-How sold under section 3.1.

4. Continuation of the Project by Nitec Pharma

4.1. Nitec Pharma shall use its Commercially Reasonable Efforts to continue to develop the Project at its own cost following the conclusion of this
Technology Transfer Agreement and of a financing agreement with a third party until respective Approval is obtained in the first country within the
Option Area. Exceptions hereto are regulated by section 5.1.

4.2. Nitec Pharma shall be the owner of all approvals.

4.3. In the case of joint regulatory activities Nitec Pharma shall bear external costs, if these have been initiated and/or approved by Nitec Pharma.

4.4. Nitec Pharma shall involve Merck in the activities of the clinical trials for the Project in such a manner that Nitec Pharma’s trials can be used as pre-
marketing activity for the subsequent launch in the Option Area.

4.5. Nitec Pharma shall, following prior consultation with Merck, utilize the trial report specified in section 5.1 upon delivery, and publish parts thereof.
5. Support of Nitec Pharma by Merck following the assignment of Rights and Know-How

5.1. Since Nitec Pharma will not have a GxP system at its disposal following its establishment, Merck declares its willingness to support Nitec Pharma in the following manner [...***…] (unless specifically set forth otherwise below), in order to minimise the delay until Approval is granted:

- Merck shall appear as sponsor of the trial under the appellation EMR 62215-003
- Merck shall conclude the contract with CRO for the implementation of the said trial, [...***…]
- Costs of such trial (CRO and test centres) shall be pre-financed by Merck up to [...***…]. For the pre-financed costs Merck shall issue a bill to Nitec Pharma without a mark-up on a […***…]. Payment shall be effected in each case within […***…] after receipt of invoice. Costs, occurring after the pre-financed period, shall be budgeted in advance on a quarterly basis. Such budgeted costs shall be paid by Nitec Pharma to Merck latest on […***…] of the first month following each quarter for which the amounts have been budgeted for. Any deviations from the estimated to the actual costs shall be compensated by Merck to Nitec Pharma or by Nitec Pharma to Merck, as the case may be, by the next quarterly payment, respectively up to the end of the phase III trial.
- Merck shall provide an experienced clinician until the end of the first Phase 3 trial (expected to take place in Q2 of 2006).
- Conclusion of a patients’ insurance for the EMR 62215-003 trial by Merck
- Merck shall prepare a trial report and provide the latter to Nitec Pharma for its unlimited and exclusive use, whereby Merck shall remain entitled to use same within the framework of the marketing activities in the countries concerning which Merck has concluded a licensing agreement with Nitec Pharma providing for the marketing products by Merck
- The publication of intermediate results and any lectures on this topic during and after the conclusion of the aforementioned trial shall only be permitted with the approval of both parties, insofar as Merck is mentioned in the publication.

5.2. During the period following the transfer of rights and Know-How pursuant to section 3, and pending the successful conclusion of the mutual recognition procedure, Merck shall […***…] grant Nitec Pharma Access to Data and access to all documents and all know-how stored electronically or in paper form in MEDISI, which could be reasonably necessary or useful for obtaining Approval for the Project. The parties in balance of their mutual interest shall agree on the type of access to be granted. Merck shall, in particular, support Nitec Pharma with the information in its possession, such as e.g. competition and market research data. Access to data under this section shall include data pertaining to Decortin, which shall be mentioned

***Confidential Treatment Requested
as a reference product in the licence, and Decortin H. The access relates primarily to data on technical development, production, quality control, quality assurance, regulatory affairs, clinical development, market research results, contact addresses of all pertinent clinics for rheumatology and of established rheumatologists as well as access to data banks in Merck’s possession which are of indication relevance (e.g. Datamonitor, IMS, Decision Resources). Access and receipt are subject to the confidentiality provisions hereof.

5.3. Insofar as information is potentially relevant for obtaining the Approval for the Project, especially, but not limited to, information with regard to Decortin and Decortin H, Merck shall forward such information promptly and without charge to Nitec Pharma. Nitec Pharma shall utilise this information, as far as possible, for the purposes of obtaining such Approval. Merck shall keep Nitec Pharma continuously informed of the respective status of the licence for Decortin and Decortin H. This relates to all markets in which Merck distributes the Active Agent.

5.4. Merck shall maintain complete and accurate records of the expenses subject to reimbursement in this section 5. Such records shall be available for inspection, during reasonable business hours and upon reasonable notice, for the period of [***…] after expense increment for examination at such place or places where such records are customarily kept, at Nitec Pharma’s expense (subject to the rest of this paragraph 5.4), and not more often than once each calendar year, by an internationally recognised accounting firm (the “Accountant”), selected and employed by Nitec Pharma and acceptable to Merck, but solely for the purpose of verifying for Nitec Pharma the correctness of the expenses. The Accountant may be required by Merck to enter into a reasonably acceptable confidentiality agreement, and in no event shall the Accountant disclose to Nitec Pharma any information, other than such information as is specified and the amount of any overpayment or underpayment of expenses. The report of the Accountant regarding such expenses reports expenses shall be binding on the parties, other than in the case of manifest error. Nitec Pharma shall bear the cost of any such inspection; provided that if the inspection shows an overpayment of expenses of more than [***…], then Merck shall promptly reimburse Nitec Pharma for all costs incurred in connection with such inspection. Merck shall, within twenty (20) calendar days of its receipt of the report of the Accountant, pay to Nitec Pharma the amount of any overpayment, plus interest calculated at [***…] per annum.

6. Marketing and Distribution in the Option Area, Rights to Information, Precedence in Negotiations

The right to distribute and market the Project in Germany and Austria for Merchandise containing the Active Agent as the sole active ingredient shall only transfer to Nitec Pharma upon occurrence of the events as further detailed in this section 6.

6.1. Nitec Pharma shall pursue the Approval of the Project in Germany and Austria in its own name. Merck shall support Nitec Pharma to the extent deemed necessary by Merck within the framework of the Approval procedure. In the case of an inspection within the framework of the conferral of the Approval, in Germany or other countries, Merck shall provide the resources necessary for a successful approval [***…]. Nitec Pharma shall, upon request, inform Merck at any time of the status of the approval procedure.

***Confidential Treatment Requested
6.2. Nitec Pharma shall notify Merck in writing without delay of the Initial Application for the Project. Upon receipt of said notification Merck shall inform Nitec Pharma in writing whether or not Merck intends to exercise its right to market and distribute or to have marketed or distributed Merchandise delivered by Nitec Pharma in the Option Area under the terms specified in greater detail herein pursuant to section 6.4 ("Merck Option").

6.3. The Merck Option shall lapse in the event that Nitec Pharma has not received any written notice by Merck within [...***…] following receipt by Merck of the notification by Nitec Pharma per section 6.2 above, stating that Merck will make use of such option ("Option Exercise"). During these [...***…] Merck has the possibility of reviewing its interest in marketing the Project. For this purpose Nitec Pharma shall provide Merck in due time with appropriate documents (e.g. the results of the phase 3 trial, approval file, etc.) and Merck shall draw up a statistically valid pricing study of a type that is customary in this market and make same available to Nitec Pharma at its own cost and in due time. This obligation shall cease to apply if objective reasons make this trial appear irrelevant.

6.4. In the event that Merck exercises the Merck Option, Merck and Nitec Pharma shall, at the request of either party, negotiate and conclude a purchase and licensing agreement (including jointly concluded forecasts and ex-factory prices and/or floor-prices/price corridors) containing terms customary in the market within 90 days following Option Exercise, whereby it is agreed

   a) that [...***…] shall be made to Nitec Pharma under the purchase and licensing agreement
   b) that under the agreement Nitec Pharma shall deliver to Merck Merchandise and samples under the following conditions: [...***…]
   c) In case any of the Parties should be liable to withhold taxes on any payments such withholding taxes may be deducted.

6.5. Should Merck exercise the Merck Option, Merck shall

   • launch the Project in Germany and/or Austria no later than [...***…] following Approval, price approval or other official approvals, insofar as these constitute a precondition for launching a product and market the Project in its own name.

   • display, at Nitec Pharma’s request, Nitec Pharma’s name and logo on the packaging and package inserts, undertake all commercially significant and necessary marketing activities, in order to meet the forecasts, which were fixed promptly after the exercise of the Merck Option. If, after [...***…] following the Launch, the sales goals defined therein have been attained at a rate less than [...***…] section 6.7 below shall apply, unless the shortfall from the minimum sales requirement is due to reasons for which Merck is not responsible. Nitec Pharma shall support Merck
in meeting the forecasts by ensuring that the phase 3 trial is implemented in at least 10 trial centres in Germany.

6.6. Should Merck make use of the Option Exercise and should the agreement specified in section 6.4 fail to be concluded within [...***...] specified therein or within an agreed extended deadline, because the parties cannot find agreement on detailing terms, than the parties shall within [...***...] as of the lapse of such [...***...] period or the agreed upon extension period submit all relevant information to an independent professional project evaluator mutually acceptable to the parties and shall request that such evaluator proposes within another [...***...] as of accepting the office of evaluator equitable terms for an agreement as set forth in section 6.4. If Merck does not conclude the license agreement within [...***...] as of both parties receiving the proposal of the evaluator, then the right to distribute and market the Project in Germany and/or Austria, as the case may be, automatically transfers to Nitec Pharma upon the expiry of such 30 days period.

6.7. Should Merck be in breach of one of the aforementioned provisions in section 6.5 and should said breach, following a written notice to Merck, fail to be remedied promptly, but in no event later than within [...***...] as of such notice to Merck, then with effect as per the expiry of such [...***...] period the exclusive licence of the Merck Option transforms into a non-exclusive licence without minimum sales and Merck grants to Nitec Pharma the royalty free, semi-exclusive right to market either directly or indirectly the Project in the Option Area,

6.8. Irrespective of the lapse of the Merck Option, Nitec Pharma shall, in any case, advise Merck [...***...] before the conclusion of a licence agreement for any country of the Option Area, of the fact that the conclusion of an agreement is being planned, so that Merck, for its part, has the opportunity within this period of submitting a bid for such a licence. Conditions offered to a third party shall in no event be more favourable for the third party than those offered to Merck prior to the expiry or the waiver by Merck of the Merck Option taking into consideration all relevant aspects. Nitec Pharma shall be free to conclude a licence agreement for the Option Area with a third party after the said [...***...] have expired unless Merck prior to such expiry provides Nitec Pharma with a new bid and Merck’s new bid for Germany and/or Austria is at least equivalent in value to the best bid submitted by a third party prior to such expiry. In the event Merck’s bid for Germany and/or Austria shall be at least equivalent in value to the best bid submitted by such third party, then Nitec Pharma shall conclude the licence agreement exclusively with Merck.

7. Marketing and Distribution of Merchandise outside of the Option Area

The exclusive right to distribute and market the Project outside the Option Area resides with Nitec Pharma.

***Confidential Treatment Requested
In all countries outside of the Option Area with the exception of the U.S.A., Canada and Japan Nitec Pharma shall offer Merck the conclusion of a licence agreement for marketing the Project following the commencement of the EMR 62215-003 trial for the Project. If the parties are unable within [...***...] to conclude in good faith such licence agreement, then Nitec Pharma shall be free to conclude a licence agreement to that effect with third parties. The said time limit shall cease to apply as soon Merck states that it has no interest in concluding a licence.

8. Further Developments, further Indications

8.1. Nitec Pharma shall offer Merck any product improvements or further developments in the RA Indication for the sole purpose of marketing these in the Option Area and shall not conclude pertinent contracts with third parties for [...***...] following such an offer. For Germany and Austria the said offer shall be made at market conditions on an exclusive basis. Further details shall be mutually agreed upon between the parties. Following the expiry of the time limit, Nitec Pharma shall be free to conclude a licence agreement with third parties with respect to product improvements or further developments, including the Project itself. The said time limit shall cease to apply as soon as Merck states that it has no interest in concluding a licence.

8.2. Should the Project become applicable for other indications (e.g. asthma), Nitec Pharma shall advise Merck thereof before the commencement of phase III trials and offer a marketing licence, which shall be on an exclusive basis for the countries in which Merck has an exclusive licence for the RA indication and non-exclusive in the countries in which Merck has a non-exclusive licence for the RA indication. Details of such a licence agreement shall be negotiated between the parties at the proper time. In this connection the terms and conditions specified in section 6.4. are not binding, but shall be negotiated in good faith. If the parties are unable within [...***...] of the commencement of phase III trials to agree in good faith on such marketing license, Nitec Pharma shall be free to conclude a licence agreement to that effect with third parties. The said time limit shall cease to apply as soon as Merck states that it has no interest in concluding a licence.

9. Confidentiality

9.1. Except as required by applicable law or legal process or in connection with the customary submissions to regulatory authorities, the publication by Nitec Pharma of results of clinical studies and presentations at conferences, the parties undertake with respect to all information put at their disposal or obtained by them in another manner in connection with the preparation hereof during the term hereof and for 10 years subsequently thereto

- to treat said information in a strictly confidential manner,
- to use it exclusively for the purpose of implementing this Agreement and
- to grant access thereto only to those employees, advisers (tax advisers, lawyers, management consultants), and sublicensees who are involved in the object of this Agreement.

***Confidential Treatment Requested
9.2. The parties undertake to obligate in writing all persons as per 9.1.c) who are given access to information - insofar as same are not subject to a duty of secrecy by virtue of professional rules - to maintain confidentiality pursuant to this Agreement. In doing so, the parties shall, within the framework of legally permissible acts, ensure that their employees' duty of confidentiality shall also apply where the employees terminate their employment during the term hereof.

9.3. The duty of confidentiality shall not apply to such information concerning which it can be proved that

- it was already publicly known at the time of the signing hereof and/or at the time it was transmitted to third parties or
- it was already known to the receiving party or
- it was independently obtained by employees of the receiving party, who did not themselves have any access to the transmitted information or
- it was lawfully obtained by a third party or
- it is not subject to a duty of confidentiality on the basis of a written declaration of the disclosing party.

10. Term of Agreement, Discontinuation of the Project by Nitec Pharma (partial), Denial of Approval

10.1. The validity of this Agreement is dependent on the effective assignment of the Skye/Jagotec DLA attached hereto as Appendix 2.1 to Nitec Pharma. This Agreement shall run for an indefinite period. The Agreement can be terminated by either party by giving […] months notice of termination, which shall take effect at the end of a contractual calendar year, but no earlier than the expiry of the year […**…]. The right to terminate this agreement with immediate effect in case of a severe breach is reserved. In the event of any termination hereunder, Articles 3, 9 and this Article 10 shall survive without limitation.

10.2. Should Nitec Pharma be unsuccessful in finding one or more investors to acquire an interest in Nitec Pharma against a contribution of equity capital and/or by providing outside capital within […] days following the conclusion of this Technology Transfer Agreement, Nitec Pharma shall reassign to Merck without delay all the rights transferred by Merck to Nitec Pharma hereunder against repayment of the proved business expenses and other costs, which have been incurred up to the reassignment date by the founders of Nitec Pharma in connection with the Project. However, the amount shall not exceed EUR […] .

10.3. If Nitec Pharma does obtain the support of an investor described in section 10.2 above, but finally discontinues pursuit of the Project at a later point in time, Nitec Pharma shall invite Merck to acquire the Project, including all further developments and improvements at the market value that shall have been achieved by that time less the amount described in section 10.4. The market value is either (i) the value for which it can be proved that a third party is willing to acquire the Project or (ii) the value of the Project determined under the terms of section 10.5, whichever value is the higher.

10.4. The amount to be deducted pursuant to section 10.3 sentence 1 shall be ***Confidential Treatment Requested
• in the case of a reassignment following the commencement and prior to the conclusion of phase III of the trial (verification of effectiveness) the sum invested by Merck into the Project prior to the date of the transfer of the Project from Merck to Nitec Pharma ("Merck Investment"), less the costs of phase III of the trial incurred by Nitec Pharma or reimbursed to Merck by Nitec Pharma up to the date of reassignment,

• in the case of a reassignment following the conclusion of phase III of the trial: zero

10.5. In case of discontinuation of the Project as per 10.3 and irrespective of the Project being reassigned to Merck or transferred to a third party, Merck shall in any case be reimbursed promptly upon such discontinuation for the costs disbursed by Merck within the framework of the EMR 62215-003 study for Nitec Pharma, insofar as said costs have not already been repaid.

10.6. The parties can mutually stipulate the market value pursuant to section 10.3 (ii) and the Merck Investment. Should the parties be unable to so agree, this issue shall be adjudged with binding effect by a panel consisting of three experts, whereby Merck and Nitec Pharma shall each appoint one expert and both appointed experts shall then agree upon the identity of the third expert. The findings of the experts shall only be subject to review by the state courts on the grounds of an obvious mistake within the meaning of § 319 (1) German Civil Code. Should the experts be unable to agree upon a value, the average sum contained in the experts’ opinions shall be deemed to be the market value. In the case of transfers to a third party Merck shall be reimbursed for the aforementioned amounts, insofar as said amounts have not already been repaid.

10.7. The costs of a reassignment shall be borne by Merck.

11. Miscellaneous

11.1. Changes, amendments or alterations must be made in writing in order to be effective. This applies also to a waiver of such requirement of written form. Fax or email transmissions do not satisfy the requirement of the written form.

11.2. For disputes arising out of or in connection with the stipulations set forth in sections 6.3, 6.4, 6.6, 6.7 and sections 10.3 and 10.4 the procedure as described in section 10.6 shall apply.

11.3. The jurisdictional venue for all disputes arising hereunder shall be Nitec Pharma’s last domestic principal place of business or, where no domestic principal place of business has been established, Frankfurt am Main.

11.5. If any provision of this Agreement were to be or become fully or partly invalid or unenforceable for any reason whatever, or to violate any applicable law, the same shall be considered divisible as to such provision and such provision shall be deemed deleted herefrom, and the remainder hereof shall be valid and binding as if such provision were not included herein. The parties hereto shall then, if necessary, negotiate for an appropriate amendment of this Agreement.

Bard, August 2, 2004

Place, Date

/s/ Dr. Hubertus Ludwig
Nitec Pharma AG
represented by: Dr. Hubertus Ludwig
(Verwaltungsrat)

Darmstadt, July 14, 2004

ppa.

/s/ Rosemarie Schiemer
Merck KGaA
represented by: Rosemarie Schiemer

I.V.

/s/ Christiane Kaltenschnee
Merck KGaA
represented by: Christiane Kaltenschnee

13
Transfer, License and Supply Agreement

between

Merck Pharma GmbH
Alsfelder Straße 17,
64289 Darmstadt, Germany
(“Merck”),

and

Nitec Pharma AG
Röschenerstr. 9,
4153 Reinach, Switzerland
(“Nitec AG”)

and

Nitec GmbH
Joseph-Meyer-Str. 13-15
68167 Mannheim, Germany
(“Nitec Germany”)

Nitec AG and Nitec Germany are collectively referred to as “Nitec”

(all Nitec AG, Nitec Germany and Merck are the “Parties” and each of them – as the case may be – a “Party”)

Preamble

1. Whereas, Merck KGaA having its registered office at Frankfurter Str. 250, 64271 Darmstadt, Germany, (“Merck KGaA”) is the parent company of Merck;

2. Whereas, Nitec AG and Merck KGaA as of October 1st, 2004 have concluded a Technology Transfer Agreement (“TTA”) under which the rights of Merck’s development activities regarding the medicinal product Prednison Night Time Release for the indication rheumatoid arthritis have been transferred to Nitec AG. Nitec has further developed the Project (as defined in the TTA) and owns any rights relating to the PRODUCT, as defined;
3. Whereas, under the TTA Merck KGaA has been granted by Nitec AG the option to obtain exclusively the distribution and marketing rights pertaining to the PRODUCT in Germany and Austria and desires to make use of this option in Germany via Merck;

4. Whereas, Nitec AG, through Nitec Germany, has applied for the MARKETING AUTHORIZATION for the PRODUCT in Germany with the competent authority thereby becoming a Marketing Authorization Holder (“MAH”), as defined in § 4 subp. 18 Arzneimittelgesetz (“AMG”);

5. Whereas, Nitec AG is willing to cause Nitec Germany to transfer the MARKETING AUTHORIZATION to Merck, if and when the MARKETING AUTHORIZATION has been obtained by Nitec Germany;

6. Whereas, Nitec AG - through Nitec Germany - intends to apply for additional marketing authorizations for products which are — except its names - identical with the PRODUCT (“Duplicate Authorization”) and whereas, Nitec will not make use of more than one Duplicate in the TERRITORY and only to the extent as provided for in Art. 5.8 of this AGREEMENT;

7. Whereas, Nitec AG is the owner of the registered trademark “Lodotra” and whereas, Nitec AG is willing to grant Merck an exclusive licence in the TERRITORY to use the TRADEMARK;

8. Whereas, neither Nitec AG nor Nitec Germany are holder of manufacturing authorizations and whereas, Nitec AG has entrusted third parties with the manufacture of the PRODUCT.

Now, therefore, the Parties agree as follows:

Article 1 - Definitions
As used in this AGREEMENT, the following words and phrases shall have the following meanings:

“AGREEMENT” means this Transfer, License and Supply Agreement between the Parties as set out and described herein.

“ANNUAL MINIMUM SALES” shall mean […] of the TARGET SALES.

“EX FACTORY PRICE” is the list price of the PRODUCT without discounts by Merck to each independent customer.

“LAUNCH” refers to the day on which the PRODUCT is brought onto the market in the TERRITORY.

***Confidential Treatment Requested
2/22
“MARKETING AUTHORIZATION” shall mean the authorization and related documents granted by the German competent authority, the Bundesinstitut für Arzneimittel und Medizinprodukte (“BfArM”) for the marketing, distribution and sale of the PRODUCT in the TERRITORY.

“PRODUCTION COSTS” are all costs incurred by Nitec in the complete provision of PRODUCT to one of Merck’s supply depots.

“PRODUCT” shall mean the medicinal product in its finished form ready for sale in the TERRITORY and in accordance with the SPECIFICATIONS described in Appendix 1 attached hereto.

“SPECIFICATIONS” means the specifications for PRODUCT (including shelf life), attached hereto, incorporated in and made part of this AGREEMENT as Appendix 1.

“TARGET SALES” shall mean the target sales as set forth in Appendix 2, such sales of the PRODUCT in the TERRITORY by Merck shall be those reported by IMS or by any other source mutually agreed by the Parties offering a service similar to the one currently offered by IMS. At the date of signature of this AGREEMENT Appendix 2 is a preliminary estimation and the definite number will be calculated in accordance with the actual daily therapy costs. An example calculation is incorporated in Appendix 2.

“TERM” shall mean the term set forth in Section 16.1.

“TERRITORY” shall mean the territory of Germany.

“TRADEMARK” shall mean “Lodotra”, Swiss Registration No. 535 303. If this TRADEMARK should be rejected by the BfArM in connection with the application for the MARKETING AUTHORIZATION for PRODUCT filed by Nitec Germany, Nitec shall use an alternative trademark for the PRODUCT, such alternative trademark to become automatically the TRADEMARK.

Article 2- Transfer and License

2.1 Subject to the terms and conditions of this AGREEMENT, Nitec AG hereby undertakes to transfer to Merck — through Nitec Germany — the MARKETING AUTHORIZATION for the PRODUCT and hereby grants to Merck an exclusive licence to use the TRADEMARK for the PRODUCT during the TERM of this AGREEMENT in the TERRITORY. The term exclusive license shall mean for the purpose of this AGREEMENT that Nitec shall not grant a license to use the TRADEMARK in the TERRITORY to any other party.

2.2 Merck is not entitled to transfer, assign or sublicense its granted rights pursuant to Article 2.1 without the prior written consent of Nitec AG.

2.3 Merck shall be considered as an independent contractor and shall not be considered a partner, agent or representative of Nitec. As such, no Party shall
have the authority to create or assume any obligation in the name of the other Party nor to bind the other Party in any manner whatsoever.

Article 3- Marketing Authorization and Trademark

3.1 When the MARKETING AUTHORIZATION in the TERRITORY has been obtained by Nitec Germany, Nitec AG shall cause Nitec Germany to transfer to Merck for the duration of this AGREEMENT the MARKETING AUTHORIZATION and shall license the TRADEMARK to Merck for Merck’s exclusive use hereof, in each case limited to the TERRITORY.

3.2 Merck shall not market, sell and distribute the PRODUCT in the TERRITORY under any other name than the TRADEMARK.

3.3 At Merck’s sole expense, Merck agrees to (a) maintain the transferred MARKETING AUTHORIZATION in the TERRITORY, (b) diligently promote, market, sell and distribute the PRODUCT in the TERRITORY and (c) promptly assign back to Nitec Germany or any other party, designated by Nitec Germany, the MARKETING AUTHORIZATION and relating rights in the TERRITORY upon termination of this AGREEMENT.

3.4 If at any time during the TERM of this AGREEMENT either Party shall become aware of any infringement or threatened infringement by a third party of the TRADEMARK or any other right belonging to one of the Parties pursuant to this AGREEMENT, the Party having the knowledge thereof shall give prompt notice to the other Party, and the Parties shall consult as to the action to be taken. Any such action shall be taken by Nitec AG at the cost of Nitec AG. Merck may, at its own cost, assist Nitec AG holding the TRADEMARK infringed upon or threatened to be infringed upon in taking legal action against such infringement or threatened infringement.

3.5 Upon termination of this AGREEMENT, Merck’s right to use the TRADEMARK ceases.

Article 4- Maintenance of Marketing Authorization, Launch

4.1 Merck shall make all declarations and filings to maintain the MARKETING AUTHORIZATION.

4.2 The PRODUCT, subject to Nitec AG’s ability to deliver the PRODUCT, shall be launched within […] after the MARKETING AUTHORIZATION has been transferred by Nitec Germany to Merck.

4.3 If LAUNCH of the PRODUCT shall be delayed due to reasons beyond reasonable control of Merck and Nitec, Parties will share those resulting losses […] which are caused

***Confidential Treatment Requested

4/22
by a reduction of the shelf-life to less than ⋯. Sharing of such losses shall lead to reimbursement of payments already made by Merck for purchase of the PRODUCT whose shelf-life is so reduced.

Article 5- Marketing and Sales Activities

5.1 Merck will perform all industry-standard and customary pre-marketing activities ⋯ prior to the envisaged LAUNCH of the PRODUCT.

5.2 Merck will use its commercially reasonable efforts to market the PRODUCTS comparable to the common practice of the industry for products of a comparable market size.

In any event, but subject to Section 4.2, Merck will launch the PRODUCT in the TERRITORY no later than ⋯ following transfer of the MARKETING AUTHORIZATION to Merck by Nitec Germany hereunder, price approval and other official approvals, to the extent that these approvals are a condition for so launching PRODUCT.

5.3 Merck agrees that all material used in connection with the promotion and distribution of the PRODUCT shall comply with the applicable law and any information contained in such material shall be consistent with the MARKETING AUTHORIZATION.

The marketing plan of the PRODUCT for the following year shall be presented and provided to Nitec AG during the fourth quarter of each year.

5.4 No written or printed material relating to the PRODUCT shall be used by Merck without Nitec AG’s prior written consent. Any information on written or printed materials provided to Nitec shall be subject to Article 12.

If within ⋯ business days after receipt of such material, Nitec AG or Nitec Germany does not inform Merck, that it objects to the presented materials or, if Nitec AG or Nitec Germany, in case of objections, within ⋯ more working days do not inform Merck in writing of the reasons for the objection, such material shall be considered approved by Nitec AG. The consent of Nitec AG may not be unreasonably withheld.

Merck shall not initiate and/or conduct any Phase III/IV clinical studies for the PRODUCT without Nitec AG’s prior written consent.

5.5 Each Party will provide the other free of charge with the results of its market research activities for the PRODUCT in the TERRITORY. Additionally, Nitec AG shall provide Merck with all results obtained by studies conducted by or on behalf of Nitec AG in relation to the indication rheumatoid arthritis.

5.6 Within ⋯ days following each calendar quarter, Merck shall send to Nitec a copy of the Merck’s internal sales report covering the preceding quarter.

***Confidential Treatment Requested
Each such quarterly sales report shall show the total distribution of the PRODUCT (sales) in units and values for each dosage form.

The sales report shall include separate figures for wholesaler and hospital supply.

During the twelve (12) month period starting with the first commercial introduction Merck will provide Nitec AG monthly sales (in units and values).

Each Party shall inform the other Party of any proposed and/or approved regulations and/or laws which could influence the sales of the PRODUCT.

5.7 Should Merck not reach TARGET SALES or, respectively, the ANNUAL MINIMUM SALES as agreed upon same shall not be regarded as a breach of this AGREEMENT. Upon such occurrence representatives of both Parties shall propose measures to reach the TARGET SALES. The evaluation of achieved versus TARGET SALES will be performed every [...] months.

5.8 Should ANNUAL MINIMUM SALES not be reached in any [...] (the first such period to commence upon LAUNCH) during the TERM due to reasons not attributable to Nitec and/or the third party manufacturer, and same shall not be remedied within [...] after respective notice by Nitec to Merck, Nitec’s exclusive remedy shall be the right to make use of the Duplicate Authorization, as defined in No. 6 of the Preamble effective as of the end of the [...] period and to introduce or to have introduced a product in the TERRITORY under such duplicate authorization. In such a case, the continuation of this AGREEMENT shall not be subject to any ANNUAL MINIMUM SALES.

5.9 For the purposes of Art. 5.6 and 5.7, the sales of the PRODUCT in the TERRITORY by Merck shall be those reported by IMS or by any other source mutually agreed by the Parties offering a service similar to the one currently offered by IMS.

Article 6- Ex factory Price

6.1 Merck shall draw up a statistically valid pricing study of a type that is customary in this market at its own cost in due time based on the clinical Phase III study results and make same available to Nitec free of charge.

6.2 The EX FACTORY PRICES will be discussed by the Parties sufficiently in advance of the LAUNCH based on the above described pricing study and further relevant criteria, it being understood that the prices shall be set by Merck. The EX FACTORY PRICE will be discussed by the Parties upon either Party’s written request at any time in light of the then current market situation without limiting Merck’s right to set the price.

6.3 In case of reductions of the price imposed by the Health Insurance Institutions and to be paid by the ultimate customer or to be reimbursed by the Health

***Confidential Treatment Requested

6/22
Insurance in accordance with the Sozialgesetzbuch Tell V (SGB V) or the possibility of such price reductions Merck will use its reasonable best efforts to convince the Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG) (§ 139a SGBV) (or any other similar institution) about the additional benefit of the PRODUCT compared to standard prednisone tablets to avoid any reference price (Festbetrag) or other price reduction.

**Article 7- Supply and Orders**

7.1 Merck agrees to exclusively purchase from Nitec AG, all of Merck’s requirements of the PRODUCT. Nitec AG hereby agrees to use commercially reasonable efforts to meet Merck’s requirements for the PRODUCT. Nitec AG is entitled to have the PRODUCT in its name directly delivered by the third party manufacturer under contract to Merck. For the avoidance of doubt, Nitec AG remains liable for the delivery of the PRODUCT.

7.2 The minimum purchase order, irrespective of the dosage for the tablets, shall be [...***...], divided into [...***...]. Purchase orders in excess of such [...***... shall be the multiple of [...***... tablets. Merck and Merck Gesellschaft mbH, Austria may internally combine purchase orders for PRODUCT to reach the amounts mentioned in this section 7.2.

7.3 The PRODUCT will be delivered in accordance with Appendix 1.

7.4 The Parties shall agree upon the packaging design which shall comply with the legal requirements in the TERRITORY.

7.5 At the end of each calendar quarter Merck shall provide Nitec AG with a written non-binding rolling forecast of Merck’s requirements of the PRODUCT, per month, for the next 18 months. The first rolling forecast shall be provided to Nitec AG at the same time as placement of first purchase order. Orders shall also be placed at the end of each calendar quarter.

7.6 At least [...***...] months in advance of the requested delivery date of the PRODUCT, Merck shall submit to Nitec AG a written purchase order for the desired quantities of the PRODUCTS. Such purchase order shall be firm and binding upon Merck when accepted by Nitec AG, Nitec shall not be entitled to decline any orders which are up to [...***...] of the respective forecast and shall use its reasonable commercial efforts to fulfill orders above [...***...]. Each order placed by Merck will bear the exact quantity (including pack-size and dose strengths) ordered in accordance with section 7.2, the delivery date and the address at which the PRODUCT must be sent. When shorter delivery times could be achieved, Nitec AG shall promptly inform Merck hereof.

7.7 Merck shall maintain a minimum inventory level of the PRODUCT corresponding to at least [...***...] sales calculated on the basis of the

***Confidential Treatment Requested
7/22
actual sales forecast or otherwise agreed upon by the Parties provided that Nitec AG supplies to Merck the PRODUCT in accordance with this AGREEMENT.

**Article 8- QUALITY of the PRODUCT**

8.1 The PRODUCT to be delivered by a third party manufacturer in the name of Nitec AG to Merck hereunder shall be finished and released goods, be free from defects, conform to the analysis certificates which are delivered with the PRODUCT and will be in accordance with the SPECIFICATIONS for the PRODUCT. Nitec assures that the third party manufacturer at any time complies with the requirements of the Betriebsverordnung für pharmazeutische Unternehmer (PharmBetrV) and of the EC-Guideline of Good Manufacturing Practice for medicinal products, Part I: Basic requirements for medicinal products (GMP) and that the quality of the PRODUCT complies with the MARKETING AUTHORIZATION dossier.

8.2 The provisions contained in § 377 Handelsgesetzbuch shall not be applicable. Merck shall, however, inspect PRODUCT delivered within five (5) working days of receiving delivery and shall inform the party effecting the delivery (with a copy to Nitec AG) within such five day period of any shortages, defects or obvious off specification characteristics. Other defects have to be reported promptly upon discovery, but in no event later than five (5) working days after such discovery.

**Article 9- Supply Price and Terms of Payment**

9.1 The prices to be paid by Merck to Nitec AG for the PRODUCT (including samples) shall be at the higher of (i) [...] of the EX FACTORY PRICES or (ii) PRODUCTION COSTS plus [...] of the EX FACTORY PRICES. In the event that the PRODUCT becomes subject to mandatory reimbursements imposed by the authorities (e.g. Zwangsrabatte), NITEC AG and Merck shall share the economic burden of such mandatory reimbursements as follows:

- In the event that Merck has paid NITEC AG according to lit. (i) above Nitec AG shall re-imburse to Merck [...] of the reduction amounts actually paid by Merck to the authorities.

- In the event that Merck has paid NITEC AG according to lit. (ii) above Nitec AG shall re-imburse to Merck the share of the reduction amounts actually paid by Merck to the authorities which is equal to PRODUCTION COSTS plus [...] of the EX FACTORY PRICE divided by the EX FACTORY PRICE. Reimbursements by NITEC AG shall be limited to [...] of the EX FACTORY PRICES.

***Confidential Treatment Requested

8/22
9.2 Invoices shall be payable without discount within [...***...] days from the date of invoice.

Article 10- General Obligations of Merck

Merck shall have the following general obligations:

10.1 Merck shall comply with all applicable laws and regulations, especially with the AMG, with the Heilmittelwerbegesetz (“HWG”), with the PharmBetrV and with the Betriebsverordnung für Arzneimittelgroßhandelsbetriebe.

10.2 Merck will use its reasonable best efforts to further the marketing, selling and distribution of the PRODUCT in the TERRITORY in accordance with the terms of this AGREEMENT and to obtain the relevant authorizations, if any;

10.3 Merck shall promptly respond to all inquiries from customers, including complaints, process all orders, and effect all dispatches of the PRODUCT.

10.4 Merck shall promptly provide Nitec AG with written reports of any importation or sale of the PRODUCT in the TERRITORY of which Merck has knowledge from any source other than Nitec AG, as well as with any other information related to the PRODUCT, which Nitec AG may reasonably request in order to be updated on the market conditions in the TERRITORY.

10.5 Merck shall inform Nitec AG of any requirements for changes of the packaging, labelling, Patient information in the TERRITORY.

10.6 The Parties agree to establish a joint product committee to meet regularly, at least every four (4) months, to evaluate marketing and sales performance as related to annual sales and purchase plans delivered to Nitec AG according to Article 7.5 of this AGREEMENT.

Article 11- General Obligations of Nitec

Nitec shall have the following obligations during the TERM of this AGREEMENT:

11.1 Nitec AG shall secure that Nitec Germany files a variation notice with the BfArM relating to the transfer of the MARKETING AUTHORIZATION to Merck in accordance with § 29 subp. 1 AMG and informs Merck of that notification by copy.

11.2 Nitec AG will supply Merck with all presently available or future documents and information concerning the PRODUCT as far as such documents and information are needed by Merck for the fulfillment of its obligations under this AGREEMENT.

***Confidential Treatment Requested

9/22
Nitec AG will provide Merck with examples for technical literature, promotional and advertising material, etc. as both Parties consider to be reasonably sufficient to promote sales of the PRODUCT in the TERRITORY and as far as available within Nitec.

**Article 12 - Secrecy**

12.1 The Parties agree and undertake that they will keep secret all disclosures by the other Party, written or oral, made either before or during the TERM of this AGREEMENT. The receiving Party will not without the prior written consent of the other Party use, except as expressly contemplated by this AGREEMENT, or disclose to any third party any information relating to the PRODUCTS learned by or disclosed to the other Party pursuant to or in connection with this AGREEMENT (together “Information”).

12.2 The confidentiality obligations hereinabove mentioned shall not apply to:

a) Information in the public domain

b) Information known by the receiving Party before the date hereof and which the receiving Party can conclusively prove that it was not obtained, directly or indirectly from the disclosing Party.

c) Information legally obtained by the receiving Party after the date hereof from a third party which has it in its possession legally.

d) Information which the receiving Party is legally obliged to reveal to authorities or clients.

12.3 The provisions of this Article shall remain in force during the period of this AGREEMENT and for a further period of two (2) years after the termination thereof.

**Article 13 - Responsibility, Liability and Indemnification**

13.1 Merck shall be responsible for fulfilling and securing all requirements, regulations, licenses and permissions which are necessary to distribute, sell and market the PRODUCT in finished form in the TERRITORY.

13.2 Nitec AG indemnifies Merck from all damages arising out of any negligent or willful breach of its obligations according to this AGREEMENT or arising out of the use by Merck in the performance of this AGREEMENT of information or data disclosed by Nitec pursuant to this AGREEMENT. Subject to the limitation in Section 13.4, Nitec AG will indemnify Merck and its Affiliates (and their respective officers, directors and employees) from and
against any and all damages sustained or incurred by any of them because of any third party personal injury or wrongful death claim to the extent such damages arise out of: (i) the negligence or willful misconduct of Nitec or its Affiliates (or their respective officers, directors or employees), (ii) any breach by Nitec of any provision of this AGREEMENT, including without limitation any PRODUCT warranty made by Nitec in this AGREEMENT; or (iii) any latent defect in PRODUCT. Nitec AG will indemnify and hold Merck and its Affiliates (and their respective officers, directors and employees) harmless from and against any and all damages sustained or incurred by any of them to the extent that they arise out of any third party claim of violation or infringement of any proprietary right of said third party relating to Nitec’s proprietary information used in the manufacture of PRODUCT. Notwithstanding the foregoing, Nitec shall have no such indemnity obligation to the extent such third party claims are based on, arise out of, or are caused by, the negligence or willful misconduct of Merck or its Affiliates (or their respective officers, directors or employees).

Upon filing of any such claim, Merck shall immediately notify Nitec AG in writing and shall offer Nitec AG to control the defense against any such claim. If Nitec AG declines the offer to so control the defense, then Merck shall keep Nitec AG fully informed at all times of its own measures to defend such claim and shall allow Nitec AG to comment on any material measures prior to Merck taking such measures in the course of the defense. Any settlement or acknowledgement of such claim or any waiver of a defense by Merck shall require the prior written consent of Nitec AG. Failure to obtain such consent shall exclude Merck’s right to recover damages under this section 13 for the respective claim.

13.3 Merck, subject to the limitations in Section 13.4, indemnifies Nitec from all damages arising out of the breach of any obligation of Merck according to this AGREEMENT. Merck will indemnify Nitec for all damage resulting from any third party claims against Nitec, which arise from the distribution, marketing and sale of the PRODUCTS, if not attributable to Nitec as per clause 13.2. Upon filing of any such claim, Nitec shall immediately notify Merck and the third full paragraph of section 13.2 shall apply mutatis mutandis.

13.4 Subject to mandatory law, neither party shall be liable or responsible for any exemplary, punitive, special, indirect, consequential or incidental damages of any kind whether based on contract, tort (including negligence), strict liability, or any other theory or form of action even if a party has been advised of the possibility thereof.

Article 14- Exchange of Information and Pharmacovigilance

14.1 The Parties shall keep each other informed on all matters related to the PRODUCT and on any information received from any source concerning
adverse drug reactions coming to either Party’s knowledge with regard to the PRODUCT.

14.2 Merck is responsible for fulfilling the documentation and reporting obligations in accordance with the legal requirements. If both Parties are marketing authorisation holders in the TERRITORY they will agree on appropriate measurements in order to avoid double reporting to competent authorities. Independently of any national reporting requirements, the Parties hereto shall in relation to the PRODUCT report to each other all serious adverse events from clinical trials with a reasonable suspicion of causal relationship to the administered PRODUCT and all serious spontaneously reported suspected adverse drug reactions.

14.3 In any case where a change in the risk-benefit-ratio becomes evident or risk minimizing steps due to adverse drug reactions seem to be necessary (e.g. change of the label, PRODUCT information, special information/warnings to the medical profession, patients, authorities or recall of the PRODUCT), the Parties hereto will inform each other without delay and harmonise further measures as appropriate. Such exchange of information is realised through direct contacts between the appropriately qualified persons responsible for pharmacovigilance (Stufenplanbeauftragte) of each party pursuant to § 63 a AMG. Therefore, both Parties undertake to inform each other on any change in the responsible persons, the address, telephone and fax-numbers.

14.4 Any information on drug safety issues as pointed out above shall be furnished by a Party to the other Party in the English language.

14.5 Merck will be responsible for preparing the periodic safety update reports in accordance with the law and shall provide copies of same to Nitec.

14.6 Nitec agrees that the obligations contained in this Article 14 may be performed by Merck KGaA. Further details will be set forth in the Safety Data Exchange AGREEMENT between Nitec AG and Merck KGaA to be concluded in due course. Merck agrees that the obligations of Nitec may be performed by a third party selected by Nitec.

**Article 15- Non Competition**

Within the first three (3) years following the LAUNCH of the PRODUCT, Merck shall refrain from launching oral glucocorticoids in the indication “rheumatoid arthritis”.

***Confidential Treatment Requested***

12/22
Article 16- Term and Termination

16.1 Term
This AGREEMENT shall take effect as of the signature by all parties and, unless otherwise terminated as provided in this AGREEMENT, shall remain in full force and effect for a period of 10 (ten) years as of the LAUNCH.

Thereafter, the AGREEMENT will be automatically renewed for successive periods of [...***...] until terminated by either Party giving [...***...] months prior written notice to the other Party.

16.2 Termination
Notwithstanding other rights to terminate this AGREEMENT pursuant to Art. 16.1, this AGREEMENT may be terminated with immediate effect in accordance with the following provisions:

a) Either Party may terminate this AGREEMENT at any time by giving notice in writing to the other Party, which notice shall be effective upon dispatch, should the other Party file a petition of any type as to its bankruptcy, be declared a bankrupt, become insolvent, make an assignment for the benefit of creditors, go into liquidation or receivership;

b) Either Party may terminate this AGREEMENT by giving notice in writing to the other Party should an event of force majeure as provided in Article 17.4 continue for more than [...***...] months;

c) Either Party may terminate this AGREEMENT by giving notice in writing to the other Party stating that this AGREEMENT might terminate under this Article 16.2., if the other Party (i) commits a material breach of any condition herein contained, and does not within [...***...] days from receipt of written notice by the other Party of such breach remedy the same, if capable of remedy, or offer full compensation therefore; or (ii) if the other Party repetitiously commits a breach of any condition contained herein, and the aggregate of such repetitious breach represents a material breach of this AGREEMENT.

16.3 Rights and Obligations on Expiration and Termination
In the event of termination or expiration of this AGREEMENT for any reason, the Parties shall have the following rights and obligations:

a) Merck shall without undue delay transfer the MARKETING AUTHORIZATION for the PRODUCT to Nitec Germany or to a third party designated by Nitec Germany.

b) All of Merck’s rights under or related to the TRADEMARK automatically end upon termination of this AGREEMENT.

***Confidential Treatment Requested
13/22
Termination of this AGREEMENT shall not release either Party from the obligation to deliver or to make payment of all amounts then or thereafter due and payable;

16.4 Both Parties' obligations pursuant to secrecy in Article 12 shall survive termination of this AGREEMENT;

16.5 In case of termination or expiration of this AGREEMENT, Merck will discontinue to distribute, to market and to sell the PRODUCT, if not stated otherwise in this AGREEMENT.

16.6 In the event of termination of this AGREEMENT, Nitec AG may repurchase stocks of PRODUCT held by Merck at the prices Merck has bought the PRODUCT from Nitec AG, if Nitec AG so chooses. Otherwise Merck is entitled to distribute the remaining stocks within […] within the TERRITORY. All stocks remaining after this period of […] including but not limited to all PRODUCT which might be returned thereafter, have to be destroyed at Merck’s responsibility and costs, a proof of which shall be submitted to Nitec AG.

Article 17- Miscellaneous

17.1 Notices.
All notices, demands and communications required to be made under this AGREEMENT shall be in writing and delivered personally or sent by telefax and confirmed by airmail letter to the addresses shown above. Notice shall be deemed delivered on the date of delivery when delivered personally or on the third business day after the day on which they were sent by telefax or fourteen (14) days after being mailed by airmail letter, which provides for a signed receipt upon delivery.

17.2 Headings.
It is agreed by the Parties hereto, that the headings of the clauses herein have been included for convenience only and do not form any part of the AGREEMENT.

17.3 Severability.
In the event that any provision of this AGREEMENT is held by a court of competent jurisdiction to be unenforceable because it is invalid or in conflict with any law of any relevant jurisdiction, the Parties shall replace any Article or part of an Article found to be invalid or unenforceable by alternative provisions which shall be as similar as possible in their conditions with regard to their spirit and commercial effect. The validity of the remaining provisions shall not be affected.

***Confidential Treatment Requested
17.4 **Force Majeure.**

In the event that the performance of this AGREEMENT or of any obligation hereunder, other than payment of money as herein provided, by either Party is prevented, restricted or interfered with by reasons of any cause not within the control of the respective Party, and which could not by reasonable diligence have been avoided by such Party, the Party so effected, upon giving prompt notice to the other Party as to the nature and probable duration of such event, shall be excused from such performance to the extent and for the duration of such prevention, restriction or interference, provided that the Party so affected shall use its best efforts to avoid or remove such cause of non-performance and shall fulfill and continue performance hereunder with the utmost dispatch whenever and to the extent such cause or causes are removed.

17.5 **Assignment.**

Merck and Nitec may assign its rights and obligations under this AGREEMENT, in whole or in part, to any AFFILIATE upon prior written consent from Nitec or Merck respectively, which consent shall not be unreasonably withheld or delayed, provided that in each case the transferring party agrees to be fully responsible for the receiving AFFILIATE'S performance of this AGREEMENT.

17.6 **Hardship.**

Should the effects of this AGREEMENT resulting from future unforeseen events and developments lead to an unjust hardship for either Party and which hardship does not correspond with the intention of the Parties in good faith, the Parties shall without delay enter into negotiations to see in what way the conditions of the AGREEMENT can be made to suit altered circumstances.

17.7 **Waiver.**

If any Party should at any time refrain from enforcing its rights arising from a breach or default by the other Party of any of the provisions of this AGREEMENT, such waiver shall not be construed as a continuing waiver regarding that breach or default or other breaches or defaults of the same or other provisions of this AGREEMENT.

17.8 **Conflicting Agreements.**

In the event any provisions contained in the TTA shall conflict with the provisions contained in this AGREEMENT, this AGREEMENT shall prevail.

17.9 **Written Form.**

No waiver, alteration or modification of any of the provisions hereof shall be binding unless made in writing and signed by duly authorized officers of the Parties. Any waiver of this written form requirement shall be in writing.
Article 18 - Governing Law

This AGREEMENT shall be governed by and interpreted in accordance with the laws of Germany without its provisions on the conflict of laws and without the UN Convention on the international Sale of Goods (CISG) and the rules incorporating this convention into German law.

