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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549**

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**FORM 10-Q/A  
(Amendment No. 1)**

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(Mark One)

**Quarterly report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**

For the quarterly period ended June 30, 2012

or

**Transition report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**

For the transition period from to

Commission File Number: 001-33500

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**JAZZ PHARMACEUTICALS PUBLIC LIMITED COMPANY**

(Exact name of registrant as specified in its charter)

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**Ireland**  
(State or other jurisdiction of  
incorporation or organization)

**98-1032470**  
(I.R.S. Employer  
Identification No.)

**45 Fitzwilliam Square  
Dublin 2, Ireland  
011-353-1-634-4183**

(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

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**Securities registered pursuant to Section 12(b) of the Act:**

<u>Title of each class</u>	<u>Name of each exchange on which registered</u>
Ordinary shares, nominal value \$0.0001 per share	The NASDAQ Stock Market LLC

**Securities registered pursuant to Section 12(g) of the Act:**

None

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

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

Indicate by check mark whether 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.

Large accelerated filer	<input checked="" type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/> (Do not check if a smaller reporting company)	Smaller reporting company	<input type="checkbox"/>

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

As of July 31, 2012, 57,536,632 ordinary shares of the registrant, nominal value \$0.0001 per share, were outstanding.

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JAZZ PHARMACEUTICALS PLC  
AMENDMENT NO. 1 TO QUARTERLY REPORT ON FORM 10-Q/A  
FOR THE QUARTER ENDED JUNE 30, 2012  
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**PART II – OTHER INFORMATION**

[Item 6. Exhibits](#)

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**EXPLANATORY NOTE**

Jazz Pharmaceuticals Public Limited Company (the “Company”) is filing this Amendment No. 1 to Quarterly Report on Form 10-Q/A (this “Amendment”) to amend the Company’s Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2012, as filed with the Securities and Exchange Commission (the “SEC”) on August 7, 2012 (the “10-Q”). This Amendment is being filed solely to file Exhibit 10.11 to the 10-Q (certain portions of which are omitted pursuant to a confidential treatment request filed with the SEC) and in connection therewith, to amend Part II, Item 6 of the 10-Q and the Exhibit Index to the 10-Q. In addition, as required by Rule 12b-15 under the Securities Exchange Act of 1934, as amended, new certifications by our principal executive officer and principal financial officer are filed as exhibits to this Amendment.

No attempt has been made in this Amendment to modify or update the other disclosures presented in the 10-Q. This Amendment does not reflect events occurring after the filing of the original 10-Q (i.e., those events occurring after August 7, 2012) or modify or update those disclosures that may be affected by subsequent events.

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### Item 6. Exhibits.