Reinach, den 19.12.2006

Nitec Pharma AG

/s/ Dr. Hubertus Ludwig
(Dr. Hubertus Ludwig)

Mannheim, den 19.12.06

Nitec Pharma GmbH

/s/ Jochen Mattis
(Jochen Mattis)

Darmstadt, den 19.12.2006

Merck Pharma GmbH

/s/ Rosemarie Schiemer
(Rosemarie Schiemer)

Appendix 1 Specifications and Supply Conditions
Appendix 2 Target Sales
**Transfer, License and Supply Agreement**  

**Appendix 1**  

**1) Composition of the medicinal products**

Lodotra 1mg

<table>
<thead>
<tr>
<th>Component</th>
<th>Per Tablet Formula</th>
<th>Percentage Formula</th>
<th>Function</th>
<th>Quality Standard</th>
</tr>
</thead>
<tbody>
<tr>
<td>[...***...]</td>
<td>[...***...]</td>
<td>[...***...]</td>
<td>[...***...]</td>
<td>[...***...]</td>
</tr>
<tr>
<td>[...***...]</td>
<td>[...***...]</td>
<td>[...***...]</td>
<td>[...***...]</td>
<td>[...***...]</td>
</tr>
<tr>
<td>[...***...]</td>
<td>[...***...]</td>
<td>[...***...]</td>
<td>[...***...]</td>
<td>[...***...]</td>
</tr>
<tr>
<td>[...***...]</td>
<td>[...***...]</td>
<td>[...***...]</td>
<td>[...***...]</td>
<td>[...***...]</td>
</tr>
<tr>
<td>[...***...]</td>
<td>[...***...]</td>
<td>[...***...]</td>
<td>[...***...]</td>
<td>[...***...]</td>
</tr>
<tr>
<td>[...***...]</td>
<td>[...***...]</td>
<td>[...***...]</td>
<td>[...***...]</td>
<td>[...***...]</td>
</tr>
<tr>
<td>[...***...]</td>
<td>[...***...]</td>
<td>[...***...]</td>
<td>[...***...]</td>
<td>[...***...]</td>
</tr>
<tr>
<td>[...***...]</td>
<td>[...***...]</td>
<td>[...***...]</td>
<td>[...***...]</td>
<td>[...***...]</td>
</tr>
<tr>
<td>[...***...]</td>
<td>[...***...]</td>
<td>[...***...]</td>
<td>[...***...]</td>
<td>[...***...]</td>
</tr>
<tr>
<td>[...***...]</td>
<td>[...***...]</td>
<td>[...***...]</td>
<td>[...***...]</td>
<td>[...***...]</td>
</tr>
</tbody>
</table>

***Confidential Treatment Requested***
## Lodotra 2mg

<table>
<thead>
<tr>
<th>Component</th>
<th>Per Tablet Formula</th>
<th>Percentage Formula</th>
<th>Formula</th>
<th>Quality Standard</th>
</tr>
</thead>
<tbody>
<tr>
<td>[...***...]</td>
<td>[...***...]</td>
<td>[...***...]</td>
<td>[...***...]</td>
<td>[...***...]</td>
</tr>
<tr>
<td>[...***...]</td>
<td>[...***...]</td>
<td>[...***...]</td>
<td>[...***...]</td>
<td>[...***...]</td>
</tr>
<tr>
<td>[...***...]</td>
<td>[...***...]</td>
<td>[...***...]</td>
<td>[...***...]</td>
<td>[...***...]</td>
</tr>
<tr>
<td>[...***...]</td>
<td>[...***...]</td>
<td>[...***...]</td>
<td>[...***...]</td>
<td>[...***...]</td>
</tr>
<tr>
<td>[...***...]</td>
<td>[...***...]</td>
<td>[...***...]</td>
<td>[...***...]</td>
<td>[...***...]</td>
</tr>
<tr>
<td>[...***...]</td>
<td>[...***...]</td>
<td>[...***...]</td>
<td>[...***...]</td>
<td>[...***...]</td>
</tr>
<tr>
<td>[...***...]</td>
<td>[...***...]</td>
<td>[...***...]</td>
<td>[...***...]</td>
<td>[...***...]</td>
</tr>
<tr>
<td>[...***...]</td>
<td>[...***...]</td>
<td>[...***...]</td>
<td>[...***...]</td>
<td>[...***...]</td>
</tr>
</tbody>
</table>

***Confidential Treatment Requested***

18/22
<table>
<thead>
<tr>
<th>Component</th>
<th>Per Tablet Formula</th>
<th>Percentage Formula</th>
<th>Formula</th>
<th>Quality Standard</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>[...***…]</td>
<td>[...***…]</td>
<td>[...***…]</td>
<td>[...***…]</td>
</tr>
<tr>
<td></td>
<td>[...***…]</td>
<td>[...***…]</td>
<td>[...***…]</td>
<td>[...***…]</td>
</tr>
<tr>
<td></td>
<td>[...***…]</td>
<td>[...***…]</td>
<td>[...***…]</td>
<td>[...***…]</td>
</tr>
<tr>
<td></td>
<td>[...***…]</td>
<td>[...***…]</td>
<td>[...***…]</td>
<td>[...***…]</td>
</tr>
<tr>
<td></td>
<td>[...***…]</td>
<td>[...***…]</td>
<td>[...***…]</td>
<td>[...***…]</td>
</tr>
<tr>
<td></td>
<td>[...***…]</td>
<td>[...***…]</td>
<td>[...***…]</td>
<td>[...***…]</td>
</tr>
<tr>
<td></td>
<td>[...***…]</td>
<td>[...***…]</td>
<td>[...***…]</td>
<td>[...***…]</td>
</tr>
<tr>
<td></td>
<td>[...***…]</td>
<td>[...***…]</td>
<td>[...***…]</td>
<td>[...***…]</td>
</tr>
<tr>
<td></td>
<td>[...***…]</td>
<td>[...***…]</td>
<td>[...***…]</td>
<td>[...***…]</td>
</tr>
</tbody>
</table>

***Confidential Treatment Requested***
<table>
<thead>
<tr>
<th>Test</th>
<th>Specifications on release</th>
</tr>
</thead>
<tbody>
<tr>
<td>[...***... ]</td>
<td>[...***... ]</td>
</tr>
<tr>
<td>[...***... ]</td>
<td>[...***... ]</td>
</tr>
<tr>
<td>[...***... ]</td>
<td>[...***... ]</td>
</tr>
<tr>
<td>[...***... ]</td>
<td>[...***... ]</td>
</tr>
<tr>
<td>[...***... ]</td>
<td>[...***... ]</td>
</tr>
<tr>
<td>[...***... ]</td>
<td>[...***... ]</td>
</tr>
<tr>
<td>[...***... ]</td>
<td>[...***... ]</td>
</tr>
<tr>
<td>[...***... ]</td>
<td>[...***... ]</td>
</tr>
<tr>
<td>– [...***... ]</td>
<td>[...***... ]</td>
</tr>
<tr>
<td>– [...***... ]</td>
<td>[...***... ]</td>
</tr>
</tbody>
</table>

***Confidential Treatment Requested

20/22
Transfer, License and Supply Agreement

between

Merck GesmbH
Zimbagasse 5
A-1 147 Vienna, Austria
(“Merck”),

and

Nitec Pharma AG
Kagenstr 17,
4153 Reinach, Switzerland
(“Nitec AG”)

and

Nitec GmbH
Joseph-Meyer-Str. 13–15
68167 Mannheim, Germany
(“Nitec Germany”)

Nitec AG and Nitec Germany are collectively referred to as “Nitec”

(all, Nitec AG, Nitec Germany and Merck are the “Parties” and each of them – as the case may be – a “Party”)

Preamble

1. Whereas, Merck KGaA having its registered office at Frankfurter Str. 250, 64271 Darmstadt, Germany, (“Merck KGaA”) is the parent company of Merck;

2. Whereas, Nitec AG and Merck KGaA as of October 1st, 2004 have concluded a Technology Transfer Agreement (“TTA”) under which the rights of Merck’s development activities regarding the medicinal product Prednison Night Time Release for the indication rheumatoid arthritis have been transferred to Nitec AG. Nitec has further developed the Project (as defined in the TTA) and owns any rights relating to the PRODUCT, as defined;
3. Whereas, under the TTA Merck KGaA has been granted by Nitec AG the option to obtain exclusively the distribution and marketing rights pertaining to the PRODUCT in Germany and Austria and desires to make use of this option in Austria via Merck;

4. Whereas, Merck Austria wishes to apply for reimbursement of the PRODUCT within the Austrian Reimbursement Code and further market and sell the PRODUCT once the reimbursement status has been approved;

5. Whereas, Nitec AG, through Nitec Germany, has applied for the MARKETING AUTHORIZATION for the PRODUCT in Austria with the competent authority thereby becoming a Marketing Authorization Holder (“MAH”), as defined in § 2 subp. 13a Arzneimittelgesetz (“AMG”);

6. Whereas, Nitec AG is willing to cause Nitec Germany to transfer the MARKETING AUTHORIZATION to Merck, if and when the MARKETING AUTHORIZATION has been obtained by Nitec Germany;

7. Whereas, Nitec AG is the owner of the registered trademark “Lodotra” and whereas, Nitec AG is willing to grant Merck an exclusive licence in the TERRITORY to use the TRADEMARK;

8. Whereas, neither Nitec AG nor Nitec Germany are holder of manufacturing authorizations and whereas, Nitec AG has entrusted third parties with the manufacture of the PRODUCT.

9. Whereas, Nitec AG – through Nitec Germany– intends to apply for additional marketing authorizations for products which are – except its names – identical with the PRODUCT (“Duplicate Authorization”) and whereas, Nitec will not make any use of these authorizations in the TERRITORY.

Now, therefore, the Parties agree as follows:

**Article 1 - Definitions**

As used in this AGREEMENT, the following words and phrases shall have the following meanings:

“AGREEMENT” means this Transfer, License and Supply Agreement between the Parties as set out and described herein.

“ANNUAL MINIMUM SALES” shall mean […***…] of the TARGET SALES.

***Confidential Treatment Requested***
“EU AVERAGE PRICE” means the arithmetic mean of all officially available prices (EX FACTORY or pharmacy purchasing prices) of the PRODUCT within the European Union.

“EX FACTORY PRICE” is the list price of the PRODUCT without discounts by Merck to each independent customer.

“LAUNCH” refers to the day on which the PRODUCT is included into the “Yellow Box” of the Reimbursement Code in the TERRITORY.

“MARKETING AUTHORIZATION” shall mean the authorization and related documents granted by the Austrian competent authority, the Bundesamt für Sicherheit im Gesundheitswesen (“AGES PharmMed”) for the marketing, distribution and sale of the PRODUCT in the TERRITORY.

“PRODUCTION COSTS” are all costs incurred by Nitec in the complete provision of PRODUCT to one of Merck’s supply depots.

“PRODUCT” shall mean the medicinal product in its finished form ready for sale in the TERRITORY and in accordance with the SPECIFICATIONS described in Appendix 1 attached hereto.

“RED BOX” means the area of restricted reimbursement for all products following an application for reimbursement within the Austrian Reimbursement Code. The RED BOX spans the time from application until the official decision on acceptance or denial of reimbursement (evaluation phase). Reimbursement in the RED BOX is subject to ex ante control by the head medical service of the Austrian social insurance companies. The EX FACTORY PRICE in the RED BOX equals the actual EU AVERAGE PRICE.

“SPECIFICATIONS” means the specifications for PRODUCT (including shelf life), as per Quality/Technical agreement.

“TARGET SALES” shall mean the target sales as set forth in Appendix 2, such sales of the PRODUCT in the TERRITORY by Merck shall be those reported by IMS or by any other source mutually agreed by the Parties offering a service similar to the one currently offered by IMS. At the date of signature of this AGREEMENT Appendix 2 is a preliminary estimation and the definite number will be calculated in accordance with the actual daily therapy costs and the special reimbursement requirements as detailed below (YELLOW BOX). An example calculation is incorporated in Appendix 2.

“TERM” shall mean the term set forth in Section 16.1.

“TERRITORY” shall mean the territory of Austria.

“TRADEMARK” shall mean the trademark “Lodotra”, reg. no. 877023 registered with the World International Property Organisation for the EU and other territories used in
conjunction with the design attached hereto as Appendix 2. If this TRADEMARK should be rejected by the AGES PharmMed in connection with the application for the MARKETING AUTHORIZATION for PRODUCT filed by Nitec Germany, Nitec shall use an alternative trademark for the PRODUCT, such alternative trademark to become automatically the TRADEMARK.

“YELLOW BOX” means the area of restricted reimbursement for innovative products within the Austrian Reimbursement Code. Precise rules on reimbursed indications, subsets of patients and/or special requirements for prescribing physicians (“Regelvorschlag”) apply for all products within the YELLOW BOX and are determined during the application phase. Reimbursement is subject to ex ante or post hoc control by the head medical service of the Austrian social insurance companies. The EX FACTORY PRICE in the YELLOW BOX in general lies beneath the actual EU average price.

Article 2 - Transfer and License

2.1 Subject to the terms and conditions of this AGREEMENT, Nitec AG hereby undertakes to transfer to Merck – through Nitec Germany – the MARKETING AUTHORIZATION for the PRODUCT and hereby grants to Merck an exclusive licence to use the TRADEMARK for the PRODUCT during the TERM of this AGREEMENT in the TERRITORY. The term exclusive license shall mean for the purpose of this AGREEMENT that Nitec shall not grant a license to use the TRADEMARK in the TERRITORY to any other party.

2.2 Merck is not entitled to transfer, assign or sublicense its granted rights pursuant to Article 2.1 without the prior written consent of Nitec AG.

2.3 Merck shall be considered as an independent contractor and shall not be considered a partner, agent or representative of Nitec. As such, no Party shall have the authority to create or assume any obligation in the name of the other Party nor to bind the other Party in any manner whatsoever.

Article 3 - Marketing Authorization and Trademark

3.1 When the MARKETING AUTHORIZATION in the TERRITORY has been obtained by Nitec Germany, Nitec AG shall cause Nitec Germany to transfer to Merck for the duration of this AGREEMENT the MARKETING AUTHORIZATION and shall license the TRADEMARK to Merck for Merck’s exclusive use hereof, in each case limited to the TERRITORY.

3.2 Merck shall not market, sell and distribute the PRODUCT in the TERRITORY under any other name than the TRADEMARK.

3.3 At Merck’s sole expense, Merck agrees to (a) maintain the transferred MARKETING AUTHORIZATION in the TERRITORY, (b) diligently promote,
market. sell and distribute the PRODUCT in the TERRITORY and (c) promptly assign back to Nitec Germany or any other party, designated by Nitec Germany, the MARKETING AUTHORIZATION and relating rights in the TERRITORY upon termination of this AGREEMENT.

3.4 If at any time during the TERM of this AGREEMENT either Party shall become aware of any infringement or threatened infringement by a third party of the TRADEMARK or any other right belonging to one of the Parties pursuant to this AGREEMENT, the Party having the knowledge thereof shall give prompt notice to the other Party, and the Parties shall consult as to the action to be taken. Any such action shall be taken by Nitec AG at the cost of Nitec AG. Merck may, at its own cost, assist Nitec AG holding the TRADEMARK infringed upon or threatened to be infringed upon in taking legal action against such infringement or threatened infringement.

3.5 Upon termination of this AGREEMENT, Merck’s right to use the TRADEMARK ceases.

Article 4 - Maintenance of Marketing Authorization, Reimbursement

4.1 Merck shall make all declarations and filings to maintain the MARKETING AUTHORIZATION provided that Nitec Germany maintains and updates its international filing such as that within the Decentralized Procedure the national license can be adequately maintained. Nitec Germany has to provide Merck a copy of the relevant documents so that Merck can fulfill this obligation.

Merck shall provide Nitec Germany with drafts of all documents other than those provided by Nitec to Merck to be submitted and shall obtain Nitec Germany’s written consent prior to any submission to any regulatory authority in connection with the subject matters of this agreement. Nitec Germany shall not unreasonably withhold or delay its consent. Merck shall provide Nitec Germany with copies of all such submissions including all documents submitted other than those provided by Nitec to Merck.

4.2 Merck shall make all declarations and filings to apply for inclusion of the PRODUCT into the YELLOW BOX of the Austrian Reimbursement Code at Merck’s own expense. Nitec Germany shall provide Merck with all documents and certificates required for this application.

4.3 The exact date of this application for the YELLOW BOX shall be determined by Nitec AG’s ability to deliver minimum quantities of the PRODUCT, required for this application, to Merck and shall not occur later than 6 weeks after the delivery of such minimum quantities to Merck.

4.4 It is understood by all parties that during the evaluation phase of Merck’s application for reimbursement (RED BOX), sales of the PRODUCT will be close to zero.
The PRODUCT, subject to Nitec AG's ability to deliver the PRODUCT, shall be launched as soon as possible but in no event later than [...***...]
after it has; been officially included into the YELLOW BOX.

If LAUNCH of the PRODUCT shall be delayed due to reasons beyond reasonable control of Merck and Nitec, Parties will share those resulting
losses [...***...] which are caused by a reduction of the shelf-life to less than [... ***...]. Sharing of such losses shall lead to reimbursement of
payments already made by Merck for purchase of the PRODUCT whose shelf-life is so reduced.

Should the application for the YELLOW BOX fail to succeed, representatives of both Parties shall discuss in good faith whether this AGREEMENT
could be modified in the best interest of both parties.

Should the application for the YELLOW BOX fail to succeed, the costs for the application for the YELLOW BOX, in total 7700€ (§2 Abs. 1 der 1.
Änderung der Verfahrenskostenordnung) will be shared between Merck and Nitec AG in equal parts.

Article 5 - Marketing and Sales Activities

Merck will perform all industry-standard and customary pre-marketing activities [...***...] prior to the envisaged LAUNCH of the PRODUCT.

Merck will use its commercially reasonable efforts to market the PRODUCTS comparable to the common practice of the industry for products of a
comparable market size.

Merck agrees that all material used in connection with the promotion and distribution of the PRODUCT shall comply with the applicable law and
any information contained in such material shall be consistent with the MARKETING AUTHORIZATION.

The marketing plan of the PRODUCT for the following year shall be presented and provided to Nitec AG during the fourth quarter of each year.

No written or printed material relating to the PRODUCT shall be used by Merck without Nitec AG's prior written consent. Any information on
written or printed materials provided to Nitec AG shall be subject to Article 12. If within five (5) business days after receipt of such material, Nitec
AG or Nitec Germany does not inform Merck, that it objects to the presented materials or, if Nitec AG or Nitec Germany, in case of objections,
within five (5) more working days do not inform Merck in writing of the reasons for the objection, such material shall be considered approved by
Nitec AG. The consent of Nitec AG may not be unreasonably withheld.

***Confidential Treatment Requested
Merck shall not initiate and/or conduct any Phase III/IV clinical studies for the PRODUCT without Nitec AG’s prior written consent.

5.5 Each Party will provide the other free of charge with the results of its market research activities for the PRODUCT in the TERRITORY. Additionally, Nitec AG shall provide Merck with all results obtained by studies conducted by or on behalf of Nitec AG in relation to the indication rheumatoid arthritis.

5.6 Within [...] following each calendar quarter, Merck shall send to Nitec a copy of the Merck’s internal sales report covering the preceding quarter. Each such quarterly sales report shall show the total distribution of the PRODUCT (sales) in units and values for each dosage form. The sales report shall include separate figures for wholesaler and hospital supply.

During the twelve (12) month period starting with the first commercial introduction Merck will provide Nitec AG monthly sales (in units and values).

Each Party shall provide the other free of charge with the results of its market research activities for the PRODUCT in the TERRITORY. Additionally, Nitec AG shall provide Merck with all results obtained by studies conducted by or on behalf of Nitec AG in relation to the indication rheumatoid arthritis.

5.7 Should Merck not reach TARGET SALES or, respectively, the ANNUAL MINIMUM SALES as agreed upon same shall not be regarded as a breach of this AGREEMENT. Upon such occurrence representatives of both Parties shall propose measures to reach the TARGET SALES. The evaluation of achieved versus TARGET SALES will be performed every [...] months.

5.8 Should ANNUAL MINIMUM SALES not be reached in any [...] (the first such period to commence upon LAUNCH) during the TERM due to reasons not attributable to Nitec and/or the third party manufacturer, and same shall not be remedied within [...] after respective notice by Nitec to Merck. Nitec reserves the right to terminate this AGREEMENT. Prior to such termination, however, representatives of both Parties shall discuss in good faith whether this AGREEMENT could be modified in the best interest of both parties.

5.9 For the purposes of Art. 5.6 and 5.7, the sales of the PRODUCT in the TERRITORY by Merck shall be those reported by IMS or by any other source mutually agreed by the Parties offering a service similar to the one currently offered by IMS. Monthly hospital sales reported by Merck during the twelve (12) month period starting with the first commercial introduction will be based on Merck data solely, since no comparable data exist with IMS or other sources.

Article 6 - Ex factory Price

6.1 Merck shall use its reasonable best efforts to convince the Austrian Health Insurance Institutions (Hauptverband der österreichischen Sozialversiche-
rungsträger) about the additional benefit of the PRODUCT compared to immediate-release glucocorticoid tablets to justify inclusion into the YELLOW BOX.

6.2 The target EX FACTORY PRICES and the reimbursement rules ("Regelvorschlag") will be discussed by the Parties sufficiently in advance of the application for reimbursement and prior to all negotiations with the Health Insurance Institutions. The EX FACTORY PRICE shall be further discussed by the Parties upon either Party’s written request at any time in light of the then current market situation.

6.3 In case of reductions of the price imposed by the Health Insurance Institutions or the possibility of such price reductions, Merck shall promptly notify Nitec and shall use its reasonable best efforts as described in section 6.1 to avoid or at least delay such occurrence.

Article 7 - Supply and Orders

7.1 Merck agrees to exclusively purchase from Nitec AG, all of Merck’s requirements of the PRODUCT. Nitec AG hereby agrees to use commercially reasonable efforts to meet Merck’s requirements for the PRODUCT. Nitec AG is entitled to have the PRODUCT in its name directly delivered by the third party manufacturer under contract to Merck. For the avoidance of doubt, Nitec AG remains liable for the delivery of the PRODUCT.

7.2 Merck will internally combine purchase orders for PRODUCT to reach minimum purchase order amounts agreed between Nitec AG and Merck Pharma GmbH, Germany, specifying in each case which portion of an order is designated to be sold in Austria or in Germany.

7.3 The PRODUCT will be delivered in accordance with the SPECIFICATIONS as per Quality/Technical Agreement.

7.4 The Parties shall agree upon the packaging design which shall comply with the legal requirements in the TERRITORY.

7.5 At the end of each calendar quarter Merck shall provide Nitec AG with a written non-binding rolling forecast of Merck’s requirements of the PRODUCT, per month, for the next [...***…]. The first rolling forecast shall be provided to Nitec AG at the same time as placement of first purchase order. Orders shall also be placed at the end of each calendar quarter.

7.6 The PRODUCT will be shipped DDP (Incoterms 2000) to one certain location in the Territory specified by Merck according to the product specifications and together with certificate of analysis confirmed by the signature of an EU Qualified Person as well as according to the requirements of the Arzneimittelbetriebsordnung AMBO, especially regarding temperature control.

***Confidential Treatment Requested

8/20
Article 8 - QUALITY of the PRODUCT

8.1 The PRODUCT to be delivered by a third party manufacturer in the name of Nitec AG to Merck hereunder shall be finished and released goods, be free from defects, conform to the analysis certificates which are delivered with the PRODUCT and will be in accordance with the SPECIFICATIONS for the PRODUCT and end-released by the EU Qualified Person of Nitec or the manufacturer. Nitec assures that all third party manufacturer at any time comply with the requirements of the Arzneimittelbetriebsordnung (AMBO) and of the EC-Guideline of Good Manufacturing Practice for medicinal products, Part I: Basic requirements for medicinal products (GMP) and that the quality of the PRODUCT complies with the MARKETING AUTHORIZATION dossier.

Further details concerning manufacturing, specifications and the supply relationship shall be set forth in the Quality/Technical Agreement to be concluded in due course.

8.2 The provisions contained in § 377 Handelsgesetzbuch shall not be applicable. Merck shall, however, inspect PRODUCT (including temperature data logger logs) delivered within five (5) working days of receiving delivery and shall inform the party effecting the delivery (with a copy to Nitec AG) within such five day period of any shortages, defects or obvious off specification characteristics. Other defects have to be reported promptly upon discovery, but in no event later than five (5) working days after such discovery.

Article 9 - Supply Price and Terms of Payment

9.1. The prices to be paid by Merck to Nitec AG for the PRODUCT (including samples) shall be at the higher of (i) [...***...] of the EX FACTORY PRICES or (ii) PRODUCTION COSTS plus [...***...] of the EX FACTORY PRICES. In the event that the PRODUCT becomes subject to mandatory reimbursements imposed by the authorities (e.g. Zwangsrabatte), NITEC AG and Merck shall share the economic burden of such mandatory reimbursements as follows:

- In the event that Merck has paid NITEC AG according to lit. (i) above Nitec AG shall re-imburse to Merck [...***...] of the reduction amounts actually paid by Merck to the authorities.

- In the event that Merck has paid NITEC AG according to lit. (ii) above Nitec AG shall re-imburse to Merck the share of the reduction amounts actually paid by Merck to the authorities which is equal to PRODUCTION COSTS plus [...***...] of the EX FACTORY PRICE divided by the EX FACTORY PRICE. Reimbursements by NITEC AG shall be limited to [...***...] of the EX FACTORY PRICES.

In the event, should the price to be paid by Merck to Nitec AG for the PRODUCT exceed [...***...] of the EX FACTORY PRICES, representatives of

***Confidential Treatment Requested
both Parties shall discuss in good faith whether this AGREEMENT could be modified in the best interest of both parties, or rather be terminated by Merck.

9.2. Invoices shall be payable without discount within […] days from the date of invoice.

**Article 10 - General Obligations of Merck**

Merck shall have the following general obligations:

10.1 Merck shall comply with all applicable laws and regulations, especially with the AMG and the AMBO.

10.2 Merck will use its reasonable best efforts to further the marketing, selling and distribution of the PRODUCT in the TERRITORY in accordance with the terms of this AGREEMENT and to obtain the relevant authorizations, if any;

10.3 Merck shall promptly respond to all inquiries from customers, including complaints, process all orders, and shall effect all dispatches of the PRODUCT.

10.4 Merck shall promptly provide Nitec AG with written reports of any importation or sale of the PRODUCT in the TERRITORY of which Merck has knowledge from any source other than Nitec AG, as well as with any other information related to the PRODUCT, which Nitec AG may reasonably request in order to be updated on the market conditions in the TERRITORY.

10.5 The parties shall agree upon the packaging design which shall comply with the legal requirements in the Territory and the internal guidelines of Merck. In case Merck requests a change of the packaging or related information material and such request is beyond customary practice in the industry (e.g. with regard to either reasonableness of the change or frequency of requested changes) or results in a material cost increase, the additional costs resulting from such request shall be borne by Merck. Merck shall inform Nitec of any requirements for changes of the packaging, labeling or patient information in the Territory.

10.6 The Parties agree to establish a joint product committee to meet regularly, at least every four (4) months, to evaluate marketing and sales performance as related to annual sales and purchase plans delivered to Nitec AG according to Article 7.5 of this AGREEMENT.

**Article 11 - General Obligations of Nitec**

Nitec shall have the following obligations during the TERM of this AGREEMENT:

***Confidential Treatment Requested***

10/20
11.1 Nitec AG shall enable Merck to file the required notice with the AGES PharmMed relating to the transfer of the MARKETING AUTHORIZATION to Merck (Austria or Germany) in accordance with § 25 AMG and informs Merck of that notification by copy.

11.2 Nitec AG will supply Merck with all presently available or future documents and information concerning the PRODUCT as far as such documents and information are needed by Merck for the fulfillment of its obligations under this AGREEMENT, including the assessment report of the reference member state for submission to the Hauptverband and the complete dossier for the PRODUCT.

11.3 Nitec AG will provide Merck with examples for technical literature, promotional and advertising material, etc. as both Parties consider to be reasonably sufficient to promote sales of the PRODUCT in the TERRITORY and as far as available within Nitec.

Article 12 - Secrecy

12.1 The Parties agree and undertake that they will keep secret all disclosures by the other Party, written or oral, made either before or during the TERM of this AGREEMENT. The receiving Party will not without the prior written consent of the other Party use, except as expressly contemplated by this AGREEMENT, or disclose to any third party any information relating to the PRODUCTS learned by or disclosed to the other Party pursuant to or in connection with this AGREEMENT (together “Information”).

12.2 The confidentiality obligations hereinabove mentioned shall not apply to:
   a) Information in the public domain
   b) Information known by the receiving Party before the date hereof and which the receiving Party can conclusively prove that it was not obtained, directly or indirectly from the disclosing Party.
   c) Information legally obtained by the receiving Party after the date hereof from a third party which has it in its possession legally.
   d) Information which the receiving Party is legally obliged to reveal to authorities or clients.

12.3 The provisions of this Article shall remain in force during the period of this AGREEMENT and for a further period of two (2) years after the termination thereof.
Article 13 - Responsibility, Liability and Indemnification

13.1 Merck shall be responsible for fulfilling and securing all requirements, regulations, licenses and permissions which are necessary to distribute, sell and market the PRODUCT in finished form in the TERRITORY.

13.2 Nitec AG indemnifies Merck from all damages arising out of any negligent or willful breach of its obligations according to this AGREEMENT or arising out of the use by Merck in the performance of this AGREEMENT of information or data disclosed by Nitec pursuant to this AGREEMENT. Subject to the limitations of Section 13.4, Nitec AG will indemnify Merck and its Affiliates (and their respective officers, directors and employees) from and against any and all damages sustained or incurred by any of them because of any third party personal injury or wrongful death claim to the extent such damages arise out of: (i) the negligence or wilful misconduct of Nitec or its Affiliates (or their respective officers, directors or employees), (ii) any breach by Nitec of any provision of this AGREEMENT, including without limitation any PRODUCT warranty made by Nitec in this AGREEMENT; or (iii) any latent defect in PRODUCT. Nitec AG will indemnify and hold Merck and its Affiliates (and their respective officers, directors and employees) harmless from and against any and all damages sustained or incurred by any of them to the extent that they arise out of any third party claim of violation or infringement of any proprietary right of said third party relating to Nitec’s proprietary information used in the manufacture of PRODUCT. Notwithstanding the foregoing, Nitec shall have no such indemnity obligation to the extent such third party claims are based on, arise out of, or are caused by, the negligence or wilful misconduct of Merck or its Affiliates (or their respective officers, directors or employees).

Upon filing of any such claim, Merck shall immediately notify Nitec AG in writing and shall offer Nitec AG to control the defense against any such claim. If Nitec AG declines the offer to so control the defense, then Merck shall keep Nitec AG fully informed at all times of its own measures to defend such claim and shall allow Nitec AG to comment on any material measures prior to Merck taking such measures in the course of the defense. Any settlement or acknowledgement of such claim or any waiver of a defense by Merck shall require the prior written consent of Nitec AG. Failure to obtain such consent shall exclude Merck’s right to recover damages under this section 14 for the respective claim.

13.3 Merck, subject to the limitations in Section 13.4, indemnifies Nitec from all damages arising out of the breach of any obligation of Merck according to this AGREEMENT. Merck will indemnify Nitec for all damage resulting from any third party claims against Nitec, which arise from the distribution, marketing and sale of the PRODUCTS, if not attributable to Nitec as per clause 13.2. Upon filing of any such claim, Nitec shall immediately notify Merck and the third full paragraph of section 13.2 shall apply mutatis mutandis.
Article 14 - Exchange of Information and Pharmacovigilance

14.1. The Parties shall keep each other informed on all matters related to the PRODUCT and on any information received from any source concerning adverse drug reactions coming to either Party’s knowledge with regard to the PRODUCT.

14.2 Merck is responsible for fulfilling the documentation and reporting obligations in accordance with the legal requirements. Independently of any national reporting requirements, the Parties hereto shall in relation to the PRODUCT report to each other all serious adverse events from clinical trials with a reasonable suspicion of causal relationship to the administered PRODUCT and all serious spontaneously reported suspected adverse drug reactions.

14.3 In any case where a change in the risk-benefit-ratio becomes evident or risk minimizing steps due to adverse drug reactions seem to be necessary (e.g. change of the label, PRODUCT information, special information/warnings to the medical profession, patients, authorities or recall of the PRODUCT), the Parties hereto will inform each other without delay and harmonise further measures as appropriate. Such exchange of information is realised through direct contacts between the appropriately qualified persons responsible for pharmacovigilance of each party. Therefore, both Parties undertake to inform each other on any change in the responsible persons, the address, telephone and fax-numbers.

14.4 Any information on drug safety issues as pointed out above shall be furnished by a Party to the other Party in the English language.

14.5 Nitec GmbH will be responsible for preparing the periodic safety update reports and will maintain the respective EU database in accordance with the law and shall provide copies of same to Merck.

14.6 Merck agrees that the obligations of Nitec may be performed by a third party selected by Nitec. Further details will be set forth in the Safety Data Exchange AGREEMENT between Nitec and Merck to be concluded in due course.
Article 15 - Non Competition

Within the first three (3) years following the LAUNCH of the PRODUCT, Merck shall refrain from launching oral glucocorticoids in the indication "rheumatoid arthritis".

Article 16 - Term and Termination

16.1 Term

This AGREEMENT shall take effect as of the signature by all parties and, unless otherwise terminated as provided in this AGREEMENT, shall remain in full force and effect for a period of 10 (ten) years as of the LAUNCH.

Thereafter, the AGREEMENT will be automatically renewed for successive periods of [...] until terminated by either Party giving 12 (twelve) months prior written notice to the other Party.

16.2 Termination

Notwithstanding other rights to terminate this AGREEMENT pursuant to Art. 16.1, this AGREEMENT may be terminated with immediate effect in accordance with the following provisions:

a) Either Party may terminate this AGREEMENT at any time by giving notice in writing to the other Party, which notice shall be effective upon dispatch, should the other Party file a petition of any type as to its bankruptcy, be declared a bankrupt, become insolvent, make an assignment for the benefit of creditors, go into liquidation or receivership;

b) Either Party may terminate this AGREEMENT by giving notice in writing to the other Party should an event of force majeure as provided in Article 17.4 continue for more than [...] months;

c) Either Party may terminate this AGREEMENT by giving notice in writing to the other Party stating that this AGREEMENT might terminate under this Article 16.2., if the other Party (i) commits a material breach of any condition herein contained, and does not within [...] days from receipt of written notice by the other Party of such breach remedy the same, if capable of remedy, or offer full compensation therefore; or (ii) if the other Party repetitiously commits a breach of any condition contained herein, and the aggregate of such repetitious breach represents a material breach of this AGREEMENT.

d) In any event, should the application for the YELLOW BOX fail to succeed or should the PRODUCT be removed from the YELLOW BOX later and moved to the NO BOX (non-reimbursable products but in case of individual authorization an a case by case basis), then the parties shall meet and shall discuss the issue in good faith. Failing agreement within [...] on a joint course of action, either party may terminate this agreement.

***Confidential Treatment Requested

14/20
e) Should the Hauptverband require a 7 tablets/pack and should Nitec not elect to deliver such pack, then the parties shall meet and shall discuss the issue in good faith. Failing agreement on a joint course of action, either party may terminate this agreement.

16.3 Rights and Obligations on Expiration and Termination

In the event of termination or expiration of this AGREEMENT for any reason, the Parties shall have the following rights and obligations:

a) Merck shall without undue delay take any measures necessary to transfer the MARKETING AUTHORIZATION for the PRODUCT and all documentation relating thereto to Nitec Germany or to a third party designated by Nitec Germany.

b) All of Merck’s rights under or related to the TRADEMARK automatically end upon termination of this AGREEMENT.

Termination of this AGREEMENT shall not release either Party from the obligation to deliver or to make payment of all amounts then or thereafter due and payable;

16.4 Both Parties’ obligations pursuant to secrecy in Article 12 shall survive termination of this AGREEMENT;

16.5 In case of termination or expiration of this AGREEMENT, Merck will discontinue to distribute, to market and to sell the PRODUCT, if not stated otherwise in this AGREEMENT.

16.6 In the event of termination of this AGREEMENT, Nitec AG may repurchase stocks of PRODUCT held by Merck at the prices Merck has bought the PRODUCT from Nitec AG, if Nitec AG so chooses. Otherwise Merck is entitled to distribute the remaining stocks within […] within the TERRITORY. All stocks remaining after this period of […] including but not limited to all PRODUCT which might be returned thereafter, have to be destroyed at Merck’ responsibility and costs, a proof of which shall be submitted to Nitec AG.

Article 17 - Miscellaneous

17.1 Notices

All notices, demands and communications required to be made under this AGREEMENT shall be in writing and delivered personally or sent by telefax and confirmed by airmail letter to the addresses shown above. Notice shall be deemed delivered on the date of delivery when delivered personally or on the third business day after the day on which they were sent by telefax or fourteen

***Confidential Treatment Requested

15/20
17.2 **Headings.**
It is agreed by the Parties hereto, that the headings of the clauses herein have been included for convenience only and do not form any part of the AGREEMENT.

17.3 **Severability.**
In the event that any provision of this AGREEMENT is held by a court of competent jurisdiction to be unenforceable because it is invalid or in conflict with any law of any relevant jurisdiction, the Parties shall replace any Article or part of an Article found to be invalid or unenforceable by alternative provisions which shall be as similar as possible in their conditions with regard to their spirit and commercial effect. The validity of the remaining provisions shall not be affected.

17.4 **Force Majeure.**
In the event that the performance of this AGREEMENT or of any obligation hereunder, other than payment of money as herein provided, by either Party is prevented, restricted or interfered with by reasons of any cause not within the control of the respective Party, and which could not by reasonable diligence have been avoided by such Party, the Party so effected, upon giving prompt notice to the other Party as to the nature and probable duration of such event, shall be excused from such performance to the extent and for the duration of such prevention, restriction or interference, provided that the Party so affected shall use its best efforts to avoid or remove such cause of non-performance and shall fulfil and continue performance hereunder with the utmost dispatch whenever and to the extent such cause or causes are removed.

17.5 **Assignment.**
Merck and Nitec may assign its rights and obligations under this AGREEMENT, in whole or in part, to any AFFILIATE upon prior written consent from Nitec or Merck respectively, which consent shall not be unreasonably withheld or delayed, provided that in each case the transferring party agrees to be fully responsible for the receiving AFFILIATE’S performance of this AGREEMENT.

17.6 **Hardship.**
Should the effects of this AGREEMENT resulting from future unforeseen events and developments lead to an unjust hardship for either Party and which hardship does not correspond with the intention of the Parties in good faith, the Parties shall without delay enter into negotiations to see in what way the conditions of the AGREEMENT can be made to suit altered circumstances.

17.7 **Waiver.**
If any Party should at any time refrain from enforcing its rights arising from a breach or default by the other Party of any of the provisions of this

16/20
AGREEMENT, such waiver shall not be construed as a continuing waiver regarding that breach or default or other breaches or defaults of the same or other provisions of this AGREEMENT.

17.8 **Conflicting Agreements.**

In the event any provisions contained in the TTA shall conflict with the provisions contained in this AGREEMENT, this AGREEMENT shall prevail.

17.9 **Written Form.**

No waiver, alteration or modification of any of the provisions hereof shall be binding unless made in writing and signed by duly authorized officers of the Parties. Any waiver of this written form requirement shall be in writing.

**Article 18 - Governing Law**

This AGREEMENT shall be governed by and interpreted in accordance with the laws of Germany without its provisions on the conflict of laws and without the UN Convention on the international Sale of Goods (CISG) and the rules incorporating this convention into German law.

Reinach, den 26/3/09

Wien, den 10/03/2009

**Nitec Pharma AG**

/s/ Dr. Anders Härfstrand

(Dr. Anders Härfstrand)

Mannhein, den 25/03/09

Nitec Pharma GmbH

/s/ Achim Schäffler

(Achim Schäffler)

**Merck GesmbH**

/s/ Andreas Peilowich

(Andreas Peilowich)

Appendix 1    Target Sales
Appendix 2     Design for Lodotra Trademark

17/20
Transfer, Licence and Supply Agreement

Appendix 1

<p>| | | | | | | | | | | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="https://via.placeholder.com/150" alt="Redacted" /></td>
<td><img src="https://via.placeholder.com/150" alt="Redacted" /></td>
<td><img src="https://via.placeholder.com/150" alt="Redacted" /></td>
<td><img src="https://via.placeholder.com/150" alt="Redacted" /></td>
<td><img src="https://via.placeholder.com/150" alt="Redacted" /></td>
<td><img src="https://via.placeholder.com/150" alt="Redacted" /></td>
<td><img src="https://via.placeholder.com/150" alt="Redacted" /></td>
<td><img src="https://via.placeholder.com/150" alt="Redacted" /></td>
<td><img src="https://via.placeholder.com/150" alt="Redacted" /></td>
<td><img src="https://via.placeholder.com/150" alt="Redacted" /></td>
<td><img src="https://via.placeholder.com/150" alt="Redacted" /></td>
<td><img src="https://via.placeholder.com/150" alt="Redacted" /></td>
</tr>
<tr>
<td><img src="https://via.placeholder.com/150" alt="Redacted" /></td>
<td><img src="https://via.placeholder.com/150" alt="Redacted" /></td>
<td><img src="https://via.placeholder.com/150" alt="Redacted" /></td>
<td><img src="https://via.placeholder.com/150" alt="Redacted" /></td>
<td><img src="https://via.placeholder.com/150" alt="Redacted" /></td>
<td><img src="https://via.placeholder.com/150" alt="Redacted" /></td>
<td><img src="https://via.placeholder.com/150" alt="Redacted" /></td>
<td><img src="https://via.placeholder.com/150" alt="Redacted" /></td>
<td><img src="https://via.placeholder.com/150" alt="Redacted" /></td>
<td><img src="https://via.placeholder.com/150" alt="Redacted" /></td>
<td><img src="https://via.placeholder.com/150" alt="Redacted" /></td>
<td><img src="https://via.placeholder.com/150" alt="Redacted" /></td>
</tr>
<tr>
<td><img src="https://via.placeholder.com/150" alt="Redacted" /></td>
<td><img src="https://via.placeholder.com/150" alt="Redacted" /></td>
<td><img src="https://via.placeholder.com/150" alt="Redacted" /></td>
<td><img src="https://via.placeholder.com/150" alt="Redacted" /></td>
<td><img src="https://via.placeholder.com/150" alt="Redacted" /></td>
<td><img src="https://via.placeholder.com/150" alt="Redacted" /></td>
<td><img src="https://via.placeholder.com/150" alt="Redacted" /></td>
<td><img src="https://via.placeholder.com/150" alt="Redacted" /></td>
<td><img src="https://via.placeholder.com/150" alt="Redacted" /></td>
<td><img src="https://via.placeholder.com/150" alt="Redacted" /></td>
<td><img src="https://via.placeholder.com/150" alt="Redacted" /></td>
<td><img src="https://via.placeholder.com/150" alt="Redacted" /></td>
</tr>
<tr>
<td><img src="https://via.placeholder.com/150" alt="Redacted" /></td>
<td><img src="https://via.placeholder.com/150" alt="Redacted" /></td>
<td><img src="https://via.placeholder.com/150" alt="Redacted" /></td>
<td><img src="https://via.placeholder.com/150" alt="Redacted" /></td>
<td><img src="https://via.placeholder.com/150" alt="Redacted" /></td>
<td><img src="https://via.placeholder.com/150" alt="Redacted" /></td>
<td><img src="https://via.placeholder.com/150" alt="Redacted" /></td>
<td><img src="https://via.placeholder.com/150" alt="Redacted" /></td>
<td><img src="https://via.placeholder.com/150" alt="Redacted" /></td>
<td><img src="https://via.placeholder.com/150" alt="Redacted" /></td>
<td><img src="https://via.placeholder.com/150" alt="Redacted" /></td>
<td><img src="https://via.placeholder.com/150" alt="Redacted" /></td>
</tr>
<tr>
<td><img src="https://via.placeholder.com/150" alt="Redacted" /></td>
<td><img src="https://via.placeholder.com/150" alt="Redacted" /></td>
<td><img src="https://via.placeholder.com/150" alt="Redacted" /></td>
<td><img src="https://via.placeholder.com/150" alt="Redacted" /></td>
<td><img src="https://via.placeholder.com/150" alt="Redacted" /></td>
<td><img src="https://via.placeholder.com/150" alt="Redacted" /></td>
<td><img src="https://via.placeholder.com/150" alt="Redacted" /></td>
<td><img src="https://via.placeholder.com/150" alt="Redacted" /></td>
<td><img src="https://via.placeholder.com/150" alt="Redacted" /></td>
<td><img src="https://via.placeholder.com/150" alt="Redacted" /></td>
<td><img src="https://via.placeholder.com/150" alt="Redacted" /></td>
<td><img src="https://via.placeholder.com/150" alt="Redacted" /></td>
</tr>
<tr>
<td><img src="https://via.placeholder.com/150" alt="Redacted" /></td>
<td><img src="https://via.placeholder.com/150" alt="Redacted" /></td>
<td><img src="https://via.placeholder.com/150" alt="Redacted" /></td>
<td><img src="https://via.placeholder.com/150" alt="Redacted" /></td>
<td><img src="https://via.placeholder.com/150" alt="Redacted" /></td>
<td><img src="https://via.placeholder.com/150" alt="Redacted" /></td>
<td><img src="https://via.placeholder.com/150" alt="Redacted" /></td>
<td><img src="https://via.placeholder.com/150" alt="Redacted" /></td>
<td><img src="https://via.placeholder.com/150" alt="Redacted" /></td>
<td><img src="https://via.placeholder.com/150" alt="Redacted" /></td>
<td><img src="https://via.placeholder.com/150" alt="Redacted" /></td>
<td><img src="https://via.placeholder.com/150" alt="Redacted" /></td>
</tr>
</tbody>
</table>

***Confidential Treatment Requested***

18/20
Appendix 2

Design of Lodotra Trademark

[...***...]

***Confidential Treatment Requested
DATED 24th March 2009

NITEC PHARMA AG

AND

MUNDIPHARMA MEDICAL COMPANY

MANUFACTURING AND SUPPLY AGREEMENT
THIS AGREEMENT is made the 26th day of March 2009

BETWEEN:

(1) NITEC PHARMA AG a company incorporated in accordance with the laws of Switzerland with its registered office at Kägenstrasse 17, CH-4153 Reinach, Switzerland (“Nitec”); and

(2) MUNDIPHARMA MEDICAL COMPANY a partnership organised in accordance with the laws of Bermuda with Registered No. EC – 16260 and with its registered office at Canon’s Court, 22 Victoria Street, Hamilton, HM 12 Bermuda (“Mundipharma”).

RECITALS

(A) Nitec is able to procure the manufacture of the Products (as hereinafter defined) and supply the same.

(B) Nitec has appointed Mundipharma’s Associate, Mundipharma International Corporation Limited (“MICL”), as its exclusive distributor and licensee of the Products in the Territory pursuant to a Distribution Agreement between Nitec and MICL of even date herewith (the “Distribution Agreement”);

(C) MICL wishes Nitec to procure the manufacture of the Products and supply the same and has designated Mundipharma to purchase the Products from Nitec for distribution in accordance with the Distribution Agreement.

NOW IT IS HEREBY AGREED as follows:

1 Definitions

In this Agreement, in addition to the terms listed in the Recitals, the following terms shall have the following meanings:-
<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>“Associate”</td>
<td>means with respect to either one of the parties, any person, firm, trust, corporation or other entity or combination thereof which directly or indirectly (a) controls said party, (b) is controlled by said party, or (c) is under common control with said party; the terms “control” and “controlled” meaning ownership of fifty percent (50%) or more, including ownership by trusts with substantially the same beneficial interests, of the voting and equity rights of such person, firm, trust, corporation or other entity or combination thereof or the power to direct the management of such person, firm, trust, corporation or other entity or combination thereof;</td>
</tr>
<tr>
<td>“Average Net Selling Price”</td>
<td>means the aggregate Net Sales for a country in the Territory divided by the aggregate number of units of the Finished Product sold in the same period in that country by MICL, its Associates or sub-licensees, less those rejected, returned and recalled in a manner consistent with Mundipharma or its Associates’ customary policy;</td>
</tr>
<tr>
<td>“Calendar Quarter”</td>
<td>means a calendar quarter ending on 31st March, 30th June, 30th September and 31st December in any calendar year;</td>
</tr>
<tr>
<td>“Commencement Date”</td>
<td>means the date of execution of this Agreement;</td>
</tr>
<tr>
<td><strong>“Delivery Address”</strong></td>
<td>means the following address for delivery of the Finished Products: Alloga (Nederland) BV, De Amert 603, 5462 GH Veghel, Nederland;</td>
</tr>
<tr>
<td><strong>“Distribution Agreement”</strong></td>
<td>has the meaning set out in the Recital B hereto;</td>
</tr>
<tr>
<td><strong>“Finished Products”</strong></td>
<td>means all packaged Products ready to be distributed under the trade mark Lodotra™ or such other trade mark determined by the parties under the Distribution Agreement;</td>
</tr>
<tr>
<td><strong>“Improvements”</strong></td>
<td>any improvement, modification or enhancement (including new presentation(s)) of or to the Product or any of its components or constituent parts and any related Nitec intellectual Property (as defined below), which shall include (without limitation) all dosage strengths and line extensions to the Product and any improvement thereof;</td>
</tr>
<tr>
<td><strong>“Intellectual Property”</strong></td>
<td>means patents, registered designs, unregistered rights in designs, trade marks, domain names, service marks, logos, trade names, copyright, utility models, rights in know-how and other intellectual property rights, in each case whether registered or unregistered and including applications for registration, and all rights or forms of protection having equivalent or similar effect anywhere in the world;</td>
</tr>
<tr>
<td><strong>“Launch”</strong></td>
<td>means for each country of the Territory when MICL launches the Product in that country in the Territory under the Distribution Agreement.</td>
</tr>
</tbody>
</table>
“Manufacturing” and “Manufacture” means the totality of the following operations:

(a) purchasing, supply and storage of active ingredients, excipients and packaging materials;

(b) checks performed on the active ingredients, excipients, packaging materials, semi-finished or Finished Products and their release;

(c) production operations performed from the active ingredients and excipient stage to the semi-finished product stage;

(d) packaging, packing and labelling of semi-finished products, to produce the Finished Product;

(e) analysis and release of batches of Finished Product and delivery of these batches, accompanied by certificates of compliance signed by a qualified person in the EU;

(f) management and archiving of files relating to batches of each of the Products, and retention of samples for the period provided for in current laws and regulations;

“Manufacturing Premises” means the facilities located at SkyePharma SAS, ZA de Chesnes Quest, 55 rue du Montmurier, BP 4538291 Saint-Quentin-Fallavier where the Third Party Manufacturer shall manufacture bulk tablets of the Product or any other site approved by the Regulatory Authorities for the Manufacture of the Product;
“Net Sales” means the gross amount invoiced by MICL, its Associates or sub-licensees for sales of the Finished Product in a particular country within the Territory, less deductions for:

(a) quantity and cash discounts and sales rebates actually given;
(b) freight, shipping insurance and other transportation expenses;
(c) sales, value-added, excise taxes, tariffs and duties, and other taxes directly related to the sale;
all to the extent that items (a), (b) and (c) are included in the gross invoice price and specified on the invoice (but not including taxes assessed against the income derived from such sale);
(d) returns (including withdrawals and recalls other than returns by third parties to MICL or Mundipharma on account of lack of sufficient remaining shelf life); and
(e) amounts repaid, discounted or credited by reason of (i) retroactive price reductions, discounts, or rebates, which are, in any case, imposed on MICL or its Associates or sub-licensees by any governmental or non-governmental body with the authority to impose such price reductions, discounts or rebates, all to the extent reasonably demonstrated by MICL by written records or (ii) retroactive price reductions, discounts or rebates (not specified in an invoice) granted to
a third party without the authority to impose such price reductions, discounts or rebates to the extent these are either pre-agreed with Nitec or do not exceed […] of the gross invoice price.

The transfer of the Finished Product by MICL to an Associate or sub-licensee will not be deemed a sale;

“Nitec Intellectual Property” means any and all Intellectual Property relating to the Product and/or corticosteroids owned by, licensed to or under the control of Nitec including (without limitation) the Intellectual Property licensed from SkyePharma plc and/or Jagotec AG regarding GeoClock Technology and its use with corticosteroids, the patent applications […] (and any patents, divisional patents, supplementary protection certificates and extensions granted in relation to such applications) insofar as they relate to corticosteroids, and any know-how relating to the Product including pharmacokinetic and clinical data, technical information, manufacturing formulae and methods and further techniques and designs of a confidential nature;

“Packaging Premises” means the facilities located at Catalent Solutions Germany Schorndorf GmbH, Steinbeisstraße 1-2, D 73614 Schorndorf, Germany where the Third-Party Packager shall package the Products or any other site approved by the Regulatory Authorities for the packaging of the Product;
<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>“Product”</td>
<td>means the modified release formulation of prednisone 1mg, 2mg, 5mg in all pack presentations and including Improvements;</td>
</tr>
<tr>
<td>“Registrations”</td>
<td>means any marketing authorisations granted under the relevant legislation in the Territory for the Manufacture, distribution and sale of the Finished Products;</td>
</tr>
<tr>
<td>“Regulatory Authority”</td>
<td>means any competent regulatory authority or other governmental body (for example, but not by way of limitation the EMEA or other national or international regulatory bodies) responsible for granting a marketing authorisation or pricing approval in the relevant country of the Territory;</td>
</tr>
<tr>
<td>“Sales Forecast”</td>
<td>means the sales forecast for the Product for each country or group of countries in the Territory as set out in Table 1 of Schedule 2;</td>
</tr>
<tr>
<td>“Specification”</td>
<td>means the specification for the Finished Products given in the Technical Agreement;</td>
</tr>
<tr>
<td>“Technical Agreement”</td>
<td>means the technical agreement to be entered into between Nitec Pharma GmbH and Mundipharma or its Associate within ninety (90) days as of the date of this Agreement;</td>
</tr>
<tr>
<td>“Territory”</td>
<td>means the countries listed in Schedule 1;</td>
</tr>
<tr>
<td>“Testing Premises”</td>
<td>means the facilities located at Phast Gmbh Kardinal-Wendel-Str. 16 D-66424 Homburg/Saar, Germany where the Third Party Tester shall test the Product or any other</td>
</tr>
</tbody>
</table>
site approved by the Regulatory Authorities for the testing of the Product;

“Third-Party Manufacturer” means Jagotec AG or any other party appointed and approved by the Regulatory Authorities for the Manufacture of the Product;

“Third-Party Packager” means Catalent Solutions Germany Schorndorf GmbH or any other party approved by the Regulatory Authorities for the packaging of the Product;

“Third-Party Service Providers” means the Third-Party Manufacturer, the Third-Party Packager and the Third-Party Tester;

“Third-Party Tester” means Phast GmbH or any other party approved by the Regulatory Authorities for the testing of the Product.

2 Interpretation

2.1 Any reference in this Agreement to “writing” or cognate expressions includes a reference to facsimile transmission.

2.2 The headings in this Agreement are for convenience only and shall not affect its interpretation.

3 Duration

3.1 This Agreement shall take effect on the Commencement Date and subject as hereinafter provided shall continue in force for so long as the Distribution Agreement remains in effect and shall terminate on the date on which the Distribution Agreement terminates or expires.
4 Manufacture and Supply

4.1 Nitec shall procure that the Third-Party Manufacturer shall Manufacture the Products at the Manufacturing Premises and shall procure that the Third-Party Packager shall package the Products at the Packaging Premises and shall procure that the Third-Party Tester shall test the Products at the Testing Premises and Nitec shall supply the Finished Products to Mundipharma, all in accordance with the Specification, the terms and conditions of this Agreement and the Technical Agreement.

4.2 Nitec shall fully exercise all of its rights under its agreements with the Third-Party Service Providers to cause the Third Party Manufacturer and the Third Party Packager at all times to take reasonable precautions in order to ensure that Nitec is able to satisfy Mundipharma’s estimated requirements of the Finished Products for the next […] (as shown in the Firm Forecast pursuant to Clause 5). Without prejudice to Clause 4.3 below, Nitec shall promptly notify and keep Mundipharma informed about any manufacturing, packaging, testing or supply problems that may affect Nitec’s ability to fulfill Mundipharma’s orders for the Finished Products in a timely manner and use commercially reasonable efforts to resolve or work around such problems as soon as possible.

4.3 As soon as is reasonably practicable, Nitec shall identify, evaluate and select an organization capable of providing services identical in nature, scope and quality to the services provided by the Third-Party Manufacturer (the “Alternative Third-Party Manufacturer”) and shall submit that Alternative Third-Party Manufacturer to the Regulatory Authorities for their approval. If the Alternative Third-Party Manufacturer selected by Nitec is not approved by the Regulatory Authorities, Nitec shall use all reasonable endeavours to select an alternative manufacturer acceptable to the Regulatory Authorities as soon as reasonably practicable. Following approval from the relevant authorities, Nitec shall enter into a legally-binding agreement with the Alternative Third-Party Manufacturer requiring the Alternative Third-Party Manufacturer to supply such services to Nitec upon reasonable notice.

4.4 Nitec shall provide the Alternative Third-Party Manufacturer with (or procure that the Alternative Third Party Manufacturer be provided with) any and all information, data,
licences (including intellectual property licences), permissions, authorizations, resources, materials and a press-coater in advance as required by the Alternative Third-Party Manufacturer to provide the services under Clause 4.3.

4.5 In the event that Nitec (having complied with Clause 4.4) or its designee is unable or expects to be unable to supply the Products in accordance with this Agreement owing to the failure of the Third-Party Manufacturer to supply its services to Nitec for any reason, Nitec shall procure the provision of equivalent services from the Alternative Third-Party Manufacturer so as to enable Nitec to supply the Finished Products in accordance with this Agreement. Following Nitec’s procurement of equivalent services from the Alternative Third-Party Manufacturer, that Alternative Third-Party Manufacturer shall be deemed the Third-Party Manufacturer for the purposes of Clauses 4.1 and 4.2 above and Nitec shall enter into good-faith discussions with Mundipharma during which the parties shall endeavour to agree on appropriate additional measures to be made in order to secure the continued and successful Manufacture and supply of the Product. Unless the parties agree alternative measures within a reasonable period of time, Nitec shall re-execute its obligations under Clauses 4.3 and 4.4 above in order to secure a new Alternative Third-Party Manufacturer.

4.6 In the event that changes are requested or required to be made to the packaging for the Products, the following provisions shall apply:

4.6.1 Nitec shall use all of its contractual rights to cause the Third-Party Packager to use reasonable efforts to use up its existing stocks of packaging materials as expeditiously as possible to minimize any write-offs of surplus packaging materials.

4.6.2 If Mundipharma requests packaging changes and the timescale for implementation of the changes is such that the Third-Party Packager will not be able, despite its reasonable efforts, to use up its existing stocks of packaging materials before implementing the changes, Mundipharma shall reimburse Nitec for any costs it reasonably incurs as a result of the surplus packaging materials being required to be written off by the Third-Party Packager.

4.6.3 Subject to Clause 4.6.4, if packaging changes are required by the action or
pronouncement of a governmental or Regulatory Authority in the Territory, the parties shall bear equally the cost of writing off any surplus packaging materials.

4.6.4 Any and all fees (including, without limitation, fees imposed by a governmental or Regulatory Authority in the Territory) incurred by either party owing to a change in the packaging of the Finished Product directly or indirectly requested or required by a party to this Agreement shall be paid solely by that party. For the purposes of this clause, Nitec shall also be liable of any fees incurred owing to a change in packaging directly or indirectly requested or required by a licensee of Nitec.

4.7 Should Mundipharma wish Nitec to make use of a Mundipharma packaging site such that Mundipharma be the Third-Party Packager for the purposes of this Agreement, Mundipharma shall so notify Nitec and the parties shall enter into good faith negotiations to agree the terms of such collaboration.

5 Estimates and Orders

5.1 Within a reasonable period of time prior to the first Launch of the Product in the Territory, Mundipharma shall provide Nitec with an estimate of Mundipharma’s requirement for delivery of the Finished Products for the following [...***...] and shall [...***...] prior to each Calendar Quarter thereafter during the term of this Agreement provide a new [...***...] for the next period. The [...***...] shall be set out on a quarterly basis, such quarters being [...***...] estimating Mundipharma’s requirements of Product in the Territory, which forecasts shall be used by Nitec for planning purposes.

The estimates for the first [...***...] of the [...***...] shall be firm (the “Firm Forecast”) and the estimates for the remaining [...***...] of such forecast shall be tentative (the “Tentative Forecast”).

The submission of each [...***...] shall oblige Mundipharma to place a binding order for the quantity of Product set forth in Q1 in accordance with Clause 5.2. In

***Confidential Treatment Requested
Page 11 of 25
each [...***...] (other than the very first such forecast submitted under this Agreement), the quantity of Product set forth in Q1 shall be (i) within [...***...] of the quantities of the Product set out in Q2 in the [...***...] immediately preceding the most recent [...***...] and (ii) within [...***...] of the quantities set out in Q3 in the [...***...] immediately preceding the [...***...] referred to in (i).

This Clause 5.1 reflects the current terms of Nitec’s agreement with the Third Party Service Providers. If Nitec is able to modify the terms of its agreement with the Third Party Service Providers (and/or the Alternative Third Party Manufacturer, if applicable), the relevant time periods in this Clause 5.1 shall be shortened by an equivalent amount.

5.2 Mundipharma shall submit written orders seven (7) days prior to each Calendar Quarter in the amount of the Firm Forecast and, following written confirmation from Nitec, Nitec shall deliver such quantities of the Finished Products to Mundipharma by the date(s) specified in such orders, which shall be within [...***...] after placement of the binding order. If Mundipharma should require additional quantities of Finished Products upon short notice, Nitec shall use its reasonable endeavours to meet such requirements.

6 Prices and Payment

6.1 Mundipharma shall purchase the Finished Products exclusively from Nitec at a unit price of [...***...] of the Average Net Selling Price of the relevant strength of the Finished Products for the relevant country for the first [...***...] following first Launch of the Product in that country and at a price of [...***...] of the Average Net Selling Price of the relevant strength of Finished Products for the relevant country from [...***...] after first Launch of the Product in that country subject always to a minimum price of [...***...] per tablet (the “Payment Price”), inclusive of all packaging and materials, insurance, import taxes and transport costs for delivery to the Delivery Address. Such prices are exclusive of Value Added Tax which, if applicable, shall be paid at the prevailing rate.

6.2 The Average Net Selling Prices used to calculate the supply prices pursuant to Clause 6.1 for supplies of Product in each country for the initial period up until the first reconciliation

***Confidential Treatment Requested
Page 12 of 25
pursuant to Clause 6.3 following Launch in that country shall be based upon Mundipharma’s reasonable estimate of the Average Net Selling Prices for the first six (6) months following Launch in that country. For the following six (6) months and all six (6) month periods thereafter supply prices shall be calculated pursuant to Clause 6.1 based on the actual Average Net Selling Prices from the preceding six (6) month (or shorter initial) period for that country determined in accordance with Clause 6.3.

6.3 Within three (3) months of the end of the six (6) month period following first Launch of the Products in the Territory, and within three (3) months of every six (6) month period thereafter Mundipharma and its Associates shall calculate the actual Average Net Selling Prices for each and every country in the Territory in which the Product is Launched during all or part of the preceding six (6) months. Once the actual Average Net Selling Prices have been so calculated, Mundipharma shall notify the same to Nitec accompanied by documentation allowing Nitec to verify the calculation of the Average Net Selling Price. Mundipharma shall also calculate and notify to Nitec the supply prices it would have paid had the actual Average Net Selling Prices been used to calculate the supply prices in the preceding six (6) month period. Nitec shall then reimburse to Mundipharma any amounts actually paid by it in excess of the amounts it would have paid if the actual Average Net Selling Prices had been used to calculate the supply prices and Mundipharma shall pay to Nitec any shortfall in the amounts actually paid by Mundipharma versus the amounts it would have paid if the Average Net Selling Prices had been used to calculate the supply prices.

6.4 Payment against invoices submitted by Nitec for the Finished Products sold hereunder shall be made within […***…] of the date of Nitec’s invoice.

6.5 At the end of each successive twelve month period following the Launch of the Finished Product in a particular country (or group of countries) the Net Sales attained in that country (or group of countries) in that period shall be compared with the Sales Forecast for that country (or group of countries) and for that period. If the Net Sales attained exceed the forecast sales for that particular country (or group of countries) and for that period then Nitec shall promptly pay to Mundipharma a rebate equivalent […***…] of the Net Sales attained in that country (or group of countries) in that period for every […***…] that such Net Sales exceed the forecast sales for that particular country (or group of countries) for that period provided that

***Confidential Treatment Requested

Page 13 of 25
the maximum rebate payable under this clause shall be [...***...] of the Net Sales attained.

7 Storage and Delivery Arrangements

7.1 Nitec shall use all of its contractual rights to cause the Third-Party Service Providers to safely and correctly store all raw materials, excipients, intermediate products and preparations, and packaging material used in the Manufacture of the Finished Products whilst in the possession of the Third-Party Service Providers. Nitec shall sign (or will have signed) technical agreements with Third-Party Service Providers and the Alternative Third-Party Manufacturer to assure appropriate storage under cGMP.

7.2 Nitec shall deliver the Finished Products DDP (INCOTERMS 2000) to the Delivery Address. After delivery Mundipharma shall be responsible for the appropriate storage and shipment of Product and shall comply with the written shipment and storage conditions provided by Nitec in the Technical Agreement.

8 Manufacturing Processes

8.1 Nitec shall use all of its contractual rights to cause the Third-Party Service Providers at all times to operate in accordance with the criteria defined in the Technical Agreement and in compliance with the Registrations and cGMP and all other relevant regulations and legislation. Nitec shall regularly audit the Third-Party Service providers and endeavour to ensure that they receive regular inspections by the relevant Medicines Inspectorate to ensure that the Manufacturing processes are always in conformity with such requirements.

8.2 Any delivery of Finished Products to Mundipharma or its designee must first be inspected by the Third-Party Tester or Nitec and released by the Third-Party Tester or Nitec’s Qualified Person (the “QP”), or a person acting on their authority in the capacity of person responsible for quality assurance. This QP shall draw up a written report certifying the conformity of the delivery to the conditions specified in the Technical Agreement. Nitec shall use all of its contractual rights to ensure that the Third-Party Tester shall not, without the prior written consent of Nitec, assign the responsibility for inspection and release of the Finished Products to a third party.

***Confidential Treatment Requested
Page 14 of 25
8.3 The parties shall enter into the Technical Agreement as soon as practicable after the Commencement Date.

9 Quality of the Products, Inspection and Recalls

9.1 Nitec will use its reasonable endeavours to ensure that the Finished Products shall upon delivery to the Delivery Address be free of defects, of satisfactory quality and fit for the purpose for which they are intended to be used.

9.2 Mundipharma shall inspect the Finished Products delivered within five (5) working days of receiving delivery and shall inform the party effecting the delivery (with a copy to Nitec) within such five day period of any shortages or any defects visible on inspection. Should Mundipharma subsequently become aware of any latent defects, it shall inform Nitec within five (5) working days of becoming so aware of the same. Failure to comply with the duty to inform Nitec of any defects (including latent defects) within the timeframes provided in this Clause 9.2 shall result in Mundipharma forfeiting its right to a replacement of the relevant defective Finished Products under Clause 9.3 below.

9.3 In the event that any of the Finished Products are defective and Mundipharma informs Nitec within the timeframes provided in Clause 9.2, Nitec shall replace the defective Finished Products free of charge.

9.4 The Finished Products shall have a minimum shelf life of at least […] from the date of delivery to Mundipharma or its designee, such minimum shelf life to be increased from time to time based on the latest shelf life for the Products approved by the applicable Regulatory Authorities in the Territory.

9.5 In the event that a recall or a withdrawal of any of the Finished Products is required by any governmental or Regulatory Authority in the Territory, or if a recall or withdrawal of any of the Finished Products or suspension of sales of any of the Finished Products is reasonably deemed advisable by Mundipharma, then such recall, withdrawal or suspension, as applicable, shall be implemented and administered by Mundipharma (and/or its designee) in a
manner that is appropriate and reasonable under the circumstances and in conformity with any requests or orders of the applicable governmental or Regulatory Authority, as well as accepted trade practices. For the avoidance of doubt: Mundipharma shall at all times and before taking any action — unless action is required to be taken immediately without consultation to avoid material damage — inform Nitec about the underlying facts, the action Mundipharma intends to take as well the reasons for such actions and meet with the QP and/or Nitec’s management to discuss the most appropriate course of action. Details for such prior consultation shall be as set forth in the Technical Agreement.

9.6 The party responsible for the circumstances giving rise to the recall, withdrawal or suspension shall pay the administrative costs and expenses for the same. If neither party is at fault, both parties are at fault or fault cannot be determined, each party shall bear fifty percent (50%) of the administrative costs and expenses; provided that nothing herein shall limit Nitec’s indemnification obligations set forth in Clause 11.

10 Access and Right to Audit

10.1 Nitec shall procure that Mundipharma has access to Nitec, or whoever is responsible for the release of Product though its authorized qualified person, on reasonable prior notice at all reasonable times during normal working hours to inspect its quality control systems for the purpose of ensuring compliance with the Registrations, cGMP and any other relevant legislation. Details are set forth in the Technical Agreement.

10.2 Mundipharma shall procure that MICL shall maintain and procure the maintenance of accurate and up-to-date records and books of account showing all figures necessary to calculate the Average Net Selling Price for the Product since the Product was first Launched in each and every country of the Territory including but not limited to the quantity, description and value of the Product supplied in each country of the Territory during the previous six (6) years.

10.3 Mundipharma shall during business hours, on no less than fourteen (14) days’ written notice from Nitec and not more than once in any Calendar Year, procure that MICL makes available
for inspection the records and books referred to in Clause 10.2. Such inspection shall be undertaken by an independent auditor appointed by Nitec and reasonably acceptable to Mundipharma for the sole purpose of verifying whether Mundipharma has calculated correctly the Average Net Selling Prices for the Product in each country of the Territory in which the Product has been Launched in accordance with Clauses 6.2 and 6.3.

10.4 Nitec shall procure that any independent auditor shall maintain all information and materials received, directly or indirectly, by it from Mundipharma, MICL or their Associates in strict confidence and shall not use or disclose the same to any third party save for the sole purpose of reporting the results of the audit.

11 Indemnity

11.1 Nitec shall indemnify and hold harmless Mundipharma and its employees against legal liability for costs, claims and damages in respect of any death and personal injury, damage or loss which may be caused by the use of the Finished Products to the extent that any such death or personal injury, damage or loss is due to negligence or fault on the part of Nitec, its Associates or their sub-contractors or any of their respective employees. Nitec shall keep in force insurance to provide [...***...] cover in respect of the risks referred to in this clause.

11.2 Mundipharma shall indemnify and hold harmless Nitec and its employees against legal liability for costs, claims and damages in respect of any death and personal injury, damage or loss which may be caused by Mundipharma’s activities under this Agreement other than the use of the Finished Products to the extent that any such death or personal injury, damage or loss is due to negligence on the part of Mundipharma or its employees. Mundipharma shall keep in force insurance to provide [...***...] cover in respect of the risks referred to in this clause.

12 Confidentiality

***Confidential Treatment Requested
Page 17 of 25
12.1 Mundipharma will keep any information provided to it by Nitec in relation to Nitec or to the Products secret and confidential and procure that any consultant, adviser or Associate or other party to whom disclosure is made shall keep secret and confidential all such information save to the extent that the same:

(i) is in the public domain at the time of the disclosure or after the disclosure enters into the public domain by publication or otherwise through no fault of Mundipharma or its Associates; or

(ii) has already become or subsequently becomes available to Mundipharma or its Associates from any legitimate source without obligation of confidentiality or non-use or is disclosed to the Mundipharma or its Associates by a third party having lawful right to make such disclosure; or

(iii) was legitimately known to Mundipharma or its Associates prior to disclosure by Nitec.

12.2 Nitec and Mundipharma shall regard this Agreement and any arrangement between the parties in relation thereto as confidential and shall not disclose the same to any third party without the written consent of the other or as may be required by law.

13 **Force Majeure**

13.1 Neither party shall have any liability to the other in respect of any failure to carry out its obligations under this Agreement where such failure is due to an event of “force majeure”. For the purpose of this clause an event of force majeure means an event which by its nature could not have been foreseen by the party in default or, if it could have been foreseen, was not avoidable by the taking of reasonable commercial measures; and shall include but shall not be limited to acts of God, storms, flood, tempest, strikes or other industrial action (whether at the premises of the party in default or elsewhere), fire, riots, sabotage, war, civil commotion or unrest, failure of essential supplies of raw materials, energy or otherwise, interference by civil or military authorities.
In the event of force majeure, the affected party shall keep the other party fully informed and shall use its best efforts to comply to the fullest extent possible with its obligations pursuant to this Agreement and subject to the use of such best efforts the time for performance of the obligation(s) prevented by the force majeure event shall be extended by a period equivalent to that during which performance is prevented, provided that if the event of force majeure shall continue for more than [...***...], the other party shall be entitled to terminate this Agreement and/or any order made pursuant to this Agreement.

14 Assignment

Neither this Agreement nor any rights or obligations under this Agreement shall be assigned or encumbered in any way by a party, other than by assignment in whole or in part to an Associate, without the other party’s prior written consent, which shall not be unreasonably withheld or delayed, provided that the assigning party shall remain responsible for the receiving party’s full and timely performance of its obligations under this Agreement as of the assignment.

15 Termination

15.1 Either party shall be entitled to terminate this Agreement by written notice to the other if:

(i) that other party commits any continuing or material breach of any of the provisions of this Agreement and, in the case of such a breach (whether in respect of an individual Product or generally) which is capable of remedy, fails to remedy the same within [...***...] of receipt of written notice giving full particulars of the breach and the action required to remedy such breach (and if such notice relates to an individual Product or Finished Product then this Agreement shall be terminated in respect of that Product or Finished Product only);

(ii) an encumbrancer takes possession or a receiver is appointed over any of the property or assets of that other party;

(iii) that other party makes a voluntary arrangement with its creditors or becomes subject to an administration order;
that other party goes into liquidation (except for purposes of an amalgamation, reconstruction or other reorganisation and in such manner that Nitec resulting from the reorganisation effectively agrees to be bound by or to assume the obligations imposed on that other party under this Agreement); 

(v) that other party ceases, or threatens to cease, to carry on business; or 

(vi) a like event to one referred to in (ii) to (v) above occurs in any jurisdiction in the Territory.

15.2 Termination shall operate without prejudice to the rights and obligations of either party in relation to the other which have accrued prior to the date on which the term hereof expires and in the event of the termination of this Agreement if any order for Finished Products has already been despatched prior to the date of termination Mundipharma shall take delivery of and make payment for such Finished Products as herein provided but if any order has not been despatched prior to such date Nitec shall not be bound to despatch it.

15.3 Upon the termination of this Agreement for any reason, subject as otherwise provided in this Agreement and to any rights or obligations which have accrued prior to termination, neither party shall have any further obligation to the other under this Agreement provided however that the indemnity under Clause 11 and the obligation of confidentiality in Clause 12.1 shall continue after termination.

16 Notices

Any notice, request, approval or other document required or permitted to be given under this Agreement shall be in writing and shall be deemed to have been sufficiently given, and effective upon the date of dispatch, if delivered in person or by internationally recognized courier service or transmitted by facsimile, provided, that in the case of facsimile delivery, such notice shall be confirmed by certified or registered mail, return receipt requested, addressed to the addresses of the parties shown at the top of this Agreement or to such other address or addresses as may be specified from time to time by written notice.
Choice of Law
THE VALIDITY INTERPRETATION AND PERFORMANCE OF THIS AGREEMENT ITS AMENDMENTS AND EACH OF ITS PROVISIONS SHALL BE GOVERNED EXCLUSIVELY BY AND CONSTRUED IN ACCORDANCE WITH SWISS SUBSTANTIVE LAW.

Arbitration
ANY DISPUTE, CONTROVERSY OR CLAIM ARISING OUT OF OR IN RELATION TO THIS AGREEMENT, 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 ARBITRATION SHALL BE ZURICH. THE ARBITRAL PROCEEDINGS SHALL BE CONDUCTED IN ENGLISH.

General
19.1 Nothing in this Agreement shall create or be deemed to create a partnership, agency or joint venture between the parties.
19.2 This Agreement (and the other agreements referred to herein) contains the entire agreement between the parties with respect to the subject matter hereof and supersedes all previous agreements and understandings between the parties with respect thereto.
19.3 Any variation of this Agreement shall be effective only if agreed in writing and signed by duly authorised representatives of the parties.
19.4 The waiver of any right herein contained by either party shall not be construed as a waiver of
the same right at a future date or as a waiver of any other right herein contained.

19.5 Nothing in this Agreement is intended to nor shall it confer an enforceable benefit on any third party, except in respect of Associates of the parties as specifically set out herein.

19.6 All invoices to be issued by Nitec will be denominated in EURO (€) and any amounts referred to in this Agreement is intended to be denominated in EURO (€). In case any currency conversion is required the parties will refer to the average Euro foreign exchange reference rates, as published by the European Central Bank, for the previous [...***...].

19.20 This Agreement may be executed in any number of counterparts, each of which when executed and delivered shall constitute an original of this Agreement, but all the counterparts shall together constitute the same Agreement.

20 Invalidity and Severability

20.1 If any provision of this Agreement shall be found by any court or administrative body of competent jurisdiction to be invalid or unenforceable the invalidity or unenforceability of such provision shall not affect the other provisions of this Agreement and all provisions not affected by such invalidity or unenforceability shall remain in full force and effect.

20.2 The parties hereby agree to attempt to substitute for any invalid or unenforceable provision a valid or enforceable provision which achieves to the greatest extent possible the economic legal and commercial objectives of the invalid or unenforceable provisions.

21 Announcements

Unless required by law or by any applicable regulation, neither of the parties hereto shall make any press statement or other public announcement in connection with this Agreement without the prior agreement of the other both as to the timing and text of such statement or announcement.

*** Confidential Treatment Requested
Page 22 of 25
In WITNESS WHEREOF the PARTIES hereto have caused this Agreement to be executed in duplicate by their duly authorized officers as of the Commencement Date.

SIGNED for and on behalf of:

NITEC PHARMA AG
by: Anders Härfstrand
23/3/09

/s/ Anders Härfstrand
Anders Härfstrand
CEO
Print Name

SIGNED for and on behalf of:
NITEC PHARMA AG
by: Jochen Mattis
23/3/09

/s/ Jochen Mattis
Jochen Mattis
EVP Marketing & Sales, Business Development
Print Name

SIGNED for and on behalf of:
MUNDIPHARMA MEDICAL COMPANY

) /s/ Douglas Docherty
) Douglas Docherty
) GENERAL MANAGER
) Print Name
SCHEDULE 1

THE TERRITORY

Albania
Belgium
Bosnia-Herzegovina
Bulgaria
Croatia
Cyprus
Czech Republic
Denmark
Estonia
Finland
France
Greece
Hungary
Iceland
Italy
Israel
Latvia
Lithuania
Lichtenstein
Luxembourg
Macedonia
Malta
Montenegro
Netherlands
Norway
Poland
Portugal
Ireland
Romania
Serbia
Former Soviet Union Countries
Slovakia
Slovenia
Spain
Sweden
Switzerland
Turkey
UK
## SCHEDULE 2
### SALES FORECAST

**Table 1**

<table>
<thead>
<tr>
<th>Sales (€m)</th>
<th>Year 1</th>
<th>Year 2</th>
<th>Year 3</th>
<th>Year 4</th>
<th>Year 5</th>
<th>Year 6</th>
<th>Year 7</th>
<th>Year 8</th>
<th>Year 9</th>
<th>Years 10-15</th>
</tr>
</thead>
<tbody>
<tr>
<td>[…] *** …</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
DATED 24th March 2009

NITEC PHARMA AG

AND

MUNDIPHARMA INTERNATIONAL CORPORATION LIMITED

EXCLUSIVE DISTRIBUTION AGREEMENT
THIS AGREEMENT is made the 24th day of March 2009

BETWEEN:

(1) Nitec Pharma AG a company incorporated in accordance with the laws of Switzerland with its registered office at Kägenstrasse 17, CH-4153 Reinach, Switzerland (the “Principal”); and

(2) Mundipharma International Corporation Limited a company incorporated in accordance with the laws of Bermuda with its registered office at Canon’s Court, 22 Victoria Street, Hamilton, HM 12 Bermuda (the “Distributor”).

WHEREAS:

(A) The Principal wishes to register itself or to have the Product registered, marketed, sold and distributed by the Distributor in the Field in the Territory (the terms Product, Field and Territory are defined below), as set forth in further detail in this Agreement.

(B) The Distributor wishes to acquire an Exclusive (as defined below) licence to register itself or to have the Product registered by Principal, market, sell and distribute the Product in the Field in the Territory, as set forth in further detail in this Agreement.

(C) The Principal has agreed with the Distributor to grant Exclusive licences and rights as set out and upon and subject to the terms and conditions in this Agreement.

IT IS AGREED as follows:

1. DEFINITIONS AND INTERPRETATION

1.1 In this Agreement, the following terms shall have the following meanings:

“Associate” with respect to either one of the parties, any person, firm, trust, corporation or other entity or combination thereof of which directly or indirectly (a) controls said
party, (b) is controlled by said party, or (c) is under common control with said party; the terms “control” and “controlled” meaning ownership of fifty percent (50%) or more, including ownership by trusts with substantially the same beneficial interests, of the voting and equity rights of such person, firm, trust, corporation or other entity or combination thereof or the power to direct the management of such person, firm, trust, corporation or other entity or combination thereof;

“Calendar Quarter”

a calendar quarter ending on 31st March, 30th June, 30th September and 31st December in any Calendar Year;

“Calendar Year”

the twelve (12) month period from January 1st to December 31st;

“Commencement Date”

the date of execution of this Agreement;

“Commercially Reasonable Efforts”

the level of resources, effort and urgency to market and sell the Product in the Territory applied by the Distributor that is consistent with the Distributor’s practices in actively pursuing the marketing and sales of its other pharmaceutical products at a similar stage of product life to the Product and of similar market potential and profit potential, based on conditions then prevailing, taking into account, without limitation, competing products, market demand, proprietary position, safety, regulatory status, medical or scientific developments in the Indication, any adverse governmental interventions and any potential legal liability or other legal issues;
<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>“Development and Licence Agreement”</td>
<td>the Development and Licence Agreement dated 20 August 2004 entered into between Jagotec AG (“Jagotec”), SkyePharma AG (“SkyePharma”) and the Principal and all amendments thereto;</td>
</tr>
<tr>
<td>“EEA”</td>
<td>the European Economic Area as constituted from time to time;</td>
</tr>
<tr>
<td>“Exclusive”</td>
<td>exclusive to the Distributor and its Associates and excluding the Principal and all others;</td>
</tr>
<tr>
<td>“Field”</td>
<td>the treatment of human diseases;</td>
</tr>
<tr>
<td>“Force Majeure”</td>
<td>any act, event, non-occurrence, omission or accident beyond the reasonable control of the parties including (without limitation) strikes, lock-outs or other industrial action; civil commotion, riot, invasion, terrorist attack or threat of terrorist attack, war (whether declared or not) or threat or preparation for war; or fire, explosion, storm, flood, earthquake, subsidence, epidemic or other natural disaster;</td>
</tr>
<tr>
<td>“Guiding Principles”</td>
<td>the guiding principles of Drug Regulatory Affairs (DRA) activities between the Principal and the Distributor as set out in Schedule 6;</td>
</tr>
<tr>
<td>“Improvements”</td>
<td>any improvement, modification or enhancement (including new presentation(s)) of or to the Product or any of its components or constituent parts and any</td>
</tr>
</tbody>
</table>
related Principal Intellectual Property, which shall include (without limitation) all dosage strengths and line extensions to the Product and any improvement thereof;

“Independent Expert”

an independent third party with significant expertise and experience in the strategic marketing, pricing and reimbursement of pharmaceutical products similar to the Product in the Territory;

“Indication”

the treatment of moderate to severe active rheumatoid arthritis in adults particularly when accompanied by morning stiffness as described in the current SMPC documentation of Principal or any subsequent amendments thereto;

“Industry Association”

the European Federation of Pharmaceutical Industries and Associations (EFPIA);

“Initial Term”

fifteen (15) years from the date the Product is first Launched (as defined in Clause 5.8) in a country within the Territory;

“Intellectual Property”

patents, registered designs, unregistered rights in designs, trade marks, domain names, service marks, logos, trade names, copyright, utility models, rights in know-how and other intellectual property rights, in each case whether registered or unregistered and including applications for registration, and all rights or forms of protection having equivalent or similar effect anywhere in the world;

“Marketing Authorisation”

all necessary regulatory and governmental approvals by a Regulatory Authority or other governmental body required to develop, market, sell or otherwise deal in the
Product in the Indication in a particular country but excluding any Pricing Approval;

“Milestone Event”

each event identified in Schedule 5 which triggers a one-off Milestone Payment;

“Milestone Payment”

each one-off payment by the Distributor to the Principal identified in Schedule 5 which is triggered by a Milestone Event;

“Net Sales”

the gross amount invoiced by Distributor, its Associates or sub-licensees for sales of the Product in a particular country within the Territory, less deductions for:

(a) quantity and cash discounts and sales rebates actually given;
(b) freight, shipping insurance and other transportation expenses;
(c) sales, value-added, excise taxes, tariffs and duties, and other taxes directly related to the sale;

all to the extent that items (a), (b) and (c) are included in the gross invoice price and specified on the invoice (but not including taxes assessed against the income derived from such sale);

(d) returns (including withdrawals and recalls) other than returns by third parties to Distributor on account of lack of sufficient remaining shelf life; and

(e) amounts repaid, discounted or credited by reason of (i) retroactive price reductions, discounts and rebates, which are, in any case, imposed on Distributor or its Associates or sub-licensees.
by any governmental or non-governmental body with the authority to impose such price reductions, discounts or rebates, all to the extent reasonably demonstrated by Distributor by written records, or (ii) retroactive price reductions, discounts or rebates (not specified in an invoice) granted to a third party without the authority to impose such price reductions, discounts or rebates to the extent these are either pre-agreed with Principal or do not exceed [...] of the gross invoice price.

The transfer of Product by Distributor to an Associate or sub-licensee will not be deemed a sale;

“New Product”  
either (a) any corticoid product or formulation (other than an Improvement or the Product), whether alone or in combination for use in the treatment of inflammatory diseases; or (b) any product or formulation containing prednisone (other than an Improvement or the Product), whether alone or in combination used for the treatment of diseases other than inflammatory diseases, that is developed or acquired by the Principal or its Associates or to which the Principal or its Associates has or is granted a licence;

“North America and Asia Pacific Territory”  
the countries listed in Schedule 2;
“Pharmacovigilance Agreement” the pharmacovigilance agreement to be entered into between the parties within ninety (90) days of the signing of this Agreement;

“Pricing Approval” both pricing and (where approval is required for reimbursement) reimbursement approval as applied for by the Distributor and/or its Associates in any country of the Territory;

“Principal Intellectual Property” any and all Intellectual Property related to the Product and/or corticosteroids owned by, licensed to or under the control of the Principal including (without limitation) the Trade Mark (as defined in Clause 2.3) and the Intellectual Property licensed from SkyePharma plc and/or Jagotec AG regarding GeoClock Technology and its use with corticosteroids (the “SkyePharma Intellectual Property”), the patent applications [...***...] (the “Principal Patent Applications”) (and any patent applications, divisional patent applications, continuation applications, continuation in part applications, patents, supplementary protection certificates and extensions derived from or granted in relation to such Principal Patent Applications) insofar as they relate to corticosteroids, and any know-how relating to the Product including pharmacokinetic and clinical data, technical information, manufacturing formulae and methods and further techniques and designs of a confidential nature;

“Product” modified release formulation of prednisone 1mg, 2mg, 5mg in all pack presentations and including Improvements;
<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Proof of Concept</td>
<td>a concept for a New Product under development or acquired or licensed by the Principal or its Associates in respect of which either in vitro laboratory data, in vivo pharmacokinetic or clinical data or other appropriate tests reasonably confirm that such concept is feasible;</td>
</tr>
<tr>
<td>Reference Member State</td>
<td>Germany;</td>
</tr>
<tr>
<td>Regulatory Authority</td>
<td>any competent regulatory authority or other governmental body (for example, but not by way of limitation the EMEA or other national or international regulatory bodies) responsible for granting a Marketing Authorisation or Pricing Approval in the relevant country of the Territory;</td>
</tr>
<tr>
<td>Semi-Exclusive</td>
<td>excluding all others except the Principal or a licensee of the Principal;</td>
</tr>
<tr>
<td>Supply Agreement</td>
<td>the supply agreement entered into between the Principal and Mundipharma Medical Company signed on the same date as this Agreement;</td>
</tr>
<tr>
<td>Technical Agreement</td>
<td>the technical agreement to be entered into between Nitec Pharma GmbH, Mannheim/Germany and the Distributor or one of its Associates within ninety (90) days of the signing of this Agreement;</td>
</tr>
<tr>
<td>Territory</td>
<td>the countries listed in Schedule 1;</td>
</tr>
<tr>
<td>Term</td>
<td>the period of time specified by Clause 19.1;</td>
</tr>
</tbody>
</table>

1.2 Any reference in this Agreement to “writing” or cognate expressions includes a reference to facsimile transmission.

1.3 The headings in this Agreement are for convenience only and shall not affect its interpretation.
1.4 References to “persons” includes individuals, bodies corporate (wherever incorporated), unincorporated associations and partnerships.

1.5 Any reference to an enactment or statutory provision is a reference to it as it may have been, or may from time to time be amended, modified, consolidated or re-enacted.

2. APPOINTMENT OF DISTRIBUTOR

2.1 The Principal appoints the Distributor as an Exclusive distributor of the Product in the Territory, and the Distributor agrees to act in that capacity, in accordance with the provisions of this Agreement.

2.2 The rights provided to the Distributor under Clause 2.1 above shall include (without limitation) an Exclusive licence to:

2.2.1 register (where this Agreement allocates registration responsibility to Distributor), import, warehouse, promote, market, distribute, sell and use the Product in the Field in the Territory; and

2.2.2 use the Principal Intellectual Property if and to the extent that such use is required for Distributor to exercise its rights and to perform its obligations hereunder in the Field in the Territory, provided that the use of rights licensed to Principal by third parties is granted to Distributor only to the extent that Principal is under its licence agreement with the respective third party authorized to provide such rights to Distributor.

2.3 The rights provided to the Distributor under Clause 2.2.2 above shall include an Exclusive licence to use the Principal’s trade mark Lodotra™ (the “Trade Mark”) and any registered brand images related to the same and the right to apply for, acquire and/or register domain names specific to the countries comprised in the Territory that incorporate the Trade Mark in the Principal’s name and at its own cost, and any such domain names shall be owned by the Principal. If the Trade Mark is not acceptable to a Regulatory Authority then the Principal shall grant to the Distributor an Exclusive
licensure to use a suitable alternative trade mark owned by or under control of the Principal for the relevant country ("Alternative Trade Mark"), which shall then be deemed the Trade Mark in that country for the purposes of this Clause 2.3. If the Alternative Trade Mark is not acceptable to a Regulatory Authority then the Distributor may either:

2.3.1 require the Principal to grant to the Distributor an Exclusive licence to use any other trade mark owned by or under the control of Principal of the Distributor's choice that is acceptable to the relevant Regulatory Authority; or

2.3.2 choose to use any other trade mark for the Product (subject to the prior agreement of the Principal which shall not be unreasonably withheld or delayed) which is acceptable to the Principal and to the relevant Regulatory Authority provided that such trade mark shall be transferred to and owned by the Principal before any use thereof by the Distributor,

and such trade mark shall then be deemed the Trade Mark for the purposes of this Clause 2.3 in the relevant country.

2.4 The Distributor shall have the right to describe itself as an "Authorised Distributor" of the Principal for the Product in the Field in the Territory but shall not hold itself out as the Principal’s agent for sales of the Product or otherwise as being entitled to bind the Principal in any way.

2.5 Subject to Clause 2.7, the Distributor shall not put the Product on the market, sell, export or otherwise deal, whether directly or indirectly in the Product outside the Territory, and shall refer all enquiries for supply outside the Territory to the Principal.

2.6 Subject to Clause 2.7, the Principal shall not put the Product on the market, sell, export or otherwise deal, whether directly or indirectly in the Product within the Territory, and shall refer all enquiries for supply within the Territory to the Distributor.
2.7 The limitations set out in Clauses 2.5 and 2.6 above are subject always to the right of the Principal or the Distributor, as the case may be, to sell or deliver the Product to countries within the EEA and to Switzerland in response to a passive (i.e. unsolicited) purchase order.

2.8 The Distributor may not grant sub-licences of its rights or obligations under this Agreement to any third party without the prior written consent of the Principal, which consent shall not be unreasonably withheld or delayed; provided, however, that the Distributor may grant sub-licences of its rights under this Agreement to its Associates without the right of such Associates to further sub-license their rights or obligations to non-Associates, without the consent of the Principal.

3. RELATED AGREEMENTS

3.1 Both parties or their Associates shall enter (or shall have entered) into the Supply Agreement, the Technical Agreement and the Pharmacovigilance Agreement. The Principal shall maintain the Global Safety Database in accordance with (and as defined in) the Pharmacovigilance Agreement.

3.2 The Distributor shall have the right to register the licences granted to the Distributor and its Associates under Clause 2 with the patent offices and/or trade mark offices and/or other relevant authorities in each of the countries in the Territory and both parties shall execute such formal licences as the Distributor may reasonably consider necessary or reasonably appropriate for such registration(s), on condition that the parties shall use reasonable endeavours to ensure that, to the extent permitted by relevant authorities, this Agreement shall not form part of any public record. Any such formal licences so executed shall operate subject to the terms of this Agreement and, in the event of any conflict, the terms of this Agreement shall prevail wherever possible.

3.3 The Principal shall be permitted to enter into an agreement with SkyePharma under which the Principal Patent Applications (in so far as they are still in force) and any applications derived therefrom will be assigned to SkyePharma in return for which SkyePharma will contemporaneously assign all its rights in divisional applications (and any other derivative applications) to the Principal.
4. **OBLIGATIONS OF PRINCIPAL**

4.1 The Principal shall promptly procure (or have procured) original Marketing Authorisations using the EU DCP for the First Wave countries listed in Schedule 3 and shall use all reasonable endeavours to obtain original Marketing Authorisations using the EU DCP for the Second Wave countries listed in Schedule 3, and shall ensure and maintain the same for the Term. The Principal shall promptly transfer all original Marketing Authorisations obtained under this Clause 4.1 into the name of the Distributor or its Associate at the Principal’s expense.

4.2 The Principal may obtain a duplicate Marketing Authorisation in the name of the Principal for each original Marketing Authorisation obtained under Clause 4.1 above. The Principal shall ensure that each duplicate Marketing Authorisation obtained for a particular country will at all times be identical to the provisions of its corresponding original Marketing Authorisation. For the avoidance of doubt, any duplicate Marketing Authorisation corresponding to an original Marketing Authorisation transferred to the Distributor under Clause 4.1 shall remain in the name of the Principal.

4.3 Any and all original and duplicate Marketing Authorisations obtained by the Principal under Clauses 4.1 and 4.2 above (including, for the avoidance of doubt, any original Marketing Authorisations transferred to the Distributor) shall be obtained and maintained (including where the Distributor is required to maintain such Marketing Authorisations) at the sole expense of the Principal and, without prejudice to the generality of this Clause 4.3, the Principal shall prepare the necessary paperwork and pay any and all fees charged by Regulatory Authorities for any variations made to such Marketing Authorisations and any related costs and expenses including, without limitation, any related translation fees, except where such variations are requested by
the Distributor in accordance with the Guiding Principles in which case such costs and expenses shall be paid by the Distributor.

4.4 The Principal shall use commercially reasonable efforts to comply with the Guiding Principles. The Principal shall provide the Distributor with all documents and information including the EU-DCP dossier necessary to compile a dossier to obtain, maintain and update the Marketing Authorisations for the Product in each of the countries in the Territory not listed in Schedule 3 (the “Non-EU Countries”) and any other documentation or information that the Principal must provide to the Distributor in order to comply with the Guiding Principles.

4.5 The Principal shall furnish the Distributor or its Associate with supplies of the Product as set out in the Supply Agreement and the Technical Agreement.

4.6 The Principal shall share with the Distributor any and all market research study results and any other data procured or conducted by the Principal or made available to the Principal before or after the Commencement Date relating to the Product in the Field in the Territory and (provided and to the extent the Principal is legally entitled to do so) outside the Territory. The Distributor may use such results and data in relation to the Indication without limitation or obligations of confidence and may use any results and data not in relation to the Indication for its own internal purposes only unless the Principal provides consent to use otherwise.

4.7 The Principal shall promptly inform the Distributor in writing of any clinical studies with the Product in the Field conducted by or on behalf of the Principal or its Associates before or after the Commencement Date and will share any and all results related to the same with the Distributor. The Distributor may use such results and data in relation to the Indication without limitation or obligations of confidence and may use any results and data not in relation to the Indication for its own internal purposes only unless the Principal provides consent to use otherwise.

4.8 The Principal shall promptly inform the Distributor from time to time of any new data relating to the Product in the Field which shall include (without limitation) any data concerning marketing activities, new study results, market research data and copies of notices from and correspondence with Regulatory Authorities.
4.9 The Principal shall make available to the Distributor the consultancy services of [...] for a minimum of [...] following the Commencement Date to assist the Distributor in its planning and preparation for Launch, after which the parties may subsequently agree for further provision of consultancy services.

4.10 The Principal shall (and shall exercise any rights available to the Principal under the Development and Licence Agreement to require that SkyePharma plc shall), at the Principal’s cost and expense maintain the Principal Intellectual Property which shall include (without limitation) the prosecution, filing, maintenance and renewal of any patents and any reissues or re-examinations of any patents, including the payment of all related fees. Before the Commencement Date, the Principal shall have provided the Distributor with a reasonably detailed written report of all material matters concerning the maintenance of the Principal Intellectual Property. After the Commencement Date, upon written request by the Distributor (but not more often than on a quarterly basis), the Principal shall provide the Distributor with reasonably detailed written reports on material matters concerning the maintenance of the Principal Intellectual Property. The Principal shall (and shall exercise any rights available to the Principal under the Development and Licence Agreement to require that SkyePharma plc shall) promptly sign all documents and take all other actions as may be necessary or desirable to maintain the Principal Intellectual Property. The Principal shall not (and shall exercise any rights available to the Principal under the Development and Licence Agreement to require that SkyePharma plc shall not) intentionally abandon or fail to maintain the Principal Intellectual Property including (without limitation) failing to prosecute or failing to pay any fees relating to the maintenance of any patents. If the Principal abandons, declines to consent, or fails to assume responsibility for the maintenance of the Principal Intellectual Property, the Distributor shall have the right, at its sole cost and expense, to (i) take any steps to maintain the Principal Intellectual Property including (without limitation) the preparation, filing or prosecution of any patents, and (ii) request reimbursement of such costs and expenses from the Principal, and if the Principal refuses to reimburse, then the Distributor shall be entitled to credit such costs and expenses against any payments due to the Principal under this Agreement.

***Confidential Treatment Requested

Page 14 of 46
4.11 In the event of termination of this Agreement by the Distributor pursuant to Clause 19.4, the Principal shall (a) introduce the Distributor to its contacts at the third party manufacturer and shall facilitate the initiation of negotiations between the Distributor and the third party manufacturer with a view to those parties entering into a licence agreement under which the third party manufacturer will manufacture the Product and supply the same to the Distributor; and (b) use all reasonable endeavours to facilitate good-faith negotiations between the Distributor and Jagotec under which those parties will endeavour to agree that Jagotec will grant to the Distributor exclusive distribution and manufacture rights in relation to the Product under terms materially the same as provided to the Principal under the Development and Licence Agreement.

5. **OBLIGATIONS OF DISTRIBUTOR**

**Marketing Authorisation, Reimbursement and Price**

5.1 Following the transfer of any original Marketing Authorisation from the Principal to the Distributor under Clause 4.1 above, the Distributor shall use Commercially Reasonable Efforts to comply with the Guiding Principles in order to ensure that the Marketing Authorisation so transferred in the concerned member state is and remains in compliance with the Marketing Authorisation in the Reference Member State.

5.2 Following the Distributor’s receipt of all documents and information required to be provided by the Principal under Clause 4.4, the Distributor shall at its own expense and within a reasonable time apply for an original Marketing Authorisation including, if the Principal so elects in writing, a duplicate Marketing Authorisation at the expense of the Principal in each of the Non-EU Countries in the name of the Distributor and following successful grant shall ensure and maintain the same at the Distributor’s expense (in respect of the original Marketing Authorisations) and at the Principal’s expense (in respect of any duplicate Marketing Authorisations) for the Term, and at all times shall use Commercially Reasonable Efforts to comply with the Guiding Principles. The Distributor shall ensure that each duplicate Marketing Authorisation obtained for a
particular country will at all times be identical to the provisions of its corresponding original Marketing Authorisation. Upon written direction from the Principal, the Distributor shall promptly transfer any duplicate Marketing Authorisation directed by the Principal into the name of the Principal at the Principal’s expense. For the avoidance of doubt, the original Marketing Authorisation corresponding to any duplicate Marketing Authorisation so transferred shall remain in the name of the Distributor.

5.3 The Distributor shall prepare and prosecute, and pay any and all fees charged by Regulatory Authorities for, any variations made to any and all original Marketing Authorisations obtained by the Distributor under Clause 5.2 above and any related costs and expenses including, without limitation, any related translation fees, except where such variations are requested by the Principal or its Associates or licensees in which case such costs and expenses shall be paid by the Principal. The Principal shall pay any and all fees charged by Regulatory Authorities for any variations made to any and all duplicate Marketing Authorisations obtained by the Distributor under Clause 5.2 above and any related costs and expenses including, without limitation, any related translation fees, except where such variations are requested by the Distributor in which case such costs and expenses shall be paid by the Distributor.

5.4 The Distributor shall use Commercially Reasonable Efforts to obtain in each country in the Territory a price and reimbursement for the Product acceptable to the Distributor. If having used its Commercially Reasonable Efforts the Distributor does not obtain a price and reimbursement acceptable to the Distributor for an individual country the Distributor may decide (acting reasonably and having consulted and taken the views of the Principal into consideration) to Launch the Product in the relevant country without reimbursement.

5.5 The Distributor shall endeavour to agree with the Principal the order of countries in the Territory in which the Distributor will Launch the Product (the “Launch Sequence”).

5.6 The Distributor may elect to not Launch the Product in any country in the Territory for which the Distributor considers (acting reasonably) to do so would materially impair or
prevent the performance of its obligations under this Agreement or otherwise not be beneficial to or in the commercial interests of the parties, and
the Launch Sequence shall be deemed amended accordingly. The Distributor may only make such election on a country by country basis for
commercial reasons, which reasons may include (without limitation) the Distributor failing to obtain an acceptable price or reimbursement in the
relevant country.

5.7 If the Principal disagrees with the Distributor’s decision to not Launch the Product in a particular country under Clause 5.6 above, the parties shall
endeavour to negotiate in good faith to resolve the matter. If the parties are still in disagreement after fourteen (14) days from commencement of
such negotiations the parties shall endeavour to agree on the appointment of an Independent Expert to resolve the matter. If the parties are unable to
agree on such appointment then the parties shall ask the Industry Association to appoint the Independent Expert. Following appointment of the
Independent Expert, the parties shall endeavour to agree terms of reference to be provided to the Independent Expert which shall include (without
limitation) terms requiring the Independent Expert to take into account the impact of the Distributor’s decision in relation to the commercial
interests of both parties under this Agreement and in particular the commercial impact in relation to both the country in which the Distributor has
elected to not Launch and the impact in the remaining countries in the Territory. If the Independent Expert disagrees with the Distributor’s decision
to not Launch in a particular country, then the Principal shall have the right to make use of the duplicate Marketing Authorisation for the Product in
the relevant country using a trade mark other than the Trade Mark and shall have the right to market the Product in that country on a Semi-
Exclusive basis.

Launch

5.8 Within […] of the later of a Marketing Authorisation and Pricing Approval being obtained in a country within the Territory, the Distributor
shall launch the Product ("Launch") in that country provided that to do so would fit with the Launch Sequence. If a Launch at that time in that
country would not fit with the Launch Sequence, the Launch in that country shall be deferred until such time as would fit with

***Confidential Treatment Requested
Page 17 of 46
the Launch Sequence. Following Launch in each country in the Territory the Distributor shall:

5.8.1 use Commercially Reasonable Efforts to import, warehouse, promote, market, distribute and develop sales of the Product in the Territory and maintain a competent and adequate staff and distribution network in the area in which it is carrying out direct sales in the Territory to achieve this;

5.8.2 ensure that it conforms to governmental laws and regulations in the Territory applicable to the promotion of the Product;

5.8.3 arrange at its own expense and in its sole discretion sales promotion, advertising and marketing materials for the promotion and sale of the Product in the Territory;

5.8.4 only name the Principal in publicity or similar material where such material is approved in advance by the Principal (such approval not to be unreasonably withheld or delayed), not itself register any rights over the Product except any trade mark or domain names it is permitted to register in accordance with this Agreement and the Distributor further shall place on the Product such reasonable notices as the Principal may require; and

5.8.5 be responsible for negotiating and determining the terms of sale with its customers and shall maintain true and accurate records and accounts for all sales and related activities conducted in the Territory.