<b>Exhibit Number</b>	<b>Description of Document</b>
2.1	Agreement and Plan of Merger and Reorganization, dated as of September 19, 2011, by and among Azur Pharma Public Limited Company (formerly Azur Limited Company), Jaguar Merger Sub Inc., Jazz Pharmaceuticals, Inc. and Seamus Mulligan as Indemnitors' Representative (incorporated herein by reference to Exhibit 2.1 in Jazz Pharmaceuticals, Inc.'s current report on Form 8-K (File No. 001-33500), as filed with the SEC on September 19, 2011).
2.2	Letter Agreement, dated as of January 17, 2012, by and among Jazz Pharmaceuticals plc, Jaguar Merger Sub Inc. Jazz Pharmaceuticals, Inc. and Seamus Mulligan, solely in his capacity as the Indemnitors' Representative (incorporated by reference to Exhibit 2.2 in Jazz Pharmaceuticals plc's current report on Form 8-K (File No. 001-33500), as filed with the SEC on January 18, 2012).
2.3	Agreement and Plan of Merger, dated as of April 26, 2012, by and among Jazz Pharmaceuticals plc, Jewel Merger Sub Inc., EUSA Pharma Inc., and Essex Woodlands Health Ventures, Inc., Mayflower L.P., and Bryan Morton, in their capacity as the representatives of the equity holders of EUSA Pharma Inc. (incorporated herein by reference to Exhibit 2.1 in Jazz Pharmaceuticals plc's current report on Form 8-K (File No. 001-33500), as filed with the SEC on April 27, 2012).
2.4	Assignment, dated as of June 11, 2012, by and among Jazz Pharmaceuticals plc and Jazz Pharmaceuticals, Inc. (incorporated herein by reference to Exhibit 2.1B in Jazz Pharmaceuticals plc's current report on Form 8-K (File No. 001-33500), as filed with the SEC on June 12, 2012).
3.1	Memorandum and Articles of Association of Jazz Pharmaceuticals plc (incorporated herein by reference to Exhibit 3.1 in Jazz Pharmaceuticals plc's current report on Form 8-K (File No. 001-33500), as filed with the SEC on January 18, 2012).
4.1	Reference is made to Exhibit 3.1.
4.2A	Third Amended and Restated Investor Rights Agreement, made effective as of June 6, 2007, by and between Jazz Pharmaceuticals, Inc. and the other parties named therein (incorporated herein by reference to Exhibit 4.3 in Jazz Pharmaceuticals, Inc.'s quarterly report on Form 10-Q (File No. 001-33500) for the period ended June 30, 2007, as filed with the SEC on August 10, 2007).
4.2B	Waiver and Amendment Agreement, dated as of March 12, 2008, by and between Jazz Pharmaceuticals, Inc. and the other parties named therein (incorporated herein by reference to Exhibit 4.3B in Jazz Pharmaceuticals, Inc.'s annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2007, as filed with the SEC on March 31, 2008).
4.2C	Waiver and Amendment Agreement, dated as of May 7, 2008, by and between Jazz Pharmaceuticals, Inc. and the other parties named therein (incorporated herein by reference to Exhibit 4.3C in Jazz Pharmaceuticals, Inc.'s current report on Form 8-K (File No. 001-33500), as filed with the SEC on May 9, 2008).
4.2D	Waiver and Amendment Agreement, dated as of July 6, 2009, by and between Jazz Pharmaceuticals, Inc. and the other parties named therein (incorporated herein by reference to Exhibit 4.3D in Jazz Pharmaceuticals, Inc.'s quarterly report on Form 10-Q (File No. 001-33500) for the period ended June 30, 2009, as filed with the SEC on August 14, 2009).
4.2E	Assignment, Assumption and Amendment Agreement, dated as of January 18, 2012, by and among Jazz Pharmaceuticals, Inc., Jazz Pharmaceuticals plc and the other parties named therein (incorporated herein by reference to Exhibit 4.2E in the annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2011, filed by Jazz Pharmaceuticals plc on behalf of and as successor to Jazz Pharmaceuticals, Inc. with the SEC on February 28, 2012).
4.3	Form of Jazz Pharmaceuticals plc Warrant to Purchase Ordinary Shares issued to holders of assumed Common Stock Warrants originally issued by Jazz Pharmaceuticals, Inc. (incorporated herein by reference to Exhibit 4.4 in the annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2011, filed by Jazz Pharmaceuticals plc on behalf of and as successor to Jazz Pharmaceuticals, Inc. with the SEC on February 28, 2012).
4.4	Form of Jazz Pharmaceuticals plc Warrant to Purchase Ordinary Shares issued to holders of assumed Registered Direct Common Stock Warrants originally issued by Jazz Pharmaceuticals, Inc. (incorporated herein by reference to Exhibit 4.5 in the annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2011, filed by Jazz Pharmaceuticals plc on behalf of and as successor to Jazz Pharmaceuticals, Inc. with the SEC on February 28, 2012).