Minimum Sales

5.9 For each country or group of countries set out in Table 1 of Schedule 4 in which the Product is Launched, the Distributor shall attain [...] of the sales forecast for the Product for each of the five years following the Launch of the Product as listed in that table (the “Volume Target”). Any sales made by way of parallel

***Confidential Treatment Requested

Page 18 of 46
importation to a country shall be considered sales in the importing country for the purposes of this Clause 5.9.

5.10 For each country in which the Product is Launched, the Distributor shall promptly provide the Principal with a sales report on each quarter year following the date of Launch in the country showing volume sales and Net Sales for the country.

5.11 If the Distributor fails to meet the Volume Target for [...] following Launch of the Product in a country or group of countries (the “Period of Non-Performance”) then the Distributor shall make up the shortfall during the [...] period following the end of the Period of Non-Performance by paying to the Principal a sum equivalent to [...] of the Payment Price (as defined in and calculated in accordance with the Supply Agreement) multiplied by the number of tablets falling short of the Volume Target for the Period of Non-Performance for that country or group of countries. If the Distributor fails to make up the shortfall during the [...] then the Principal shall have the right to make use of a duplicate Marketing Authorisation for the Product in the country or group of countries in which the shortfall occurred using a trade mark other than the Trade Mark and shall have the right to market the Product in that country or group of countries on a Semi-Exclusive basis for the remainder of the Term. Clause 5.9 and this Clause 5.11 shall not apply to the extent that the Distributor is prevented from meeting the Volume Target due to:

5.11.1 any unreasonable act(s) or omission(s) of the Principal that materially reduces the commercial value and/or marketability of the Product in the Territory;

5.11.2 any actual or threatened infringement of third-party Intellectual Property rights by the Distributor’s development, manufacture, use, promotion, offering to sell, sale, distribution, importation or warehousing of the Product in accordance with this Agreement;

***Confidential Treatment Requested

Page 19 of 46
5.11.3 the Principal making variation(s) to any Marketing Authorisation held in its, its Associate’s or its licensee’s name that materially reduce(s) the commercial value and/or marketability of the Product; or
the Principal being in breach of its obligations under this Agreement or the Supply Agreement or if any shortfall is due to an event of Force Majeure or circumstances otherwise beyond the reasonable control of the Distributor (including without limitation the Principal’s failure to supply the Product).

5.12Clauses 5.9 and 5.11 above shall immediately cease to apply for a country of the Territory if: (a) a generic version of the Product exhibiting pharmacokinetic profiles that are bioequivalent to the Product is launched in that country of the Territory; or (b) in respect of a particular country if the Distributor’s rights in that country become Semi-Exclusive.

Right to Audit Minimum Sales

5.13 The Distributor shall maintain and shall procure the maintenance of accurate and up-to-date records and books of account showing the quantity, description and value of the Product supplied in each country of the Territory during the previous six (6) years.

5.14 The Distributor shall during business hours, on no less than fourteen (14) days’ written notice from the Principal and not more than once in any Calendar Year, make available for inspection the records and books referred to in Clause 5.13. Such inspection shall be undertaken by an independent auditor appointed by the Principal and reasonably acceptable to the Distributor for the purpose of verifying whether the Distributor has achieved the Volume Targets and whether the Distributor has made the correct payments for any shortfalls in Volume Targets as required by Clause 5.11.

5.15 The Principal shall procure that any independent auditor appointed under Clause 5.14 shall maintain all information and materials received, directly or indirectly, by it from the Distributor in strict confidence and shall not use or disclose the same to any third
party nor to the Principal save for the sole purpose of reporting the results of the audit pursuant to this Clause 5.

5.16 In the event that an auditor appointed pursuant to this Clause 5 concludes that there has been an underpayment or overpayment, the Principal shall deliver to the Distributor a copy of such auditor’s report. Any deficit payable by the Distributor or any excess refundable by the Principal shall be payable within [***] of the Distributor’s receipt of such report. The fees charged by such auditor shall be payable by the Principal, provided that if the audit reveals that payments due to the Principal for any year have been understated by more than [***] the fees charged by such auditor shall be payable by the Distributor.

Purchasing

5.17 The Distributor or its Associate shall purchase the Product exclusively from the Principal and pursuant to and in accordance with the Supply Agreement.

Miscellaneous

5.18 The Distributor shall share any and all market research data and results of mutually agreed clinical studies relating to the Product in the Field and the Territory with the Principal who may use such data without limitation for its own sole purposes outside of the Territory.

5.19 The Distributor shall promptly inform the Principal from time to time of any new data relating to the Product and the Field which shall include (without limitation) any data concerning marketing activities, new study results and market research data.

5.20 The Distributor shall obtain the prior written approval of the Principal (such approval not to be unreasonably withheld or delayed) for any and all clinical and regulatory activities relating to the Product undertaken by the Distributor which shall include (without limitation) any new clinical developments and regulatory filings.

***Confidential Treatment Requested

Page 21 of 46
6. MILESTONE PAYMENTS

6.1 Upon occurrence of each Milestone Event, the corresponding Milestone Payment shall become payable by the Distributor to the Principal.

6.2 Each Milestone Payment shall be due once only upon the first occurrence of the given Milestone Event.

6.3 Milestone Payments due under this Clause 6 shall be paid within […] of the date of occurrence of the Milestone Event.

7. COMMITTEE

7.1 The parties shall establish a joint product committee (“Committee”) consisting of four (4) individuals (“Committee Members”); two of whom shall be nominated by the Principal; and two of whom shall be nominated by the Distributor. The Committee Members may be replaced by notice to the other party and shall be appropriately qualified and experienced in order to make a meaningful contribution to Committee meetings.

7.2 The purpose of the Committee is to provide a forum for the parties to share such information and knowledge on the on-going development and commercialisation of the Product as is permitted by law including, but not limited to, monitoring progress on formulation, manufacturing scale up and validation, clinical studies, reviewing clinical trial and regulatory programmes, reviewing marketing and promotional plans, reviewing market conditions and discussing any regulatory, technical, quality assurance or safety issues in relation to the Product. The Committee shall conduct its discussions diligently and in good faith with a view to operating to the mutual benefit of the parties and in furtherance of the successful development and marketing of the Product.

7.3 The Committee shall meet as often as the Committee Members may determine, but in any event not less than twice per Calendar Year. The Committee may invite

***Confidential Treatment Requested

Page 22 of 46
individuals with special skills to attend such meetings where considered to be relevant and appropriate. The quorum for Committee meetings shall be two Committee Members, comprising one Committee Member from each party. Where any issues being considered by the Committee are deadlocked then:

7.3.1 the Principal shall have the casting vote in respect of:
   7.3.1.1 any matters relating to the registration of the Product in the countries of the Territory listed in Schedule 3; and
   7.3.1.2 any matters relating to the Manufacturing (as defined in the Supply Agreement) and packaging of the Product in the Territory,
   (provided that such casting vote shall not be used in a way which is materially detrimental to the rights granted to the Distributor in the Territory under this Agreement);

7.3.2 The Distributor shall have the casting vote in respect of any and all matters relating to:
   7.3.2.1 the registration of the Product in the Non-EU Countries; and
   7.3.2.2 pricing, reimbursement, formation of the Launch Sequence and commercialisation of the Product in all countries in the Territory,
   (provided that such casting vote shall not be used in a way which is materially detrimental to the rights of the Principal outside the Territory);
8. **NORTH AMERICA AND ASIA PACIFIC TERRITORY**
   For three (3) months following the Commencement Date, the Principal grants to the Distributor and its Associates an Exclusive right to enter into good faith negotiations with the Principal during which the parties shall endeavour to form an agreement for the Exclusive supply of the Product in the Field in the North America and Asia Pacific Territory.

9. **NEW PRODUCTS**
   If the Principal or its Associates during the Term shall develop themselves or through a third party one or more New Products, then the Principal shall notify the Distributor in writing when the New Product attains Proof of Concept, together with such data in the Principal’s possession relating to such New Product and shall grant to the Distributor and its Associates an Exclusive right to enter into good faith negotiations with the Principal for a period of […] for the Exclusive licence to that New Product in the Field in the Territory.

10. **NON-COMPETE**
    Except for the Product in accordance with this Agreement, the Distributor shall not, and shall cause its Associates not to, directly or indirectly, including through any acquisition, license, partnership, joint venture or distribution arrangement, promote, market, sell or distribute any modified release oral solid dosage form of a glucocorticoid product in any country of the Territory in the following indications: the Indication; Polymyalgia rheumatic (PMR), Asthma and any other indication for the Product that may be registered by the Principal.

11. **WARRANTIES**
   11.1 Distributor has conducted a due diligence review of Principal and third parties employed by Principal in connection with the activities contemplated hereunder and during such due diligence the Principal has answered all of the questions of Distributor and complied with all of the document requests of Distributor.
   11.2 The Principal represents and warrants that as at the Commencement Date:

***Confidential Treatment Requested***

Page 24 of 46
11.2.1 it has disclosed to the Distributor all material information known to it or its Associates concerning the safety or efficacy of the Product and it is not aware of any safety or efficacy concerns which are not reflected in the documentation made available in the course of Distributor’s due diligence review and/or summarized in the approval documentation submitted by Principal as part of its DCP efforts, including (without limitation) the SMPC and disclosed to the Distributor before the Commencement Date;

11.2.2 to its knowledge, there are no litigations, suits, actions, arbitration, judicial or legal, administrative or other proceedings or governmental investigations pending or threatened against the Principal or its Associates which would be reasonably expected to affect or restrict the activity of the Principal to consummate the transactions under this Agreement or to perform its obligations under this Agreement; nor to its knowledge are there any litigation, suits, actions, disputes, claims, arbitrations, judicial or legal, administrative or other proceedings or governmental investigations pending against the Principal or its Associates in connection with the Product or the Principal Intellectual Property;

11.2.3 the Principal Intellectual Property comprises all the Intellectual Property owned, licensed or controlled by the Principal and its Associates relating to the manufacture, use or sale of the Product in the Territory;

11.2.4 the Principal and its Associates have on the Commencement Date no knowledge that would cast doubt upon the validity or enforceability of the Principal Intellectual Property, or upon the freedom from any third party rights of the Product or its manufacture;

11.2.5 the Principal has disclosed to the Distributor all Intellectual Property rights licensed to the Principal by third parties and necessary for the Distributor to lawfully exercise its rights and perform its obligations under this Agreement and the Principal is lawfully authorized to sub-license the same in accordance with this Agreement;
11.2.6 the Principal has no knowledge that, with respect to the Product, it will infringe in any material respect any Intellectual Property of any third party in the Territory. The Principal has not received any notice that, with respect to the Product, it is violating or has violated the trademarks, patents, copyrights, inventions, trade secrets, proprietary information and technology, know-how, formulae, rights of publicity or other Intellectual Property rights of any third party;

11.2.7 neither the execution and delivery of this Agreement nor the performance hereof by the Principal requires the Principal to obtain any permits, authorisations or consents from any governmental authority (subject to obtaining all necessary approvals with respect to the manufacture, use or sale of the Product in the Territory) or from any other person, firm or corporation;

11.2.8 the Principal is not under any obligation to any person, contractual or otherwise, that is conflicting or inconsistent in any respect with the terms of this Agreement or that would impede the diligent and complete fulfilment of the Principal’s obligations under this Agreement in any material respect;

11.2.9 SkyePharma plc and/or Jagotec AG have represented to the Principal that the Principal is the exclusive licensee of SkyePharma plc’s and/or Jagotec AG’s proprietary rights regarding SkyePharma’s and/or Jagotec’s technology in connection with oral glucocorticoids and Principal has no reason to believe that SkyePharma and/or Jagotec have misrepresented the fact to Principal in this regard;

11.2.10 the Principal has full power and authority to lawfully enter into this Agreement and shall not breach any term of any agreement with any third party in doing so; and

11.2.11 the Principal is not in default of any provision of the Development and Licence Agreement and no event has occurred that with the giving of notice and/or passage of time would constitute a default under the same.

11.3 The Distributor represents and warrants that as at the Commencement Date:
11.3.1 to its knowledge, there are no claims or investigations pending or threatened against the Distributor or any of its Associates, relating to the matters contemplated under this Agreement which would materially adversely affect the Distributor’s ability to perform its obligations hereunder nor to its knowledge are there any other circumstances within its control which can reasonably be expected to prevent, delay or to have any other detrimental influence on the launch of the Product as contemplated hereunder; and

11.3.2 the Distributor is not under any obligation to any person, contractual or otherwise, that is conflicting or inconsistent in any respect with the terms of this Agreement or that would impede the diligent and complete fulfilment of the Distributor’s obligations under this Agreement in any material respect.

11.4 Except as provided herein, neither the Principal nor the Distributor makes any other warranties under this Agreement.

12. INDEMNIFICATION AND INSURANCE

12.1 Subject to mandatory law, neither party shall be liable or responsible for any exemplary, punitive, special, indirect, or incidental damages of any kind whether based on contract, tort (including negligence), strict liability, or any other theory or form of action even if a party has been advised of the possibility thereof. Subject to Clause 12.3, the Principal shall not be responsible for any damages, claims or losses which the Distributor or any third parties may suffer by reason of the Distributor’s actions or inactions regarding the Product (other than in accordance with this Agreement or as directed by the Principal).

12.2 The Distributor shall indemnify and hold the Principal, and any of its Associates, directors, representatives, officers, employees, shareholders, agents, successors, and/or assignees named in the proceeding, harmless against any and all losses, liabilities, costs and expenses (including attorneys fees), debts, or other obligations arising or resulting from or relating to claims, actions, suits, proceedings, demands, assessments, fines, penalties, judgments, damages, arbitral awards, and amounts paid in settlement of any of the foregoing claims, judgements, legal (including judicial, arbitral and administrative) proceedings and the like which claims, judgements, legal
proceedings and the like arise out of (a) any breach of the Distributor’s warranties, covenants or obligations contained in this Agreement or (b) the Distributor’s clinical investigation, or direct or indirect research or testing of the Product, or the marketing, sale or distribution of the Product, including but not limited to third party claims arising from those activities of the Distributor except in each case to the extent such claims are attributable to matters that are subject to indemnification by the Principal.

12.3 The Principal shall indemnify and hold the Distributor, and any of its Associates, directors, representatives, officers, employees, shareholders, agents, successors and/or assignees named in the proceeding, harmless against any and all losses, liabilities, costs and expenses (including attorneys fees), debts, or other obligations arising or resulting from or relating to claims, actions, suits, proceedings, demands, assessments, fines, penalties, judgements, damages, arbitral awards, and amounts paid in settlement of any of the foregoing claims, judgements, legal (including judicial, arbitral and administrative) proceedings and the like which claims, judgements, legal proceedings and the like arise out of (a) any breach of the Principal’s warranties, covenants or obligations contained in this Agreement or (b) any liability suffered from clinical trials conducted by the Principal prior to the Commencement Date, or (c) the Principal’s development activities, direct or indirect research or testing of the Product by the Principal, or the labelling, manufacturing or packaging of Product by or on behalf of the Principal, except in each case to the extent such claims are attributable to matters that are subject to indemnification by the Distributor.

12.4 The Principal and the Distributor shall notify each other promptly in writing upon learning of any claim, judgement, or legal proceeding or the like pertaining directly or indirectly to the Product or any indemnification obligation pursuant to this Clause 12. The party obliged to indemnify the other party under this Clause 12 (the “Indemnifying party”) shall be entitled to defend against any such claims, judgement and legal proceedings or the like with counsel selected by it and reasonably acceptable to the other party (the “Indemnified party”). In any event the Indemnifying party will inform the Indemnified party of all developments concerning the claim and shall not settle any claim without the Indemnified party’s prior written consent, which consent shall not be unreasonably withheld or delayed (and it is understood that the absence of a general liability release is a reasonable basis to withhold consent).
Indemnified party may seek to intervene in such proceedings at any time to protect its own interest and the attorneys of the Indemnifying party shall fully inform and cooperate with the attorneys of the Indemnified party. Termination shall not in any way affect the provisions of Clauses 12.2 and 12.3 hereof or relieve or discharge any Indemnifying party with respect thereto.

12.5 Each party shall, at its own expense, maintain with a reputable insurance company during the Term as well as [...] thereafter adequate product liability insurance or self-insurance arrangements against liability and claims of liability for personal injury, death or property damage relating to the Product, such coverage providing for a minimum aggregate liability of [...] The parties’ insurance policies or self-insurance arrangements shall provide cover to the extent required by local laws or pharmaceutical industry practice, whichever is broader and higher. Each party shall upon the request of the other party produce to such party a copy of the certificate of insurance and/or the policy of insurance together with a copy of the latest renewal receipt or evidence of self-insurance arrangement.

13. INFRINGEMENT OF THIRD PARTY RIGHTS

13.1 In the event of a party becoming aware that the exercise of either party’s rights and obligations pursuant to this Agreement are infringing or may infringe the rights of a third party, it will promptly so notify the other party and provide it with such details of the third party rights and the extent of the infringement as are known to it. The Principal shall be entitled at its discretion to contest any such third-party claim or proceedings or otherwise to take such steps to terminate such infringement or remedy the position and where necessary enter any third party licence agreement in respect of such infringement such that the Distributor will lawfully be able to practice the rights and licences granted hereunder. No later than [...] from becoming aware of or receiving notification in relation to such infringement of the rights of a third party, the Principal shall inform the Distributor whether it intends to contest the claim or take such other steps necessary to terminate any such infringement (including the negotiation of a third-party licence agreement) and if the Principal decides not to contest the claim or take other steps necessary to terminate such infringement the

***Confidential Treatment Requested

Page 29 of 46
Distributor may thereafter contest any such third-party claim or proceedings at the Distributor’s own cost. If the Principal does contest the claim or take steps to terminate such infringement it shall keep the Distributor informed of its actions in this regard. If the Principal enters into a third-party licence agreement any third party royalties or licence fees incurred in regard shall be borne solely by the Principal.

13.2 Where the Distributor has assumed responsibility for contesting any such third-party claim or proceedings in accordance with Clause 13.1 (including the negotiations of a third-party licence agreement), the Distributor shall keep the Principal reasonably informed of its actions in this regard and the Principal will provide the Distributor with all reasonable co-operation in connection with such actions. Without limitation this shall include the Distributor furnishing the Principal with drafts of any proposed third-party licence agreement and the Distributor seeking the Principal’s approval to the terms of any such agreement. The Distributor shall not enter into any such third-party licence agreement without the prior written approval of the Principal to such agreement (which shall not be unreasonably withheld or delayed). The Principal shall reimburse the Distributor’s reasonable costs in defending any such claim. Any third-party licence fees incurred in this regard shall be borne solely by the Principal.

13.3 Should there be any unresolved dispute between the parties as to the necessity for or the commercial terms of any third-party licence agreement, an expert (which for these purposes shall be deemed to be suitably expert senior patent counsel) shall be appointed to resolve the issue.

14. INFRINGEMENT OF PRINCIPAL INTELLECTUAL PROPERTY

14.1 In the event that the Distributor becomes aware of any actual or suspected infringement or misuse of Principal Intellectual Property or an attack on its validity in the Territory it shall promptly notify the Principal and provide it with all details thereof in its possession.

14.2 No later than [...] from becoming aware of or receiving notification of any actual or suspected infringement or misuse of the Principal Intellectual Property or an attack on its validity in the Territory, the

***Confidential Treatment Requested***

Page 30 of 46
Principal shall inform the Distributor whether it intends to institute proceedings against the infringer or attacker.

14.3 The Principal shall be entitled at its discretion to take such action to seek an abatement of such infringement, or to defend such attack on validity, as it sees fit, which may include the institution or defence of proceedings against the infringer or attacker. The Distributor shall provide all such assistance at the Principal’s cost and expense as the Principal may reasonably require in the prosecution or defence of any such proceedings.

14.4 Any damages, award or settlement monies actually received by the Principal in respect to such infringement and paid in compensation for sales lost by the Distributor shall belong to the Distributor, subject to the Principal deducting its reasonable costs in pursuing such infringement from such damages, award or settlement actually received, and to such payments by way of damages, award or settlement being treated as Net Sales and the Principal deducting therefrom any payment it would be due had the Distributor achieved such Net Sales. Any damages, award or settlement monies actually received by the Principal in respect to such infringement and not paid in compensation for sales lost by the Distributor shall belong to the Principal.

14.5 Should in accordance with Clause 14.2 the Principal notify the Distributor that it does not intend to pursue any such infringement or defend such attack, the Distributor may thereafter pursue such infringement or defend such attack. Any damages, award or settlement monies actually received by the Distributor in respect to such infringement and paid in compensation for sales lost by the Distributor shall belong to the Distributor, subject to such payments (net of reasonable costs of pursing the infringement) being treated as Net Sales and the Distributor paying to the Principal therefrom any payment which would be due to the Principal had the Distributor achieved such Net Sales. Any damages, award or settlement monies actually received by the Distributor in respect to such infringement and not paid in compensation for sales lost by the Distributor shall belong to the Principal, save that the Distributor shall be entitled to set off its reasonable costs in pursuing such infringement against such damages, award or settlement actually received by the Distributor.

15. COMMUNICATIONS
15.1 Neither Principal nor Distributor nor any of their Associates shall publicly disclose this Agreement in whole or in part, except to the extent required by law or with the consent of the other party, such consent not to be unreasonably withheld or delayed.

15.2 Neither party may issue any press release or public communication relating to the Agreement (including the parties’ discussions relating thereto) without prior written approval of the other which shall not be unreasonably withheld or delayed.

16. CONFIDENTIALITY

16.1 The parties and their Associates shall keep strictly confidential, other than disclosures to Associates for purposes related to this Agreement, and shall not publish or otherwise divulge or use for any purpose other than as contemplated by this Agreement:

16.1.1 any confidential information received from the other party to this Agreement except such which:

16.1.1.1 can be shown to have been known to the receiving party prior to disclosure by the providing party,

16.1.1.2 is now, or comes into, the public domain by publication or otherwise without the fault of the party seeking exemption from this Clause 16,

16.1.1.3 is made known to the receiving party from another source under no obligation to the providing party, or

16.1.1.4 is required by law, regulation or judicial order to be disclosed.

16.2 The obligations in this Clause 16 and Clause 19.9 below shall survive this Agreement.

16.3 Notwithstanding the foregoing, either party may disclose confidential information to governmental agencies to the extent that this is required or desirable in proceedings to obtain marketing approval for the Product, to outside consultants, advisers, agents, sub-licensees and to non-clinical and clinical investigators provided the relevant...
persons are subject to a secrecy agreement, which mirrors the secrecy agreement of this Clause 16.

16.4 Each of the parties to this Agreement shall be responsible for the imposition of the confidentiality provisions provided for in this Clause 16 upon its own staff, its Associates, consultants and others prior to disclosing any confidential information in relation to the Product or its mode of manufacture.

16.5 All written information in connection with the subject matter of this Agreement disclosed by either party prior hereto shall be deemed to be subject to this Clause 16.

17. GOVERNING LAW AND JURISDICTION
THE VALIDITY INTERPRETATION AND PERFORMANCE OF THIS AGREEMENT ITS AMENDMENTS AND EACH OF ITS PROVISIONS SHALL BE GOVERNE EXCLUSIVELY BY AND CONSTRUED IN ACCORDANCE WITH SWISS SUBSTANTIVE LAW.

18. ARBITRATION
ANY DISPUTE, CONTROVERSY OR CLAIM ARISING OUT OF OR IN RELATION TO THIS AGREEMENT, 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 ARBITRATION SHALL BE ZURICH. THE ARBITRAL PROCEEDINGS SHALL BE CONDUCTED IN ENGLISH.

19. TERM AND TERMINATION
19.1 This Agreement shall commence as of the Commencement Date and, unless sooner terminated as provided hereunder, shall continue in full force and effect for the Initial Term. Unless terminated by written notice to the other party served at least six months
prior to expiry, this Agreement shall be extended automatically for successive […] terms at the end of the Initial Term and any subsequent term.

19.2 In the event that a party materially fails to fulfil or breaches any material term or condition of this Agreement, and in case such failure or breach should if capable of remedy not be remedied by the party concerned or if not capable of remedy the party concerned should not have offered and paid full compensation therefor, in each case within […] days of written notice of such breach — which notice shall have to include specific reference to this section of this Agreement - given by the other party, the other party may terminate this Agreement with a further […] days written notice. Repeated breaches, that are not material individually, represent a material breach of this Agreement if they are material in the aggregate. Time periods under this section shall be suspended during negotiations among the parties until one party informs the other party that it does not wish such suspension to occur.

19.3 Following a valid termination by Principal or expiration of this Agreement and subject to Clause 19.6, the Distributor shall immediately cease all work or activities regarding the Product. Principal shall have the free right to use any data and information relating to the Product and registration applications or registrations in the Territory without any further obligation or liabilities to the Distributor.

19.4 Either party may terminate this Agreement at any time by giving notice in writing to the other party, which notice shall be effective upon dispatch, if the other party becomes insolvent, make an arrangement or composition for the benefit of creditors, or in the event that its assets become subject to a receivership, administration or liquidation or come under the control of a receiver, administrator or liquidator or other official appointed by a court or other governmental body or a like event should occur in any jurisdiction.

19.5 The Distributor shall have the continuing right to terminate this Agreement for a specific country immediately by written notice if the Marketing Authorisation for the Product is cancelled, withdrawn or suspended in any country of the Territory. The Distributor shall also have the right to terminate this Agreement if there is a material

***Confidential Treatment Requested

Page 34 of 46
risk that third parties may suffer personal injury or other damage in their using the Product in any country of the Territory.

19.6 Termination or expiration of this Agreement shall not release either party from the obligation to deliver or to make payment of all amounts then or thereafter due and payable. Both parties’ obligations pursuant to the secrecy provisions of this Agreement shall survive termination of this Agreement;

19.7 In the event of termination or expiration of this Agreement, the Principal may repurchase stocks of Product held by the Distributor at the prices the Distributor has bought the Product, if the Principal so chooses. Otherwise the Distributor is entitled to distribute the remaining stocks within […] within the Territory. All stocks remaining after this period of […] including but not limited to all Product which might be returned thereafter, have to be destroyed at the Distributor’s responsibility and costs.

19.8 Upon expiration of this Agreement or termination of this Agreement by the Principal under Clauses 19.2 or 19.4, the Distributor shall promptly transfer to Principal all Marketing Authorisations and related rights and documentation obtained by Distributor under or in connection with this Agreement or its activities hereunder.

19.9 Upon termination of this Agreement by the Distributor under Clause 19.4 above, the Distributor must along with its Associates immediately cease using the Principal Intellectual Property and immediately cease making, having made, using, selling, and importing the Product, and return to Principal, or deliver or destroy as Principal directs, the Product, all copies of the Principal Intellectual Property and any of Principal’s confidential information then in its possession, all of the foregoing to be returned, delivered or destroyed at Principal’s cost. Furthermore, all of the rights granted pursuant to Clause 2 shall revert to Principal, Distributor shall provide Principal with access to all data pertaining to the Product in the Territory developed pursuant to this Agreement and Distributor shall assign or cause to be assigned to Principal all filings pertaining to the Product (including any regulatory filings and certifications and trade mark applications, regulatory approvals and Pricing

***Confidential Treatment Requested

Page 35 of 46
Approvals that are in the name of Distributor or any of its Associates), with all of such rights, data, applications, filings and approvals to be delivered, assigned or transferred at Principal’s cost.

20. **MISCELLANEOUS**

20.1 Neither this Agreement nor any interest herein shall be assigned or encumbered in any way by a party other than by assignment in whole or in part to an Associate without the other party’s prior written consent, which shall not be unreasonably withheld or delayed, provided that the assigning party shall remain responsible in addition to the party receiving assignment for the full and timely performance of this Agreement.

20.2 Failure by either party to this Agreement to avail itself of one or more clauses of this Agreement shall in no event be construed as a waiver thereof.

20.3 Any notice, request, approval or other document required or permitted to be given under this Agreement shall be in writing and shall be deemed to have been sufficiently given, and effective upon the date of dispatch, if delivered in person or by internationally recognized courier service or transmitted by facsimile, provided, that in the case of facsimile delivery, such notice shall be confirmed by certified or registered mail, return receipt requested, addressed to the addresses of the parties shown at the top of this Agreement or to such other address or addresses as may be specified from time to time by written notice.

20.4 This Agreement constitutes the entire agreement between the parties with respect to the subject matter hereof, and supersedes any promise, agreement or consent on the Product made between the parties hereto by officers or employees of the parties before the execution of this Agreement. Existing confidentiality agreements in force among the parties shall remain in force with the proviso that in each case the stricter rule shall prevail.

20.5 The parties hereto shall not be liable for failure of or delay in performing any obligation under this Agreement, if such failure or delay is due to Force Majeure provided, however, that the party affected shall promptly notify the other party of the
Force Majeure and shall exert all reasonable efforts to eliminate, cure or overcome any such causes and to resume performance of its obligation with all possible speed.

20.6 If any provision of this Agreement is held to be invalid, illegal or unenforceable under applicable law the remaining provision shall continue to be in full force and effect. The parties undertake to replace the invalid provision or parts thereof by a new provision which will approximate as closely as possible the economic result intended by the parties.

20.7 Nothing in this Agreement shall create, or be deemed to create, a partnership, agency or joint venture between the parties.

20.8 No amendment, modification or addition hereto shall be binding unless set forth in writing. This includes amendments, modifications and additions to this Clause 20.

20.9 All invoices to be issued by Nitec and all payments to be made to Nitec will be denominated and made in EURO (€) and any amount referred to in this Agreement is intended to be denominated in EURO (€). In case any currency conversion is required the parties will refer to the average Euro foreign exchange reference rates, as published by the European Central Bank, for the previous 30 days.

20.10 This Agreement may be executed in any number of counterparts, each of which when executed and delivered shall constitute an original of this Agreement, but all the counterparts shall together constitute the same Agreement.

In WITNESS WHEREOF the PARTIES hereto have caused this Agreement to be executed in duplicate by their duly authorized officers as of the Commencement Date.

SIGNED for and on behalf of: )
NITEC PHARMA AG ) /s/ Anders Härfstrand
By: Anders Härfstrand ) Anders Härfstrand
23/3/09 ) CEO
SIGNED for and on behalf of: NITEC PHARMA AG
By: Jochen Mattis
23/3/09

/s/ Jochen Mattis
Jochen Mattis
EVP Marketing & Sales, Business Development

SIGNED for and on behalf of: MUNDIPHARMA INTERNATIONAL CORPORATION LIMITED
/s/ Douglas Docherty
DOUGLAS DOCHERTY
GENERAL MANAGER
SCHEDULE 1
THE TERRITORY

Albania
Belgium
Bosnia-Herzegovina
Bulgaria
Croatia
Cyprus
Czech Republic
Denmark
Estonia
Finland
France
Greece
Hungary
Iceland
Italy
Israel
Latvia
Lithuania
Lichtenstein
Luxembourg
Macedonia
Malta
Montenegro
Netherlands
Norway
Poland
Portugal
Ireland
Romania
Serbia
Former Soviet Union Countries
Slovakia
Slovenia
Spain
Sweden
Switzerland
Turkey
UK
USA
Canada
Mexico
Japan
Korea
China
India
Indonesia
Philippines
Malaysia
Singapore
Thailand
Australia
New Zealand
SCHEDULE 3
EU DCP COUNTRIES

First Wave countries:
Belgium
Denmark
Finland
France
Italy
Luxembourg
Netherlands
Norway
Poland
Portugal
Spain
Sweden
United Kingdom

Second Wave countries:
Bulgaria
Greece
Iceland
Ireland
Cyprus
Czech Republic
Estonia
Hungary
Latvia
Lithuania
Malta
Romania
Slovak Republic
Slovenia
### Table 1
**Volume Forecast**

<table>
<thead>
<tr>
<th>Volume tablets (m)</th>
<th>year 1</th>
<th>year 2</th>
<th>year 3</th>
<th>year 4</th>
<th>year 5</th>
</tr>
</thead>
<tbody>
<tr>
<td>...***...</td>
<td>...***...</td>
<td>...***...</td>
<td>...***...</td>
<td>...***...</td>
<td>...***...</td>
</tr>
<tr>
<td>...***...</td>
<td>...***...</td>
<td>...***...</td>
<td>...***...</td>
<td>...***...</td>
<td>...***...</td>
</tr>
<tr>
<td>...***...</td>
<td>...***...</td>
<td>...***...</td>
<td>...***...</td>
<td>...***...</td>
<td>...***...</td>
</tr>
<tr>
<td>...***...</td>
<td>...***...</td>
<td>...***...</td>
<td>...***...</td>
<td>...***...</td>
<td>...***...</td>
</tr>
<tr>
<td>...***...</td>
<td>...***...</td>
<td>...***...</td>
<td>...***...</td>
<td>...***...</td>
<td>...***...</td>
</tr>
</tbody>
</table>

***Confidential Treatment Requested***

### Table 2
**Sales Forecast**

<table>
<thead>
<tr>
<th>Sales (£m)</th>
<th>year 1</th>
<th>year 2</th>
<th>year 3</th>
<th>year 4</th>
<th>year 5</th>
<th>year 6</th>
<th>year 7</th>
<th>year 8</th>
<th>year 9</th>
<th>years 10-15</th>
</tr>
</thead>
<tbody>
<tr>
<td>...***...</td>
<td>...***...</td>
<td>...***...</td>
<td>...***...</td>
<td>...***...</td>
<td>...***...</td>
<td>...***...</td>
<td>...***...</td>
<td>...***...</td>
<td>...***...</td>
<td>...***...</td>
</tr>
<tr>
<td>...***...</td>
<td>...***...</td>
<td>...***...</td>
<td>...***...</td>
<td>...***...</td>
<td>...***...</td>
<td>...***...</td>
<td>...***...</td>
<td>...***...</td>
<td>...***...</td>
<td>...***...</td>
</tr>
<tr>
<td>...***...</td>
<td>...***...</td>
<td>...***...</td>
<td>...***...</td>
<td>...***...</td>
<td>...***...</td>
<td>...***...</td>
<td>...***...</td>
<td>...***...</td>
<td>...***...</td>
<td>...***...</td>
</tr>
<tr>
<td>...***...</td>
<td>...***...</td>
<td>...***...</td>
<td>...***...</td>
<td>...***...</td>
<td>...***...</td>
<td>...***...</td>
<td>...***...</td>
<td>...***...</td>
<td>...***...</td>
<td>...***...</td>
</tr>
<tr>
<td>...***...</td>
<td>...***...</td>
<td>...***...</td>
<td>...***...</td>
<td>...***...</td>
<td>...***...</td>
<td>...***...</td>
<td>...***...</td>
<td>...***...</td>
<td>...***...</td>
<td>...***...</td>
</tr>
</tbody>
</table>

***Confidential Treatment Requested***

Page 42 of 46
### SCHEDULE 5

**MILESTONE PAYMENTS**

<table>
<thead>
<tr>
<th>Milestone Event</th>
<th>Milestone Payment</th>
</tr>
</thead>
<tbody>
<tr>
<td>[...***...]</td>
<td>[...***...]</td>
</tr>
<tr>
<td>[...***...]</td>
<td>[...***...]</td>
</tr>
<tr>
<td>[...***...]</td>
<td>[...***...]</td>
</tr>
<tr>
<td>[...***...]</td>
<td>[...***...]</td>
</tr>
<tr>
<td>[...***...]</td>
<td>[...***...]</td>
</tr>
<tr>
<td>[...***...]</td>
<td>[...***...]</td>
</tr>
<tr>
<td>[...***...]</td>
<td>[...***...]</td>
</tr>
<tr>
<td>[...***...]</td>
<td>[...***...]</td>
</tr>
<tr>
<td>[...***...]</td>
<td>[...***...]</td>
</tr>
<tr>
<td>[...***...]</td>
<td>[...***...]</td>
</tr>
</tbody>
</table>

***Confidential Treatment Requested***
SCHEDULE 6

GUIDING PRINCIPLES OF REGULATORY AFFAIRS

These Guiding Principles establish the rules of co-operation regarding the Drug Regulatory Affairs (“DRA”) of Principal and Distributor. They do not change the local legal responsibilities of the Marketing Authorisation Holders.

1. Principal and Distributor shall nominate one DRA contact person to handle their respective DRA activities (hereinafter referred to as “DRA Principal” and “DRA Distributor”).

2. DRA Principal shall make the current EU CTD file, documents and information directly available to DRA Distributor.

3. Principal shall be the Marketing Authorisation Holder (“MAH”) in the Reference Member State and shall maintain the same for the Term. All EU DCP procedures shall be co-ordinated by DRA Principal and supported by DRA Distributor as best as reasonably possible.

4. After the transfer of any national EU Marketing Authorisation from the Principal to the Distributor under Clause 4.1, DRA Distributor shall require the written approval from DRA Principal (subject to paragraph 11 below) on any changes to the dossiers and documents before submission to the Regulatory Authorities. DRA Principal shall take into account all commercial considerations as Distributor may submit to Principal in deciding whether to provide such approval.

5. DRA Principal shall provide DRA Distributor with all documents and information necessary for DRA Distributor to compile, obtain, maintain, update, transfer or withdraw the Marketing Authorisations for the Product in the Non-EU Countries in a format that complies with the local authorities’ requirements.

6. The responsibility for the technical and scientific content of the dossiers and documents lies with the Principal through DRA Principal.

7. The prior written consent of DRA Principal (subject to paragraph 11 below) is required before any regulatory activities, e.g. variations, updates, withdrawals, or transfers to a third party, on existing, or pending MAs are undertaken by DRA Distributor. DRA Principal shall take into account all commercial considerations as Distributor may submit to Principal in deciding whether to provide such consent.
8. DRA Distributor shall inform DRA Principal about the submission date at the earliest opportunity and shall provide copies of all relevant correspondence with the Regulatory Authorities as well as their English translation.

9. DRA Distributor shall keep DRA Principal informed of relevant changes to local legislation or guidelines of which it is aware to promote a good flow of regulatory intelligence.

10. Communication between DRA Principal and DRA Distributor and exchange of dossiers or documents will preferably be made by electronic media.

11. Any variation that either Principal or Distributor wishes to make to any Marketing Authorisation (including that in the Reference Member State) shall be first referred to the Committee by the DRA Principal or DRA Distributor as appropriate and the Committee shall decide whether to proceed with such variation.
This Technical Transfer Agreement (together with the Schedules hereto, this “Agreement”) is entered into as of November 9, 2009 (the “Effective Date”) by and between SANOFI-AVENTIS U.S. LLC, a limited liability company duly organized and existing under the laws of the State of Delaware with offices at 55 Corporate Drive, Bridgewater, New Jersey 08807 (“sanofi-aventis US”) and HORIZON THERAPEUTICS, INC., a corporation with offices at 1033 Skokie Boulevard, Suite 355, Northbrook, Illinois 60062 (“Horizon”). Horizon and sanofi-aventis US may be referred to herein individually as a “Party” and collectively as the “Parties”

WHEREAS, sanofi-aventis US is engaged in the manufacture, marketing, sales and distribution of pharmaceutical products and operates directly or through one or more Affiliates certain manufacturing or packaging facilities located in Laval Quebec, St Louis MO and Compiegne France (the “Facilities”); and

WHEREAS, Horizon is engaged in the development of pharmaceutical products and desires to have sanofi-aventis US or an Affiliate designated by sanofi-aventis US undertake the technical transfer of HZT-501 tablets (the “Product”), and confirms Horizon’s intent to engage sanofi-aventis US to undertake, whether directly or through one or more designated Affiliates, exclusive commercial supply of the Product under an agreement (the “Commercial MSA”) to be negotiated in good faith between the Parties.

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

1. **DEFINITIONS**

1.1 “Affiliate” shall mean, with respect to either Party, any corporation, partnership or other entity controlled by, controlling or under common control with, such Party, with “control” meaning direct or indirect beneficial ownership of more than 50% of the voting power of, or more than 50% ownership interest in, such corporation, partnership or other entity. More specifically with respect to sanofi-aventis US, Affiliate refers to legal entities controlled by, controlling or under common control with sanofi-aventis US that own or operate the Facilities.
1.2 “Certificate of Analysis” shall mean a document signed by an authorized representative of a Facility, certifying the specifications for, and testing methods applied to, the Product, and the results thereof, and which includes the Product date of manufacture, date of release, and expiration date.

1.3 “Certificate of Manufacturing” shall mean a document, signed by an authorized representative of a Facility, certifying that the bulk Product being delivered to Horizon has been manufactured in conformity with cGMPs.

1.4 “cGMP” or “current Good Manufacturing Practice” shall mean current good manufacturing practices for medicinal products established by U.S. laws, rules and regulations (including 21 CFR Parts 210 and 211, as amended, and any successor regulations thereto, each as in effect from time to time).

1.5 “Facility Equipment” shall mean such equipment owned by a sanofi-aventis Affiliate used in the manufacture of the Product at the Facility.

1.6 “Horizon Equipment” shall mean the equipment listed in Exhibit 2, to be purchased by Horizon in order to allow, in combination with the Facility Equipment, the manufacture of the Product at the Facilities.

1.7 “Horizon Materials” shall mean Ibuprofen DC-85 and Famotidine, in each case meeting the specifications for such materials set forth in Schedule 1.7 hereto.

1.8 “HZT-501 IP” shall mean all Intellectual Property Rights made available to sanofi-aventis US or its affiliates by Horizon pursuant to this Agreement, including, without limitation, the Base Technology, Know-How, information, documents and tangible and intangible materials made available to sanofi-aventis US or an Affiliate designated by sanofi-aventis US by Horizon that are required for sanofi-aventis US or its designated Affiliate to perform sanofi-aventis US’s obligations under this Agreement.

1.9 “Information” shall mean, as the case may be, any and all information relating to the Product, manufacture of the Product or the business of either Party, owned and/or disclosed by one Party to the other in written, electronic or any other form. This includes, but is not limited to, Know-How, operational methods, formulae, samples, Specifications, analytical methods as well as any details of a commercial, technical, pharmaceutical, scientific and industrial nature whether disclosure of such information occurred prior to or after the Effective Date.

1.10 “Intellectual Property Rights” shall mean patents and patent applications, Know-How, utility models, trademarks, design rights, copyrights and any other proprietary rights.

1.11 “Know-How” shall mean all confidential and identified technical and scientific information and data, irrespective of its subject-matter and form, including, but not limited to, processes, formulae, designs and data as well as inventions and improvements whether patentable or not.

1.12 “SAUS IP” shall mean all Intellectual Property Rights provided by sanofi-aventis US or its affiliates pursuant to this Agreement, including, without limitation, the Base Technology, Know-How, information, documents and tangible and intangible materials provided by sanofi-aventis US or an Affiliate designated by sanofi-aventis US that are required for
2. TECHNICAL TRANSFER

2.1 Technical Transfer

Horizon shall provide to sanofi-aventis US or its designated Affiliate without any cost or expense to sanofi-aventis US and such Affiliate, all analytical, manufacturing, technical and other methods, processes, records and Know-How in Horizon’s control and necessary or useful to enable sanofi-aventis US or such Affiliate to produce the Product in conformance with the Product Specifications and current Good Manufacturing Practice, including, but not limited to, any manufacturing instructions, specifications (including, without limitation, Product Specifications, starting material specifications, and specifications for the Product or any intermediate version of the Product), development reports, production summaries, regulatory filings, validation reports, quality control and quality assurance documents, analytical methods and validation reports and any production or development batch records (the “Technical Transfer”). Should sanofi-aventis US or its designated Affiliate reasonably require any analytical, manufacturing, technical and other methods, processes, records and Know-How to perform its obligations under this Agreement, Horizon is responsible for obtaining such information at its own cost and providing it to sanofi-aventis US or such Affiliate as promptly as reasonably practicable.

A preliminary manufacturing process description is attached hereto as Exhibit 1. The Parties acknowledge that a final manufacturing process has not yet been developed. Accordingly, the Parties agree that, to the extent that the definitive manufacturing process or final Product Specifications have an adverse financial impact on the projected costs set forth in Section 4 hereto, including, without limitation, any supply price, each Party agrees to negotiate revisions to such costs in good faith. To the extent that, despite good faith efforts, the Parties cannot reach agreement on modified costs, either Party may terminate this agreement.

2.2 Analytical Method Transfer

The Parties shall cooperate to transfer any and all analytical methods for existing Product from Horizon to sanofi-aventis US or its designated Affiliate as promptly as practicable following the execution of this Agreement, but in no event later than 60 days prior to the date on which the manufacture of the validation batches is scheduled to commence. Sanofi-aventis US’ or its designated Affiliate’s costs in relation with any such transfer shall be deemed included in the expenditure set forth in Section A of Exhibit 3. Horizon shall bear its own costs in connection with said analytical transfer. For purposes of clarification, the costs outlined in Exhibit 3 are merely for transfer of any such analytical methodologies and do not include costs associated with method optimization.

2.3 Engineering Study Batches

Horizon shall provide sanofi-aventis US or its designated Affiliate, without any cost or expense to sanofi-aventis US or such Affiliate, all Horizon Materials necessary for the production of the engineering study batches. Sanofi-aventis US or an Affiliate designated by sanofi-aventis US will utilize its current suppliers for other raw materials and excipient unless otherwise required by
Horizon. Should there be a need for sanofi-aventis US or its designated Affiliate to qualify a new supplier (or new material), Horizon will bear the added cost involved with such activities. The manufacturing cost, cost of excipients and physical destruction of the Product resulting from the engineering study batches shall be deemed to be included in the expenditure set forth in Section A of Exhibit 3. The planned costs outlined in Exhibit 3 A, include one (1) core tablet engineering study and two (2) finished product engineering studies. It may be necessary, as determined by mutual agreement of the Parties, for sanofi-aventis US or its designated Affiliate to perform one or more additional engineering study batches to ensure successful validation or to address changes in the formulation of the Product. In such cases, Horizon shall supply free of charge to sanofi-aventis US or its designated Affiliate any Horizon Materials necessary for the production of such additional engineering study batches and shall pay sanofi-aventis US a sum of […] per additional core batch and […] per additional finished goods batch, unless the need for additional batches results from the gross negligence or willful misconduct of sanofi-aventis US or its designated Affiliate, in which case sanofi-aventis US or its designated Affiliate shall bear all costs associated with any such additional batch.

2.4 Installation Qualification
Sanofi-aventis US or its designated Affiliate shall be responsible for performing any installation qualification for the Facility Equipment and Horizon Equipment and for setting up protocols and reports thereof. Horizon shall provide sanofi-aventis US or its designated Affiliate, without cost or expense to sanofi-aventis US or such Affiliate, any Horizon Materials required by sanofi-aventis US or such designated Affiliate to conduct the installation qualification of the Facility Equipment and Horizon Equipment. Participation in factory acceptance testing, labor hours, any cost of excipients, and physical destruction of the materials resulting from installation qualification shall be deemed included in the expenditure set forth in Section A of Exhibit 3. Horizon will bear the cost of vendor visits, provision of the tablet press qualification package, and training performed by the vendors of the Horizon Equipment.

2.5 Validation Batches
The three (3) planned validation batches shall be manufactured under current Good Manufacturing Practices, sanofi-aventis US or its designated Affiliate local site requirements and all applicable laws rules and regulations. Horizon shall provide sanofi-aventis US or its designated Affiliate, without any cost or expense to sanofi-aventis US or such Affiliate, all required Horizon Materials and shall pay the price set forth in Section 4.2 for such validation batches. The batch size used to manufacture such validation batch shall be determined in good faith by the Parties. Sanofi-aventis US or its designated Affiliate shall provide a written report for the manufacturing of the validation batches to support Horizon’s preparation of the regulatory dossiers. Following approval of the NDA each Party understands and agrees that some of the Product manufactured in the validation activities and meeting all release specifications may be packaged and distributed for patient use as pharmaceutical samples. However, for any validation material deemed not saleable due to dating or hold time constraints, Horizon shall pay the price set forth in section 4.2.

2.6 Filing
Neither Sanofi-aventis US nor its designated Affiliate will be required to write any section of any regulatory dossier, but sanofi-aventis US and its designated Affiliate will provide reasonable support in the review of the Chemistry, Manufacturing and Controls (“CMC”) sections, and will use reasonable efforts to provide comments or supporting data on the CMC sections connected with

***Confidential Treatment Requested
drug product manufacturing and Facility Equipment used. Horizon represents that it will take into account all reasonable comments so provided by sanofi-aventis US or designated Affiliate.

2.7 **Need for Additional Batches**

Horizon shall provide sanofi-aventis US or its designated Affiliate, without any cost or expense to sanofi-aventis US or its designated Affiliate, all required Horizon Materials and shall pay the unit price set forth in Section 4.2 for any additional validation batches it may request from sanofi-aventis US or its designated Affiliate, unless the need for additional validation batches results from the gross negligence or willful misconduct of sanofi-aventis US and its designated Affiliate, in which case sanofi-aventis US shall bear all costs associated with the additional validation batches.

2.8 **Right to Audit**

Sanofi-aventis US or its designated Affiliates reserve the right to audit any supplier of Horizon Materials to ensure it is fulfilling its obligations under cGMP. Nothing in the foregoing sentence, however, discharges Horizon from its obligation, as auditor of record for any Horizon Materials, to audit such suppliers. Horizon will supply a copy of any audit reports for such suppliers to sanofi-aventis US or its designated Affiliates to the extent necessary to comply with applicable law or regulations.

2.9 **Documentation and Change Control**

A. Sanofi-aventis US or its designated Affiliate will develop and release master batch records in accordance with its existing standard operating procedures. Sanofi-aventis US and its designated Affiliate are responsible for its own batch numbering system. Batch numbers are assigned by sanofi-aventis US in accordance with its standard operating procedures and are unique to a given item.

B. Sanofi-aventis US or its designated Affiliate will draft engineering study protocols necessary to commence the transfer and scale-up activities. These protocols will follow sanofi-aventis US or its designated Affiliate internal cGMP formats to comply with the Facility’s local compliance requirements. Horizon shall participate in the review of the engineering study protocols and final reports for the development/scale up work up to validation batches. Such review and involvement should occur within reasonable review time to avoid delays of the project proceeding to next steps.

C. Once validation phase begins, sanofi-aventis US or its designated Affiliates will prepare validation master plan and individual validation protocols for each of the major manufacturing stages (granulation, core tablets, etc.) in accordance with sanofi-aventis US or its designated Affiliate internal cGMP formats to comply with the Facility’s local compliance requirements. Horizon can review such protocols and provide comments as desired.

D. **Certificate of Analysis / Certificate of Conformance**

Sanofi-aventis US or its designated Affiliate will furnish Horizon’s quality unit with a signed Certificate of Analysis and Certificate of Manufacturing upon shipment of each bulk batch of Product to Horizon.

E. **Change Control**
Sanofi-aventis US or its designated Affiliate will follow its internal procedures established to meet cGMP requirements. Changes to master batch record and specifications to the established manufacturing process (established via the technical transfer) shall be made in accordance with sanofi-aventis US’s or its designated Affiliate change control procedure. All change control documentation will be made available to Horizon upon request.

F. Electronic Records / Signatures
Sanofi-aventis US or its designated Affiliate shall comply with 21 CFR Part 11 requirements regarding the use of electronic records / signatures involved in the manufacture, packaging, and testing of the Product. Originals of all batch and laboratory documents (including raw data) will be retained by Sanofi-aventis for the duration of the labeled Product shelf life plus one year, but in all cases for not less than ten (10) years.

2.10 Quality Roles and Responsibilities
Horizon will be responsible for final release of validation batches for the market. Sanofi-aventis US or its designated Affiliate will be responsible for the quality review of the manufacturing batch records, testing of the Product, preparing a Certificate of Analysis and Certificate of Manufacturing following its internal standard format. The batch records will be available for review upon request.

2.11 Stability Program
Sanofi-aventis US or its designated Affiliate will perform stability study on the final validation batches on stability program following its internal established programs based on typical ICH stability guidelines for Zone I & II climate. The stability study will be carried out at 25C/60%RH through product expiry and under accelerated conditions at 40C/75%RH up to 6 months. Samples will be stored at 30C/65%RH but will not be tested unless required (subject to an additional fee). The program includes bulk tablets hold time study (up to 6 months), three validation batches carried out to a 5 year program, and one batch per year for routine study to support product shelf life confirmation. If there are requests to include additional conditions that are not typically required for the conditions mentioned above, Horizon will bear the added cost to support such additional program. Sanofi-aventis will develop stability protocol following its internal procedures. The protocol will be jointly reviewed and approved by Horizon Regulatory prior to commencing the validation stability study. Specific testing requirements and time-points will be provided in the stability protocol which should include all necessary regulatory requirements to register the Facility as the manufacturing site.

3. CAPITAL EXPENDITURE

3.1 Horizon Equipment
Horizon shall bear at its own cost and shall be responsible for procurement, installation, and qualification of the Horizon Equipment identified on Exhibit 2. The Horizon Equipment shall be delivered to the Facility and installed at the Facility at Horizon’s sole cost and expense. Estimated milestone dates in Exhibit 3b assume delivery of tablet tooling for core tablets in [***] and delivery of Kikusui tablet presses and tooling by [***].

In the event that additional equipment or modification of the Horizon Equipment is requested by Horizon, or necessary for manufacturing, Horizon will pay for the purchase, installation and qualification performed by sanofi-aventis US or its designated Affiliate in relation with such [***Confidential Treatment Requested]
additional equipment or modification. Upon payment by Horizon, any additional equipment shall be deemed Horizon Equipment.

Both Parties acknowledge that the Horizon Equipment will not fulfill the currently anticipated commercial demand for Products and that additional presses required for market supply will be purchased by Horizon.

3.2 Ownership of Equipment

Horizon owns all Horizon Equipment as listed in Exhibit 2 and any additional equipment purchased by Horizon pursuant to the second paragraph of Article 3.1. The Parties will take appropriate measures to ensure that any equipment owned by Horizon located at a sanofi-aventis US or its designated Affiliate facility will be clearly identified for future audit purposes, and Horizon shall have the right to secure possession of such equipment, at its sole cost and expense, at the expiry or termination of this Agreement in accordance with the terms and conditions set forth herein. Removal of any Horizon Equipment is conditional on Horizon bearing responsibility for the reasonable cost and expense of restoring any sanofi-aventis US or its designated Affiliate equipment affected by the installation, modification or use of the Horizon Equipment to the status of such equipment at the time immediately prior to the installation or modification of any Horizon Equipment (ordinary wear and tear excepted and not including any modification made by sanofi-aventis US or an Affiliate without the approval of Horizon). Sanofi-aventis US and its designated Affiliate will remove any Horizon Equipment and restore any sanofi-aventis US or Affiliate equipment, but any such removal or restoration may, at the option of Horizon, be witnessed by Horizon.

3.3 Maintenance of Equipment

Sanofi-aventis US and its designated Affiliates are responsible for the cost of routine maintenance of the Horizon Equipment while installed at the Facility. Horizon is responsible for the cost of replacement parts, third party service, and any installation costs, except where any replacement costs results from the gross negligence or willful misconduct of sanofi-aventis US or its designated Affiliate with respect to the Horizon Equipment, in which case sanofi-aventis US or its designated Affiliate shall bear said replacement cost.

3.4 Liability in relation to Equipment and Horizon Materials

Title to the Horizon Equipment and title to any Horizon Materials and any other consignment stock and risk of loss, damage to or destruction of such Horizon Equipment, Horizon Materials, or any other consignment stock remain with Horizon. Sanofi-aventis US or designated Affiliate will have no liability for loss, damage or destruction of the Horizon Equipment, Horizon Materials, or other consignment stock unless such loss, damage or destruction resulted from the gross negligence or willful misconduct of sanofi-aventis US or designated Affiliate. Horizon will maintain commercially reasonable levels of insurance on any Horizon Equipment to cover any potential liability associated therewith.

4. PAYMENT

4.1 Payments related operational expenditure


Section B of Exhibit 3 sets forth the schedule of milestones and the estimated dates at which and amounts that sanofi-aventis US shall invoice to Horizon in relation with the operational expenditure costs. Payment shall be made by Horizon in US dollars by transfer to the bank account indicated on the invoice within […] after the date of the invoice.

4.2 Payment for Validation Batches
In addition to the technical transfer costs outlined in Exhibit 3h, Horizon will pay sanofi-aventis US a selling price for any validation batch, whether manufactured pursuant to Section 2.5, 2.7 or otherwise, equal to either (i) […] per 1000 bulk tablets (ii) or […] for each 90 count container or […] for each 3 count container. Such purchase price will be due within […] of the later of (i) receipt of an invoice from sanofi-aventis US or (ii) issuance of a Certificate of Analysis for such validation batch.

4.3 Taxes
Amounts referred to under this Article 4 are exclusive of any taxes, duties, such as sales, export, import, value added tax, excise duty, which shall be additionally invoiced by sanofi-aventis US (other than taxes on sanofi-aventis US income) as appropriate.

5. INTELLECTUAL PROPERTY
5.1 Ownership of Rights
Each Party shall exclusively own and retain all right, title and interest in and to all Intellectual Property Rights, information, documents and tangible and intangible materials (with respect to each Party, its “Base Technology”) (i) owned by it as of the Effective Date, and (ii) conceived, reduced to practice, or created by such Party or its Affiliates or agents (including without limitation Intellectual Property Rights, information, documents and tangible and intangible materials based upon any background or preexisting technology of such Party) from and after the Effective Date. Each Party shall be solely responsible for the conduct and costs of filing, prosecution and maintenance of patents and patent applications on its own Intellectual Property Rights, information, documents and tangible and intangible materials. Except as expressly set forth herein, nothing in this Agreement grants either Party any right, title or interest in the Intellectual Property Rights of the other Party hereto. sanofi-aventis US represents that, to its knowledge, sanofi-aventis US does not currently have any right, title, or interest in any Intellectual Property Rights primarily relating to the Product. Each Party shall have the right to bring, defend, maintain and settle any suit, action or proceeding involving infringement of its Intellectual Property Rights, including without limitation its patent rights. Each Party shall pay all expenses incurred in connection with such suit, action or proceeding. Any amount recovered in any such suit, action or proceeding, whether by judgment or settlement shall be retained by the Party bringing the action.

Horizon represents and warrants that, to the best of Horizon’s knowledge, practice by sanofi aventis US or designated Affiliate of the HZT 501 IP that Horizon provides to sanofi-aventis US or designated Affiliate pursuant to this Agreement to perform the services to be performed by sanofi aventis in compliance with this Agreement do not and, will not infringe the Intellectual Property Rights of any third party.

Sanofi-aventis US represents and warrants that, to the best of sanofi-aventis US’s knowledge, practice by sanofi aventis US of the SAUS IP that sanofi-aventis US provides pursuant to this
Agreement to perform the services to be performed by sanofi aventis US in compliance with this Agreement do not and, will not infringe the Intellectual Property Rights of any third party.

5.2 **License from Horizon**

Horizon hereby grants to sanofi-aventis US and its Affiliates a royalty-free, non-exclusive, license during the Term to use and/or practice the HZT-501 IP solely to perform sanofi-aventis US’ or designated Affiliates’ obligations in accordance with the terms of this Agreement.

6. **INDEMNIFICATION**

6.1 **By sanofi-aventis US**

Sanofi-aventis US shall indemnify, defend and hold harmless Horizon and its officers, directors, agents, affiliates and their respective employees and representatives, from and against any and all loss, damage, claim, injury, cost or expenses, including reasonable attorneys’ fees and expenses of litigation, including any illness or personal injury, including death, or property damage (collectively, “Losses”) that arise out of or are attributable to (a) the failure of the Product to meet the Product Specifications set forth in Schedule 1.12 hereto at the time of delivery to Horizon; (b) any claim by a third party that the use by sanofi-aventis US of the SAUS IP to perform the obligations of sanofi-aventis US under this Agreement in compliance with the terms of this Agreement, including, without limitation, the manufacture or testing of the Products, infringes its intellectual property rights; (c) any breach of any representation, warranty or covenant made by sanofi-aventis US hereunder; or (d) the gross negligence or willful misconduct or wrongdoing of sanofi-aventis US or any person whose actions or omissions sanofi-aventis US is legally liable for, except, in each of (a), (b), (c), or (d) to the extent that such Losses are indemnified by Horizon pursuant to Section 6.2.

6.2 **By Horizon**

Horizon shall indemnify, defend and hold harmless sanofi-aventis US and its officers, directors, agents, affiliates and their respective employees and representatives from and against any and all Losses that arise out of or are attributable to (a) the failure of the Horizon Materials to meet the specifications for such materials set forth in Schedule 1.7 hereto at the time of delivery to sanofi-aventis US; (b) any claim by a third party that the use by sanofi-aventis US of the HZT-501 IP to perform the obligations of sanofi-aventis US under this Agreement in compliance with the terms of this Agreement or as directed by Horizon, including, without limitation, the manufacture or testing of the Products, infringes its intellectual property rights; (c) any breach of any representation, warranty or covenant made by Horizon hereunder; (d) any development, testing, use marketing, distribution, importation, sale or offer for sale of the Product by or on behalf of Horizon (including, without limitation, product liability claims) or (e) the gross negligence or willful misconduct or wrongdoing of Horizon or any person whose actions or omissions Horizon is legally liable for, except, in each of (a), (b), (c), (d), or (e) to the extent that such Losses are indemnified by sanofi-aventis US pursuant to Section 6.1.

If a party becomes aware of any claim or allegation by any third party that the performance of any services contemplated by this Agreement infringe such third party’s intellectual property rights, it shall promptly inform the other party, and the parties shall discuss such matter and a proposed resolution. Either party may, following such discussion, delay performance of its obligations.
hereunder pursuant to the force majeure provision in Section 9.1 pending satisfactory resolution of such matter or terminate this Agreement upon written notice to the other party. If the use of the HZT-501 IP in the manufacture or testing of the Product pursuant to this Agreement becomes, or in Horizon’s opinion is likely to become, the subject of an action by a third party alleging infringement of such third party’s intellectual property rights, Horizon may, at Horizon’s sole election and expense, either (a) procure, in form an manner satisfactory to sanofi-aventis US, the right to continue using the relevant the HZT-501 IP to perform its obligations under this Agreement without infringing such rights, or (b) replace or modify the HZT-IP or the process for manufacturing or testing the Product with non-infringing intellectual property. If the use of the SAUS IP in the manufacture or testing of the Product pursuant to this Agreement becomes, or in sanofi-aventis US’s opinion is likely to become, the subject of an action by a third party alleging infringement of such third party’s intellectual property rights, sanofi-aventis US may, at sanofi-aventis US’s sole election and expense, either (a) procure, in form an manner satisfactory to Horizon, the right to continue using the relevant the SAUS to permit sanofi-aventis US to perform its obligations under this Agreement without infringing such rights, or (b) replace or modify the SAUS IP with non-infringing intellectual property.

6.3 Third Party Claims

If any third party notifies a Party or any of its officers, agents or affiliates, or their respective employees or representatives (an “Indemnified Party”) with respect to any matter (a “Third Party Claim”) that may give rise to a claim against the other Party (the “Indemnifying Party”) under this Article, then the Indemnified Party will promptly give written notice to the Indemnifying Party; provided, however, that no delay on the part of the Indemnified Party in notifying the Indemnifying Party will relieve the Indemnifying Party from any obligation under this Article, except to the extent such delay actually prejudices the Indemnifying Party. The Indemnifying Party will be entitled to participate, at its sole expense, in the defense of any Third Party Claim that is the subject of a notice given by an Indemnified Party pursuant to this Section. In addition, the Indemnifying Party will have the right to defend the Indemnified Party against the Third Party Claim with counsel of its choice reasonably satisfactory to the Indemnified Party so long as (i) the Indemnifying Party gives written notice to the Indemnified Party of its assumption of responsibility for any Losses arising out of such Third Party Claim and its assumption of control and defense of the Third Party Claim within fifteen (15) days after the Indemnified Party has given notice of the Third Party Claim to the Indemnifying Party, (ii) the Indemnifying Party provides the Indemnified Party with evidence reasonably acceptable to the Indemnified Party that such Indemnifying Party has and will have adequate financial resources to defend against the Third Party Claim and fulfill its indemnification obligations hereunder, (iii) the Third Party Claim does not seek an injunction or other equitable relief against the Indemnified Party (provided, however, that to the extent that sanofi-aventis US has sought indemnification from Horizon regarding a Third Party Claim that the HZT-501 IP infringes the intellectual property rights of a third party, Horizon shall have the right to defend such Third Party Claim with counsel of its choice reasonably satisfactory to sanofi-aventis US and, provided further that to the extent that Horizon has sought indemnification from sanofi-aventis US regarding a Third Party Claim that the SAUS IP infringes the intellectual property rights of a third party, sanofi-aventis US shall have the right to defend such Third Party Claim with counsel of its choice reasonably satisfactory to Horizon), (iv) the Third Party Claim does not relate to or otherwise arise in connection with any criminal or regulatory enforcement action, and (v) the Indemnifying Party conducts the defense of the Third Party Claim actively and diligently. The Indemnified Party may retain separate co-counsel at its own cost and expense and participate in the defense of the Third Party Claim. The Indemnifying Party will not consent to the entry of any judgment or enter into any compromise or settlement with respect to the Third Party Claim without the prior written consent of the Indemnified Party unless such judgment, compromise or
settlement (i) provides for the payment by the Indemnifying Party of money as sole relief for the claimant, and (ii) results in the full and general release of the Indemnified Party from all liabilities arising or relating to, or in connection with, the Third Party Claim. The Indemnifying Party is expressly prohibited from consenting to the entry of any judgment or entering into any compromise or settlement that (i) involves a finding or admission of any violation of legal requirements or the rights of any Person by the Indemnified Party or (ii) grants an injunction or other equitable relief against the Indemnified Party, and any such purported consent, compromise or settlement entered into without the prior written consent of the Indemnified Party shall be null and void ab initio. The Indemnified Party may not consent to the entry of any judgment or enter into any compromise or settlement with respect to a Third Party Claim with respect to which indemnification is being sought hereunder without the prior written consent of the Indemnifying Party. If the Indemnifying Party does not assume the control and defense of a Third Party Claim under this Section, the Indemnified Party may defend such Third Party Claim and seek indemnification hereunder from the Indemnifying Party for any Losses associated therewith. The Indemnifying Party or the Indemnified Party, as the case may be, shall at all times use reasonable efforts to keep the other reasonably apprised of the status of the defense of any Third Party Claim and to cooperate in good faith with each other with respect to the defense of any such matter.

6.4 **Disclaimer of Warranties**

EXCEPT FOR THE EXPRESS REPRESENTATIONS AND WARRANTIES IN THIS AGREEMENT NEITHER PARTY MAKES ANY REPRESENTATIONS OR WARRANTIES OF ANY KIND, EXPRESS OR IMPLIED, INCLUDING IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR ANY OTHER MATTER RELATING TO THE PRODUCT, INFORMATION, MATERIALS OR EQUIPMENT PROVIDED UNDER THIS AGREEMENT.

6.5 **Damages**

NEITHER PARTY SHALL BE LIABLE TO THE OTHER UNDER THE TERMS OF THIS AGREEMENT OR OTHERWISE BY REASON OF ANY REPRESENTATION OR WARRANTY, CONDITION OR OTHER TERM OR ANY DUTY OF COMMON LAW, OR UNDER THE EXPRESS TERMS OF THIS AGREEMENT, FOR ANY CONSEQUENTIAL, SPECIAL OR INCIDENTAL OR PUNITIVE LOSS OR DAMAGE, WHETHER FOR LOSS OF CURRENT OR FUTURE PROFITS, LOSS OF ENTERPRISE VALUE OR OTHERWISE AND WHETHER OCCASIONED BY THE NEGLIGENCE OR INTENTIONAL ACTS OF THE RESPECTIVE PARTIES, THEIR EMPLOYEES OR AGENTS OR OTHERWISE, EXCEPT TO THE EXTENT SUCH CONSEQUENTIAL, SPECIAL OR INCIDENTAL OR PUNITIVE LOSS OR DAMAGE SHALL BE PAYABLE TO A THIRD PARTY; PROVIDED THAT, THE LIMITATIONS IN THIS SECTION 6.5 ON CLAIMS FOR CONSEQUENTIAL, SPECIAL OR INCIDENTAL DAMAGES (BUT NOT PUNITIVE DAMAGES) SHALL NOT APPLY TO LOSSES SUSTAINED AS A RESULT OF BREACH OF THE CONFIDENTIALITY PROVISIONS OF ARTICLE 7.

6.6 **Limitation**

IN NO EVENT SHALL SANOFI-AVENTIS US’ TOTAL AGGREGATE LIABILITY FOR ALL CLAIMS ARISING OUT OF OR RELATED TO THIS AGREEMENT EXCEED, ON A CUMULATIVE BASIS, […], REGARDLESS OF THE CAUSE OF ACTION UPON WHICH SUCH CLAIM IS BASED. NOTHING IN THIS AGREEMENT WILL PERMIT ANY PARTY TO RECOVER TWICE FOR THE SAME LOSS.
7. CONFIDENTIALITY

7.1 The Party receiving Information (the “Receiving Party”) from the other Party (the “Disclosing Party”) undertakes to treat the Information as strictly confidential and to use the Information in accordance with the terms and conditions set forth herein and will use such Information strictly to comply with its obligations set forth in this Agreement.

7.2 The Receiving Party undertakes to make the Information available only to its employees on a need-to-know basis and to take all steps necessary to protect the Information and to ensure that these employees shall not disclose or use at any time such Information in a manner which is not authorized under this Agreement. In no event shall the Receiving Party communicate the Information to third parties without the prior written approval of the Disclosing Party. Notwithstanding the foregoing, should the Receiving Party require the assistance of third parties, these third parties will be subject to substantially similar conditions of confidentiality as the Receiving Party.

In the case of a breach of these obligations by these third parties, the Receiving Party remains responsible for them towards the Disclosing Party.

7.3 The obligations of this Section 7 shall not apply however to Information that:

a. was known to the Receiving Party prior to its receipt from the Disclosing Party as documented by the Receiving Party’s written records, or,

b. was known to the public, or generally available to the public prior to its receipt from the Disclosing Party, or,

c. became known to the public or generally available to the public subsequent to its receipt from the Disclosing Party, through no breach of this Agreement by the Receiving Party, or,

d. was received by the Receiving Party, at any time, from a third party under no obligation of confidentiality to the Disclosing Party concerning such part of the Information, or,

e. was independently developed by the Receiving Party prior to disclosure or thereafter by the Disclosing Party, as documented by the Receiving Party’s written records.

7.4 For the purposes of this Agreement, no Information shall be deemed to be in the public domain or knowledge or in the possession or knowledge of the Receiving Party merely because such Information is embraced by more general information in the public domain or knowledge or in the possession or knowledge of the Receiving Party.

7.5 The Receiving Party may disclose the Information without violating its obligations under this Article 7, to the extent such disclosure is required by law or by court, provided that, in the event the Receiving Party is required to disclose Information, the Receiving Party shall provide prompt written notice to the Disclosing Party of such requirement so that the Disclosing Party may seek a protective order or other appropriate remedy. In the event no such protective order or other remedy is obtained, the Receiving Party agrees to disclose only that portion of Information it is legally required to disclose and to exercise all reasonable efforts to obtain confidential treatment for such Information.
7.6 Within thirty (30) days after the termination or expiration of this Agreement and upon the written request of the Disclosing Party, the Receiving Party shall return or destroy all such Information and copies thereof in its possession, except that each Party may keep one copy of such Information in its Legal Department confidential files solely for archival purposes and this copy will not be distributed in any manner other than as provided in this Agreement, without the express prior written permission of the Disclosing Party.

7.7 Each Party specifically recognizes that any breach by it of this Article 7 may cause irreparable injury to the other Party and that actual damages may be difficult to ascertain, and in any event, may be inadequate. Accordingly (and without limiting the availability of legal or equitable, including injunctive, remedies under any other provisions of this Agreement), each Party agrees that in the event of any such breach, notwithstanding the provisions of this Agreement, the other Party shall be entitled, by way of private litigation in the first instance, injunctive relief and such other legal and equitable remedies as may be available, without an obligation to post bond.

7.8 Except as otherwise required by law or by any securities exchange, regulatory or governmental body having jurisdiction over it, neither Party shall issue a press release or make any other public disclosure of the terms of this Agreement or regarding the manufacture of the Product without the prior approval of the press release or public disclosure by the other Party. Each Party shall submit any such press release or public disclosure to the other Party which the other Party shall acknowledge in writing.

7.9 This Article 7 shall survive the expiration or termination of this Agreement for a period of [...***…].

8. TERM AND TERMINATION

8.1 Term
This Agreement shall commence on the Effective Date and shall, unless earlier terminated in accordance with this Article 8, remain in effect until the earlier of the completion of the activities described in Article 2 of this Agreement (the “Term”) or December 31, 2011, unless extended by a mutual written agreement of both Parties.

8.2 Termination
Either Party may terminate this Agreement prior to the expiration of the Term upon [...***…] days written notice to the other Party (i) upon the bankruptcy, insolvency, dissolution or winding up of the other Party (other than dissolution or winding up for the purposes of reconstruction or amalgamation) or (ii) upon or after the breach of any material provision of this Agreement by the other Party if the breaching Party has not cured such breach, or if the Parties have not agreed upon a written plan for curing such breach, within [...***…] days after written notice thereof by the non-breaching Party, (iii) in case of termination by either Party of the negotiations regarding the Commercial MSA (except by reason of the execution and delivery of a definitive Commercial MSA), (iv) in case of expiration or termination by either Party of the Commercial MSA, or (v) pursuant to Section 2.1 hereof in accordance with the terms and conditions set forth herein and therein. In addition, either Party may terminate this Agreement as provided in the second paragraph of Section 6.2.

***Confidential Treatment Requested
8.3 **Duties Upon Termination**

Upon the termination or expiration of this Agreement, neither Party shall have any obligation whatsoever hereunder, except (i) for obligations that by their terms may be or are to be performed after the termination or expiration of this Agreement, and (ii) for any obligation or liability arising prior to such termination or expiration including but not limited to any remaining materials, work in process or finished goods.

Upon termination of this Agreement and if mandated, (i) each Party shall return Information received from the other Party (save for one copy the Receiving Party shall keep in confidence in its files for the sole purpose of identifying its obligations hereunder) or as needed to comply with applicable regulatory requirements, (ii) sanofi-aventis US or its designated Affiliate shall, at Horizon’s expense and request, make available to Horizon all property and materials in sanofi-aventis US’ and its designated Affiliate possession or control owned by and paid for by Horizon, and (iii) sanofi-aventis US and its designated Affiliate shall return to Horizon any unexpended funds delivered by Horizon to sanofi-aventis US or designated Affiliate pursuant to Section B of Exhibit 3, less any applicable development costs, including, without limitation, any out-of-pocket commitments or costs associated with early termination of any such commitments.

9. **MISCELLANEOUS**

9.1 **Force Majeure**

Neither Party shall be liable to the other for such Party’s failure to perform any provision of this Agreement if such failure or delay results from an act of God, war conditions, sabotage, governmental regulations or actions, embargo, fire, strike, failure of supply, or any other cause beyond the affected Party’s reasonable control; provided, however, that such performance shall be excused only to the extent of and during such disability. Upon the occurrence of any such event that results or will result in failure or delay to perform hereunder as described above, the Party whose performance is hereby prevented or delayed shall immediately give notice of such occurrence and the effect and/or anticipated effect of such occurrence on the performance of such Party to the other Party. The Party whose performance is so affected shall use commercially reasonable efforts to minimize disruptions in performance and to resume full performance hereunder as soon as possible under the circumstances.

9.2 **Severability**

If and to the extent that any provision (or any part thereof) of this Agreement is held to be invalid, illegal or unenforceable, such holding shall in no way affect the validity, legality or enforceability of the remainder of this Agreement. In the event any provision of this Agreement shall be held invalid, illegal or unenforceable, the Parties shall negotiate in good faith to substitute a valid, legal and enforceable provision which, insofar as practical, implements the purposes hereof.

9.3 **Assignment**

Neither Party may assign its interests, rights, duties or obligations under this Agreement to a third party without the prior written consent of the other Party, which shall not be unreasonably withheld. However, each Party may assign without the other Party’s consent its interests, rights, duties or obligations under this Agreement to (i) a successor in interest to all or substantially all of the business to which this Agreement relates, whether by merger, sale of stock, sale of assets or
otherwise, or (ii) any Affiliate, provided that such third party or Affiliate can reasonably assume all the obligations of that Party under this Agreement.

9.4 **Modifications and Amendments**
This Agreement shall not be modified or otherwise amended except pursuant to an instrument in writing executed and delivered by each of the Parties hereto.

9.5 **Governing Law**
This Agreement shall be governed by and shall be construed in accordance with the laws of New York.

9.6 **Waiver**
The failure of either Party to require the performance of any term of this Agreement, or the waiver of either Party of any breach of this Agreement, shall not prevent a subsequent exercise or enforcement of such terms or be deemed a waiver of any subsequent breach of the same or any other term of this Agreement.

9.7 **No Agency**
Except as expressly provided for herein, the Parties are not authorized to act as agents of one another as to any matter or make any representations to any third parties indicating or implying the existence or any such agency relationship.

9.8 **Headings**
The Section headings contained in this Agreement are for reference purposes only and shall not affect in any way the meaning and interpretation of this Agreement.

9.9 **Interpretive Rules**
In the event of an ambiguity or if a question of intent or interpretation arises, this Agreement shall be construed as if drafted jointly by the Parties, and no presumption or burden of proof shall arise favoring or disfavoring any Party by virtue of the authorship of any provisions of this Agreement. The definitions of the terms used in this Agreement shall apply equally to the singular and plural forms of the terms defined. Whenever the context may require, any pronoun shall include the corresponding masculine, feminine and neuter forms. References in this Agreement to a Party or other person or entity include their respective successors and permitted assigns. The words “include,” “includes” and “including” when used in this Agreement shall be deemed to be followed by the phrase “without limitation” unless such phrase otherwise appears.

9.10 **Counterparts and Facsimile**
This Agreement may be executed in two or more counterparts and via facsimile, each of which shall be deemed to be an original and all of which shall be deemed to constitute the same Agreement.

9.11 ** Entire Agreement**

15
This Agreement, together with its Exhibits, constitutes the entire agreement and understanding between the Parties and supersedes all previous understandings, agreements and representations between the Parties, written or oral, with respect to the subject matter hereof.
IN WITNESS hereof, the Parties hereto have caused this Agreement to be executed as of the date first written above by their duly authorized officers.

Executed in two copies, each Party receiving an original copy.

Horizon Therapeutics, Inc.

11-9-09

By: /s/ Timothy P. Walbert
Name: Timothy P. Walbert
Title: President & CEO

sanofi-aventis US. LLC

By: /s/ Osric Reavis
Name: Osric Reavis
Title: Vice President U.S. Industrial Affairs

By:
Name:
Title:
EXHIBIT 1

A—Bulk Manufacturing Process Description

B—Manufacturing Specifications:
Exhibit 1-A
HZT-501 MANUFACTURING FLOW DIAGRAM OF PROCESS

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

***Confidential Treatment Requested
EXHIBIT 2

Outline of capital expenditure and equipment ownership.

[***...]

[***...]

[***...]

[***...]

6

***Confidential Treatment Requested
EXHIBIT 3

A—Operational expenditures estimate

<table>
<thead>
<tr>
<th>Operational Expenditure Estimate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total OPEX</td>
</tr>
<tr>
<td>[…***…]</td>
</tr>
<tr>
<td>[…***…]</td>
</tr>
<tr>
<td>[…***…]</td>
</tr>
<tr>
<td>[…***…]</td>
</tr>
</tbody>
</table>

B—Invoicing Schedule

EXHIBIT 3(B)

<table>
<thead>
<tr>
<th>Milestone</th>
<th>Estimated Invoice Date</th>
<th>Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>[…***…]</td>
<td>[…***…]</td>
<td>[…***…]</td>
</tr>
<tr>
<td>[…***…]</td>
<td>[…***…]</td>
<td>[…***…]</td>
</tr>
<tr>
<td>[…***…]</td>
<td>[…***…]</td>
<td>[…***…]</td>
</tr>
<tr>
<td>[…***…]</td>
<td>[…***…]</td>
<td>[…***…]</td>
</tr>
<tr>
<td>[…***…]</td>
<td>[…***…]</td>
<td>[…***…]</td>
</tr>
<tr>
<td>[…***…]</td>
<td>[…***…]</td>
<td>[…***…]</td>
</tr>
<tr>
<td>[…***…]</td>
<td>[…***…]</td>
<td>[…***…]</td>
</tr>
<tr>
<td>[…***…]</td>
<td>[…***…]</td>
<td>[…***…]</td>
</tr>
</tbody>
</table>

6

***Confidential Treatment Requested
LEASE AGREEMENT
for rented commercial premises

Between

Alters- und Hinterbliebenen-Versorgungsstelle der Technischen Überwachungsvereine VVaG
Kurfürstenstraße 58
45138 Essen

- Lessor -

UST (turnover tax) ID: DE11 98 24807

and

Business name
Nitec Pharma GmbH

- Lessee -

UST (turnover tax) ID: 37009/52183

the following agreement will be concluded:
§ 1 - Leased Object

1.1 The Lessor is the owner of the property, Joseph-Meyer-Straße 13-15, 68167 Mannheim, Germany.

1.2 The Lessor shall lease office space totalling 171.18 sqm. on the 2nd floor of the building described above to the Lessee. This includes main floor space and ancillary space and the associated public thoroughfares and floor space occupied by technical and building service installations. The enclosed site plan is part of the Lease Agreement (Annex II).

1.3 If subsequent measurements of the rental space deviate from the floor space provided here, neither Party has the right to rescind this Agreement, to terminate this Agreement or to demand a change in rent. The floor space indicated is to be taken as the basis whenever the size of the rental space is referred to in the provisions of this Agreement.

1.4 The space is being rented for use as an office. Any changes in this type of use are only permissible upon obtaining written permission from the Lessor. In all cases, permission given by the Lessor shall be granted subject to first obtaining a required official permit to change the type of use, even if the Lessor does not remind the Lessee of the need to do this at that time. The Lessee must acquire this permit at his own expense and present it to the Lessor.

§ 2 - Use of Leased Object

2.1 The leased object shall be leased by the Lessee for the type of use specified in item 1.4.

2.2 The Lessor does not guarantee that the business the Lessee plans to conduct in the leased object is permissible according to public law. The Lessee must fulfill numerous criteria at his own expense in relation to the conduct of his business for the duration of lease. The Lessee must comply with requirements imposed by the trade supervisory office or other authorities and do so regarding space-related requirements as well. The validity of this Lease Agreement is not contingent on an official permit permitting the lessee’s business activities.

2.3 The Lessee undertakes to actively conduct his business and keep it open and operating in accordance with the type of business being conducted (contractual operation to use, open or operate) for the duration of this Agreement.

2.4 The Lessor shall not grant the Lessee any protection against competition.

Page 3 of the Lease Agreement of December 21, 2004
2.5 The Lessee shall ask the Lessor for information about the load limit of the ceilings and obtain the Lessor's written approval before setting up machines, heavy objects or other equipment in the rental space. The Lessee shall be liable for any damages that occur because of failure to comply with these provisions. If the Lessee's equipment as described above causes damage to the building (shaking, cracks, etc.) or disturbances or has detrimental effects (e.g., noise, dust, disturbing smells, etc.) for other lessees of the building, the Lessor may revoke his approval and demand that the Lessee refrain from these activities.

2.6 Lease of the object shall include the right of free access to the leased object.

§ 3 - Furnishing and Transfer of the Rental Space by the Lessor

3.1 The Lessee is aware of the current condition and layout of the leased object.

3.2 The leased object will be handed over to the Lessee by January 2005 at the latest. A record shall be made of the transfer.

§ 4 - Length of Lease and Termination

4.1 Tenancy shall begin on January 1, 2005, and terminate after 1.5 years on June 30, 2006. Section 568 of the German Civil Code (BGB) does not apply to the Contracting Parties once tenancy has been terminated.

4.2 Ordinary notice of termination shall be excluded for the duration of tenancy. The right of both Parties to immediate termination without notice for good cause shall remain unaffected. The right of the Lessor to effect immediate termination without notice applies particularly when:

a) the Lessee is behind by more than one month's rent or has not provided the security agreed to in the amount, period of time and means stipulated in the Agreement;

b) the Lessee makes structural changes to the leased object or to parts thereof without first obtaining the Lessor's permission or uses it for purposes other than those stipulated in the Agreement, in particular subletting it to third parties;

c) the Lessee ceases payment, it comes to legal or out-of-court settlement or bankruptcy proceedings regarding his assets or he is required to make an oath regarding his assets;
4.3 The Lessee has the option to extend the Lease Agreement by one, two or three years once the term of the Lease Agreement as specified under item 4.1 has expired. If the Lessee chooses to exercise this option, he shall notify the Lessor of this decision in writing 6 months prior to expiration of tenancy. The Agreement shall be terminated 6 months prior to the relevant date of expiration.

4.5 If the Lessee is a natural person, the right of early termination pursuant to section 569 of the German Civil Code (BGB) shall hereby be excluded.

§ 5 - Rent

5.1 Rent for the basic leasing period from January 1, 2005, until June 30, 2006, shall be calculated as follows:

<table>
<thead>
<tr>
<th>Description</th>
<th>X</th>
<th>171.18 sqm</th>
<th>[...***...]</th>
<th>[...***...]</th>
<th>[...***...]</th>
<th>[...***...]</th>
<th>[...***...]</th>
<th>[...***...]</th>
<th>[...***...]</th>
<th>[...***...]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Office space</td>
<td></td>
<td>171.18 sqm</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3 underground parking spaces</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Advance payment of service charges</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Subtotal, net

16% value-added tax

Gross total

If the Lessee decides to exercise the option stipulated in item 4 for one year, the rent in the amount of [...***...] shall remain the same. For a two-year duration, rent shall be reduced to [...***...] per sqm and to [...***...] per sqm for a duration of three years.

5.2 In addition to basic rent, the Lessee shall pay all operating expenses for the leased object that are attributed directly to him (e.g., electricity, gas, water, telephone and other communications expenses) as well as all of the building operating expenses and service charges. Operating expenses and service charges comprise all costs listed in Annex I of this Agreement as well as any costs that may arise in the future, having been newly introduced for the leased object by law, regulation, by-law or for any other reason. The list of operating expenses and service charges pursuant to Annex I is therefore an example and not a final listing of all possible costs.

5.3 The Lessor shall apportion these operating expenses and service charges to the Lessee and settle these with him. If there are several lessees in the building, the Lessor shall determine how these costs should be distributed (distribution legend) to the extent he is required to do so by legal provisions and shall do so in accordance with these provisions. The distribution legend shall be based on the share of leased space from the total area.

Page 5 of the Lease Agreement of December 21, 2004

***Confidential Treatment Requested
5.4 The Lessor shall invoice these expenses annually by December 15th of the following year at the latest. Should tenancy end during a billing period, the expenses shall be invoiced within the scope of the following annual accounting activities.

5.5 If operating costs increase or can be reasonably expected to increase (e.g., due to notification of an increase in local charges), the Lessor has the right to demand a corresponding increase in the advance payments.

§ 6 - Turnover Tax

6.1 In addition to the stipulated basic rent including operating expenses and service charges, the Lessor shall pay turnover tax as it falls due as prescribed under law. The Lessee guarantees that he intends to use the rental space exclusively for generating turnover which does not exclude the Lessor from deducting input tax. If the Lessee does not use the rental space exclusively to generate profit that does not exclude input tax deduction as promised (use having negative tax effects), basic rent including service charges shall increase for the period of use having negative tax effects by whichever amount is equal to the basic rent plus operating expenses and service charges for the turnover tax paid.

6.2 Upon the Lessor's request, the Lessee shall provide proof that he is using the leased object solely to generate profit that does not exclude input tax deduction. The Lessee shall immediately inform the Lessor before he starts using the leased object for use having negative tax effects and compensate the Lessor for any damage that may arise due to the Lessee violating his obligation to give notice; this particularly includes damage caused to the Lessor by paying turnover tax to the internal revenue service after the leased object has begun to be used for purposes having negative tax effects, even though lease of the object is at that time no longer subject to turnover tax. Claims for damages of this nature shall not become statute-barred until 6 months after a tax authority or tax court has determined that the Lessor does not or no longer has the right to input tax deduction.

§ 7 - Changes to Rent

7.1 If the price index determined by the German Federal Statistics Office for the standard of living for all private households (consumer price index for Germany) (base year 2000 = 100 points) changes as compared to its state as of June 30, 2009, or as compared to the last adjustment of rent by more than [...***...], the basic rent stipulated in item 5 shall be proportionally modified accordingly. Changes shall become effective on the first day of the month in which the change has been made.

Page 6 of the Lease Agreement of December 21, 2004

***Confidential Treatment Requested
7.2. If this adjustment clause cannot be considered approved pursuant to item 4 of the price clause decree, the Parties undertake to agree on an adjustment clause that comes as close as possible to the commercial concept and purpose of the original clause which can be approved according to the provisions valid at that time.

§ 8 - Payment of Rent

Payment of rent shall begin on January 1, 2005.
Rent is due by the 3rd business day of each month at the latest and shall be paid to the following account: […***…].

§ 9 - Transfer of Leased Object / Condition of Leased Object

9.1 Transfer of the leased object is scheduled to take place at the start of the rental period pursuant to item 4.1. The Lessor shall notify the Lessee of the official transfer date in writing as soon as possible.
Any work that still needs to be done, e.g., complete provision of outdoor facilities and/or repair of defects, shall not prevent transfer of the leased object.

9.2 The Parties shall make a record of the transfer at the time of transfer documenting the condition of the leased object as well as any defects present at that time.
The Lessor shall repair any defects identified in the record of transfer within a reasonable amount of time.

§ 10 - Use by Third Parties

10.1 Any partial or complete use by third parties, particularly subletting the leased object, requires the Lessor’s prior consent. The Lessee shall not have the right to terminate the lease should the Lessor not give his consent. The Lessee shall be responsible for and bear the costs of meeting any conditions stipulated by the authorities within the scope of such transfer of use so that the leased object can be used for other purposes that have been approved by the Lessor.

10.1 The Lessor may revoke his approval of a subletting arrangement for good cause. However, this may not be done at an inopportune time.
§ 11 - Maintenance/Repairs/Decorative Repairs/Liability for Damages

11.1 The Lessee shall be responsible for decorative repairs as well as other maintenance and repair work inside the rental space as well as any damage caused by lessee use (wear and tear, deterioration, damage caused by the Lessee or his helpers).

§ 12 - Insurance

12.1 Standard building insurance (fire, storm, damage from mains water, extended coverage) and premises liability insurance shall be concluded by the Lessor and billed together with the operating expenses and service charges. The installation of any fixtures in or additions or renovations to the leased object conducted by the Lessee shall not be covered by the building insurance. The Lessee shall be obliged to obtain insurance for these fixtures, additions or renovations at his own cost.

12.2 The Lessee shall be obliged to obtain sufficient business liability insurance as well as insurance covering breaking and entering as well as theft and sufficient insurance against any damage to equipment and objects brought into the leased object at his own expense and to maintain these insurance policies for the length of the lease.

12.3 The Lessor has the right to view the insurance contracts as proof that the Lessee has obtained the insurance policies listed under item 12.2 and that these are being maintained. This also applies to payment of the first premium for each insurance policy.

§ 13 - Signage/Advertising

13.1 The Lessee shall be permitted to place nameplates and company signs in the entrance area and at the doors to the rented rooms in those places designated by the Lessor for this purpose. Other building sections or areas of the property are not part of this lease; advertising installations, vending machines, display windows, stands, signs, awnings, antennae, etc., may therefore not be installed or set up.

13.2 Any additional advertising installations or materials pursuant to item 13.1 that the Lessee wishes to install or set up shall require the Lessee to obtain the Lessor's written, prior consent, which may involve conditions and expenses to be paid by the Lessee.

13.3 The Lessor shall reserve the right to make sure that signage or any advertising or other installations are designed in accordance with a joint advertising concept for the property. The Lessee must adjust his signage and advertising and other installations so that they correspond to this uniform concept. The Lessee shall bear the costs for signage.
§ 14 - Property Surveillance and Security Systems

14.1 Should the Parties deem surveillance measures necessary for the property, the Lessee shall tolerate these to the extent he is notified of said measures in due time. The Lessee shall be obliged to bear any costs incurring with respect to this matter. If there are several lessees, these costs shall be divided among them in accordance with the scale used for other operating expenses and service charges.

14.2 This shall also apply should the Lessor install security systems. Installation of security systems inside the premises by the Lessee shall require the prior consent from the Lessor.

§ 15 - Defects to Leased Object/Counterclaims

The legal provisions shall apply.

§ 16 - Modifications to Leased Object made by the Lessee

16.1 Modifications made to and in the leased object, particularly rebuilding, fixtures, installations and similar modifications, may only be made after obtaining written consent from the Lessor.

16.2 Gas, electronic and other devices may only be hooked up to the available supply network to an extent that does not exceed the usage limit designated for the leased object.

§ 17 - Modifications to Leased Object made by the Lessor

17.1 The Lessor shall have the right to make repairs and structural changes that become necessary or are advisable for maintenance, to avoid possible hazards, repair damages or improve the leased object and rental thereof even without the Lessee's consent. The Lessee shall make sure that the affected rooms and space are accessible and may not prevent or delay completion of the work; should he do this, the Lessee shall pay for any damage that arises.

17.2 The Lessor shall make allowances for the Lessee's business affairs. In particular, the Lessor shall inform the Lessee of such work in due time. This obligation to inform the Lessee shall not apply in the case of imminent danger.

Page 9 of the Lease Agreement of December 21, 2004
§ 18 - Accessing and Entering the Leased Object

The Lessee shall guarantee that the Lessor or his agents, experts or interested parties are able to enter and view the leased object at any time during standard business hours for the purposes of re-letting, sale, assessing the condition of the leased object or doing work on the leased object, if the Lessee has been notified in advance.

The Lessee shall guarantee that the leased object can be accessed and entered at any time of day or night in the case of imminent danger.

§ 19 - Lessor’s Lien / Provision of Security

19.1 The Lessor has a lessor’s lien on items brought into the leased object by the Lessee (office furniture, machines and other objects for business use and furnishing) for all present and future claims under this Agreement.

19.2 If third parties pledges items brought into the leased object by the Lessee, the Lessee shall be obliged to immediately notify the Lessor of the details and scope of the pledge by providing him with the relevant documents.

19.3 At least 14 days prior to the commencement of the lease pursuant to section 4.1 the Lessee shall provide security (guarantee) in the amount of [...] rent plus the agreed or estimated operating expenses and service charges as well as the applicable value-added tax in the amount of [...] as security for all the Lessor's claims under this Agreement and its termination.

(Translator’s note: The amount indicated in numbers and that indicated in words do not correspond in the original document and have therefore been translated as such.)

Security shall be provided in the form of an unconditional, irrevocable and unlimited guarantee for which the Lessee is liable as the sole principal from a major bank headquartered in the Federal Republic of Germany for which the guaranteeing bank shall waive the right to appeal, to offset and to deposit and the rights and objections from sections 768 and 776 of the German Civil Code (BGB) and which is obligated to pay on the first request to do so by the Lessor.

The guarantee may not contain any further conditions or limitations beyond the provision that the guarantee obligation shall be returned, if the Lessor returns the bank guarantee to the guarantor or if the lease is terminated and all of the Lessee's obligations arising from said lease have been fulfilled, if applicable reduced by the amount claimed by the Lessor.
In the event changes are made to basic rent during tenancy and/or to the operating expenses and service charges by at least [...] of the previous monthly total, the Lessee shall be obliged to adjust his provision of security accordingly, if requested to do so by the Lessor within 14 days of receiving said request.

§ 20 - Termination of Lease

20.1 Once lease has been terminated, the Lessee shall return the leased object cleaned and in suitable condition together with all keys to the Lessor. The Lessee shall also conduct any necessary decorative repairs, maintenance and other repairs that he is obligated to conduct pursuant to section 11 until the end of the lease; should the Lessee fail to do so, the Lessor may conduct such repairs and measures himself instead of the Lessee at the Lessee's cost without reminding the Lessee that he is obligated to make such repairs.

20.2 Objects that the Lessee has placed in the leased object and any changes made by him to the leased object during the lease, particularly fixtures and renovation, including signage, advertising installations and other installations in accordance with item 13 of this Agreement must be professionally removed and the original state of the lease object needs to be established by the Lessee.

The Lessee shall not remove the cabling, the built-in server room and the air conditioning unit located in the server room present in the premises at the commencement of the lease, after moving out of the leased object.

The Lessor may avert the exercise of this right to remove an article by paying suitable compensation based on the current value of the object.
§ 21 Miscellaneous

21.1 Place of fulfillment and court of jurisdiction for all obligations in connection with this Agreement shall be Mannheim, Germany.

21.2 Should one or more provisions of this Agreement be invalid, this shall not affect the validity of the other provisions. The Parties shall replace the invalid provision by an effective provision with retroactively effect, on which they would reasonably have agreed had they previewed the invalidity or absence of the respective provision.

21.3 Supplementary agreements, changes, additions and cancellation of the Agreement are only effective if conducted in writing. This also applies to any kind of permission or consent. The written form requirement may only be waived expressly and in written form. In particular, any declarations arising within the scope of this Agreement such as cancellations, consent, permits and similar declarations shall be made in writing to be effective.

21.4 The built-in server room in the offices, including technical installations (e.g., additional cabling, air conditioning unit) as well as the additional door closing system including installations shall remain in the premises after the Lessee has moved out.

21.5 Reference shall be made to the Annexes I - II associated with this Agreement.

Essen, January 6, 2005                                                                 Munich, December 22, 2004

[Illegible Signature] [Illegible Signature] [Illegible Signature]
(Lessor) (Lessee)

Page 12 of the Lease Agreement of December 21, 2004
LIST OF OPERATING EXPENSES AND SERVICE CHARGES

The following running costs that are incurred by the owner due to his ownership of the property or due to the intended use of the building or the economic unit, the adjoining buildings, facilities, installations and property, unless they are usually borne directly by the Lessee in addition to the rent, constitute the operating expenses and service charges:

1. **Current public rates and charges for the property**
   These namely comprises the land tax.

2. **Costs for water supply**
   These comprise the costs for water consumption, basic charges and charges for renting meters, costs for using intermediate meters as well as operating costs.

3. **Drainage costs**
   These comprise the charges for use of a public drainage system, including discharge of rainwater as well as operating costs.

4. **Heating system costs**
   These comprise the operating and cleaning costs
   a) for the heating system as well as the costs for using measuring equipment to measure consumption. Heating systems may, for example, be central heating systems or heating systems connected to the hot water supply system, central fuel supply systems or floor heating systems
   b) costs for district heating and operating costs
   c) costs for reading and analysis of the equipment to measure consumption.

5. **Costs of hot water supply**
   These include the operating and cleaning costs for
   a) hot water supply facilities, such as central hot water supply facilities or hot water supply facilities connected to the heating system;
   b) costs for supplying with district hot water and operating costs for the associated facilities in the building;
c) hot water units and equipment to measure consumption;
d) costs for reading and analysis of the equipment to measure consumption.

6. **Costs for air conditioning and ventilation systems**
   These comprise the operating costs.

7. **Costs for the passenger elevator or freight elevator**
   These comprise the costs for the operational electricity, supervision costs, service costs, costs of monitoring the installation and maintenance costs, costs for regularly checking it for operational readiness and operational safety, including adjustment by an expert and cleaning costs.

8. **Costs for street cleaning and garbage disposal**
   These comprise the fees to be paid for public street cleaning and garbage disposal as well as the costs for corresponding non-public measures.

9. **Costs for cleaning and pest control**
   Cleaning costs include, among others, costs for cleaning the property, in particular access and entrance areas, corridors, staircases, basements, attic spaces, laundry rooms, technology rooms, lift cages and facades as well as costs for glass cleaning.

10. **Costs for outside facilities**
    These comprise costs for horticultural upkeep and ground maintenance, including replanting of plants and trees and the upkeep of playgrounds, including replacing sand. These also include upkeep, cleaning, snow removal and strewing sand or other suitable material in areas, access areas and driveways that are not used for public traffic.

11. **Lighting costs**
    These comprise the electricity costs for outdoor lighting and the indoor lighting of general building sections, such as access and entrance areas, corridors, staircases, basements, attic areas, laundry rooms and technology rooms.
12. **Costs of cleaning pipes and chimneys**
   These comprise fees for cleaning pipes and chimneys pursuant to the applicable list of fees.

13. **Insurance costs**
   These comprise the costs for all insurance policies that have been taken out for the object, such as building insurance with all-risk coverage, glass insurance, liability insurance for the building, the oil tank and the elevator as well as insurance against loss of rent.

14. **Costs for the janitor, porter or doorman and all other staff required for building operation**
   These include, inter alia, ancillary labor costs and special remuneration.

15. **Costs for signage and advertising installations**
   These comprise costs for installing and operating signs and advertising installations. Signage comprises business name, name, location and information signs.

16. **Property management costs**
   These comprise the costs for property management with technical and commercial support.

17. **Costs for a lightning protection system**

18. **Costs for parking facilities**
   These comprise costs for operating, cleaning and maintenance of parking facilities.

19. **Operational electricity costs**
   These comprise operational electricity costs for the common building sections and facilities, to the extent they are not borne by the users themselves or are included in the above-mentioned items.

20. **Maintenance costs**
   These comprise the costs for all maintenance work carried out on the property that are not included in the above-mentioned items.
21. **Other public charges**

22. **Costs**
   of operation
   a) of the common aerial system or
   b) the private distribution system connected to a broadband cable network or
   c) of the satellite reception equipment

23. **Costs for property surveillance and security installations**
   These comprise the costs for regular and special monitoring and surveillance measures as well as the costs for manufacturing, installing and operating security installations.

24. **Costs for other equipment**
   These include operating costs such as those for washing machine and dryer facilities.