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4.5	Form of Jazz Pharmaceuticals plc Warrant to Purchase Ordinary Shares issued to holders of assumed Common Stock Warrants originally issued by Jazz Pharmaceuticals, Inc. (incorporated herein by reference to Exhibit 4.6 in the annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2011, filed by Jazz Pharmaceuticals plc on behalf of and as successor to Jazz Pharmaceuticals, Inc. with the SEC on February 28, 2012).
4.6A	Investor Rights Agreement, dated July 7, 2009 by and between Jazz Pharmaceuticals, Inc. and the other parties named therein (incorporated herein by reference to Exhibit 10.88 in Jazz Pharmaceuticals, Inc.'s current report on Form 8-K (File No. 001-33500), as filed with the SEC on July 7, 2009).
4.6B	Assignment, Assumption and Amendment Agreement, dated as of January 18, 2012, by and among Jazz Pharmaceuticals, Inc., Jazz Pharmaceuticals plc and the other parties named therein (incorporated herein by reference to Exhibit 4.7B in the annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2011, filed by Jazz Pharmaceuticals plc on behalf of and as successor to Jazz Pharmaceuticals, Inc. with the SEC on February 28, 2012).
4.7	Registration Rights Agreement made as of January 13, 2012, by and among Jazz Pharmaceuticals plc and certain shareholders named therein (incorporated herein by reference to Exhibit 10.2 in Jazz Pharmaceuticals plc's current report on Form 8-K (File No. 001-33500), as filed with the SEC on January 18, 2012).
10.1	Credit Agreement, dated as of June 12, 2012, by and among Jazz Pharmaceuticals plc, Jazz Pharmaceuticals, Inc, the Lenders and Barclays Bank PLC, as Administrative Agent, Collateral Agent, Swing Line Lender and L/C Issuer (incorporated herein by reference to Exhibit 10.1 in Jazz Pharmaceuticals plc's current report on Form 8-K (File No. 001-33500), as filed with the SEC on June 12, 2012).
10.2	Lease, dated May 8, 2012, by and between John Ronan and Castle Cove Property Developments Limited and Jazz Pharmaceuticals plc (incorporated herein by reference to Exhibit 10.2 in Jazz Pharmaceuticals plc's quarterly report on Form 10-Q (File No. 001-33500) for the period ended June 30, 2012, as filed with the SEC on August 7, 2012).
10.3+	Jazz Pharmaceuticals plc 2012 Executive Officer Compensation Arrangements (incorporated herein by reference to Exhibit 10.3 in Jazz Pharmaceuticals plc's quarterly report on Form 10-Q (File No. 001-33500) for the period ended June 30, 2012, as filed with the SEC on August 7, 2012).
10.4+	Employment Agreement by and between Fintan Keegan and Jazz Pharmaceuticals plc (incorporated herein by reference to Exhibit 10.4 in Jazz Pharmaceuticals plc's quarterly report on Form 10-Q (File No. 001-33500) for the period ended June 30, 2012, as filed with the SEC on August 7, 2012).
10.5+	Noncompetition Agreement by and between Fintan Keegan and Jazz Pharmaceuticals plc (incorporated herein by reference to Exhibit 10.5 in Jazz Pharmaceuticals plc's quarterly report on Form 10-Q (File No. 001-33500) for the period ended June 30, 2012, as filed with the SEC on August 7, 2012).
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10.7+	Form of Stock Option Grant Notice and Form of Option Agreement (U.S.) under the Jazz Pharmaceuticals plc 2011 Equity Incentive Plan (updated as of July 27, 2012) (incorporated herein by reference to Exhibit 10.7 in Jazz Pharmaceuticals plc's quarterly report on Form 10-Q (File No. 001-33500) for the period ended June 30, 2012, as filed with the SEC on August 7, 2012).
10.8+	Form of Stock Option Grant Notice and Form of Option Agreement (Ireland) under the Jazz Pharmaceuticals plc 2011 Equity Incentive Plan (updated as of July 27, 2012) (incorporated herein by reference to Exhibit 10.8 in Jazz Pharmaceuticals plc's quarterly report on Form 10-Q (File No. 001-33500) for the period ended June 30, 2012, as filed with the SEC on August 7, 2012).
10.9+	Form of Restricted Stock Unit Grant Notice and Form of Restricted Stock Unit Award Agreement (U.S.) under the Jazz Pharmaceuticals plc 2011 Equity Incentive Plan (updated as of July 27, 2012) (incorporated herein by reference to Exhibit 10.9 in Jazz Pharmaceuticals plc's quarterly report on Form 10-Q (File No. 001-33500) for the period ended June 30, 2012, as filed with the SEC on August 7, 2012).