25. **Costs for property service charge accounts**
   These comprise the capital cost for the property service charge accounts, including bank service charges, account-keeping fees, interest charges.

26. **Other operating costs**
   These comprise the operating costs not mentioned in clause 1 to 25, namely operating costs for adjoining buildings, facilities and installations.

Essen, January 6, 2005

Mannheim, December 22, 2004

[Lessor] [Lessee]
Alters- und Hinterbliebenen-Versorgungsstelle
der Technischen Überwachungs-Vereine (VVaG)
Kurfürstenstraße 56
45138 Essen
between

Alters- und Hinterbliebenen Versicherung der Technischen Überwachungsvereine VVaG
Kurfürstenstr. 56
45138 Essen, Germany
UST ID: DE 11 98 24807

represented by its managing executive board member, Dr. rer. pol. G. Wiedemann,

and

the company
Nitec Pharma GmbH
Joseph-Meyer-Str. 13-15
68167 Mannheim, Germany,

represented by its general manager, Mr. Jochen Mattis

- hereinafter referred to as the “Lessee” -

1. **Amendment of § 1 Rental Property** *(Translator’s note: Item 1 of the Lease Agreement is called “Leased Object” and not “Rental Property”)*

   The rental space shall be extended by 57.65 sqm on the second floor. The ground plan is attached as Annex 1 to this Addendum.

3. **Amendment of § 4 Rent, Service Charges and Value-added Tax**

   As of February 1, 2006, the rent for the second floor shall be composed of the following:

   | Presently occupied office space       | 171.18 sqm x [...***... [...***... |
   | New office space                      | 57.65 sqm x [...***... [...***... |
   | 4 underground parking spaces          | [...***... [...***... |
   | Advance payment of service charges    | 228.83 sqm x [...***... [...***... |
   | Net sub-total                         | [...***... [...***... |
   | 16%VAT.                               | [...***... [...***... |
   | **Total sum gross**                   | [...***... [...***... |

Page 1 of the Addendum of December 7, 2005

***Confidential Treatment Requested***
4. Miscellaneous

1. The Lessor shall bear the costs for the relocation of electricity and server cables as well as for the fitting of carpet in the newly rented premises. The Lessee shall bear the costs for moving the walls.

2. All other provisions of the main Lease Agreement of January 6, 2005/ December 22, 2004, shall remain in force without change.

Essen, January 30, 2006

Mannheim, January 13, 2006

Alters- und Hinterbliebenen Versicherung

Fa. Nitec Pharma GmbH

der Technischen Oberwachungsvereine VVAG

Joseph-Meyer-Str. 13-15

Kurfürstenstr. 58

68167 Mannheim

45138 Essen

[Illegible Signature] [Illegible Signature]

(Lessor) (Lessee)

[stamp: Alters-und Hinterbliebenen-Versicherung] [stamp: Fa. Nitec Pharma GmbH]
Annex to the Addendum
Addendum No. 2 to the Lease Agreement of January 6, 2005 / December 22, 2004
Object: Janus-Office-Center,
Josef-Meyer-Str. 13-15, 68167 Mannheim

between
Alters- und Hinterbliebenen Versicherung der
Technischen Überwachungsvereine VVaG
Kurfürstenstr. 56
45138 Essen, Germany
UST ID: DE 11 98 24807,
represented by its executive board, Dr. rer. pol. G. Wiedemann, and Mr. Ralf Heynck,
and
the company
Nitec Pharma GmbH
Joseph-Meyer-Str. 13-15
68167 Mannheim, Germany,
represented by its managing director, Dr. Achim Schäffler

- hereinafter referred to as the “Lessee” -

1. Amendment to § 1 Rental Property
   As of February 1, 2007, the rental space on the second floor shall be expanded by 214.17 sqm. The Lessee will thus occupy the complete second floor. The overall space will amount to 443 sqm.

2. Amendment to § 4 Term of Lease and Termination
   As of February 1, 2007, the lease for the complete second floor shall be extended by another two years until January 31, 2009 [changed Jaas]

3. Amendment to § 5 Rent
   As of February 1, 2007 the rent for the second floor is composed as follows:

<table>
<thead>
<tr>
<th>Description</th>
<th>Area</th>
<th>Charge</th>
</tr>
</thead>
</table>
   | Basic rent for the office space on the 2nd floor | 443.00 sqm | [...]***... | [...***...]
   | Underground parking spaces 125, 126,127,128      |      | [...***... | [...***...]
   | Parking spaces No. 33+32                         |      | [...***... | [...***...]
   | Basic rent total                                  |      | [...***... | [...***...]
   | Advance payment of service charges               | 443.00 sqm | [...]***... | [...***...]
   | **Net total: rent including heating**            |      | [...***... | [...***...]
   | + 19% VAT                                        |      | [...***... | [...***...]

   **Total amount**

Page 1 of the Addendum No. 2 AHV/Nitec

***Confidential Treatment Requested
4. Miscellaneous

1. The Lessee shall bear the costs for the installation of the electricity and server cables as well as for the demolition of the added wall.

2. The Lessor shall bear the costs for the fitting of carpet in the newly rented premises.

3. All other provisions of the main Lease Agreement of January 6, 2005/ December 22, 2004, shall remain in force without change.

Essen,  
Mannheim, January 3, 2007

Alters- und Hinterbliebenen-Versicherung der  
Technischen Überwachungs-Vereine VVaG  
Kronprinzenstr. 30  
45128 Essen

[Illegible Signature]  
(Lessor)

Fa. Nitec Pharma GmbH  
Joseph-Meyer-Str. 13-15  
68167 Mannheim

[Illegible Signature]  
(Lessee)

Page 2 of the Addendum No. 2 AHV/Nitec
between

Alters- und Hinterbliebenen-Versicherung der
Technischen Überwachungs-Vereine VVaG
Kronprinzenstr. 30
45128 Essen
UST ID: DE 11 98 24807,
represented by the executive board, Dr. rer. pol. G. Wiedemann, and Mr. Ralf Heynck,
- hereinafter referred to as the “Lessor” -
and

the company
Nitec Pharma GmbH
Joseph-Meyer-Str. 13-15
68167 Mannheim
represented by its managing director, Dr. Achim Schäffler,
- hereinafter referred to as the “Lessee” -

1. Amendment to § 1 Rental Property
   As of April 1, 2008, the rental space shall be expanded by 247.29 sqm on the sixth floor.
   Thus, the floor space will amount to a total of 690.29 sqm (second and sixth floor).

2. Amendment to § 5 Rent
   As of April 1, 2008, the rent shall be composed of the following:

   Basic rent office space on the 2nd floor
   Basic rent for the office space on the 6th floor
   Underground parking spaces 125,126,127,128,132,133
   Parking spaces No. 32+33+10+11+2

   Basic rent total
   + Advance payment of service charges
   Net total: rent including heating
   + 19% VAT
   Total amount

Page 1 of the Addendum No. 3 AHV/Nitec

***Confidential Treatment Requested
4. Miscellaneous

1. The Lessee shall bear the costs for the paintwork and the cleaning of the carpet in the offices on the sixth floor.
2. The Lessor shall replace the carpet in those offices in which the carpet is heavily worn out.
3. The Lessor shall bear the costs for a dishwasher.
4. The furniture on the sixth floor shall be transferred to the company Nitec Pharma free of charge.
5. All other provisions of the main Lease Agreement of January 6, 2005/ December 22, 2004, shall remain in force without change.

Essen, April 4, 2008

Alters- und Hinterbliebenen-Versicherung der Technischen Überwachungs-Vereine WaG
Kronprinzenstr. 30
45128 Essen

Fa. Nitec Pharma GmbH
Joseph-Meyer-Str. 13-15
68167 Mannheim

[Illegible Signature]
(Lessor)

[Illegible Signature]
(Lessee)

Annex I: Ground plan of the sixth floor
Annex II: Underground parking spaces and parking spaces on the first floor

Page 2 of the Addendum No. 3 AHV/Nitec
Addendum No. 4 to the Lease Agreement of January 6, 2005 / December 22, 2004

Object: Janus-Office-Center,
Josef-Meyer-Str. 13-15, 68167 Mannheim

between

Alters- und Hinterbliebenen-Versicherung der
Technischen Überwachungs-Vereine VVaG
Kronprinzenstr. 30

45128 Essen

UST ID: DE 11 98 24807,
represented by the executive board, Dr. rer. pol. G. Wiedemann, and Mr. Ralf Heynck
- hereinafter referred to as the “Lessor” -

and

the company
Nitec Pharma GmbH
Joseph-Meyer-Str. 13-15

68167 Mannheim

represented by its managing director, Dr. Achim Schäffler
- hereinafter referred to as the “Lessee” -

1. Amendment to § 4 Term of Lease and Termination

The lease of the whole rented space shall be extended until December 31, 2010.

2. Miscellaneous

All other provisions of the main Lease Agreement of January 6, 2005/December 22, 2004, along with all addendums shall remain in force without change.

Essen, September 24, 2008

Mannheim, September 18, 2008

Alters- und Hinterbliebenen-Versicherung der
Technischen Überwachungs-Vereine VVaG
Kronprinzenstr. 30

45128 Essen

Fa. Nitec Pharma GmbH
Joseph-Meyer-Str. 13-15

68167 Mannheim

[Illegible Signature]
(Lessor)

[Illegible Signature]
(Lessee)
Amendment to § 1 Rental Property
As of April 1, 2009, the Lessee shall in addition rent a store room on the first floor.

Amendment to § 5 Rent
Thus, as of April 1, 2009 the monthly rent payment shall amount to the following:

<table>
<thead>
<tr>
<th>Description</th>
<th>Area</th>
<th>Rate</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Basic rent for the office space on the 2nd floor</td>
<td>443.00 sqm</td>
<td></td>
<td>[...***...]</td>
</tr>
<tr>
<td>Basic rent for the office space on the 6th floor</td>
<td>247.29 sqm</td>
<td></td>
<td>[...***...]</td>
</tr>
<tr>
<td>storage area on the 1st floor</td>
<td>18.50 sqm</td>
<td></td>
<td>[...***...]</td>
</tr>
<tr>
<td>Underground parking spaces 125, 126,127,128,132,133</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Parking spaces No. 32+33+10+11+2</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Basic rent total</strong></td>
<td>690.29 sqm</td>
<td></td>
<td>[...***...]</td>
</tr>
<tr>
<td>+ Advance payment of service charges</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Net total: rent including heating</strong></td>
<td></td>
<td></td>
<td>[...***...]</td>
</tr>
</tbody>
</table>

+ 19% VAT

***Confidential Treatment Requested
2. **Miscellaneous**

   All other provisions of the main Lease Agreement of January 6, 2005 / December 22, 2004, together will all addendums, shall remain in force without change.

   Essen, March 12, 2009

   Alters- und Hinterbliebenen-Versicherung der Technischen Überwachungs-Vereine VVaG
   Kronprinzenstr. 30
   45128 Essen

   [Illegible Signature]  
   (Lessor)

   Mannheim, March 12, 2009

   Fa. Nitec Pharma GmbH
   Joseph-Meyer-Str. 13-15
   68167 Mannheim

   [Illegible Signature]  
   (Lessee)

Page 2 of the Addendum No. 5 AHV/Nitec
Addendum No. 6 to the Lease Agreement of January 6, 2005 / December 22, 2004
Object: Janus-Office-Center,
Josef-Meyer-Str. 13-15, 68167 Mannheim

between
Alters- und Hinterbliebenen-Versicherung der
Technischen Überwachungs-Vereine-WaG-
Kurfürstenstr. 56, 45128 Essen
UST ID: DE 11 98 24807
represented by the executive board Mr. R. Heynack and Ms. S. Schwierz
- hereinafter referred to as “Lessor” -
and
the company
Horizon Pharma GmbH
in former times Nitec Pharma GmbH
Joseph-Meyer-Str. 13-15, 68167 Mannheim
represented by its managing director Dr. Achim Schäffler
- hereinafter referred to as “Lessee” -

Preamble
The trade name of the company Nitec Pharma GmbH was changed to Horizon Pharma GmbH on June 22, 2010. Therefore, all rights and obligations resulting from the existing lease agreement are simultaneously transferred to the company Horizon Pharma GmbH.

1. Amendment to § 4 Term of Lease and Termination
The lease of the whole rented space shall be extended until December 31, 2011.

2. Miscellaneous
All other provisions of the main Lease Agreement of January 6, 2005 / December 22, 2004, along with all addendums shall remain in force without change.

Essen, the 26.8.2010

Mannheim, the 19. Aug. 2010

Alters-und Hinterbliebenen-Versicherung der
Technischen Überwachungs-Vereine VVaG
Kronprinzenstr.30
45128 Essen

Fa. Horizon Pharma GmbH
Joseph-Meyer-Str. 13-15
68167 Mannheim

[signature] [signature]
(Lessor) (Lessee)

[company’s stamp]

Page 1 of the Addendum No. 6 AHV/Horizon
Parking Space
Lease Agreement
Joseph-Meyer-Str. 13-15, 68167 Mannheim

between
Alters- und Hinterbliebenen Versicherung der
Technischen Überwachungsvereine VVaG
Kurfürstenstr. 56
45138 Essen
UST ID: DE 11 98 24807

represented by its managing executive board member, Dr. rer. pol. G. Wiedemann,
and
the company
Nitec Pharma GmbH
Joseph-Meyer-Str. 13-15
68167 Mannheim
represented by its managing director, Mr. Jochen Mattis,
- hereinafter referred to as the “Lessee” -

1. Leased Object
As of August 1, 2007, the Tenant shall rent the following parking spaces in Joseph-Meyer-Str. 13-15, 68167 Mannheim:

Parking spaces No. 10 +11
+ 16% VAT
Overall rent for parking spaces per month

2. Termination
The Lease Agreement may be terminated by either party by giving one month’s notice.

Filderstadt, August 7, 2007
Mannheim, July 11, 2007

[stamp: TÜV SÜD Immobilien Service GmbH]
[stamp: Nitec Pharma GmbH]

[Illegible Signature]
[Illegible Signature]
(Lessor)
(Lessee)

***Confidential Treatment Requested
MIETVERTRAG
über Gewerberäume

Zwischen
Alters- und Hinterbliebenen-Versorgungsstelle der Technischen Überwachungsvereine VVaG
Kurfürstenstraße 58
45138 Essen
-Vermieter

und

Firma
Nitec Pharma GmbH
-Mieter-

wird nachfolgender Vertrag geschlossen:
<table>
<thead>
<tr>
<th>Seite</th>
<th>Inhalt</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Inhaltsverzeichnis</td>
</tr>
<tr>
<td>3</td>
<td>§ 1 Mietsache</td>
</tr>
<tr>
<td>3</td>
<td>§ 2 Benutzung der Mietsache</td>
</tr>
<tr>
<td>4</td>
<td>§ 3 Ausstattung der Mieträume</td>
</tr>
<tr>
<td>4</td>
<td>§ 4 Mietzeit, Kündigung</td>
</tr>
<tr>
<td>5</td>
<td>§ 5 Mietzins</td>
</tr>
<tr>
<td>6</td>
<td>§ 6 Umsatzsteuer</td>
</tr>
<tr>
<td>6</td>
<td>§ 7 Änderung des Mietzinses</td>
</tr>
<tr>
<td>7</td>
<td>§ 8 Zahlung des Mietzinses</td>
</tr>
<tr>
<td>7</td>
<td>§ 9 Übergabe und Zustand der Mietsache</td>
</tr>
<tr>
<td>7</td>
<td>§ 10 Gebrauchsüberlassung an Dritte</td>
</tr>
<tr>
<td>8</td>
<td>§ 11 Instandhaltung und Instandsetzung</td>
</tr>
<tr>
<td>8</td>
<td>§ 12 Versicherungen</td>
</tr>
<tr>
<td>9</td>
<td>§ 13 Beschilderung / Reklameanlagen</td>
</tr>
<tr>
<td>9</td>
<td>§ 14 Objektabwachung und Sicherheitseinrichtungen</td>
</tr>
<tr>
<td>10</td>
<td>§ 15 Mängel der Mietsache / Gegenansprüche</td>
</tr>
<tr>
<td>10</td>
<td>§ 16 Veränderungen der Mietsache durch den Mieter</td>
</tr>
<tr>
<td>10</td>
<td>§ 17 Veränderungen der Mietsache durch den Vermieter</td>
</tr>
<tr>
<td>11</td>
<td>§ 18 Betreten der Mietsache</td>
</tr>
<tr>
<td>11</td>
<td>§ 19 Vermieterpfandrecht/Sicherheitsleistung</td>
</tr>
<tr>
<td>12</td>
<td>§ 20 Beendigung des Mietverhältnisses</td>
</tr>
<tr>
<td>13</td>
<td>§ 21 Sonstige Vereinbarungen</td>
</tr>
<tr>
<td>Anlage I</td>
<td>Aufstellung der Betriebs- und Nebenkosten</td>
</tr>
<tr>
<td>Anlage II</td>
<td>Grundrisszeichnungen der Mietflächen</td>
</tr>
</tbody>
</table>
§ 1 - Mietsache


1.2 Der Vermieter vermietet an den Mieter Büroflächen in dem vorstehend beschriebenen Gebäude im 1. Obergeschoss mit insgesamt 171,18 m², darin enthalten sind Haupt- und Nebennutzflächen und die damit verbundenen Verkehrs- und Funktionsflächen.

   Der beigefügte Lageplan ist Bestandteil des Mietvertrages (Anlage II).

1.3 Sollten sich bei nachträglicher Vermessung der Mietflächen eine Abweichung von der angegebenen Mietfläche ergeben, ist keine der Parteien berechtigt, von diesem Vertrag zurückzutreten, ihn zu kündigen oder eine Änderung des Mietzinses zu verlangen. Die angegebenen Flächen sind zugrunde zu legen, soweit es nach den Bestimmungen dieses Vertrages auf die Größe der vermieteten Flächen ankommt.

1.4 Die Vermietung erfolgt zur Nutzung als Bürobetrieb.


§ 2 - Benutzung der Mietsache

2.1 Die Mietsache wird zu dem in Ziff. 1.4 genannten Nutzungszweck durch den Mieter gemietet.

2.2 Der Vermieter übernimmt keine Gewähr dafür, dass der vorgesehene Betrieb des Mieters in der Mietsache öffentlich-rechtlich zulässig ist. Der Mieter hat auf seine Kosten sämtliche Voraussetzungen für seinen Betrieb zu schaffen und während der Mietzeit aufrechtzuerhalten. Auflagen der Gewerbeaufsicht oder anderer Stellen hat der Mieter auf eigene Kosten zu erfüllen, auch soweit es sich um Raumbezogene Auflagen handelt.

   Die Gültigkeit dieses Mietvertrages ist unabhängig von einer etwa erforderlichen behördlichen Zulassung der gewerblichen Tätigkeit des Mieters.

2.3 Der Mieter verpflichtet sich, für die Dauer dieses Vertrages seinen vorgesehenen Betrieb in den Mieträumen aktiv zu betreiben und entsprechend seiner Betriebsart geöffnet bzw. besetzt zu halten (Betriebspflicht).

2.4 Der Vermieter räumt dem Mieter keinerlei Konkurrenzschutz ein.

Seite 34 des Mietvertrages vom 21.12.2004
2.5 Vor der Aufstellung von Maschinen, schweren Gegenständen, anderen Anlagen und Einrichtungen in den Mieträumen hat sich der Mieter über die zulässige Belastungsgrenze der Stockwerksdecken beim Vermieter zu erkundigen und seine schriftliche Zustimmung einzuholen. Für Schäden, die durch Nichtbeachtung dieser Bestimmungen eintreten, haftet der Mieter. Führen solche Anlagen und Einrichtungen des Mieters zu nachteiligen Auswirkungen auf das Gebäude (Erschütterungen, Risse usw.) oder zu Nachteilen oder Unzuträglichkeiten (z. B. Lärm, Staub, störende Gerüche etc.) der Mitbenutzer im Gebäude, so kann der Vermieter die Zustimmung widerrufen und vom Mieter Unterlassung verlangen.

2.6 Zur Anmietung gehört auch das Recht des freien Zugangs und der freien Zufahrt zur Mietsache.

§ 3 - Ausstattung und Übergabe der Mieträume durch den Vermieter

3.1 Der Zustand und die Ausstattung der Mietsache, wie sie steht und liegt, ist dem Mieter bekannt.

3.2 Die Mietsache wird dem Mieter spätestens Januar 2005 übergeben. Von der Übergabe ist ein Protokoll zu erstellen.

§ 4 - Mietzeit und Kündigung

4.1 Das Mietverhältnis beginnt am 01. Januar 2005 und wird auf die Dauer von 1,5 Jahren bis zum 30.06.2006 abgeschlossen. Bei Beendigung des Mietverhältnisses findet § 568 BGB für die Vertragsparteien keine Anwendung.

4.2 Während der Dauer des Mietverhältnisses ist die ordentliche Kündigung ausge-schlossen. Das Recht zur außerordentlichen fristlosen Kündigung aus wichtigem Grund beider Parteien bleibt unberührt. Ein wichtiger außerordentlicher Kündigungsgrund für den Vermieter liegt insbesondere vor, wenn

a) der Mieter mit mehr als einer Monatsmiete in Rückstand gerät oder die vereinbarte Sicherheitsleistung nicht in der nach diesem Vertrag vorgesehenen Zeit, Höhe und Art gestellt hat;

b) der Mieter ohne Zustimmung des Vermieters die Mietsache oder Teile davon baulich verändert oder zu anderen als im Vertrag bestimmten Zwecken benutzt, insbesondere Dritten zum Gebrauch überlässt bzw. untermietet;

c) der Mieter seine Zahlungen einstellt, es zur Einleitung eines gerichtlichen oder außergerichtlichen Vergleichs—oder Konkursverfahrens über sein Vermögen—kommen lässt oder die eidesstattliche Versicherung über sein Vermögen ableisten muß;

Seite 35 des Mietvertrages vom 21.12.2004

4.5 Soweit der Mieter eine natürliche Person ist, wird das vorzeitige Kündigungsrecht gemäß § 569 BGB hiermit ausgeschlossen.

§ 5 Mietzins

5.1 Der Mietzins setzt sich für die Grundmietzeit vom 01.01.05 – 30.06.05 monatlich wie folgt zusammen:

<table>
<thead>
<tr>
<th>Betriebsmittel</th>
<th>Fläche</th>
<th>Mietzins</th>
<th>Nebenkostenvorauszahlung</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bürofläche</td>
<td>171,18 m²</td>
<td>[...***…]</td>
<td>[...***…]</td>
</tr>
<tr>
<td>3 Tiefgaragenstelplätze</td>
<td></td>
<td>[...***…]</td>
<td>[...***…]</td>
</tr>
<tr>
<td>Nebenkostenvorauszahlung</td>
<td>171,18 m²</td>
<td>[...***…]</td>
<td>[...***…]</td>
</tr>
</tbody>
</table>

Zwischensumme netto: [...***…]

Mehrwertsteuer 16 %: [...***…]

Summe brutto gesamt: [...***…]

Sollte der Mieter die in § 4 vereinbarte Option über 1 Jahr ausüben, bleibt der Mietzins in Höhe von [...***…] bestehen, bei 2 jähriger Dauer reduziert sich der Mietzins pro m² auf [...***…] bei 3 jähriger Dauer auf [...***…] pro m².


***Confidential Treatment Requested

Seite 5 des Mietvertrages vom 21.12.2004

5.5 Erhöhen sich die Betriebskosten oder sind Erhöhungen sicher zu erwarten (z. B. durch Ankündigung kommunaler Gebührenerhöhungen), so ist der Vermieter berechtigt, eine entsprechende Erhöhung der Vorauszahlungen zu verlangen.

§ 6 Umsatzsteuer

6.1 Zuzüglich zur vereinbarten Grundmiete einschließlich der Betriebs- und Nebenkosten hat der Vermieter die Umsatzsteuer in ihrer jeweiligen gesetzlichen Höhe zu entrichten. Der Mieter versichert, dass er die Mieträume ausschließlich für Umsätze verwendet oder zu verwenden beabsichtigt, welche den Vorsteuerabzug beim Vermieter nicht ausschließen. Sollte der Mieter entgegen dieser Zusicherung die Mieträume nicht ausschließlich für solche Umsätze verwenden, die den Vorsteuerabzug nicht ausschließen (steuerschädliche Verwendung), so erhöht sich die Grundmiete einschließlich Nebenkosten im Zeitraum der umsatzsteuerschädlichen Verwendung um denjenigen Betrag, welcher der jeweiligen auf die Grundmiete zuzüglich Betriebs- und Nebenkosten zu entrichtenden Umsatzsteuer entspricht.


§ 7 - Änderung des Mietzinses

7.1 Ändert sich der vom Statistischen Bundesamt festgestellte Preisindex für die Lebenshaltung aller privaten Haushalte (Verbraucherpreisindex für Deutschland) (Basisjahr 2000 = 100 Punkte) gegenüber dem Stand 30.06.2009 oder gegenüber der letzten Mietanpassung um mehr als [...***...], so ändert sich jeweils die in § 5 vereinbarte Grundmiete prozentual entsprechend. Die Änderung wird von dem Monatsersten an wirksam, der auf die Veränderung folgt.

***Confidential Treatment Requested

Seite 37 des Mietvertrages vom 21.12.2004
7.2. Sollte diese Wertsicherungsklausel nicht gem. § 4 der Preisklauselverordnung als genehmigt gelten, so verpflichten sich die Parteien eine dem wirtschaftlichen Sinn und Zweck am ehesten entsprechende Wertsicherungsklausel zu vereinbaren, die nach den dann geltenden Vorschriften genehmigungsfähig ist.

§ 8 - Zahlung des Mietzinses

Die Mietzinszahlung beginnt am 01.01.2005.

Der Mietzins ist spätestens bis zum 3. Werktag eines jeden Monats auf das Konto der […***…]

§ 9 - Übergabe der Mietsache / Zustand der Mietsache


Ausstehende Restarbeiten, wie z. B. die völlige Herstellung der Außenanlagen und/oder die Mängelbeseitigung, hindem die Übernahme der Mietsache nicht.

9.2 Anlässlich der Übergabe wird von den Parteien ein Übergabeprotokoll gefertigt, das den Zustand der Mietsache und etwaige Mängel zu diesem Zeitpunkt dokumentiert.

Übergabeprotokoll festgestellte Mängel hat der Vermieter innerhalb einer angemessenen Nachfrist zu beseitigen.

§ 10 - Gebrauchsunverlassung an Dritte


10.2 Der Vermieter kann die Zustimmung zur Untervermietung aus wichtigem Grund widerrufen. Dies darf jedoch nicht zur Unzeit geschehen.
§ 11 – Instandhaltung/Instandsetzung/Schönheitsreparaturen/Haftung für Schäden

11.1 Dem Mieter obliegen die Schönheitsreparaturen sowie die sonstigen Instandhaltungs- und Instandsetzungsarbeiten innerhalb der Mieträume, soweit die Schäden durch den Gebrauch des Mieters entstanden sind (Abnutzung, Verschleiß, Beschädigung durch den Mieter oder seine Erfüllungsgehilfen).

§ 12 - Versicherungen


12.2 Der Mieter ist verpflichtet, eine ausreichende Betriebshaftpflicht- sowie eine Einbruchdiebstahlversicherung und eine ausreichende Versicherung der eingebrachten Einrichtungen und Sachen gegen alle Beschädigungen auf eigene Kosten abzuschließen und für die Dauer der Mietzeit aufrechtzuerhalten.

12.3 Der Vermieter hat das Recht, sich von dem ordnungsgemäßen Abschluss der gem. § 12.2 vom Mieter abzuschließenden Versicherungen und deren Aufrechterhaltung durch Einsichtnahme in die Versicherungsverträge zu überzeugen. Dies gilt ebenso über die Zahlung der Erstprämie der jeweiligen Versicherung.

§ 13 - Beschilderung Reklameanlagen


13.2 Darüber hinausgehende Reklameanlagen oder andere Einrichtungen gemäß § 13.1, welche der Mieter anbringen oder aufstellen will, bedürfen der vorherigen, schriftlichen Genehmigung des Vermieters, die auch mit Auflagen und Kosten trägerpflichten verbunden werden kann.

13.3 Der Vermieter behält sich vor, die Beschilderung oder das Anbringen von Reklameanlagen und sonstigen Vorrichtungen einheitlich nach einem gemeinschaftlichen Werbekonzept für das Anwesen zu gestalten. Diesem einheitlichen Konzept hat sich der Mieter mit seiner Beschilderung und seinen Reklameanlagen und sonstigen Vorrichtungen anzupassen. Die Kosten der Beschilderung trägt der Mieter.

Seite 39 des Mietvertrages vom 21.12.2004
§ 14 - Objektbewachung und Sicherheitseinrichtungen

14.1 Falls die Parteien für das Objekt Bewachungsmaßnahmen als notwendig betrachten, sind diese vom Mieter zu dulden, soweit sie ihm rechtzeitig angezeigt werden. Der Mieter verpflichtet sich, die hierfür anfallenden Kosten zu tragen, bei mehreren Mietern anteilig nach dem Umlagemaßstab für andere Betriebs- und Nebenkosten.


§15 Mängel der Mietsache/Gegenansprüche

Es gelten die gesetzlichen Regelungen

§16 - Veränderungen der Mietsache durch den Mieter

16.1 Veränderungen an und in der Mietsache, insbesondere Um- und Einbauten, Installationen und dergleichen dürfen nur mit schriftlicher Einwilligung des Vermieters vorgenommen werden.

16.2 Gas-, Elektro- und sonstige Geräte dürfen nur in dem Umfang an das vorhandene Leitungsnetz angeschlossen werden, als die für die Mietsache vorgesehene Belastung nicht überschritten wird.

§17 - Veränderungen der Mietsache durch den Vermieter

17.1 Der Vermieter darf Ausbesserungen und bauliche Veränderungen, die zur Erhaltung oder zur Abwendung drohender Gefahren oder zur Beseitigung von Schäden oder zur Verbesserung der Mietsache und ihrer Vermietung notwendig oder zweckmäßig werden, auch ohne Zustimmung des Mieters vornehmen. Der Mieter hat die in Betracht kommenden Räume zugänglich zu halten und darf die Ausführungen der Arbeiten nicht hindern oder verzögern; andernfalls hat er den dadurch entstehenden Schaden zu ersetzen.

17.2 Auf die betrieblichen Belange des Mieters ist angemessene Rücksicht zu nehmen. Insbesondere hat der Vermieter die Durchführung solcher Arbeiten rechtzeitig anzukündigen. Die Ankündigungs pflicht gilt nicht bei Gefahr im Verzug.
§ 18 - Betreten der Mietsache
Der Mieter hat während der üblichen Geschäftszelt zu gewährleisten, dass der Vermieter oder seine Beauftragten, Sachverständige und Interessenten die Mietsache zum Zwecke der Neuvermietung, des Verkaufes, zur Feststellung des Zustandes oder zur Vornahme von Arbeiten jederzeit - nach Voranmeldung - betreten und besichtigen können.

In Fällen von Gefahr im Verzug ist das Betreten der Mietsache zu jeder Tages- und Nachtzeit durch den Mieter zu ermöglichen.

§ 19 - Pfandrecht des Vermieters / Sicherheitsleistung
19.1 Der Vermieter hat für alle auch künftigen Forderungen aus diesem Vertrag ein Pfandrecht an den eingebrachten Sachen des Mieters (Büromöbel, Maschinen und sonstige Gegenstände der Geschäftsausstattung und Einrichtung).


19.3 Der Mieter leistet zur Absicherung aller Ansprüche des Vermieters aus diesem Mietvertrag und seiner Beendigung spätestens 14 Tage vor Mietbeginn gemäß § 4.1 eine Sicherheitsleistung (Bürgschaft) in Höhe von […***…] zuzüglich vereinbarter oder geschätzter Betriebs- und Nebenkosten und zuzüglich der jeweiligen gesetzlichen Mehrwertsteuer, in Höhe von

[…***…]

[…***…]

Diese Sicherheitsleistung ist in Form einer unbedingten, unwiderruflichen, unbefristeten und selbstschuldnerischen Bürgschaft einer in der Bundesrepublik Deutschland ansässigen Großbank zu erbringen, bei welcher die bürgende Bank auf das Recht zur Anfechtung, zur Aufrechnung, zur Hinterlegung und die Rechte und Einreden aus §§ 768, 776 BGB verzichtet und sich zur Zahlung auf erstes Anfordern durch den Vermieter verpflichtet hat.

Die Bürgschaft darf über die Bestimmung hinaus, dass die Bürgschaftsverpflichtung mit Rückgabe der Bürgschaftsurkunde durch den Vermieter an die Bürgen oder dann, wenn nach Beendigung des Mietverhältnisses sämtliche Verpflichtungen des Mieters aus dem Mietverhältnis erfüllt sind, zurückzugeben ist, gegebenenfalls um vom Vermieter in Anspruch genommene Beträge gemindert, keine weiteren Bedingungen und Einschränkungen enthalten.

***Confidential Treatment Requested

Seite 10 des Mietvertrages vom 21.12.2004
Kommt es während der Mietzeit zu einer Veränderung der Grundmiete und/oder der Betriebs- und Nebenkosten um mindestens […] des bisherigen monatlichen Gesamtbetrages, so ist der Mieter auf Verlangen des Vermieters zu einer entsprechenden Anpassung seiner Sicherheitsleistung binnen 14 Tagen ab Aufforderung verpflichtet.

§ 20 - Beendigung des Mietverhältnisses

20.1 Bei Beendigung des Mietverhältnisses hat der Mieter die Mietsache gereinigt in ordnungsgemäßem Zustand mit sämtlichen Schlüsseln an den Vermieter herauszugeben. Spätestens bis zum Zeitpunkt des Mietendes hat der Mieter ferner in jedem Fall notwendige, die ihm nach § 11 obliegenden Schönheitsreparaturen, Instandhaltungs- und Instandsetzungsmaßnahmen vollständig durchzuführen; andernfalls kann der Vermieter auf Kosten des Mieters ohne nochmalige Mahnung und Fristsetzung solche Reparaturen und Maßnahmen anstelle des Mieters auf dessen Kosten selbst durchführen.


Der Vermieter kann die Ausübung dieses Wegnahmerechts durch Zahlung einer angemessenen Entschädigung abwenden, die sich nach dem Zeitwert der Einrichtung bestimmt.
§ 21 - Sonstige Vereinbarungen

21.1 Erfüllungsort und Gerichtsstand für alle sich aus diesem Vertrag ergebenden Verpflichtungen ist Mannheim.

21.2 Durch die Ungültigkeit einer oder mehrerer Bestimmungen dieses Vertrages wird die Gültigkeit der übrigen nicht betroffen. Für den Fall der Nichtigkeit einzelner Bestimmungen sind die Parteien verpflichtet, an ihrer Stelle eine solche Regelung zu treffen, die der ursprünglichen vorgestellten mit rückwirkender Kraft am nächsten kommt.


21.4 Der in den Bürroräumen eingebaute Serverraum, inklusive der technischen Einrichtungen (z.B. zusätzliche Verkabelung, Klimaanlage) sowie die zusätzliche Türschließanlage incl. der Installationen verbleibt beim Auszug des Mieters in den Räumlichkeiten.

21.5 Auf die zu diesem Vertrag gehörenden Anlagen I - II wird Bezug genommen.

Essen, den 06.01.2005                         Munich, den 22.12.04

[Illegible Signature]                                                                 [Illegible Signature]
(Vermieter)                                                                              (Mieter)

Seite 12 des Mietvertrages vom 21.12.2004
AUFSTELLUNG DER BETRIEBS- UND NEBENKOSTEN

Betriebskosten und Nebenkosten sind nachstehende Kosten, die dem Eigentümer durch das Eigentum am Grundstück oder durch den Bestimmungsmäßigen Gebrauch des Gebäudes oder der Wirtschaftseinheit, der Nebengebäude, Anlagen, Einrichtungen und des Grundstückes laufend entstehen, es sei denn, dass sie üblicherweise vom Mieter außerhalb der Miete unmittelbar getragen werden:

1. **Die laufenden öffentlichen Lasten des Grundstücks**
   Hierzu gehört namentlich die Grundsteuer.

2. **Die Kosten der Wasserversorgung**
   Hierzu gehören die Kosten des Wasserverbrauchs, die Grundgebühren und die Zählermiete, die Kosten der Verwendung von Zwischenzählem und die Kosten des Betriebs.

3. **Die Kosten der Entwässerung**
   Hierzu gehören die Gebühren für die Benutzung einer öffentlichen Entwässerungs-anlage, inklusiv der Einleitung von Regenwasser und die Kosten des Betriebs.

4. **Die Kosten der Heizungsanlage**
   Hierzu gehören die Kosten des Betriebs und der Reinigung
   a) der Heizungsanlage sowie die Kosten der Verwendung einer messtechnischen Ausstattung zur Verbrauchserfassung. Heizungsanlagen können z.B. zentrale Heizungsanlage oder mit der Warmwasserversorgungsanlage verbundene Heizungsanlagen, zentrale Brennstoffversorgungsanlagen oder Etagenheizungen sein;
   b) die Kosten der Versorgung mit Fernwärme und die Kosten des Betriebs
   c) die Kosten der Ableseung und Auswertung der Geräte zur Verbrauchserfassung.

Seite 13 des Mietvertrages vom 21.12.2004
5. **Die Kosten der Warmwasserversorgung**
   Hierzu gehören die Kosten des Betriebs und der Reinigung
   
a) der Warmwasserversorgungsanlagen, wie z. B. zentrale oder mit der Heizungsanlage verbundene Warmwasserversorgungsanlagen;
   
b) die Kosten der Versorgung mit Fernwarmwasser und die Kosten des Betriebs der zugehörigen Hausanlagen;
   
c) der Warmwassergefäße und Geräte zur Verbrauchserfassung;
   
d) die Kosten der Ableseung und Auswertung der Geräte zur Verbrauchserfassung.

6. **Die Kosten der Klima-, Be- und Entlüftungsanlagen**
   Hierzu gehören die Kosten des Betriebs

7. **Die Kosten der maschinellen Personen- oder Lastenaufzüge**
   Hierzu gehören die Kosten des Betriebsstroms, die Kosten der Beaufsichtigung, der Bedienung, Überwachung und Pflege der Anlage, der regelmäßigen Prüfung ihrer Betriebsbereitschaft und Betriebssicherheit einschl. der Einstellung durch einen Fachmann und die Kosten der Reinigung.

8. **Die Kosten der Straßenreinigung und Müllabfuhr**
   Hierzu gehören die für die öffentliche Straßenreinigung und Müllabfuhr zu entrichtenden Gebühren und die Kosten entsprechender nicht öffentlicher Maßnahmen.

9. **Die Kosten der Reinigung und Ungezieferbekämpfung**
   Zu den Kosten der Reinigung gehören u. a. die Kosten für die Säuberung des Objektes, u. a. der Zugänge, Eingangsbereiche, Flure, Treppenhäuser, Keller, Bodenräume, Waschküchen, Technikräumen, Aufzugsfahrkörbe sowie Fassaden bzw. die Glasreinigung.

10. **Die Kosten der Außenanlagen**

Seite 14 des Mietvertrages vom 21.12.2004
11. Die Kosten der Beleuchtung
Hierzu gehören die Kosten des Stroms für die Außenbeleuchtung und die Beleuchtung der allgemeinen Gebäudetelle des Objektes, wie z.B. Zugänge, Eingangsbereiche, Flure, Treppenhäuser, Keller, Bodenräume, Waschküchen und Technikräume.

12. Die Kosten der Schornsteinreinigung
Hierzu gehören die Kehrgebühren nach der maßgebenden Gebührenordnung.

13. Die Kosten der Versicherungen

Hierzu gehören u.a. die Personalnebenkosten sowie Sondervergütungen.

15. Die Kosten für Beschilderung und Werbeanlagen

16. Die Kosten des Objektmanagements
Hierzu gehören die Kosten des Objektmanagements mit technischer und kaufmännischer Betreuung.

17. Die Kosten der Blizschutzanlage

18. Die Kosten der Garagen
Hierzu gehören die Kosten des Betriebs und die Reinigung und Wartung der Garagenanlagen.

19. Die Kosten des Betriebsstroms
Hierzu gehören die Kosten des Betriebsstroms für die gemeinschaftlichen Gebäudeteile und -anlagen, soweit sie nicht von den Nutzern selbst getragen werden oder in den vorgenannten Punkten beinhaltet sind.

20. Die Kosten für Wartungen
Hierzu gehören die Kosten für alle Wartungsarbeiten, die im Objekt durchgeführt werden und nicht in den vorgenannten Punkten beinhaltet sind.

Seite 15 des Mietvertrages vom 21.12.2004
21. Sonstige öffentliche Gebühren

22. Die Kosten des Betriebs
   a) der Gemeinschafts-Antennenanlage bzw.
   b) der mit einem Breitbandkabelnetz verbundenen privaten Verteileranlage bzw.
   c) der Satellitenempfangsanlage

23. Die Kosten für die Objektbewachung und Sicherheitseinrichtungen
   Hierunter gehören die Kosten für regelmäßige und besondere Be- und Überwachungsmaßnahmen sowie die Kosten für Fertigung, Anbringung und Betrieb für Sicherheitseinrichtungen.

24. Die Kosten sonstiger Geräte
   Hierzu gehören die Kosten des Betriebs z. B. maschineller Wasch- und Trockeneinrichtungen.

25. Die Kosten der Mietnebenkostenkonten
   Hierzu gehören die Kapitalkosten der Mietnebenkostenkonten, wie z. B. Bearbeitungsgebühren, Kontogebühren, Sollzinsen.

26. Sonstige Betriebskosten
   Das sind die in den Nummern 1 bis 25 nicht genannten Betriebskosten, namentlich die Betriebskosten von Nebengebäuden, Anlagen und Einrichtungen.

Essen, den 06.01.2005
[Illegible Signature] (Vermieter)

Mannheim, den 22.12.04
[Illegible Signature] (Mieter)

Alters- und Hinterbliebenen-Versorgungsstelle der Technischen Überwachungs-Vereine (VVaG)
Kurfürstenstraße 56 - 45138 Essen

Seite 16 des Mietvertrages vom 21.12.2004
Nachtrag Nr. 1 zum Mietvertrag vom 06.01.2005 / 22.12.2004
Objekt: Janus-Office-Center,
Josef-Meyer-Str. 13-15, 68167 Mannheim

zwischen

Alters- und Hinterbliebenen Versicherung der
Technischen Überwachungsvereine VVaG
Kurfürstenstr. 56
45138 Essen
UST ID: DE 11 98 24807

Vertreten durch den Geschf. Vorstand Herr Dr. rer. Pol. G. Wiedemann

und

Firma
Nitec Pharma GmbH
Joseph-Meyer-Str. 13-15
68167 Mannheim

vertreten durch den Geschäftsführer Herr Jochen Mattis

- nachstehend Mieterin genannt

1. **Änderung zu § 1 Mietgegenstand**
   Die Mietfläche wird um 57,65 m² im 1. OG erweitert. Der Grundriss ist als Anlage 1 zum Nachtrag beigelegt.

3. **Änderung zu § 4 Mietzins, Nebenkosten und Mehrwertsteuer**
   Der Mietzins für das 1. OG setzt ab dem 01.02.2006 wie folgt zusammen:

<table>
<thead>
<tr>
<th>Gebäudeteil</th>
<th>Mietfläche (m²)</th>
<th>Mietzins (Euro)</th>
<th>Nebenkostenvorauszahlung (Euro)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bürofläche seither</td>
<td>171,18</td>
<td>[...***...]</td>
<td>[...***...]</td>
</tr>
<tr>
<td>Bürofläche neu</td>
<td>57,65</td>
<td>[...***...]</td>
<td>[...***...]</td>
</tr>
<tr>
<td>4 Tiefgaragenstellplätze</td>
<td></td>
<td></td>
<td>[...***...]</td>
</tr>
<tr>
<td>Nebenkostenvorauszahlung</td>
<td>228,83</td>
<td>[...***...]</td>
<td>[...***...]</td>
</tr>
<tr>
<td>Zwischensumme netto</td>
<td></td>
<td></td>
<td>[...***...]</td>
</tr>
<tr>
<td>Mehrwertsteuer 16 %</td>
<td></td>
<td></td>
<td>[...***...]</td>
</tr>
<tr>
<td><strong>Summe brutto gesamt</strong></td>
<td></td>
<td></td>
<td>[...***...]</td>
</tr>
</tbody>
</table>

***Confidential Treatment Requested***

Seite 1 des Nachtrags vom 07.12.2005
4. Sonstiges

1. Der Vermieter übernimmt auf seine Kosten die Umverlegung der Strom- und Serverleitungen, sowie das Teppichverlegen der neu angemieteten Räume.

   Der Mieter übernimmt die Kosten der Verschiebung der Wände.


Essen, den 30.01.06

Mannheim, den 13.01.06

Alters- und Hinterbliebenen Versicherung der Technischen Überwachungsvereine VVAG
Kurfürstenstr. 58
45138 Essen

Fa. Nitec Pharma GmbH
Joseph-Meyer-Str. 13-15
68167 Mannheim

[Illegible Signature]
(Vermieterin)

[Illegible Signature]
(Mieterin)

Alters- und Hinterbliebenen-Versicherung der Technischen Überwachungs-Vereine (VVAG)
Kronprinzenstr. 30 45128 Essen

Seite 2 des Nachtrags vom 07.12.2005
Nachtrag Nr. 2 zum Mietvertrag vom 06.01.2005 / 22.12.2004  
Objekt: Janus-Office-Center,  
Josef-Meyer-Str. 13-15, 68167 Mannheim

zwischen

Alters- und Hinterbliebenen-Versicherung der  
Technischen Überwachungs-Vereine VVaG  
Kronprinzenstr. 30  
45128 Essen  
UST ID: DE 11 98 24807

Vertreten durch den Vorstand Herr Dr. rer. pol. G. Wiedemann und Herr Ralf Heynck  
UST ID: DE 11 98 24807

und

Firma  
Nitec Pharma GmbH  
Joseph-Meyer-Str. 13-15  
68167 Mannheim

vertreten durch den Geschäftsführer Herr Dr. Achim Schäffler

- nachstehend Mieterin genannt -

1. **Änderung zu § 1 Mietgegenstand**  
Die Mietfläche wird ab 01.02.2007 um 214,17 m² im 1. OG erweitert. Somit wird das komplette 1. OG von der Mieterin belegt. Die Gesamtfläche beträgt 443 m².

2. **Änderung zu § 4 Mietzeit und Kündigung**  
Das Mietverhältnis verlängert sich ab 01.02.2007 für das komplette 1. OG um weitere 2 Jahre bis zum 31.01.2009

3. **Änderung zu § 5 Mietzins**

| Kaltmiete Bürofläche 1. OG | 443 m² | [...] *** | [...] *** |
| Tiefgaragenplätze 125,126,127,128 | [...] *** |
| Stellplätze Nr. 33+32 | [...] *** |
| **Summe Kaltmiete** | 443 m² | [...] *** |
| + Nebenkostenvorauszahlung | [...] *** |
| **Summe Warmmiete netto** | [...] *** | + 19 % MwSt. |
| **Summe gesamt** | [...] *** |

***Confidential Treatment Requested

Seite 1 des Nachtrags Nr. 2 AHV/Nitec
4. **Sonstiges**

1. Der Mieter übernimmt auf seine Kosten die Verlegung der Strom- und Serverleitungen, sowie den Abbruch der eingezogenen Wand.

2. Der Vermieter übernimmt die Kosten für das Verlegen von Teppich in den neu angemieteten Räumen.


Essen, den ____________________________

Mannheim, den 03. January 2007

Alters- und Hinterbilebenen-Versicherung der
Technischen Überwachungs-Vereine-VVaG-
Kronprinzenstr. 30

45128 Essen

[Illegible Signature]
(Vermieterin)

Seite 2 des Nachtrags Nr. 2 AHV/Nitec

[Illegible Signature]
(Mieterin)

Fa. Nitec Pharma GmbH
Joseph-Meyer-Str. 13-15

68167 Mannheim
Nachtrag Nr. 3 zum Mietvertrag vom 06.01.2005 / 22.12.2004
Objekt: Janus-Office-Center,
Josef-Meyer-Str. 13-15, 68167 Mannheim
zwischen
Alters- und Hinterbliebenen-Versicherung der
Technischen Überwachungs-Vereine VVaG
Kronprinzenstr. 30
45128 Essen
UST ID: DE 11 98 24807
Vertreten durch den Vorstand Herr Dr. rer. pol. G. Wiedemann und Herr Ralf Heynck
- nachstehend Vermieter genannt -
und
Firma
Nitec Pharma GmbH
Joseph-Meyer-Str. 13-15
68167 Mannheim
vertreten durch den Geschäftsführer Herr Dr. Achim Schäffler
- nachstehend Mieterin genannt -
1. Änderung zu § 1 Mietgegenstand
Die Mietfläche wird ab 01.04.2008 um 247,29 m² im 5. OG erweitert.
Somit beträgt die Gesamtfläche neu 690,29 m² (1. und 5. OG)
2. Änderung zu § 5 Mietzins
Der Mietzins für setzt sich ab 01.04.08 wie folgt zusammen:

<table>
<thead>
<tr>
<th>Fläche</th>
<th>Miete</th>
<th>Nebenkosten</th>
<th>Miete mit MwSt.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bürofläche 1. OG</td>
<td>443,00 m²</td>
<td>[...]</td>
<td>[...]</td>
</tr>
<tr>
<td>Bürofläche 5. OG</td>
<td>247,29 m²</td>
<td>[...]</td>
<td>[...]</td>
</tr>
<tr>
<td>Tiefgaragenplätze</td>
<td>690,29 m²</td>
<td>[...]</td>
<td>[...]</td>
</tr>
<tr>
<td>Stellplätze Nr. 32+33+10+11+2</td>
<td>[...]</td>
<td>[...]</td>
<td>[...]</td>
</tr>
</tbody>
</table>

Summe Kaltmiete
690,29 m² | [...] | [...] |

Summe Warmmiete netto
+ 19 % MwSt.

Summe gesamt

***Confidential Treatment Requested
Seite 1 des Nachtrags Nr. 3 AHV/Nitec
4. **Sonstiges**

1. Der Mieter übernimmt auf seine Kosten die Malerarbeiten und Teppichreinigung in den Büroräumen im 5 OG.
2. In Büroräumen, in welchen der Teppichboden sehr stark abgenutzt ist, ersetzt der Vermieter den Teppichboden.
3. Der Vermieter übernimmt die Kosten einer Geschirrspülmaschine.
4. Die Möbel im 5. OG gehen kostenfrei auf die Firma Nitec Pharma über.