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<u>Exhibit Number</u>	<u>Description of Document</u>
10.10+	Form of Restricted Stock Unit Grant Notice and Form of Restricted Stock Unit Award Agreement (Ireland) under the Jazz Pharmaceuticals plc 2011 Equity Incentive Plan (updated as of July 27, 2012) (incorporated herein by reference to Exhibit 10.10 in Jazz Pharmaceuticals plc's quarterly report on Form 10-Q (File No. 001-33500) for the period ended June 30, 2012, as filed with the SEC on August 7, 2012).
10.11#	Royalty Bearing License Agreement and Supply Agreement Re Erwinia-Derived Asparaginase, dated July 22, 2005, between the Health Protection Agency and EUSA Pharma SAS (formerly OPI, S.A.), as amended on each of December 22, 2009, March 23, 2012 and August 8, 2012.
31.1	Certification of Chief Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as amended (incorporated herein by reference to Exhibit 31.1 in Jazz Pharmaceuticals plc's quarterly report on Form 10-Q (File No. 001-33500) for the period ended June 30, 2012, as filed with the SEC on August 7, 2012).
31.2	Certification of Chief Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as amended (incorporated herein by reference to Exhibit 31.2 in Jazz Pharmaceuticals plc's quarterly report on Form 10-Q (File No. 001-33500) for the period ended June 30, 2012, as filed with the SEC on August 7, 2012).
31.3	Certification of Chief Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as amended.
31.4	Certification of Chief Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as amended.
32.1*	Certifications of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (incorporated herein by reference to Exhibit 32.1 in Jazz Pharmaceuticals plc's quarterly report on Form 10-Q (File No. 001-33500) for the period ended June 30, 2012, as filed with the SEC on August 7, 2012).
101.INS++	XBRL Instance Document (incorporated herein by reference to Exhibit 101.INS in Jazz Pharmaceuticals plc's quarterly report on Form 10-Q (File No. 001-33500) for the period ended June 30, 2012, as filed with the SEC on August 7, 2012).
101.SCH++	XBRL Taxonomy Extension Schema Document (incorporated herein by reference to Exhibit 101.SCH in Jazz Pharmaceuticals plc's quarterly report on Form 10-Q (File No. 001-33500) for the period ended June 30, 2012, as filed with the SEC on August 7, 2012).
101.CAL++	XBRL Taxonomy Extension Calculation Linkbase Document (incorporated herein by reference to Exhibit 101.CAL in Jazz Pharmaceuticals plc's quarterly report on Form 10-Q (File No. 001-33500) for the period ended June 30, 2012, as filed with the SEC on August 7, 2012).
101.DEF++	XBRL Taxonomy Extension Definition Linkbase Document (incorporated herein by reference to Exhibit 101.DEF in Jazz Pharmaceuticals plc's quarterly report on Form 10-Q (File No. 001-33500) for the period ended June 30, 2012, as filed with the SEC on August 7, 2012).
101.LAB++	XBRL Taxonomy Extension Labels Linkbase Document (incorporated herein by reference to Exhibit 101.LAB in Jazz Pharmaceuticals plc's quarterly report on Form 10-Q (File No. 001-33500) for the period ended June 30, 2012, as filed with the SEC on August 7, 2012).
101.PRE++	XBRL Taxonomy Extension Presentation Linkbase Document (incorporated herein by reference to Exhibit 101.PRE in Jazz Pharmaceuticals plc's quarterly report on Form 10-Q (File No. 001-33500) for the period ended June 30, 2012, as filed with the SEC on August 7, 2012).

# 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.

+ Indicates management contract or compensatory plan.

\* The certifications attached as Exhibit 32.1 to the original Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2012 filed with the SEC on August 7, 2012 (the "Form 10-Q") accompany the Form 10-Q pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, and shall not be deemed "filed" by the Registrant for purposes of Section 18 of the Securities Exchange Act of 1934, as amended.

++ Pursuant to applicable securities laws and regulations, the Registrant is deemed to have complied with the reporting obligation relating to the submission of interactive data files in such exhibits and is not subject to liability under any anti-fraud provisions of the federal securities laws as long as the Registrant has made a good faith attempt to comply with the submission requirements

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and promptly amends the interactive data files after becoming aware that the interactive data files fails to comply with the submission requirements. These interactive data files are deemed not filed or part of a registration statement or prospectus for purposes of sections 11 or 12 of the Securities Act of 1933, as amended, are deemed not filed for purposes of section 18 of the Securities Exchange Act of 1934, as amended, and otherwise are not subject to liability under these sections.

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Dated: August 9, 2012

**Jazz Pharmaceuticals Public Limited Company**  
(Registrant)

/s/ Bruce C. Cozadd

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Bruce C. Cozadd

***Chairman and Chief Executive Officer and Director  
(Principal Executive Officer)***

/s/ Kathryn E. Falberg

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Kathryn E. Falberg

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

/s/ Karen J. Wilson

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Karen J. Wilson

***Vice President, Finance  
(Principal Accounting Officer)***



**EXHIBIT INDEX**

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31.1	Certification of Chief Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as amended (incorporated herein by reference to Exhibit 31.1 in Jazz Pharmaceuticals plc's quarterly report on Form 10-Q (File No. 001-33500) for the period ended June 30, 2012, as filed with the SEC on August 7, 2012).
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32.1*	Certifications of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (incorporated herein by reference to Exhibit 32.1 in Jazz Pharmaceuticals plc's quarterly report on Form 10-Q (File No. 001-33500) for the period ended June 30, 2012, as filed with the SEC on August 7, 2012).
101.INS++	XBRL Instance Document (incorporated herein by reference to Exhibit 101.INS in Jazz Pharmaceuticals plc's quarterly report on Form 10-Q (File No. 001-33500) for the period ended June 30, 2012, as filed with the SEC on August 7, 2012).
101.SCH++	XBRL Taxonomy Extension Schema Document (incorporated herein by reference to Exhibit 101.SCH in Jazz Pharmaceuticals plc's quarterly report on Form 10-Q (File No. 001-33500) for the period ended June 30, 2012, as filed with the SEC on August 7, 2012).
101.CAL++	XBRL Taxonomy Extension Calculation Linkbase Document (incorporated herein by reference to Exhibit 101.CAL in Jazz Pharmaceuticals plc's quarterly report on Form 10-Q (File No. 001-33500) for the period ended June 30, 2012, as filed with the SEC on August 7, 2012).
101.DEF++	XBRL Taxonomy Extension Definition Linkbase Document (incorporated herein by reference to Exhibit 101.DEF in Jazz Pharmaceuticals plc's quarterly report on Form 10-Q (File No. 001-33500) for the period ended June 30, 2012, as filed with the SEC on August 7, 2012).
101.LAB++	XBRL Taxonomy Extension Labels Linkbase Document (incorporated herein by reference to Exhibit 101.LAB in Jazz Pharmaceuticals plc's quarterly report on Form 10-Q (File No. 001-33500) for the period ended June 30, 2012, as filed with the SEC on August 7, 2012).
101.PRE++	XBRL Taxonomy Extension Presentation Linkbase Document (incorporated herein by reference to Exhibit 101.PRE in Jazz Pharmaceuticals plc's quarterly report on Form 10-Q (File No. 001-33500) for the period ended June 30, 2012, as filed with the SEC on August 7, 2012).

# 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.

+ Indicates management contract or compensatory plan.

\* The certifications attached as Exhibit 32.1 to the original Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2012 filed with the SEC on August 7, 2012 (the "Form 10-Q") accompany the Form 10-Q pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, and shall not be deemed "filed" by the Registrant for purposes of Section 18 of the Securities Exchange Act of 1934, as amended.

++ Pursuant to applicable securities laws and regulations, the Registrant is deemed to have complied with the reporting obligation relating to the submission of interactive data files in such exhibits and is not subject to liability under any anti-fraud provisions of the federal securities laws as long as the Registrant has made a good faith attempt to comply with the submission requirements and promptly amends the interactive data files after becoming aware that the interactive data files fails to comply with the

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submission requirements. These interactive data files are deemed not filed or part of a registration statement or prospectus for purposes of sections 11 or 12 of the Securities Act of 1933, as amended, are deemed not filed for purposes of section 18 of the Securities Exchange Act of 1934, as amended, and otherwise are not subject to liability under these sections.

[ \* ] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

(1) THE HEALTH PROTECTION AGENCY

(2) OPI S.A.

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ROYALTY BEARING LICENCE AGREEMENT  
AND SUPPLY AGREEMENT RE ERWINIA-DERIVED  
ASPARAGINASE

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# REMOVED BY AMENDMENT

[ \* ] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

THIS AGREEMENT is made this 22 day of July, 2005

**BETWEEN:**

- (1) **THE HEALTH PROTECTION AGENCY** of Porton Down, Salisbury, Wiltshire SP4 0JG (which expression shall include its successors in title) (“HPA”); and
- (2) **Opi S.A.** whose registered office is at Les Jardins d’Eole, 3 allée des Séquoias, 69760, Limonest (“Opi”).