Essen, den __________
Mannheim, den 04. April 2008

Alters- und Hinterbliebenen-Versicherung der
Technischen Überwachungs-Vereine VVaG
Kronprinzenstr. 30

45128 Essen
68167 Mannheim

[Illegible Signature]  [Illegible Signature]
(Vermieterin) (Meiterin)

Anlage I: Grundriss 5. OG
Anlage II: Stellplätze Tiefgarage und Erdgeschoss

Seite 2 des Nachtrags Nr. 2 AHV/Nitec
Nachtrag Nr. 4 zum Mietvertrag vom 06.01.2005 / 22.12.2004
Objekt: Janus-Office-Center,
Josef-Meyer-Str. 13-15, 68167 Mannheim

Zwischen

Alters- und Hinterbliebenen-Versicherung der Technischen Überwachungs-Vereine VVaG
Kronprinzenstr. 30
45128 Essen
UST ID: DE 11 98 24807
Vertreten durch den Vorstand Herr Dr. rer. pol. G. Wiedemann und Herr Ralf Heynck
- nachstehend Vermieter genannt -

und

Firma
Nitec Pharma GmbH
Joseph-Meyer-Str. 13-15
68167 Mannheim
vertreten durch den Geschäftsführer Herr Dr. Achim Schäffler
- nachstehend Mieterin genannt -

1. Änderung zu § 4 Mietzeit und Kündigung
   Das Mietverhältnis verlängert sich für die gesamte angemietete Fläche bis zum 31.12.2010.

2. Sonstiges

Essen, den 24.09.2008
Mannheim, den 18 SEPT 2008

Alters- und Hinterbliebenen-Versicherung der Technischen Überwachungs-Vereine VVaG
Kronprinzenstr. 30
45128 Essen

[Illegible Signature] (Vermieterin)

Fa. Nitec Pharma GmbH
Joseph-Meyer-Str. 13-15

68167 Mannheim

[Illegible Signature] (Mieterin)

Seite 1 des Nachtrags Nr. 4 AHV/Nitec
**Nachtrag Nr. 5 zum Mietvertrag vom 06.01.2005/22.12.2004**

**Objekt: Janus-Office-Center,**

**Josef-Meyer-Str. 13-15, 68167 Mannheim**

Zwischen

Alters- und Hinterbliebenen-Versicherung
der Technischen Überwachungs-Vereine VVaG
Kronprinzenstr. 30

45128 Essen
UST ID: DE 11 98 24807

Vertreten durch den Vorstand Herr Dr. rer pol. G Wiedemann und Herr Ralf Heynck
- nachstehend Vermieter genannt -

und

Firma
Nitec Pharma GmbH
Joseph-Meyer-Str. 13-15

68167 Mannheim

vertreten durch den Geschäftsführer Herr Dr. Achim Schäffler
- nachstehend Mieterin genannt -

1. **Änderung zu § 1 Mietsache**
   
   Die Mieterin mietet ab 01.04.2009 zusätzlich einen Lagerraum im Erdgeschoss an.

2. **Änderung zu § 5 Mietzins**
   
   Somit endet sich die monatliche Mietzahlung ab 01.04.09 wie folgt:

<table>
<thead>
<tr>
<th>Kategorie</th>
<th>Fläche (m²)</th>
<th>Miete (EUR)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kaltmiete Bürofläche 1. OG</td>
<td>443,00</td>
<td>[...***...]</td>
</tr>
<tr>
<td>Kaltmiete Bürofläche 5 OG</td>
<td>247,29</td>
<td>[...***...]</td>
</tr>
<tr>
<td>Lagerfläche EG</td>
<td>18,50</td>
<td>[...***...]</td>
</tr>
<tr>
<td>Tiefgaragenplätze 125,126,127,128,132,133</td>
<td>125,126,127,128,132,133</td>
<td>[...***...]</td>
</tr>
<tr>
<td>Stellplätze Nr 32+33+10+11+2</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Summe Kaltmiete</strong></td>
<td></td>
<td>[...***...]</td>
</tr>
<tr>
<td>+ Nebenkostenvorauszahlung</td>
<td>690,29</td>
<td>[...***...]</td>
</tr>
<tr>
<td><strong>Summe Warmmiete netto</strong></td>
<td></td>
<td>[...***...]</td>
</tr>
<tr>
<td>+ 19% MwSt.</td>
<td></td>
<td>[...***...]</td>
</tr>
<tr>
<td><strong>Summe gesamt</strong></td>
<td></td>
<td>8,910,55</td>
</tr>
</tbody>
</table>

***Confidential Treatment Requested***
3. **Sonstiges**


Essen, den 12.3.09

Alters- und Hinterbliebenen-Versicherung der Technischen Überwachungs-Vereine (VVeG)
Kronprinzenstr. 30

45128 Essen

[Illegible Signature]  
(Vermieterin)

Alters- und Hinterbliebenen-Versicherung der Technischen Überwachungs-Vereine (VVeG)
Kronprinzenstr. 30 45128 Essen

Seite 2 des Nachtrags Nr. 5 AHV/Nitec

Mannheim, den 12.03.09

Fa. Nitec Pharma GmbH
Joseph-Meyer-Str. 13-15

68167 Mannheim

[Illegible Signature]  
(Mieterin)
Zwischen

Alters- und Hinterbliebenen-Versicherung der
Technischen Überwachungs-Vereine-VVaG-
Kurfürstenstr. 56, 45128 Essen
UST ID: DE 11 98 24807
Vertreten durch den Vorstand Herr R Heynck und Frau S. Schwierz
- nachstehend Vermieter genannt -

und

Firma
Horizon Pharma GmbH
ehemals Fa. Nitec Pharma GmbH
Joseph-Meyer-Str. 13-15, 68167 Mannheim
vertreten durch den Geschäftsführer Herr Dr. Achim Schäffler
- nachstehend Mieterin genannt -

Präambel

Die Fa. Nitec Pharma GmbH wurde am 22.06.2010 in Horizon Pharma GmbH umbenannt. Sämtliche Rechte und Pflichten aus dem bestehenden Mietvertrag gehen somit zeitgleich auf die Firma Horizon Pharma GmbH über.

1. Änderung zu § 4 Mietzeit und Kündigung

Das Mietverhältnis verlängert sich für die gesamte angemietete Fläche bis zum 31.12.2011.

2. Sonstiges


Essen, den 26.8.2010

Alters- und Hinterbliebenen-Versicherung der
Technischen Überwachungs-Vereine VVaG
Korprlnzenstr. 30
45128 Essen

/s/ illegible
(Vermieterin)

Mannheim, den 19. Aug. 2010

Fa. Horizon Pharma GmbH
Joseph-Meyer-Str. 13-15
68167 Mannheim

/s/ Achim Schäffler
(Mieterin)

Seite 1 des Nachtrags Nr. 6 AHV/Horizon
Sitz: München
Amtsgericht München HRB 89 260
HypoVereinsbank München 2 450 577
BLZ 700 202 70
UST-IdNr. DE129484259
Informationen gemäß § 2 Abs. 1 DL-InfoV
unter www.tuev-sued.de/impressum

Geschäftsführer:
Dipl.-Ing. Wolfgang Berger
69050 v2/SD
Telefon: +49 711 7005-211
Telefax: +49 711 7005-312
www.tuev-sued.de
TÜV®
Gottlieb-Daimler-Straße 7
70794 Filderstadt
Deutschland

TÜV SÜD Immobilien Service GmbH
Gottlieb-Daimler-Straße 7
70794 Filderstadt
Deutschland

®
Mietvertrag über
Stellplätze
Joseph-Meyer-Str. 13-15, 68167 Mannheim

Zwischen
Alters- und Hinterbliebenen
Versicherung der
Technischen Überwachungsvereine VVaG
Kurfürstenstr. 56
45138 Essen
UST ID: DE 11 98 24807

Vertreten durch den Geschäftsführer Herr Dr. rer. Pol. G. Wiedemann

und

Firma
Nitec Pharma GmbH
Joseph-Meyer-Str. 13-15
68167 Mannheim
vertreten durch den Geschäftsführer Herr Jochen Mattis

-nachstehend Mieterin genannt-

1. Mietobjekt
Der Mieter mietet ab 01.08.2007 in der Joseph-Meyer-Str. 13-15, 68167 Mannheim nachstehende Stellplätze an:

- Stellplatz Nr. 10+11
  - [***...***]
  - [***...***]
  + 16% MwSt.
  - [***...***]
  - [***...***]

- monatliche Stellplatzmiete gesamt
  - [***...***]

2. Kündigung
Der Mietvertrag kann von beiden Parteien mit einer Frist von 1 Monat gekündigt werden.
Filderstadt, den 07.08.07

TUV SUD Immobillien Servico GmbH

[Illegible]

[Illegible Signature]
(Vermieter)

Mannheim, den [Illegible]

Nitec Pharma GmbH
Joseph-Meyer-Straße 13-15
68167 Mannheim

[Illegible]

[Illegible Signature]
(Mieter)
PACKAGING and SUPPLY AGREEMENT

for the packaging of pharmaceuticals between

NITEC PHARMA AG, Kaegenstrasse 17, CH-4153 Reinach, Switzerland, hereinafter referred to as “NITEC” and

CATALENT GERMANY SCHORNDORF GmbH Steinbeisstraße 2, D-73614 Schorndorf, Germany, hereinafter referred to as “CATALENT” and made effective 29 Sept. 2008, (the “Effective Date”).

WHEREAS, NITEC is a company manufacturing, distributing and licensing pharmaceutical products, including LODOTRA™ prednisone (Presentations in accordance with Appendix 1), and is interested in having CATALENT package LODOTRA for use, marketing, distribution and sale by NITEC or a third party.

WHEREAS, CATALENT has extensive experience in and maintains adequate facilities and personnel for contracting services related to the packaging of pharmaceuticals (“Services”) in accordance with Appendix 7.

WHEREAS, the Parties wish to enter into a close relationship in respect of CATALENT’s assembly of NITEC’s LODOTRA (as more specifically described in Appendix 1) and its supply to NITEC to the effect that both Parties will obtain maximum economic benefits from their cooperation.

WHEREAS, NITEC and CATALENT shall enter into a separate quality agreement (the “Quality Agreement”) governing the quality issues of CATALENT’s Services for NITEC.

WHEREAS, the Parties wish to have all commercial issues of CATALENT’s Services for NITEC governed by this Agreement.

Now, therefore, the Parties agree as follows:

ARTICLE 1 - SUBJECT OF THE AGREEMENT

1. The subject matter of this Agreement is the packaging of LODOTRA as set forth in Appendix 2 (hereinafter referred to as “Packaging Requirements”) at prices and conditions set forth in Appendix 3 (hereinafter referred to as “Prices”), and the delivery of such finished products (hereinafter referred to as “Finished Product”) to NITEC or such other destinations as NITEC may request, and Catalent may agree in writing, as provided for in the Quality Agreement.

2. CATALENT acknowledges that partners or affiliated companies of NITEC might be interested in the future to become a Party of this Agreement. CATALENT therefore agrees that - subject to the execution of a respective amendment to this Agreement - partners or affiliated companies of NITEC shall upon agreement of the Parties become a Party to this Agreement.

3. CATALENT acknowledges that assembly of LODOTRA on CATALENT’s site at Schorndorf is of utmost importance for the performance of this Agreement. CATALENT

10 Sept 2008
therefore accepts that it may not render its Services from a different site without NITEC’s prior written consent.

ARTICLE 2 - DELIVERY OF NITEC PRODUCT LODOTRA

1. NITEC shall deliver to CATALENT, at NITEC’s own expense and risk of loss, tablets of LODOTRA DDP (Incoterms 2000), CATALENT’s facility in Schorndorf as specified in Appendix 1 and the Quality Agreement in order to enable CATALENT to render the Services.

2. The Parties accept the likelihood of minor losses of tablets of products when comparing the amount of tablets shipped by NITEC to CATALENT and the amount of tablets as Finished Product delivered from CATALENT to NITEC or its partners. Therefore, the Parties expressly agree that, upon the first anniversary of the date of this Agreement, they shall mutually agree on a reasonable loss rate. NITEC further acknowledges that any broken or non-conforming tablets of LODOTRA shall not be included in the calculation of such loss rate. CATALENT shall reimburse NITEC for losses only in the event its losses exceed the reasonable loss mutually agreed between the Parties.

ARTICLE 3 - FORECAST AND DELIVERY

1. The average quantities for each of NITEC’s individual orders for Finished Product are specified in Appendix 4.

2. During the term of this Agreement, NITEC shall make available to CATALENT an [...***...] rolling forecast of its requirements of Finished Product which shall be updated by NITEC every [...***...]. Only the [...***...] of such rolling forecast shall be binding for NITEC and result in separate firm purchase orders. The volumes specified for the other [...***...] of such rolling forecast shall be non-binding estimates only.

3. NITEC shall send orders to CATALENT for Finished Product and, subject to CATALENT’s written confirmation, CATALENT shall deliver the Finished Product ordered Ex Works (Incoterms 2000), CATALENT’s facility within a period of [...***...] after receipt of confirmation of NITEC’s purchase order. Subject to CATALENT’s written confirmation as set forth above, CATALENT shall use its commercially reasonable efforts to fulfill purchase orders for Finished Product. In the case of orders exceeding the volumes specified in NITEC’s forecasts for its binding period of [...***...] by up to [...***...], CATALENT will use commercially reasonable efforts to fulfill this exceeding request within the [...***...] in which the original order was placed. CATALENT shall use commercially reasonable efforts to fulfill purchase orders for Finished Product exceeding the volumes specified in NITEC’s forecast by more than [...***...]. NITEC undertakes to notify CATALENT in writing of its exceeding requirements for Products as early as reasonably possible.

4. CATALENT shall be responsible for the order and the purchase of raw materials and packaging materials, except primary packaging material (collectively “Materials”), from third parties as it deems appropriate. NITEC shall be responsible for firmly ordering primary packaging material (“Primary Packaging Materials”) from [...***...] or any other supplier chosen by NITEC in accordance with NITEC’s rolling forecast and the contract.

10 Sept 2008 2. ***Confidential Treatment Requested
between NITEC and […] a copy of which is attached as Appendix 6 and shall arrange for the delivery of such Primary Packaging Materials DDP (Incoterms 2000), CATALENT’s facility; provided, however, as set forth in Article 13.3, NITEC shall not hold CATALENT responsible or make a claim against CATALENT if a delay is attributable to […] or the respective supplier’s failure to deliver the Primary Packaging Materials properly or in a timely manner. In no event, however, shall NITEC be obliged to purchase from CATALENT Materials or otherwise pay for Materials, which exceed the amount necessary to comply with NITEC’s requirements of Finished Products set out in the binding part of the rolling forecast (which is the first three months).

5. In the event that CATALENT becomes aware of circumstances (including Force Majeure circumstances) that may cause a delay in the delivery of Finished Product, CATALENT shall notify NITEC immediately. CATALENT shall use commercially reasonable efforts to avoid any delay in delivery and, if such delay cannot be avoided, shall minimize and afford to NITEC its full co-operation to minimize the effects of delay for NITEC. Further, the Parties, shall as soon as feasible after the execution hereof, mutually prepare a crisis management plan setting out its strategies and solutions in the event of CATALENT’s inability to fulfill its contractual obligations.

6. It is expressly understood that CATALENT’s obligations pursuant to Article 3.5 is conditional upon NITEC’s delivery of tablets of LODOTRA, as set forth in Article 2 and the Quality Agreement, and NITEC’s (or a third party’s) delivery of Primary Packaging Material as set forth in Article 3.4 at least two (2) weeks prior to the confirmed date of starting the Services.

ARTICLE 4 - CONTINUOUS IMPROVEMENT PROGRAMME

1. The Parties shall hold Continuous Improvement Programme (“CIP”) meetings at appropriate intervals to identify and implement ways and means by which they can continually improve quality, time and cost of the Finished Product and Services supplied hereunder.

2. A set of reasonable continuous improvement objectives (e.g. optimisation of yield losses) shall be mutually agreed for each calendar year starting after one year of first commercial production. At the end of such year, CATALENT and NITEC shall review the CIP and measure the achievement of the CIP objectives by CATALENT.

ARTICLE 5 - PRICES AND CONDITIONS

1. The prices and conditions set forth in Appendices 2 and 3 shall apply to the Services during the first year of this Agreement. Thereafter, the Parties shall review the price structure and mutually agree on any fair and reasonable adjustments to the prices taking into particular consideration, the principles set forth in Articles 5.2 and 5.3, below.

2. NITEC or CATALENT may request that the prices for the Services be adjusted in accordance with the calculation set out in Appendix 3 if: (i) […] or (ii) […] or (iii) if NITEC requests a change in the Services to which CATALENT agrees.
3. NITEC shall pay CATALENT’s invoices within […] of the date of invoice, net. Late payments shall be subject to a surcharge of […] on all overdue accounts. All payments shall be made in Euros.

ARTICLE 6 - REPRESENTATIONS AND WARRANTIES

1. Each Party hereby represents and warrants to the other Party that such Party (i) is duly organized and validly existing under the laws of the jurisdiction in which it is organized, (ii) has the power and authority and the legal right to own and operate its property and assets, and to carry on its business as it is now being conducted, and (iii) is in compliance with all requirements of any applicable laws, except to the extent that any non-compliance would not adversely affect such Party’s ability to perform its obligations under this Agreement.

2. Each Party hereby represents and warrants to the other Party that such Party (i) has the power and authority and the legal right to enter into this Agreement and to perform its obligations hereunder, (ii) has taken all necessary action on its part to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder, and (iii) this Agreement has been duly executed and delivered on behalf of such Party, and constitutes a legal, valid, binding obligation, enforceable against such Party in accordance with its terms.

3. NITEC represents and warrants that (i) all material (content of packaging insert, promotional material and the LODOTRA) delivered to CATALENT shall comply with all applicable laws governing their manufacture, use, promotion, sale and distribution; (ii) NITEC has obtained all permits, licenses or authorizations from all relevant regulatory agencies necessary or required for the manufacture and possession of LODOTRA and for its use as set forth in the respective order; (iii) NITEC will not use LODOTRA nor any other material supplied by NITEC for any clinical study, sale, marketing or any commercial activity without ensuring that it has obtained all permits, licenses or authorizations from all relevant regulatory agencies; (iv) NITEC acknowledges that it will review all packaging inserts as well as labels, drawings and artwork and that all such material is subject to NITEC’s approval; and (v) NITEC has provided to CATALENT all available safe handling instructions, health and environment information and material safety data sheets applicable to LODOTRA and any other materials supplied by NITEC.

4. CATALENT represents and warrants that all Services rendered and all Finished Product delivered to NITEC hereunder will be in full conformance with cGMP rules, applicable local requirements and all Specifications agreed and the Quality Agreement; provided, however, CATALENT shall not be held liable and NITEC shall not make a claim for any non-conformity attributable to NITEC-supplied materials (including, but not limited to, the LODOTRA, artwork, packaging inserts and labeling).

5. NITEC or its partners shall inspect each shipment of Finished Product for obvious defects and completeness within […] after receipt of each delivery and NITEC shall notify CATALENT in writing immediately of any defects or shortages it has discovered. § 377 HGB (German Commercial Code) shall not apply.

6. In the event of hidden defects not readily ascertainable upon inspection per Article 5.5 above, the Party that first becomes aware of the defect shall notify the other Party of any such defect immediately, but in no event later than within […] after they have been...
discovered which for the purposes of the Agreement shall not be more than […] after completion of the Services.

7. If Finished Product delivered hereunder does not fully comply with the warranties given by CATALENT in Article 6.4 ("Defective Products"), NITEC may, subject to Article 9, submit within a period of […] either a demand for replacement of the Defective Products at no additional charge for the Services (if and to the extent the defect is directly attributable to CATALENT’s gross negligence (Grobe Fahrlässigkeit) or willful misconduct) for Finished Product of proper quality or rectification of the Defective Products or a credit corresponding to the invoiced amount for the Defective Products. In the event CATALENT is required to replace Defective Product, CATALENT shall replace Defective Product with conforming Product, provided that in such event, NITEC shall supply, at its cost and expense, the LODOTRA and any other materials supplied by NITEC necessary to replace the Defective Product. Conversely, any cost and expenses related to the Defective Product incurred by CATALENT and/or NITEC, including but not limited to the costs and expenses for full replacement (also in the case of hidden defects) and/or destruction of Defective Product shall be borne by CATALENT (whereby the cost of LODOTRA shall be set out in Appendix 8) only if and to the extent the defect is directly attributable to CATALENT’s gross negligence or willful misconduct.

8. If there is a dispute whether a Finished Product delivered is a Defective Product or whether a Finished Product’s defect has been caused by CATALENT or by NITEC after receipt, a sample of the rejected Finished Product and a sample retained by CATALENT shall be exchanged between the Parties for analysis. If the Parties fail to come to a mutually satisfying conclusion within a period of […] following the exchange of the samples, both samples shall be submitted to a laboratory acceptable to both Parties as agreed case by case (the “Laboratory”). The Laboratory shall determine whether the rejected Finished Product is defective and thereafter, to which Party such defect is to be attributed, and its determination, in the absence of manifest error, shall be final and binding upon the Parties. The costs charged by the Laboratory shall be borne by the Party that has been found to be wrong by the Laboratory’s determination.

9. THE OBLIGATIONS OF CATALENT TO REPLACE OR RECTIFY DEFECTIVE PRODUCT IN ACCORDANCE WITH ARTICLE 6.7 SHALL BE NITEC’S SOLE AND EXCLUSIVE REMEDY FOR DEFECTIVE PRODUCT AND IS IN LIEU OF ANY OTHER WARRANTY, EXPRESS OR IMPLIED.

ARTICLE 7 - RECALL OR WITHDRAWAL OF FINISHED PRODUCT

1. In the event that either Party is of the opinion that a recall or product withdrawal of the Finished Product should be considered, such Party shall immediately inform the other Party and the Marketing Authorisation Holder (MAH) for the Finished Product in writing (including telefax) of such conclusion. The further procedure and in particular all communication shall be coordinated by NITEC’s European Qualified Person (QP) Pharmacovigilance in coordination with the QP of the Manufacturer and the concerned national QPs for Pharmacovigilance of the other involved Parties. A final decision on a recall or product withdrawal will be made by NITEC’s committee for crisis management and executed by the relevant MAH.

10 Sept 2008

5. ***Confidential Treatment Requested
2. CATALENT shall not take any action, other than action which it is required to take by law, without first obtaining the approval of NITEC’s QP.

3. In conjunction with such recall, each Party shall assist each other in the investigation to determine the cause and extent of the problem and the Parties shall fully cooperate with each other concerning the necessity and nature of such action. Depending on the nature of such an event the Parties agree to find a consensus in due time.

4. In the event that any Finished Product is recalled because it does not conform to the warranties set forth in Article 6 and NITEC or a third party is responsible for such non-conformity, or because NITEC was negligent or intentionally acted wrongfully, or due to an omission of NITEC, NITEC shall bear the costs and expenses incurred directly from such recall, including without limitation, expenses related to communications and meetings with all required regulatory agencies, expenses of replacement stock, the cost of notifying customers and costs associated with shipment of recalled Finished Product from customers and shipment of an equal amount of replacement Finished Product to those same customers. Conversely, in the event that any Finished Product is recalled because it does not conform to the warranties set forth in Article 6 and CATALENT is responsible for such non-conformity, or because CATALENT was negligent or intentionally acted wrongfully, or due to an omission of CATALENT, CATALENT shall, subject to Article 9, bear the direct administrative costs and expenses incurred directly from such recall, as approved by CATALENT in writing in advance.

5. In the event that CATALENT becomes knowledgeable of any pharmaceutical technical complaint or an adverse reaction related to the product, the NITEC QP Pharmacovigilance should be immediately informed.

ARTICLE 8 - INDEMNIFICATION

1. Subject to Article 9, each Party shall be liable to the other Party for all damages arising for the other Party out of the breach of any obligation of the breaching Party under this Agreement.

2. Subject to Article 9, each Party (the “Indemnifying Party”) shall indemnify and hold the other Party (the “Indemnified Party”) harmless for third party claims and all related costs, expenses, liabilities, damages, losses and fees, (including reasonable legal and other reasonable professional fees and costs) (“Liability”) arising out of or resulting from the Indemnifying Party’s breach of this Agreement or any negligent, willful misconduct or other wrongful act or omission directly attributable to the Indemnifying Party in connection with this Agreement.

3. In addition to Article 8.2, NITEC shall indemnify and hold harmless CATALENT, its affiliates, and their respective directors, officers, employees, and agents from and against any and all losses arising out of or resulting from (A) any breach of its representations, warranties or obligations set forth in this Agreement; (B) any manufacture (other than the negligently performed Services), sale, promotion, distribution, use of or exposure to the LODOTRA or any materials supplied by NITEC, including, without limitation, product liability or strict liability; (C) NITEC’s exercise of control over the Services to the extent that NITEC’s instructions or directions violate applicable laws; (D) any actual or alleged infringement or violation of any patent, trade secret, copyright, trademark or other proprietary rights provided...
by NITEC; or (E) any negligence or willful misconduct of NITEC, except to the extent that any of the foregoing arises out of or results from CATALENT’s negligence, willful misconduct, or breach of this Agreement.

4. Upon receiving notice of any claim for Liability under this provision, such Party shall promptly notify the Indemnifying Party in writing with full details of the claim; provided, however, that failure to give notice shall not limit or otherwise reduce the indemnification provided for in this Agreement except to the extent the delay or failure to give notice materially impairs the defence of such claim for Liability. Regardless, unless made with the express prior written consent of the Indemnifying Party, no sums paid by the Indemnified Party in settlement of any lawsuit shall be recoverable under this provision. Conversely, under no circumstances shall the Indemnifying Party settle any claim or admit wrongdoing or liability of the Indemnified Party without the Indemnified Party’s express prior written consent.

ARTICLE 9 - LIMITATION OF LIABILITY

1. IN NO EVENT SHALL THE LIABILITY OF CATALENT UNDER THIS AGREEMENT [...***...].

2. NEITHER PARTY SHALL BE LIABLE TO THE OTHER FOR ANY INCIDENTAL, INDIRECT OR CONSEQUENTIAL DAMAGES OF ANY KIND, INCLUDING BUT NOT LIMITED TO, LOST PROFITS, LOST DATA, LOST REVENUES AND/OR LOSS OF BUSINESS OPPORTUNITY.

3. To the extent that any provision in this Agreement or any order purporting to limit either Party’s liability to the other Party or either Party’s remedies (any such provision a “Limiting Provision”) violates or contradicts any law deemed by the final, non-appealable order of a court or other body of competent jurisdiction to govern any dispute (any such law a “Mandatory Applicable Law”) such Limiting Provision shall not apply, but shall instead be replaced by (and only to the extent of) the applicable provisions of such Mandatory Applicable Law solely for the purposes of resolving such dispute. In particular, nothing in this Agreement or any order shall limit a Party’s liability for death or personal injury arising from its own negligence or for strict liability for defective products if such limitation would violate a Mandatory Applicable Law.

ARTICLE 10 - INSURANCE

1. CATALENT shall, at its own cost and expense, obtain and maintain in full force and effect the following insurance during the term of this Agreement, each covering claims brought and suits served anywhere in the world:

   (a) Commercial General Liability (Haftpflichtversicherung) or Public Liability insurance (whichever is applicable) with per-occurrence and general aggregate limits of not less than [...***...];
(b) Products and Completed Operations Liability Insurance with per-occurrence and general aggregate limits of not less than [...***...];

(c) Professional Services Errors & Omissions Liability Insurance with per claim and aggregate limits of not less than [...***...] covering sums that CATALENT becomes legally obligated to pay as damages resulting from claims made by NITEC for errors or omissions committed in the performance of the Services set forth in the Agreement.

In the event that any of the required policies of insurance are written on a claims made basis, then such policies shall be maintained during the entire term of this Agreement and for a period of not fewer than [...***...] following the termination or expiration of this Agreement. Each insurance policy that is required under this Article 10.1 shall be obtained from an insurance carrier with an A.M. Best rating of at least A- VII.

CATALENT shall furnish evidence of insurance for the required policies to NITEC as soon as practicable after entering into this Agreement and upon renewal of any such policies or upon the respective policy renewal becoming effective.

2. NITEC shall, at its own cost and expense, obtain and maintain in full force and effect the following insurance during the term of this Agreement, each covering claims brought and suits served anywhere in the world:

(a) Commercial General Liability Insurance as Marketing Authorization Holder(s) as per the applicable pharmaceutical laws and legacy of the individual countries or markets when and where a Market Authorization for LODOTRA Tablets has been granted, e.g. in Germany with a general aggregate limit of an amount equivalent to not less than [...***...]; provided, however, this sub-section (a) shall not apply to the United States and NITEC and CATALENT shall negotiate in good faith the Commercial General Liability Insurance to be procured and maintained by NITEC before LODOTRA is launched in the United States.

(b) Commercial General Liability (Haftpflichtversicherung) or Public Liability insurance (whichever is applicable) with per-occurrence and general aggregate limits of not less than [...***...].

(c) All Risk Property insurance, including transit coverage, in an amount equal to full replacement value covering NITEC’s property while it is at CATALENT’s facility, or in transit to and from CATALENT’s facility, whereby any claim for recovery shall be made under NITEC’s insurance policy before a claim is made under CATALENT’s respective policy; provided, however, NITEC acknowledges that neither CATALENT nor CATALENT’s insurance (if any) shall be responsible for, or liable for any costs, expenses, or losses that may occur during transit to or from CATALENT’s facility.

In the event that any of the required policies of insurance are written on a claims made basis, then such policies shall be maintained during the entire term of this Agreement and for a period of not fewer than [...***...] following the termination or expiration of this Agreement.

10 Sept 2008

8. ***Confidential Treatment Requested
Execution Version

Agreement. Each insurance policy that is required under this Article 10.2 shall be obtained from an insurance carrier with an A.M. Best rating of at least A-
VII.

NITEC shall furnish a certificate of insurance for the required policies to CATALENT as soon as practicable after entering into this Agreement and upon each renewal of any such policies becoming effective.

ARTICLE 11 - CONFIDENTIALITY

1. The recipient of any information provided by the other Party as a result of the operation of or in connection with this Agreement or its preparation,
negotiation or termination shall treat such information in confidence and shall not use or disclose such information to any third party except for the purposes
of this Agreement. The same applies to the contents of this Agreement.

2. The aforesaid does not apply to any information which (a) is or later comes into the public domain otherwise than by breach of this Agreement, or (b) is in
the possession of the Party receiving the information prior to its receipt under this Agreement, or (c) is independently received from a third party, which is free
to disclose the information.

3. The obligations set forth in this Article 11 do not prevent the disclosure of information to the competent authorities or agencies, in particular judicial or
administrative agencies, if required by law, but such disclosure shall be strictly limited to the extent of the disclosure required by the relevant authority or
agency. In such event, the Party making the disclosure is required to give prior written notice to the other Party and authorize it to seek an appropriate
preventive solution.

4. All confidential information shall remain the sole property of the Party disclosing such information or data. Upon termination of this Agreement, the
receiving Party shall, promptly return within thirty (30) days all such information, including any copies thereof, and cease its use or, at the request of the
disclosing Party, shall promptly destroy the same and certify such destruction to the disclosing Party.

ARTICLE 12 - TERM OF AGREEMENT

1. The Agreement shall come into force upon its Effective Date and shall remain in effect for a period of three (3) years after the launch of LODOTRA in the
EU or in the United States, whichever comes first (the “Initial Period”). After the expiry of the Initial Period the Agreement shall be extended automatically
for further [...***...] renewal periods (if any, the “Renewal Periods”) (the Initial Period and any Renewal Periods will be the “Term”) unless either Party gives
at least [...***...] months written notice to terminate the Agreement before expiry of the then current period. Such termination shall not apply to any then-
outstanding orders.

2. The right to terminate the Agreement for cause is reserved. In particular, terminations for cause are constituted by a gross failure to fulfil contractual
obligations by either Party. Without limitation to the generality of the foregoing, a gross failure on the part of CATALENT shall be deemed to have occurred
if CATALENT delivers Finished Product that does not conform to the cGMP (or that would hinder the commercialisation of the Finished

10 Sept 2008

9.

***Confidential Treatment Requested
3. NITEC may terminate this Agreement if NITEC or one of its partners decide to perform the assembly of LODOTRA at NITEC’s partner or within the NITEC group, whereby such termination shall be effective upon NITEC giving CATALENT at least [...***…] written notice. In the event that NITEC terminates this Agreement pursuant to this Article 12(3), NITEC shall pay CATALENT all fees for Services rendered to the effective date of termination in accordance with the applicable order, including any non-cancelable obligations, works-in-progress and materials ordered by CATALENT for the performance of Services under this Agreement as warranted by NITEC’s forecasts, plus all out-of-pocket expenses incurred by CATALENT on behalf of NITEC in connection with or as a result of such termination. CATALENT shall provide NITEC with an invoice for its termination expenses and charges under this Article 12.3 as soon as reasonably practicable following termination of this Agreement.

ARTICLE 13 - FINAL PROVISIONS

1. If changes in the market lead to a situation, which is not reasonable for either Party, both Parties will endeavour amicably to find a solution acceptable to both of them. The same applies if disputes arise from the performance of the Agreement.

2. Except as set forth in Article 6.8 all disputes, controversies, or differences which may arise between the Parties out of or in relation to or in connection with this Agreement shall be decided by the courts of Mannheim (if NITEC is the defendant) and Schorndorf (if CATALENT is the defendant).

3. Delay in or failure to carry out the obligations imposed on any Party under this Agreement shall not be deemed breaches of the Agreement if such delay or failure results from fire, explosion, labour dispute, natural disaster, war, legislative or governmental acts, or any other cause beyond the control of the affected Party, including for example, if [...***…], or any other supplier, or the respective legal successor (see Article 3.4), fails to deliver the Primary Packaging Materials properly or in a timely manner, in each case through no fault or negligence of the Party invoking these circumstances as an excuse (collectively “Force Majeure”). Except with respect to [...***…] or any other supplier nominated by NITEC, or the respective legal successor, A lack or failure of the affected Party’s sub-contractor shall not constitute Force Majeure unless caused by circumstances which represent Force Majeure themselves. In the event delay or failure due to Force Majeure continues for a period exceeding nine (9) months, either Party may terminate this Agreement effective immediately.

4. If individual provisions of this Agreement are invalid or become invalid, the Parties hereby agree that this shall not affect the validity of the remainder. The Parties undertake to replace the invalid provisions by others with the same economical effect as far as legally possible.

5. This Agreement including its Appendices 1 to 8 constitutes the entire agreement between the Parties concerning the subject matter.

10 Sept 2008

**Confidential Treatment Requested**
6. Any alterations of or additions to this Agreement or its Appendices must be made in writing and agreed to by both Parties. This requirement shall also apply to the preceding sentence.

7. This Agreement is and any confirmed order placed under this Agreement is subject to German law without its provisions regarding the conflict of laws or the Vienna Convention on the International Sale of Goods (CISG).

8. The rights and obligations of the Parties shall continue under Articles 8 — 11, 12.3, 13.7 and 13.8 notwithstanding expiration or termination of this Agreement.

**CATALENT GERMANY SCHORNDORF GmbH**

29. Sept. 2008

/s/ Ronan Fox
by: Ronan Fox
its: Managing Director

/s/ Jürgen Hess
by: Jürgen Hess
its: Director Sales & BD

**NITEC PHARMA AG**

29. Sept. 2008  
29.9.08

/s/ Achim Schäffler
by: Dr. Achim Schäffler
its: Head R&D & Prod. and Member of Board of Directors

[Illegible Signature]
by: [Illegible]
its: Head R&D & Prod. and Member of Board of Directors

10 Sept 2008  
11.
List of Appendices
Appendix 1 — LODOTRA Presentations
Appendix 2 — Packaging Requirements
Appendix 3 — Prices and Price Re-Calculation
Appendix 4 — Average quantities
Appendix 5 — Delivery sites
Appendix 6 — Copy of Agreement […***…] and NITEC
Appendix 7 — Services
Appendix 8 — Costs of LODOTRA

10 Sept 2008
Appendix 1 — LODOTRA presentations

Lodotra 1 mg:
Each modified-release tablet contains 1 mg of prednisone

Lodotra 2 mg:
Each modified-release tablet contains 2 mg of prednisone

Lodotra 5 mg:
Each modified-release tablet contains 5 mg of prednisone
Appendix 3 – Prices

[...***...]

***Confidential Treatment Requested
Appendix 4—Average quantities (by NITEC)

<table>
<thead>
<tr>
<th>Lodotra</th>
<th>[***]</th>
<th>[***]</th>
<th>[***]</th>
</tr>
</thead>
<tbody>
<tr>
<td>[***]</td>
<td>[***]</td>
<td>[***]</td>
<td>[***]</td>
</tr>
<tr>
<td>[***]</td>
<td>[***]</td>
<td>[***]</td>
<td>[***]</td>
</tr>
<tr>
<td>[***]</td>
<td>[***]</td>
<td>[***]</td>
<td>[***]</td>
</tr>
<tr>
<td>[***]</td>
<td>[***]</td>
<td>[***]</td>
<td>[***]</td>
</tr>
</tbody>
</table>

10 Sept 2008

16

***Confidential Treatment Requested
Appendix 5 – Delivery Sites
(by NITEC)
[...***...]
[...***...]
[...***...]
[...***...]
[...***...]
[...***...]
[...***...]
[...***...]

***Confidential Treatment Requested
Appendix 6 - Copy of Agreement between [***] and NITEC
[Please see attached.]

18

***Confidential Treatment Requested
Exclusive Supply Agreement - Pharmaceutical Plastic Packaging

Supply agreement commenced 15 October 2007

between

BUYER,
Nitec Pharma AG
Kägenstraße 9
CH-4153 Reinach
Switzerland
(hereinafter referred to as NITEC)

and

SELLER,
Gerresheimer Værløse A/5
Walgerholm 2-8, 3500 Værloose,
Denmark,
(hereafter referred to as Gerresheimer)
representing by Division President Niels Düring.

1. Subject of Agreement

NITEC wishes to enter into an agreement with Gerresheimer to buy “Products” from Gerresheimer listed under section 2 and specified under schedule 3 for the packaging of NITEC’s product LODOTRA, a novel modified release tablet containing prednisone.

Purpose and objective of this agreement is to establish a long term partnership between NITEC and Gerresheimer.
It is the intention that NITEC and Gerresheimer shall pursue a consolidation of the respective businesses under a win-win philosophy, where both part are considered, preferred supplier and customer (Key Account), respectively. Gerresheimer agrees to exclusively supply NITEC with its DUMA Multi Grip Cap – Art. No. 003424-3000- for NITEC’s LODOTRA.

This agreement will set the frame for this partnership and the background for this project is to include the Duma Multi Grip packaging concept on LODOTRA packed in containers, enabling a clear and uniform communication platform to the end-user creating preference for NITEC’s LODOTRA with a packaging awarded, easy to open packaging.

Furthermore, this agreement specifies the respective pharmaceutical responsibilities related to the manufacture and control of the “Products”, especially with respect to current Good Manufacturing Practice and to the relevant DIN EN ISO 9001 standards, as applicable, and thus fulfils the corresponding requirements of the European Union and of National Drug Laws.

This agreement will also govern as a basis for Gerresheimer and NITEC (for the Duma Multi Grip cap 003424-3000) to make necessary investments, ensuring NITEC appropriate product availability of products covered by this agreement.

2. **Products covered by this Agreement**

The agreement will reflect the total product portfolio as listed below:

<table>
<thead>
<tr>
<th>Product — Gerresheimer article no.</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>034040-3000 Duma MG 40 ml</td>
<td></td>
</tr>
<tr>
<td>034075-3000 Duma MG 75 ml</td>
<td></td>
</tr>
<tr>
<td>003424-3000 Duma Multi Grip Cap</td>
<td></td>
</tr>
<tr>
<td>045256-4000 Duma Twist-off 250 ml</td>
<td></td>
</tr>
<tr>
<td>03827D-3000 Duma Twist Cap TE</td>
<td></td>
</tr>
</tbody>
</table>

The estimated annual quantities are listed in Schedule 2.
3. Investment Requirements and Nitec Contribution

NITEC and Gerresheimer agree to the following investments by Gerresheimer, enabling a commercialisation of the project:

**Duma Multi Grip closure system 34 mm (003424-3000).**

Investment in an Injection Mould (IM) customized to NITEC requirements based upon the Gerresheimer developed cap will be made with a capacity in compliance with the estimated yearly quantities (Schedule 2).

The first Mould has a yearly capacity of approx. [...] units annually with a maximum weekly capacity of [...] units and will be initiated after written consent of Nitec but not before December 2007.

The investment in a second Mould with a yearly capacity of [...] units with a weekly maximum capacity of [...] will be initiated after having consent of both parties depending on the annual forecast.

Gerresheimer will in this way secure the capacity including back up for the future and hereby undertakes to have such capacity available to serve Nitec’s requirements of product as forecasted in accordance with this Agreement.

NITEC will have an exclusivity of the aforementioned Duma Multi Grip Closure mould covering the initial [...] calendar years following the approval of LODOTRA in the first country in the EU or US. Besides this Gerresheimer will grant NITEC for the same [...] years the same exclusivity for any corticosteroid and rheumatoid product (excluding Paracetamol). In case the yearly purchased quantities in the [...] or in any subsequent calendar year during the term of this Agreement are [...] lower than forecasted in the [...] and [...] calendar year after launch Gerresheimer shall — after serving a respective written warning to Nitec and allowing NITEC to place one more order of product, which shall then be taken into account when determining annual purchased quantities – have the right to supply the Duma Multi Grip closures to other customers, provided that NITEC has been reimbursed by Gerresheimer on a pro rata temporis basis for that portion of the Nitec contribution to the moulds which is attributable to that part of the initial five year term which has not yet expired at the time of execution of such supplies to other customers by Gerresheimer.

Gerresheimer has and will keep full ownership of the moulds. The direct costs of mould no 1 will be approx. [...] of which NITEC will pay [...] (the “Nitec Contribution”), e.g. approx. [...] of direct mould costs of mould No 1 of the Vendor/ mould maker including moulds, tests, machine parts, etc. to cover for the above mentioned exclusivity rights. Further, the prices per unit as stated in schedule 1 will be reduced in accordance with the agreed purchase volumes.

Mould costs shall be settled with an initial payment of [...] upon submission of order for the first mould to Vendor/ mould maker (earliest in December 2007), and a final payment of [...] when the first mould has been delivered and approved by NITEC. [...] were already paid by NITEC.

The companies agree that after the [...] years exclusivity Nitec orders will be prioritized against others in using the existing first mould.

The companies agree that a second mould will be 100 % financed by Gerresheimer.

21. ***Confidential Treatment Requested***
Time schedule for the investments.
The first deliveries of the Duma Multi Grip closure system 34 mm (003424-3000) can be made approx. [...] months after the submission of the order for the first mould. A separate time schedule will be made by Gerresheimer.

4. Prices
NITEC and Gerresheimer agree on the prices as of Schedule 1. All prices are in Euro currency (EUR).

These prices are per 1,000 units, DDP (Incoterms 2000), Catalent Pharma Solutions, Steinbeissstr 2, 73614 Schorndorf, Germany.

The quoted prices as per schedule 1 are based on a raw material price of [...] per kg. The prices can be subject to adjustments that are related to a possible change of +/- [...] in the price of approved Pharmaceutical raw material according to the specifications, independent of the quantities.

Prices reflecting the development of the documented raw material prices on approved Pharma raw material according to the Gerresheimer product specifications are negotiated annually by the end of 3rd quarter in each calendar year.

5. Warranty/Change Control
Gerresheimer warrants that the “Products” are manufactured in compliance with the relevant pharmaceutical regulations and legal provisions and in accordance with specifications agreed upon in writing (see Schedule 3) and that they will be free from any defects in material or workmanship.

Gerresheimer states that each carton is signed and labelled in the right way in accordance with specifications (see Schedule 3).

Gerresheimer will do its utmost not to change production process, production technology, composition of material used and examination methods during the term of this Agreement. However if such changes occur it will be described in detail with all necessary documentation. Gerresheimer is obligated to inform NITEC in advance about any such change in writing giving positive results of tests of the “Product” according to product specification. In case of product with specification no 003424-3000 such a change requires the written consent of NITEC prior to this change.

6. Responsibility/Obligations for Order and Supply
Gerresheimer is responsible for:

- holding and maintaining an appropriate manufacturing licence for the manufacture and control of the “Products”
• informing NITEC without any delay of any restrictions to the manufacturing licence for the “Products”.

• complying with the relevant pharmaceutical regulations and GMP requirements valid in the European Union and in the US and with relevant legal provisions for the manufacture and control of the “Products”.

• using of raw material only from accepted and approved vendors for the manufacture of “Product” according to the current US-Drug Master File (DMF) and other relevant legislations. Any change of raw material quality or a change of the vendor of raw material shall need written approval by NITEC.

• delivery of originally packed and labelled products to NITEC’s partner for packaging which will initially and until further notice be Catalent Pharma Solutions, Steinbeissstr 2, 73614 Schorndorf, Germany (CH).

• periodical transfer of results for microbiological examination of Gerresheimer’s production facilities upon request.

• provision of audit reports of any authority and self-inspection reports which might have an impact on the quality and supply of “Products” to NITEC or its partners

• quality of products in accordance with specifications (schedule 3) and delimitation of pharmaceutical responsibilities (schedule 5).

• transfer of new specifications, including update of relevant change control requirements according to schedule 5.

• punctuality of deliveries. Delivery 2 (two) working days before and 1 (one) working days after the time agreed upon is considered timely delivery.

• Deliveries within […***…] days after receiving any firm orders. Insofar and to the extent quarterly forecasts provided by Nitec are of binding character (cf. lit. b, 2= dash of this section 6), such forecasts are converted to fixed orders upon receipt by Gerresheimer. The parties will negotiate in good faith to reduce the […***…] days lead time for the caps and bottles after the first calendar year after launch of LODOTRA.

• delivery of Gerresheimer’s Certificate of analysis (COA) for each consignment stating the kind of material used, batch number, date of Manufacture, etc. The Certificate will be dated and signed by authorised personnel of the Quality Unit and will show the name, address and phone number of the original manufacturer.

• Provision of a security stock which will be agreed annually in respect of the required quantities and development in purchase

• not to undertake any measures or initiate any processes which could have a negative impact on the “Products” manufactured for NITEC.

• In the event that Gerresheimer becomes aware of circumstances (including Force Majeure circumstances) that may cause a delay in the delivery of or any non-conformance of the Product, Gerresheimer shall notify NITEC

23. ***Confidential Treatment Requested
NITEC is responsible for:

- nomination of a partner for the manufacturing (packaging) of LODOTRA to which Gerresheimer will deliver the Products. This company will be in a first step Catalent Pharma Solutions, Steinbeisstr 2, 73614 Schorndorf, Germany (Catalent Pharma Solutions). Any change to this will be made in writing by NITEC to Gerresheimer.
- Provision of quarterly rolling forecasts reflecting NITEC’s demand of products for the upcoming 18 months, which forecast in each case shall be binding for the next [...***…] months
- payment according to terms stated in the Agreement
- guarantee purchase of quantities set forth in the agreement and in accordance with schedule 1 and the rolling forecast to the extent converted into firm orders
- informing Gerresheimer in writing if NITEC wishes for the launch in other countries than the EU or the US special provisions or guidelines to be followed that are not yet generally known or recognized by EU or US GMP requirements. Both parties shall agree how to proceed.
- auditing Gerresheimer’s facilities, documentation and quality systems
- On behalf of NITEC Catalent Pharma Solutions is until further notice responsible for firm orders, which have to be furnished in writing, by telefax or e-mail and shall be placed by [...***…] days prior to the date when Catalent Pharma Solutions wishes to take delivery, and in accordance with schedule 2. Orders are reflecting NITEC’s quarterly rolling forecast
- NITEC may at any time upon written notice to Gerresheimer replace the party responsible for the firm orders.
- The agreed delimitation of pharmaceutical responsibilities between NITEC and Gerresheimer is given in detail in Schedule 5 of this agreement.
- NITEC and Gerresheimer designate competent contacts for technical matters. The persons and their function are named in Schedule 6 of this agreement.
- The provisions of this agreement apply to all orders for the “Products” that are issued after this agreement is signed and before its termination is effected. They also apply to orders issued by NITEC to Gerresheimer that have not yet been completed at the time of effective termination of this agreement.

24. ***Confidential Treatment Requested**
7. **Site Inspections / Auditing**

NITEC, its partners or Regulatory Authorities have the right to conduct or to have conducted periodical inspections / audits of production rooms, warehouses, records of QC samples and analytical labs and records.

8. **Product Inspections and Complaints**

NITEC or its partners will inform Gerresheimer immediately of any complaints which are related to the “Products” and will liaise with Gerresheimer in investigating the possible causes and agree on remedial actions.

In case of not proper quality of “Products” (= products not complying to the Specifications according to Schedule 3, hereinafter: “defective products”) Gerresheimer and NITEC will follow the Gerresheimer complaint procedure described in the respective product specification (schedule 3). In case of improper quality Gerresheimer at its own discretion shall, in addition to the other remedies provided for in this Agreement (i) replace the “Products” at its own expense promptly but in no invent later than 45 days or (ii) refund such portion of the sales price as is equitable. In the first case Gerresheimer shall be entitled to require NITEC to dispose of defective products at Gerresheimer’s expense according to the applicable law.

Irrespective of the foregoing, NITEC or its partners will inspect each shipment of Product for obvious defects and completeness within […] days after receipt of each delivery and NITEC shall notify or shall cause its partners to notify Gerresheimer of any defects or shortages it has discovered. § 377 HGB (German Commercial Code) shall not apply.

In the event of hidden defects not readily ascertainable upon inspection the party that first becomes aware of the defect shall notify the other party of any such defect immediately, but in no event later than within […] days, after they have been discovered.

If there is a dispute whether a Product delivered is defective or whether a Product’s defect has been caused by Nitec or Nitec’s partners after receipt, a sample of the rejected Product and a sample retained by Gerresheimer shall be exchanged between the parties for inspection. If the parties fail to come to a mutually satisfying conclusion within a period of […] weeks following the exchange of the samples, both samples shall be submitted to an expert acceptable to both parties as agreed case by case (the “Expert”). The Expert shall determine whether the rejected Product is defective or not and therefore, to which party such defect is to be attributed, and its determination, in the absence of manifest error, shall be final and binding upon the parties. The costs charged by the Expert shall be borne by the party that has been found to be wrong by the determination.

NITEC or its partner have the right to refuse shipment from Gerresheimer’s facility if “Products” can be demonstrated to be non-compliant according to the aforementioned provisions.

25. ***Confidential Treatment Requested***
Gerresheimer’s obligations under this section 8 are only valid according to the following provisions:

In no case shall a claim against Gerresheimer of any kind (i) in the event the claim is covered by an insurance, be greater in amount than the respective payment made under Gerresheimer’s insurance plus Gerresheimer’s applying deductibles; and (ii) in any other case be greater in amount than, for each claim, the value […***…] of the respective delivery of defective products, and for all claims made during one calendar year, be greater in amount than […***…]. This limitation of liability shall not apply (i) in the case of Gerresheimer’s wilful act or gross negligence or (ii) in the event and to the extent that peremptory provisions of the applicable law do not permit this limitation of liability between Gerresheimer and Nitec. Furthermore, Gerresheimer’s liability for defective products (to the extent that such defect is caused by the actions -including their omission-described hereafter in this sentence) is subject to Nitec having adhered to all procedure’s and instructions applicable to the conditions of use of the products and any damage caused by fair wear and tear or by misuse occurring after delivery to Catalent Pharma Solutions (or its successor in case of a change of the partner of Nitec according to sect. 6 lit.b, 1st dash) or Nitec is expressly excluded.

Gerresheimer’s obligations under this section 8 are Gerresheimer’s only obligations under this Agreement with regard to damage-payments for defective products, and Gerresheimer shall in this regard not be liable any way whatsoever beyond this section 8.

9. **Agreement Term**

The Agreement is valid for a period of exclusivity as defined under section 3 for five (5) calendar years after launch of LODOTRA in the first country in the EU or US (the “initial term”) with possibility of its annual prolongation in writing.

10. **Changes in the Agreement**

All changes of the terms set forth in this agreement may only be made by mutual agreement and must be in writing, otherwise would not be binding. Any waiver of this form requirement shall also have to be in writing in order to become effective.

11. **Payment**

All payments shall be made by NITEC in EUR […***…] days net following the date of the relevant invoice.
12. **Confidentiality**

Both parties undertake to maintain strict confidentiality, which shall also apply after this agreement has ended. Neither party is entitled to use the knowledge of the other disclosed to it under this agreement, after the end of the agreement or without the consent of the other party. Excluded are disclosures of information necessary for Authorities.

13. **Choice of Law**

This Agreement shall be exclusively construed in accordance with the laws of Germany without regard to its conflict of law principles or the Vienna Convention on the International Sale of Goods (CISG). The courts of Mannheim shall have exclusive jurisdiction in any matter arising under or in connection with this Agreement.

14. **Final Provisions**

If changes in the market lead to a situation, which is not reasonable for either party, both parties will endeavour amicably to find a solution acceptable to both of them. The same applies if disputes arise from the performance of the Agreement.

Delay in or failure to carry out the obligations imposed on any party under this Agreement shall not be deemed a breach of this Agreement if such delay or failure results from fire, explosion, labour dispute, natural disaster, war, legislative or governmental acts, or any other cause beyond the control of the affected party (collectively "**Force Majeure**"). Lack or failure of the affected party’s sub-contractor shall not constitute Force Majeure unless caused by circumstances which represent Force Majeure themselves. In the event delay or failure due to Force Majeure continues for a period exceeding [...***...] months, either party may terminate this Agreement effective immediately.

If individual provisions of this Agreement are invalid or become invalid, the parties hereby agree that this shall not affect the validity of the remainder. The parties undertake to replace the invalid provisions by others with the same economical effect as far as legally possible.

This Agreement including Appendices constitutes the entire agreement between the parties concerning the subject matter.

Gerresheimer acknowledges that partners or affiliated companies of NITEC might be interested in the future to become a party of this Agreement. However, Gerresheimer reserves its right to refuse its agreement to any respective amendment—which would have to be executed in writing—to this Agreement whereby partners or affiliated companies of NITEC would, at NITEC’s request, become a party to this Agreement.

27. ***Confidential Treatment Requested***
This Agreement has been prepared in 4 (four) original copies in English and each party hereto acknowledges to have received two original of this Agreement.

Date: ___________________________________________  Date: __________________/_______________________

Gerresheimer Vaerloese A/S  Nitec Pharma AG
/s/ Niels Düring Division President /s/ Jochen Mattis /s/ Dr. Achim Schaffler
Managing director E VP R&D/ Tech operations

List of Schedules

Schedule 1: Prices
Schedule 2: Order Quantities, Delivery and estimated Quantities in the Contract Period
Schedule 3: Product Specifications including complaint procedure
Schedule 4: Delimitation of Pharmaceutical Responsibilities
Schedule 5: Contacts and Responsible Persons

28.
Schedule 1: Prices
The initial prices are based on the forecast volumes for the initial three years as per Schedule 1:

<table>
<thead>
<tr>
<th>Price per 1,000 units for X units p.a.</th>
<th>0-1.5 mill.</th>
<th>1.5-3 mill.</th>
<th>3-6 mill.</th>
<th>&gt;6 mill.</th>
</tr>
</thead>
<tbody>
<tr>
<td>- 034040-3000</td>
<td>…***…</td>
<td>…***…</td>
<td>…***…</td>
<td>…***…</td>
</tr>
<tr>
<td>- 034075-3000</td>
<td>…***…</td>
<td>…***…</td>
<td>…***…</td>
<td>…***…</td>
</tr>
<tr>
<td>- 003424-3000</td>
<td>…***…</td>
<td>…***…</td>
<td>…***…</td>
<td>…***…</td>
</tr>
</tbody>
</table>

Schedule 2: Order Quantities and Delivery
Order quantities and delivery sizes are agreed to be optimised fitting to full load trucks, or whatever quantities optimising the transport cost covered by Gerresheimer.

Estimated amounts for EU market

<table>
<thead>
<tr>
<th>Product no</th>
<th>2008</th>
<th>2009</th>
<th>2010</th>
<th>2011</th>
<th>2012</th>
<th>2013</th>
</tr>
</thead>
<tbody>
<tr>
<td>034040-3000 Duma MG 40 ml</td>
<td>…***…</td>
<td>…***…</td>
<td>…***…</td>
<td>…***…</td>
<td>…***…</td>
<td>…***…</td>
</tr>
<tr>
<td>034075-3000 Duma MG 75 ml</td>
<td>…***…</td>
<td>…***…</td>
<td>…***…</td>
<td>…***…</td>
<td>…***…</td>
<td>…***…</td>
</tr>
<tr>
<td>Total containers</td>
<td>…***…</td>
<td>…***…</td>
<td>…***…</td>
<td>…***…</td>
<td>…***…</td>
<td>…***…</td>
</tr>
<tr>
<td>03424-3000 Duma Multi Grip 34 mm</td>
<td>…***…</td>
<td>…***…</td>
<td>…***…</td>
<td>…***…</td>
<td>…***…</td>
<td>…***…</td>
</tr>
<tr>
<td>Total caps</td>
<td>…***…</td>
<td>…***…</td>
<td>…***…</td>
<td>…***…</td>
<td>…***…</td>
<td>…***…</td>
</tr>
</tbody>
</table>

The above mentioned quantities are only estimated forecast (5-year quantities for the main products, e.g. 40 ml, 75 ml, Multi-Grip Cap 3424).

29. ***Confidential Treatment Requested
Schedule 3: Product Specifications including complaint procedure

<table>
<thead>
<tr>
<th>Product</th>
<th>product specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Duma MG 40 ml</td>
<td>034040-3000</td>
</tr>
<tr>
<td>Duma MG 75 ml</td>
<td>034075-3000</td>
</tr>
<tr>
<td>Duma Multi Grip 3424</td>
<td>003424-3000</td>
</tr>
<tr>
<td>Duma Twist-Off 250 ml</td>
<td>045256-4000</td>
</tr>
<tr>
<td>Duma Twist Cap TE</td>
<td>03827D-3000</td>
</tr>
</tbody>
</table>

“Product specification & Certificates” and drawings/pictures are attached

Pallet specification in accordance with Nitec Pharma and partners requirement – heights of pallets, etc to be agreed upon.
**Schedule 4:**

**Delimitation of Pharmaceutical Responsibilities**

Products: see Section 2

<table>
<thead>
<tr>
<th>Activities</th>
<th>Responsibilities</th>
</tr>
</thead>
<tbody>
<tr>
<td>[...***...]</td>
<td>[<em><strong>...</strong></em>]</td>
</tr>
<tr>
<td>[...***...]</td>
<td>[<em><strong>...</strong></em>]</td>
</tr>
<tr>
<td>[...***...]</td>
<td>[<em><strong>...</strong></em>]</td>
</tr>
<tr>
<td>[...***...]</td>
<td>[<em><strong>...</strong></em>]</td>
</tr>
<tr>
<td>[...***...]</td>
<td>[<em><strong>...</strong></em>]</td>
</tr>
<tr>
<td>[...***...]</td>
<td>[<em><strong>...</strong></em>]</td>
</tr>
<tr>
<td>[...***...]</td>
<td>[<em><strong>...</strong></em>]</td>
</tr>
<tr>
<td>[...***...]</td>
<td>[<em><strong>...</strong></em>]</td>
</tr>
<tr>
<td>[...***...]</td>
<td>[<em><strong>...</strong></em>]</td>
</tr>
<tr>
<td>[...***...]</td>
<td>[<em><strong>...</strong></em>]</td>
</tr>
<tr>
<td>[...***...]</td>
<td>[<em><strong>...</strong></em>]</td>
</tr>
<tr>
<td>[...***...]</td>
<td>[<em><strong>...</strong></em>]</td>
</tr>
<tr>
<td>[...***...]</td>
<td>[<em><strong>...</strong></em>]</td>
</tr>
<tr>
<td>[...***...]</td>
<td>[<em><strong>...</strong></em>]</td>
</tr>
<tr>
<td>[...***...]</td>
<td>[<em><strong>...</strong></em>]</td>
</tr>
<tr>
<td>[...***...]</td>
<td>[<em><strong>...</strong></em>]</td>
</tr>
<tr>
<td>[...***...]</td>
<td>[<em><strong>...</strong></em>]</td>
</tr>
<tr>
<td>[...***...]</td>
<td>[<em><strong>...</strong></em>]</td>
</tr>
<tr>
<td>[...***...]</td>
<td>[<em><strong>...</strong></em>]</td>
</tr>
<tr>
<td>[...***...]</td>
<td>[<em><strong>...</strong></em>]</td>
</tr>
<tr>
<td>[...***...]</td>
<td>[<em><strong>...</strong></em>]</td>
</tr>
<tr>
<td>[...***...]</td>
<td>[<em><strong>...</strong></em>]</td>
</tr>
<tr>
<td>[...***...]</td>
<td>[<em><strong>...</strong></em>]</td>
</tr>
<tr>
<td>[...***...]</td>
<td>[<em><strong>...</strong></em>]</td>
</tr>
<tr>
<td>[...***...]</td>
<td>[<em><strong>...</strong></em>]</td>
</tr>
</tbody>
</table>

31. ***Confidential Treatment Requested***
<table>
<thead>
<tr>
<th>Activities</th>
<th>NITEC/Partner</th>
<th>Gerresheimer</th>
</tr>
</thead>
<tbody>
<tr>
<td>[...***...]</td>
<td>[...***...]</td>
<td>[...***...]</td>
</tr>
<tr>
<td>[...***...]</td>
<td>[...***...]</td>
<td>[...***...]</td>
</tr>
<tr>
<td>[...***...]</td>
<td>[...***...]</td>
<td>[...***...]</td>
</tr>
<tr>
<td>[...***...]</td>
<td>[...***...]</td>
<td>[...***...]</td>
</tr>
<tr>
<td>[...***...]</td>
<td>[...***...]</td>
<td>[...***...]</td>
</tr>
<tr>
<td>[...***...]</td>
<td>[...***...]</td>
<td>[...***...]</td>
</tr>
<tr>
<td>[...***...]</td>
<td>[...***...]</td>
<td>[...***...]</td>
</tr>
<tr>
<td>[...***...]</td>
<td>[...***...]</td>
<td>[...***...]</td>
</tr>
<tr>
<td>[...***...]</td>
<td>[...***...]</td>
<td>[...***...]</td>
</tr>
<tr>
<td>[...***...]</td>
<td>[...***...]</td>
<td>[...***...]</td>
</tr>
<tr>
<td>[...***...]</td>
<td>[...***...]</td>
<td>[...***...]</td>
</tr>
<tr>
<td>[...***...]</td>
<td>[...***...]</td>
<td>[...***...]</td>
</tr>
<tr>
<td>[...***...]</td>
<td>[...***...]</td>
<td>[...***...]</td>
</tr>
<tr>
<td>[...***...]</td>
<td>[...***...]</td>
<td>[...***...]</td>
</tr>
<tr>
<td>[...***...]</td>
<td>[...***...]</td>
<td>[...***...]</td>
</tr>
<tr>
<td>[...***...]</td>
<td>[...***...]</td>
<td>[...***...]</td>
</tr>
<tr>
<td>[...***...]</td>
<td>[...***...]</td>
<td>[...***...]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
32. ***Confidential Treatment Requested
Schedule 5
Contacts and Responsible Persons
Products: see Section 2
NITEC:

<table>
<thead>
<tr>
<th>Function</th>
<th>Name</th>
<th>Phone</th>
<th>Fax</th>
<th>e-mail</th>
</tr>
</thead>
<tbody>
<tr>
<td>[…]</td>
<td>[…]</td>
<td>[…]</td>
<td>[…]</td>
<td>[…]</td>
</tr>
<tr>
<td>[…]</td>
<td>[…]</td>
<td>[…]</td>
<td>[…]</td>
<td>[…]</td>
</tr>
</tbody>
</table>

Gerresheimer:

<table>
<thead>
<tr>
<th>Function</th>
<th>Name</th>
<th>Phone</th>
<th>Fax</th>
<th>e-mail</th>
</tr>
</thead>
<tbody>
<tr>
<td>[…]</td>
<td>[…]</td>
<td>[…]</td>
<td>[…]</td>
<td>[…]</td>
</tr>
<tr>
<td>[…]</td>
<td>[…]</td>
<td>[…]</td>
<td>[…]</td>
<td>[…]</td>
</tr>
<tr>
<td>[…]</td>
<td>[…]</td>
<td>[…]</td>
<td>[…]</td>
<td>[…]</td>
</tr>
</tbody>
</table>

33.

***Confidential Treatment Requested
Appendix 7 – Services
(By Catalent)

- Packaging
- Quality Assurance
- Product Release for shipment

[Catalent shall invoice the annual PQR separately]
### Appendix 8 – Costs of LODOTRA
(by NITEC)

<table>
<thead>
<tr>
<th>Description</th>
<th>Costs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total (Nitec) costs per 1000 bulk tablets (5 mg Lodotra)</td>
<td>[***]</td>
</tr>
<tr>
<td>Total (Nitec) costs per 1000 bulk tablets (2 mg Lodotra)</td>
<td>[****]</td>
</tr>
<tr>
<td>Total (Nitec) costs per 1000 bulk tablets (5 mg Lodotra)</td>
<td>[****]</td>
</tr>
</tbody>
</table>

35. ***Confidential Treatment Requested***
This Master Services Agreement (this “Agreement”) is entered into the 11th day of September, 2008 between Pharmaceutics International, Inc. (“PII”) with an address at 10819 Gilroy Road, Hunt Valley, Maryland, 21031, Attn: Steve King, Senior Vice President, and Horizon Therapeutics, Inc., with an address at 8025 Lamon Avenue, Suite 110, Skokie, IL 60077 (“Customer”).

In consideration of the mutual covenants and agreements contained in this Agreement, and intending to be legally bound, the parties hereto agree as follows:

1.0 Definitions. In addition to certain terms defined elsewhere in this Agreement (including in any Service Contract attached hereto), the following words and phrases shall have the following meanings:

1.1 “cGMP” means current good manufacturing practices in the applicable jurisdiction, as may be amended or supplemented from time to time; if in the United States, then cGMP shall include, without limitation, the Current Good Manufacturing Practices set forth in 21 C.F.R. 210 and 21 C.F.R. 211 and relevant FDA guidance documents; and if in the European Union, then cGMP shall include, without limitation, the European Community Directive 91/356/EEC, Directive 2001/20/EC, Directive 2001/83/EC and all relevant implementations of such directives and relevant guidelines, including the EC Guidelines, as may be amended or supplemented from time to time. In the event of any conflict among applicable Laws pertaining to the manufacture of Product, current Good Manufacturing Practices as specified in the United States Code of Federal Regulations will be applied, unless the parties agree otherwise in writing.

1.2 “Certificate of Analysis” shall mean a summary of the test results, including the test methods, specification parameters, and the pass/fail criteria, used in the determination of the quality and suitability of a specific Batch of Product, including review and approval by the appropriate quality assurance department at PII.

1.3 “Investigation” shall mean a detailed and thorough review of any atypical manufacturing deviation (or any other matter requiring review pursuant to the terms of this Agreement) that is documented in a written report and approved at a senior management level. Each such written report shall include, without limitation, a detailed description of the atypical event, deviation or other matter, all steps taken to review such atypical event, deviation or other matter, a root cause analysis, which other lots of Product were affected, if any, the proposed and/or taken corrective actions with applicable timelines and a recommendation for permanent correction.

1.4 “Quality Agreement” shall mean the separate quality agreement; expected to be executed by PII and Customer shortly after the execution of this Agreement, and to be attached hereto as Attachment “A”, as may be amended by written agreement of PII and Customer. The Quality Agreement, when executed by the parties will constitute an integrated part of this Agreement and will define the quality assurance and regulatory responsibilities of the Parties as they relate to this Agreement.
1.5 “Specifications” shall mean the quality standards, including tests, analytical procedures and acceptance criteria that are established to confirm the quality of Product which are mutually agreed to in writing by PII and Customer and are contained or referenced in the master batch record for Product or as otherwise mutually agreed to in writing by the parties.

1.6 “Customer Material” means all quantities of Customer’s materials, including any chemical compounds (whether or not proprietary) delivered by or on behalf of Customer to PII for use by PII in connection with its services for any Project.

1.7 “Laws” means (a) all applicable United States federal, state and local laws, regulations, orders, guidelines and requirements governing conduct of any Project, including, without limitation, the Federal Food, Drug and Cosmetic Act as amended, 21 U.S.C. § 321, et seq., applicable regulations promulgated thereunder and implementing guidance, including, without limitation, cGMP, all conditions of approval and other requirements imposed by the United States Food and Drug Administration, (b) ICH Guidelines, and (c) all other applicable laws, rules, regulations and ordinances of any other country, to the extent such laws, rules, regulations and ordinances are different than those described in clauses (a) and (b), which country and such laws, rules, regulations and ordinances are identified by Customer and are specifically agreed to by the parties in a given Service Contract.

1.8 “Latent Defect” shall mean a defect that causes Product to fail to conform to the Specifications or to the warranties provided by PII hereunder, which defect is not discoverable upon reasonable physical inspection and testing but is discovered at a later time.

1.9 “Project” shall mean all activities undertaken for or on behalf of Customer by PII pursuant to a Service Contract, together with the work performed by or on behalf of PII pursuant to a Service Contract.

1.10 “Project Materials” collectively means all documentation, records, information, materials and data generated by or on behalf of PII or Customer relating to the Project, including but not limited to copies of all notebook pages, analytical results, batch records, data, memoranda and all reports created or delivered hereunder.

1.11 “Regulatory Authority” means the United States Food and Drug Administration (“FDA”), the Environmental Protection Agency (“EPA”), the Occupational Health and Safety Administration (“OSHA”) or any other United States or state or local regulatory agency, regulatory authority, or regulatory body having jurisdiction over PII or its operations, facilities, or performance of the Projects.

2.0 Project Overview

2.1 Scope of the Agreement; Service Contract. Nature of Services; Scope of Agreement. As a “master” form of contract, this Agreement allows the parties to contract for multiple Projects through the issuance of multiple Service Contract(s) without having to re-negotiate the basic terms and conditions contained herein. This Agreement covers the provision of services by PII required in connection with any Project (the “Services”), and represents a vehicle by which Customer can efficiently contract with PII for a broad range of services.

2.2 Service Contract. The specific details of each Project under this Agreement shall be separately negotiated and set forth in a service contract, each to be agreed upon in writing by PII and Horizon (each a “Service Contract”). Each Service Contract will include, as appropriate, the scope of
work, time line, and budget and payment schedule. Each Service Contract shall be subject to all of the terms and conditions of this Agreement, in addition to the specific details set forth in the Service Contract. To the extent any terms or provisions of a Service Contract conflict with the terms and provisions of this Agreement, the terms and provisions of this Agreement shall control. All Service Contracts and other exhibits hereto shall be deemed to be incorporated herein by reference.

2.3 Nature of Services.

(a) PII shall perform the Projects described in each Service Contract and shall deliver to Customer the deliverables, including any pharmaceutical product ("Product"), described in each Service Contract (the “Deliverables”) on or before the “Delivery Time” described in each Service Contract, subject to Sections 2.3(b) and 12 below. PII acknowledges that time is of the essence. Each Project shall be deemed to have been completed by PII when PII has completed the Services, including delivery of any Deliverables, as described in the applicable Service Contract. The parties shall endeavor, in good faith, to mutually agree on when each Project is completed, but in the event of a failure to so agree, such dispute shall be resolved in accordance with Section 11 below. Subject to the terms of this Agreement, PII shall perform its Services in connection with each Project in conformity with the requirements for such Services as set forth in the applicable Service Contract (the “Requirements”) and this Agreement. The parties acknowledge that PII may perform the Projects using its affiliates, provided that such performance is in accordance with this Agreement, and PII remains responsible to Customer for the performance of such Project(s).

(b) The parties acknowledge that both parties will require certain information and reasonable cooperation from each other in order to properly perform each Project, and that each party will establish mutually acceptable review periods for the development and completion of each Service Contract, prior to the initiation of work for that Service Contract. Once the Service Contract is signed and the initiation fee is paid, as applicable under such Service Contract, PII will be responsible and liable for meeting the Delivery Time and shall use its commercially reasonable efforts to deliver all Deliverables on or before the applicable Delivery Time, subject to Section 12 below and delays in its performance caused by Customer’s failure to provide Customer Materials, required information and reasonable cooperation to PII in a timely manner. In the event PII will be unable to meet the Delivery Date, PII will promptly notify Customer. In all cases, PII will attempt to limit the effect of delays on the overall Project and will use commercially reasonable efforts to mitigate the delay, which shall be at PII’s expense if it has caused the delay.

2.4 Customer Materials

(a) Customer shall, at its own expense, supply PII with sufficient quantities of Customer Materials, including active pharmaceutical ingredient (“API”), needed for the development or manufacture of Product, as specified in Service Contracts, in order to meet Customer’s requirements for quantities of Product in finished dosage form. Except as expressly set forth herein, THE API AND ALL OTHER CUSTOMER MATERIALS ARE PROVIDED “AS IS” AND WITHOUT ANY REPRESENTATION OR WARRANTY, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION ANY IMPLIED WARRANTY OF MERCHANTABILITY OR OF FITNESS FOR ANY PARTICULAR PURPOSE OR ANY WARRANTY THAT THE USE OF THE API OR OTHER CUSTOMER MATERIALS WILL NOT INFRINGE OR VIOLATE ANY PATENT OR OTHER PROPRIETARY RIGHTS OF ANY THIRD PARTY.
(b) PII agrees: (i) to account for all Customer Materials and to provide Customer with standard inventory reports upon request by the Customer, and such other reports as may be required pursuant to the terms of the applicable Service Contract, which may include, without limitation, all process materials and drug substance impurity standards, both (1) on the first day of each calendar month throughout the term of this Agreement, and (2) upon request by Customer; (ii) not to provide API or Customer Materials to any third party without the express prior written consent of Customer; (iii) not to use API or other Customer Materials for any purpose other than conducting any Project under this Agreement; and (iv) to destroy or return to Customer or its designee all unused quantities of API and other Customer Materials according to Customer's written directions, subject to the provisions of applicable Laws. If no written directions are provided to PII within thirty (30) days following termination of this Agreement, PII may dispose of such materials per cGMP(s).

2.5 Project Materials. Upon reasonable advance notice to PII, Customer shall be permitted to send certain of its employees to PII’s facilities to consult with PII’s employees and consultants engaged in the Project, to observe PII in the performance of its duties hereunder, and to inspect (and take copies of) any of the Project Materials, provided that such consultation, inspection and copying does not unreasonably interfere with PII’s operations or standard operating procedures. PII shall make PII’s employees and consultants and the Project Materials reasonably available to Customer for such purposes. PII shall provide Customer with summary data describing the interim results of each Project, and copies of all Project Materials generated in connection with the Project, from time to time upon Customer’s request, and at no extra charge to Customer, unless previously agreed to by Customer and included in the Service Contract.

2.6 Delivery. PII shall choose a commercially reasonable method of freight shipment and carrier for each of the Deliverables, unless Customer has specified a particular method of shipment and carrier to PII. All costs associated with freight, insurance, packaging and custom duties shall be paid by Customer unless otherwise provided in the applicable Service Contract. PII’s shipping dock unless otherwise provided in the applicable Service Contract. Risk of loss, damage and delay shall pass to Customer Ex Works (Incoterms 2000). PII shall provide summary data describing the interim results of each Project, and copies of all Project Materials generated in connection with the Project, from time to time upon Customer’s request, and at no extra charge to Customer, unless previously agreed to by Customer and included in the Service Contract.

2.7 Record-Keeping. PII shall maintain records of all Project Materials and Inventions in a professional manner so as to permit Customer to review such records in accordance with this Section 2.7 without disclosing to Customer any third party confidential or proprietary information; Designated representatives of Customer shall, upon reasonable notice to PII, have access to and shall be permitted to review all such records. PII will provide to Customer upon request a copy of all such records. Following expiration or termination of this Agreement, PII shall (a) continue to make such records available to Customer for a period of [***] from the date of such termination or (b) upon Customer’s prior written request, transfer ownership of such records to Customer, provided, however, PII’s obligations pursuant to this Section 2.7 shall be subject to the provisions of applicable Laws. After expiration of such retention period, PII will either transfer such records to Customer or destroy such records as determined by Customer in its sole discretion.

2.8 Acceptance of Shipments; Non-Conformance; Responsibility for Deliverables.

2.8.1. Unless otherwise instructed by Customer in writing, PII shall provide to Customer a Certificate of Analysis and a complete and accurate copy of the executed batch records (the “Batch Records”) on or before the date of delivery of the applicable Product that certify that the Product meets the Specifications for the Product set forth in the applicable Service Contract (a “COA”). Customer and PII agree that the review period and the acceptance or rejection of Product cannot commence until the COA, and Batch Records are received for each batch of Product (including all the batch **Confidential Treatment Requested**
2.8.2. Within [...***...] following delivery to Customer of the Product, COA and the Batch Record in accordance with Section 2.8.1, Customer shall have the right to give PII notice of rejection of any Product that, in whole or part, fails to conform to the Specifications. Upon receipt of a notice of rejection from Customer, PII shall conduct an internal Investigation. Customer shall at all times supply PII with any evidence it has that relates to whether any Product delivered to Customer by PII is non-conforming with the Specifications. Failure by Customer to give timely notice of rejection shall constitute acceptance by it of the shipment to which the notice of rejection would have otherwise applied; provided, however, that in the case of Product having Latent Defect(s), Customer may reject such Product by giving written notice to PII of Customer’s rejection of such Product within [...***...] after discovery of such Latent Defect(s). In the event of any disagreement between PII and Customer relating to non-conformance under this Section 2.8, the parties shall use good faith efforts to reach an amicable resolution of such disagreement. In the event that resolution cannot be reached, a mutually agreed upon, neutral, independent third party laboratory shall be brought in to resolve the disagreement upon the request of either party. The results of the independent laboratory shall be binding on the parties and non-appealable, and the cost of such independent laboratory shall be borne by the party hereunder determined by the independent laboratory to be the non-prevailing party in such disagreement. Any Product properly rejected pursuant to this Section 2.8.2 shall be returned by Customer to PII at PII’s expense and shall be replaced by PII at no extra charge to Customer, subject to Customer’s provision to PII of Customer Materials (which may be at PII’s cost, as provided herein), including any API; and in the event PII cannot replace such returned Product, it shall refund to Customer the amount paid, including any freight, insurance or other direct costs actually incurred by Customer. Customer agrees that in the event the replacement cost of the API used in any Service Contract exceeds [...***...], the amount of the replacement cost shall be conspicuously set forth in the Service Contract.

2.8.3. Notwithstanding anything to the contrary contained herein, PII shall not be responsible for the stability of any Product if PII has performed its Services in accordance with the Requirements and the terms and conditions of this Agreement. Unless PII delivers Product to Customer with a COA and Customer properly rejects any Product in accordance with the provisions of Section 2.8.2 above, as long as, with respect to any batch of non-conforming Product, PII has performed such Services in accordance with the Requirements and the terms and conditions of this Agreement: (a) PII shall be entitled to payment for its Services actually performed under any Service Contract, and (b) PII shall not be responsible for the cost of replacement API required for PII’s replacement of defective Product.

2.9 Commercial Supply. The parties hereby agree that, upon written request by Customer to PII, the parties shall negotiate in good faith and enter into a supply agreement in form mutually acceptable to the parties relating to supply by PII to Customer of Customer’s requirements of Product for Customer’s development and commercialization activities. The parties agree to use commercially reasonable efforts so that such supply agreement may be negotiated to the parties’ mutual satisfaction and executed within [...***...] following such request by Customer to PII. The supply agreement shall

***Confidential Treatment Requested
address the standard terms of supply and relevant other terms, including, without limitation, terms relating to pricing, specifications, forecasting, delivery, product warranties, indemnification, acceptance and rejection, and regulatory matters. For purposes of clarification, the obligations under this Section 2.9 shall survive any termination or expiration of this Agreement.

3.0 Reports

Reports. If required by the applicable Service Contract, PII shall prepare and deliver to Customer a written report describing the results of the Project, including all raw data generated from the Projects performed under the applicable Service Contract. PII shall make such changes to, and include such additional information in, such report as Customer may reasonably request.

4.0 Fees; Payment

4.1 Fees. The Customer shall pay as the fees for a Project as set forth in the applicable Service Contract.

4.2 Change Order. If Customer wishes to change the scope of the Project or wishes to agree to a Project not initially covered by this Agreement or in any Service Contract, then Customer shall so advise PII in writing, and PII shall promptly submit to Customer a written cost estimate therefor. No such request shall be binding unless and until it has been agreed to in a revised Service Contract or additional Service Contract signed by both Customer and PII. Any such modified or additional Project shall be governed by the terms and conditions of this Agreement and by such revised or additional Service Contracts as may be executed by the parties from time to time.

4.3 Non-Capital Materials. Customer shall pay to PII upon receipt of PII’s invoice for all non-capital materials (excipients, packaging components, HPLC columns, analytical standards and tooling that are not supplied by Customer) used in any Project at [...***...]. PII shall obtain Customer’s prior written approval for any expenditure greater than [...***...]. Customer shall pay [...***...] for any individual non-capital materials in excess of [...***...], provided that PII has obtained prior approval from Customer for such non-capital materials prior to purchase.

4.4 Travel Expenses. PII shall invoice Customer for all reasonable and normal out-of-pocket travel related expenses, including airfare, room and board, and car rental, incurred during any technology transfer phase or Project update meetings, provided such expenses are approved in advance by Customer.

4.5 Invoices; Payment. On or after the date that PII delivers each Deliverable to Customer, PII shall provide Customer with an invoice in accordance with the payment terms set forth in the applicable Service Contract that sets forth a description of the activities performed, references the applicable Service Contract, and includes such other information in such detail as Customer may reasonably request. Each PII invoice shall be payable within [...***...]. PII invoice shall be payable within [...***...] after receipt of invoice by Customer, and thereafter unpaid balances shall bear interest at a rate of [...***...] unless determined not to be properly payable in accordance with Section 11 below. The fees and charges due hereunder shall be payable in U.S. Dollars unless otherwise provided in a Service Contract. All payments due from Customer hereunder shall be paid by a check payable to PII and shall be sent to PII’s address set forth above, unless otherwise provided in a Service Contract.

***Confidential Treatment Requested
5.0 Ownership of Materials and Information

5.1 PII understands and agrees that the underlying rights to the Customer Materials, Project Materials and Products, and all intellectual property rights therein, are owned solely by Customer. Neither PII nor any Customer-approved subcontractor shall acquire any rights of any kind whatsoever with respect to any such intellectual property or materials as a result of conducting a particular Project. All data, results, products, information, and reports (whether tangible or intangible), and any and all related documentation, which are developed, generated or derived, directly or indirectly, by PII (or by any subcontractor or agent of PII) during the course of this Agreement (the “Data”), and all inventions, discoveries, designs, techniques, trade secrets, formulae, procedures, any other intellectual property, and any improvements thereto, whether patentable or not, which are made, discovered or developed during the course of this Agreement or as a result of the performance of any Project by PII (or by any subcontractor or agent of PII) (collectively, the “Inventions”), shall be and remain the sole and exclusive property of Customer, subject to the provisions of Section 5.2.

5.2 Inventions made, developed or discovered solely by PII (or by any subcontractor or agent of PII) that constitute an invention, improvement or other intellectual property relating generally to drug delivery technology, formulation, analysis or manufacturing process of pharmaceutical products and which do not relate solely to any Customer Material or Product (together with any Data relating thereto, “PII Inventions”), shall be and remain the property of PII, and PII hereby grants to Customer a perpetual, irrevocable, worldwide, royalty-free, exclusive license (with the right to sublicense) to develop, use, make, have made, import, offer for sale and sell such PII Inventions in connection with the development, use, manufacture, import, offer for sale and sale of the Product; provided that the foregoing license shall not be exclusive with respect to a Product that is a non-patented (or non-patent pending) compound. Neither PII nor its employees or agents shall have or acquire any right, title or interest in Inventions that are not PII Inventions (“Customer Inventions”). PII shall promptly disclose in writing to Customer any Customer Inventions, and PII hereby assigns any and all rights in any Customer Inventions to Customer (or to the extent any such rights are not assignable under applicable law, waives such rights or grants Customer a perpetual, irrevocable, worldwide, royalty-free exclusive license (with the right to sublicense) to Customer Inventions for all uses) and shall assist Customer, at no cost to PII, in perfecting its rights in such Customer Inventions.

6.0 Confidentiality

The parties acknowledge that the Confidentiality Agreement between the parties dated December 16, 2005 (the “Confidentiality Agreement”) shall continue to govern the parties’ respective obligations to one another with regard to the “Confidential Information” (as defined in the Confidentiality Agreement) each has disclosed to the other and shall continue to disclose to the other in connection with this Agreement, provided however, the Confidentiality Agreement shall be deemed amended to reflect the following agreements: (a) the parties’ respective obligations with regard to any such Confidential Information disclosed prior to or after the date of this Agreement shall survive the termination of this Agreement for a period of [...]*** from the date of such termination; (b) the “Purpose” shall be deemed to include PII’s performance of Services on behalf of Customer hereunder; and (c) the governing law shall be as provided in Section 14.2 below. The parties’ respective obligations with regard to any such Confidential Information shall survive the termination of this Agreement in accordance with the terms of the Confidentiality Agreement.

***Confidential Treatment Requested
7.0 Term; Termination

This Agreement shall commence on the date set forth above and continue until termination of this Agreement as set forth in this Section 7. Customer, but not PII, may terminate this Agreement or any Service Contract entered into hereunder at any time and for any reason at the sole discretion of Customer upon [...] days advance written notice to PII. Either party may terminate this Agreement if the other party is in default of any of its material obligations set forth herein, and such breach is not cured within [...] days, which time period shall be reduced to [...] days for any default of any monetary obligation, after receipt by the breaching party of a written notice from the non-breaching party that describes such breach in reasonable detail. Upon any termination described in this Section 7, Customer shall pay all costs incurred by PII for work performed in accordance with any applicable Service Contract prior to the effective date of termination, provided PII provides written evidence that such costs have been incurred and such work performed; provided that in no event shall Customer be required to make any payment in excess of the maximum payment specified in the applicable Service Contract. Upon any termination described in this Section 7, Customer shall be reimbursed any amounts paid in advance by Customer to PII for Projects not performed prior to the effective date of termination.

8.0 Compliance with Laws

Each party shall, at its own expense, comply with all applicable Laws, including any United States law, statute, ordinance, administrative order, rule or regulation, relating to its duties, obligations and performance under this Agreement, and shall procure all licenses and pay all fees and other charges required thereby.

9.0 Warranties

9.1 PII represents, warrants and covenants to Customer that it will perform all of its obligations under this Agreement in accordance with all Laws, this Agreement and the Requirements. Without limiting the generality of the foregoing, PII warrants and covenants that (a) each Project shall be performed in conformity with the Laws and the Requirements, and all Product shall be manufactured in compliance with cGMPs; (b) to PII’s actual knowledge, the performance of the Projects (including manufacture of Product) will not infringe or misappropriate any intellectual property right of any third party, except to the extent such Projects are performed in accordance with the Service Contract or other written instructions given by Customer; (c) each shipment or other delivery of Product made by it under this Agreement, as of the date of such shipment or delivery, shall conform to the Specifications, shall be free and clear of any lien or encumbrance, and shall not be adulterated or misbranded within the meaning of the Federal Food, Drug, and Cosmetic Act (“Act”), nor an article which may not, under the provisions of Section 505 of the Act, be introduced into interstate commerce; and (d) it has and will maintain during the term of this Agreement, all government permits (including without limitation health, safety, and environmental permits), licenses, and registrations required by Regulatory Authorities, that are necessary for the conduct of the actions and procedures that it undertakes pursuant to this Agreement. Further, PII represents, warrants and covenants to Customer that PII has not been debarred and shall not employ, contract with or retain any person directly or indirectly to perform work under this Agreement if such person has been debarred or is, to its knowledge, under investigation for debarment under the provisions of the Generic Drug Enforcement Act of 1992, including without limitation, 21 U.S.C. Section 335a. If at any time during the term of this Agreement PII (i) becomes debarred, or (ii) receives notice of action or threat of action with respect to its debarment, PII shall notify Customer immediately. In the event that PII or any such person becomes debarred as set forth above, PII shall immediately notify Customer and Customer shall have the right to terminate this Agreement immediately.

***Confidential Treatment Requested
9.2 Customer represents, warrants and covenants to PII that, except to the extent that any of the following are the obligations of PII: (a) Customer shall comply with applicable Laws and Customer shall keep PII fully informed of any development relating to API or Product that would affect PII’s performance of any Project with respect to the Product hereunder; (b) in the event Customer ships Product outside of the United States, Customer shall comply fully with all export administration and control laws and regulations of the United States government as may be applicable thereto; (c) any API furnished by Customer shall meet the applicable specifications provided by Customer, and shall before use in the further processing of the Product and, to the extent of Customer’s knowledge, shall not contain any viruses or other deleterious substances which could contaminate the processing operations of PII; and (d) Customer will provide PII with data on the chemical and physical properties, toxicity, and handling, storing, and shipping information for any Customer Materials (including API) and the Product (MSDS or equivalent) and any other information available to Customer that is necessary for the sale conduct of the manufacturing of the Product by PII and shall update all of such information provided to PII as such information becomes available to Customer.

9.3 Disclaimer of Warranties. EXCEPT AS EXPRESSLY SET FORTH IN THIS AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATION OR WARRANTY TO THE OTHER PARTY OF ANY KIND, EXPRESS OR IMPLIED, INCLUDING, WITHOUT LIMITATION, ANY WARRANTY OF TITLE, NON-INFRINGEMENT, MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

9.4 Limitation of Liability. EXCEPT FOR AN INTENTIONAL OR WILLFUL BREACH OF ARTICLE 6, IN NO EVENT SHALL EITHER PARTY BE LIABLE TO THE OTHER FOR ANY LOST PROFITS, LOST SAVINGS, OR ANY OTHER INCIDENTAL, SPECIAL, EXEMPLARY, OR CONSEQUENTIAL DAMAGES, EVEN IF SUCH PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES, ARISING OUT OF OR IN CONNECTION WITH THIS AGREEMENT; provided, however, that this Section 9.4 shall not limit either party’s indemnification rights or obligations under Article 10 with respect to Claims of third parties other than with respect to Claims of third parties in contractual privity with the party seeking indemnification, which shall be so limited.

10.0 Indemnification

10.1 Customer shall indemnify, defend and hold harmless PII, its affiliates, and its and their directors, officers, employees, agents and consultants from and against any and all losses, liabilities, costs and expenses, including without limitation, reasonable attorneys’ fees and the cost of recalls (collectively “Damages”) incurred by them as a result of any third party claim, lawsuit, demand, action or proceeding (“Claim”) arising out of or in connection with:

(a) injuries and/or death to humans resulting from the use of any Customer Materials provided to PII by Customer or from the commercialization, use or sale of Product or other Deliverables by or on behalf of Customer, including, without limitation, claims based on negligence, warranty, strict liability or any other theory of product liability or a violation of applicable laws or regulations,

(b) negligence or willful misconduct in advertising, labeling, or improper handling and storage of Customer Materials or Product by any person other than PII or its subcontractors,

(c) any instructions given by Customer in connection with any Customer Material,
(d) any breach by Customer of any covenant, representation, warranty or agreement hereunder, or

(e) patent infringement relating to any Customer Materials or PII’s Services in accordance with the master batch records, the applicable Service Contract and this Agreement, to the extent that such infringement does not arise as a result of a breach of this Agreement by PII, including any representation or warranty of PII hereunder,

except, in each case, to the extent Damages result from the breach by PII of any representation, warranty, covenant or agreement made by it under this Agreement or the negligence or willful misconduct of PII or any of its affiliates and their stockholders, directors, officers, employees, agents and consultants.

10.2 PII shall indemnify, defend and hold harmless Customer and Customer’s affiliates, and its and their directors, officers, employees and agents and consultants from and against any and all Damages incurred by them as a result of any Claim arising out of or in connection with:

(a) any negligence or willful misconduct of PII in performing the Services, or

(b) any breach by PH of any covenant, representation, warranty or agreement hereunder;

except, in each case, to the extent such Damages result from the breach by Customer of any representation, warranty, covenant or agreement made by it under this Agreement or the negligence or willful misconduct of Customer or any of its affiliates and their stockholders, directors, officers, employees, agents and consultants.

10.3 In the event that either party seeks indemnification (an “Indemnified Party”) under the terms of this Section 10, it shall provide written notice (the “Claim Notice”) to the other party (an “Indemnifying Party”) of the claim as soon as reasonably practicable after it receives notice thereof, and shall permit the Indemnifying Party, at the Indemnifying Party’s election and cost, to assume direction and control of the defense of the claim. After delivery of such Claim Notice, if the Indemnifying Party acknowledges in writing to the Indemnified Party that the Indemnifying Party shall be obligated under the terms of its indemnity hereunder in connection with such lawsuit or action, then the Indemnifying Party shall be entitled, if it so elects, (a) to take control of the defense and investigation of such lawsuit or action, (b) to employ and engage attorneys of its own choice to handle and defend the same, at the Indemnifying Party’s cost, risk and expense unless the named parties to such action or proceeding include both the Indemnifying Party and the Indemnified Party and the Indemnified Party has been advised in writing by counsel that there may be one or more legal defenses available to the Indemnified Party that are different from or additional to those available to the Indemnifying Party, and (c) to compromise or settle such claim, which compromise or settlement shall be made only with the written consent of the Indemnified Party, such consent not to be unreasonably withheld. If the Indemnifying Party fails to assume the defense of such claim within fifteen (15) calendar days after receipt of the Claim Notice, the Indemnified Party shall (upon delivering notice to such effect to the Indemnifying Party) have the right to undertake, at the Indemnifying Party’s cost and expense, the defense, compromise or settlement of such claim on behalf of and for the account and risk of the Indemnifying Party. In the event the Indemnified Party assumes the defense of the claim, the Indemnified Party shall keep the Indemnifying Party reasonably informed of the progress of any such defense, compromise or settlement. The Indemnifying Party shall be liable for any settlement of any action effected pursuant to and in accordance with this Section 10 and for any final judgment (subject to any right of appeal), and the Indemnifying Party agrees
to indemnify and hold harmless an Indemnified Party from and against any Damages by reason of such settlement or judgment.

10.4 Insurance

10.4.1. Effective immediately upon execution of this Agreement, PII shall maintain insurance or self-insurance that is reasonably adequate to fulfill any potential obligation to Customer under this Agreement, but in any event not less than [...] for injuries to any one person arising out of a single occurrence and [...] for injuries to all persons arising out of a single occurrence. PII shall provide Customer, upon request, with written evidence of such insurance or self-insurance. PII shall continue to maintain such insurance or self-insurance after the expiration or termination of this Agreement during any period in which PII or any of its affiliates or Customer-approved sublicensees continues to perform under this Agreement and thereafter for a period of [...].

10.4.2. Effective immediately upon execution of this Agreement, Customer shall maintain insurance or self-insurance that is reasonably adequate to fulfill any potential obligation to PII under this Agreement, but in any event not less than [...] for injuries to any one person arising out of a single occurrence and [...] for injuries to all persons arising out of a single occurrence. Customer shall provide PII, upon request, with written evidence of such insurance or self-insurance. Customer shall continue to maintain such insurance or self-insurance after the expiration or termination of this Agreement during any period in which PII or any of its affiliates or Customer-approved sublicensees continues to perform under this Agreement and thereafter for a period of [...].

11.0 Disputes; Arbitration

11.1 Except as provided in Section 11.3 below or in Section 2.8 with respect to disputes regarding non-conforming shipments, all disputes, controversies or claims arising out of or relating to the operation or interpretation of this Agreement shall be resolved by arbitration before one arbitrator in accordance with the Commercial Rules of the American Arbitration Association. The arbitrator shall be jointly selected by the parties. Any award rendered by the arbitrator shall be final and binding upon the parties and judgment upon any such award may be entered in any court having jurisdiction thereof. Arbitration shall be conducted in New York City, New York, or such other location as is mutually agreed to in writing by the parties.

11.2 The arbitrator shall award attorneys’ fees and other costs of the arbitration, including the fees and expenses of the arbitrator, to the prevailing party, as determined by the arbitrator.

11.3 Notwithstanding anything to the contrary contained in this Section, in the event of any breach or threatened breach of this Agreement by either party that the other party believes will cause irreparable harm and damage to it, such party shall be entitled to an injunction, restraining order restraining such breach or threatened breach by the other party and all other remedies which shall be available to it at law or in equity and the parties irrevocably submit to the jurisdiction of any state or federal court sitting in New York City, New York over any such suit, action or proceeding. Each party irrevocably waives, to the fullest extent permitted by law, any objection that it may now or hereafter have to the laying of the venue of any such suit, action or proceeding brought in any such court and any claim that any such suit, action or proceeding brought in any such court has been brought in an inconvenient forum.

***Confidential Treatment Requested
12. **Force Majeure** Notwithstanding anything to the contrary contained herein, neither party shall be liable for non-performance or late performance of any of its obligations under this Agreement (other than obligations to pay money) to the extent such non-performance or late performance is due to reasons of strike, riots, war, act of God, invasion, acts of terrorism, fire, explosion floods, interruption of or delay in transportation, shortage or failure in the supply of Customer Materials, acts of government or governmental agencies or instrumentalities and any other contingencies beyond the party’s reasonable control.

13. **Non-Solicitation** During the term of this Agreement and for a period of [...***…] thereafter, regardless of the reason for such termination, neither party shall, directly or indirectly, without the prior written consent of the other party, solicit or hire, as an employee or independent contractor, any person who is, or was at any time, employed by or under contract with the other party, unless at the time of the solicitation or hiring, at least [...***…] shall have elapsed since the person was last employed by or under contract with the other party; provided, however, that the limitations in this Article 13 shall not apply to the hiring of any person who replies to a general advertisement of such party.

14. **Miscellaneous**

14.1 **Use of Name.** PII shall permit Customer to reference PII’s work hereunder in any filing that Customer may make with any governmental or regulatory agency anywhere in the world, and upon Customer’s request PII shall promptly provide Customer with a letter of permission or other documentation deemed reasonably necessary by Customer to evidence such right.

14.2 **Governing Law.** This Agreement shall be governed by the laws of the State of New York without regard to the principles of conflict of law doctrines of New York or any other jurisdiction.

14.3 **Taxes.** Each party shall have the sole responsibility for the payment of all taxes and duties imposed by all governmental entities, as they pertain to its duties, obligations and performance under this Agreement, provided that Customer shall pay all federal, state and local taxes, if any, based upon the Project or Deliverables provided by PII under this Agreement.

14.4 **Assignment.** Neither party may assign this Agreement or any of its rights or obligations hereunder without prior written consent of the other party hereeto; provided, however, that each party may assign this Agreement and its rights and obligations hereunder, upon written notice to the other party, to an entity that (i) consolidates or merges with or buys all or substantially all the assets of the transferring party, or (ii) controls, is under common control with, or is controlled by the transferring party; provided, however such assignment shall not relieve the assigning party of its obligations hereunder.

14.5 **Waiver; Integration; Modification.** The waiver of the breach of any term or provision of this Agreement shall not operate as or be construed to be a waiver of any other or subsequent breach of this Agreement. This Agreement (which includes any Service Contract(s)) sets forth the entire agreement between the parties with respect to the subject matter of this Agreement and merges and supersedes all prior discussions, agreements and understandings of every nature between them. In the event of any conflict between the terms set forth herein or the terms set forth or referred to in the Service Contract(s), the terms set forth in this Agreement shall control. No modification or amendment to this Agreement, any Service Contract or any other agreement with respect to the subject matter of this Agreement shall be effective unless stated in writing and signed by the parties. Service Contracts hereunder submitted by Customer to PII shall reference this Agreement and be governed exclusively by the terms and conditions contained herein. Any term or condition in any order, confirmation, or other ***Confidential Treatment Requested
document furnished by Customer or PII which is in any way inconsistent with these terms and conditions is hereby expressly rejected.

14.6 **Construction.** Whenever the context may require, the singular form of names and pronouns shall include the plural and vice-versa. The section and subsection headings are included solely for the convenience of the parties and shall not be used in the interpretation of this Agreement. No rule of construction shall apply to this Agreement that construes any language, whether ambiguous, unclear or otherwise, in favor of or against any party based on the party that drafted such language.

14.7 **Counterparts.** This Agreement may be executed in any number of counterparts, and each such counterpart shall be deemed to be an original instrument, but all such counterparts together shall constitute but one agreement.

14.8 **Survival.** No termination or expiration of this Agreement shall relieve the parties hereto of any obligation hereunder which by its terms is intended to or may survive the termination or expiration of this Agreement, including, without limitation, Sections 2.4, 2.5, 2.7, 2.8, 2.9, 4.5, 9.3 and 9.4, and Articles 5, 6, 7, 10, 11, 12, 13 and 14, which will survive expiration or termination of this Agreement.

14.9 **Relationship Between Parties.** PII’s relationship to Customer shall be that of an independent contractor. No persons engaged by PII shall be considered under the provisions of this Agreement or otherwise as an employee of Customer. Nothing contained in this Agreement shall create or imply the creation of a partnership between Customer and PII and neither party shall have any authority (actual or apparent) to bind the other.

14.10 **Notices; English Language.** All notices, requests, consents and other communications (“Notices”) hereunder to either party shall be made in writing (whether or not specifically required herein) and deemed to be sufficient if contained in a written instrument delivered in person or duly sent by first class registered or certified mail, postage prepaid, or by next day express delivery service or by facsimile (with written confirmation of receipt) with a confirmation copy by next day express delivery service. All notices shall be addressed to such party at the address set forth above or such other address as may hereafter be designated in a notice duly given as set forth above. All Notices shall be deemed to have been received on the day of delivery, if delivered in person, or on the third business day following the date that the original notice is mailed, if delivered by first class mail, or on the next business day following the date the original notice or confirmation copy (as the case may be) is sent by next day express delivery service or facsimile. All communication hereunder, and all written Project Materials and Deliverables, shall be in the English language.

14.11 **Notification Of Sub-Contract Labs.** Insofar as PII anticipates using contract laboratories for some of the activities described in this Agreement, PII shall notify Customer, and obtain Customer’s prior written consent, when use of such contract laboratories becomes necessary. Customer hereby consents to the contract laboratories listed on Schedule 14.11 attached hereto. PII shall be responsible for assuring that any contract lab used complies with PII’s obligations hereunder.

[remainder of page intentionally blank]
IN WITNESS WHEREOF, the parties have caused this Agreement to be executed the day and year first above written.

HORIZON THERAPEUTICS, INC.

By: /s/ Robert DeVaere
Name: Robert DeVaere
Title: Executive Vice President & CFO

PHARMACEUTICS INTERNATIONAL, INC.

By: /s/ Steve King
Name: Steve King, Senior Vice President

14