**WHEREAS**

- (1) HPA wishes to license Opi to market, sell and distribute the Product (as hereinafter defined) in the Territory, on the terms and conditions hereinafter appearing.
- (2) HPA wishes to supply and Opi wishes to purchase the Product on the terms and conditions hereinafter appearing.

NOW IT IS HEREBY AGREED as follows:-

**1. DEFINITIONS AND INTERPRETATION**

1.1 In this Agreement unless the context otherwise requires:-

“**Batch**” means the quantity represented by the output of Product subject to a single freeze-drying operation.

“**Effective Date**” means the date of this Agreement.

“**Dossier**” means all medical, scientific and other information or data required to be provided to a Regulatory Agency in order to vary, obtain, maintain or renew a relevant Marketing Authorisation.

“**GMP**” shall have the meaning set forth in Schedule 5 (the Technical Agreement)

“**Opi Group Company**” means a member of the group consisting of Opi, any holding company of Opi and any subsidiary of Opi or any subsidiary of any holding Company of Opi (the expressions “holding Company” and “subsidiary” bearing the same meanings as they respectively bear in Companies Act 1985).

“**Improvements**” means any and all improvement, developments, alterations or modifications to the Know How and or the Intellectual Property made or developed by Opi or HPA.

“**Intellectual Property**” means all registered and unregistered trade marks, patents, patent applications, registered and unregistered designs, design rights, copyright works or other intellectual property rights from time to time owned by HPA in relation to the Product.

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“[ \* ]” means the holder as of the date of this Agreement of the Marketing Authorisations throughout the Territory (other than the United Kingdom).

“**Know-how**” means all of the drawings, designs, specifications, processes, knowledge, technical information and expertise from time to time owned by HPA relating to the Manufacture of the Product including any information relating to the Organism.

“**Manufacture**” includes Product manufacture, production, testing, analysis, quality control, filling and finishing Vials, storage and packing as specified in the Technical Agreement and “Manufacturing” shall be construed accordingly.

“**Marketing Authorisation**” means a licence or approval from the appropriate Regulatory Agency to market, sell or distribute the Product in a particular country of the Territory including in the case of the United States of America the treatment IND for the Product.

“**Minimum Calculation Year**” means each period of 12 consecutive calendar months ending on 31st March during the currency of this Agreement except for the first Minimum Calculation Year which shall be the period from the Effective Date to 31st March 2007.

“**MHRA**” means the Regulatory Agency in the United Kingdom.

“[ \* ]” means the [ \* ] specified in [ \* ].

“**Net Sales**” means the aggregate amount of the income received by OPi in respect of the sale of the Product whether before or after the termination of this Agreement after making reasonable deductions therefrom for commissions, returns, credit notes and the cost of any transport insurance, packing, freight, taxes, duties, rebates and trade discounts expressly included in any invoice price provided that in any case where the Product is (a) directly or indirectly sold by OPi to any member of the OPi Group or (b) is sold other than on arm’s length terms then the Net Sales value of any Product so sold shall be [ \* ] and [ \* ]. Where Product is used for research and/or clinical trials purposes or is distributed [ \* ] by way of samples or charitable donations then such Product shall not be deemed to have been sold by OPi for the purpose of calculating the Net Sales of this Agreement.

“**OPi Know How**” means all of the drawings, designs, specifications, processes, knowledge, technical information, results of clinical trials, knowledge of the customer and distributor base for the Product anywhere in the Territory, Product sales information, marketing and market intelligence and OPi expertise as from time to time owned or developed by OPi in addition including any Improvements.

“**Organism**” means the organism defined in Schedule 1.

“**Product**” means the product defined in Schedule 1.

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“**Purpose**” means the treatment of neoplastic conditions where depletion of asparagine might be expected to have a useful effect, including but not limited to Acute Lymphoblastic Leukaemia (ALL), Acute Myeloid Leukaemia (AML) and Non-Hodgkin’s Lymphoma.

“**Quarter**” means each period of three (3) months ending on the last days of March, June, September and December.

“**Regulatory Agency**” means the appropriate government or regulatory body or agency in each country of the Territory empowered to grant Marketing Authorisations.

“**Subsidiary**” and “**Holding Company**” shall have the meanings ascribed thereto by the Companies Act 1989.

“**Specification**” means the Manufacturing and technical specification for the Product and its packaging vials (including information on testing and storage) as set out in the Technical Agreement.

“**Technical Agreement**” means the agreement to be entered into between the parties in the terms agreed and contained in Schedule 5.

“**Territory**” means anywhere in the world.

“**Trade Mark**” means the trade mark Erwinase as registered or applied for registration in the Territory details of which are set out in Schedule 6.

“**United Kingdom**” means the United Kingdom of Great Britain and Northern Ireland.

“**Vial**” means a container of the Product as specified in the Technical Agreement.

1.2 References to the singular shall include the plural and vice versa.

1.3 References to Clauses and Schedules are to clauses of and schedules to this Agreement. The headings to the Clauses in this Agreement are for convenience only and have no legal effect.

## 2. LICENCE

2.1 HPA hereby grants to OPi upon the terms and conditions hereinafter appearing an exclusive licence to market, sell or distribute the Product in the Territory solely for the Purpose and to use the Trademark solely for the Purpose and a non exclusive licence to use the Intellectual Property and the Know How to the extent reasonably required by OPi in accordance with the proper performance of this Agreement and in order to carry out further research and development in relation to the Product for the Purpose.

2.2 Subject to prior written notification of HPA OPi may appoint such sub-distributors against whom HPA cannot raise any reasonable objection to market, sell or distribute the Product in the Territory subject to the restrictions imposed by this Agreement but

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otherwise on such terms as OPi in its sole discretion shall determine provided however, that the rights of any sub-distributor in relation to the Product shall terminate at the same time as this agreement.

- 2.3 OPi shall ensure that any sub-distributor performs its obligations under any distribution agreement granted hereunder.
- 2.4 OPi shall indemnify HPA against all losses, damages, expenses, and costs, which may be incurred by HPA as a result of any third party claims arising directly from a sub-distributor's failure to perform its obligations under any such distribution agreement. Subject to the provisions of Clause 9.4, 9.5 and 9.6, HPA shall indemnify OPi against all losses, damages, expenses, and costs, which may be incurred by OPi as a result of any third party claims arising directly from OPi's failure to supply Product to its sub-distributor or perform its obligations under any such distribution agreement as a result of HPA's failure to provide Product to OPi in accordance with the terms of this Agreement.
- 2.5 OPi shall not save as permitted in respect of the rights for OPi to use the Trademark pursuant to Clause 2.1 use the name or any trademark(s) of the HPA or the names of any of its employees in any advertising or sales promotional material or in any publication without prior written permission of HPA; provided, however, that OPi may use the name of HPA in filings for Marketing Authorisations and other regulatory filings including packaging elements and as required by any applicable law.

### 3. SUPPLY OF PRODUCT

3.1 Over the duration of the Agreement (and its extensions, if applicable), HPA shall:

- 3.1.1 Manufacture the Product;
- 3.1.2 Maintain the Manufacturing site held in Porton Down or (if such Manufacturing site is to be closed down) HPA shall maintain such other relocated Manufacturing site as HPA may reasonably determine at HPA's cost. In the event that any such closure and relocation is proposed by HPA, HPA will consult with OPi in advance to ensure that OPi's views on the impact and significance of the closure and on the suitability of HPA's proposals for relocation of the Manufacturing site are taken into consideration by HPA in good faith; or;
- 3.1.3 Subject to the quality of Product at all times being compliant with the provisions of this Agreement, HPA may sub-contract the Manufacture of all or part of the Product to third parties, after consultation with OPi under clause 6.7 and subject to the prior written approval of any Regulatory Agency. HPA shall ensure that any sub-contractor performs its obligations under any sub-contract and notwithstanding any such sub-contracting HPA shall remain responsible for Manufacture and the performance of this Agreement.

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- 3.2 HPA shall supply the Product to OPi:
- 3.2.1 at the price per Vial specified in Schedule 2 which shall be revised:
- (a) [ \* ] at the [ \* ] by [ \* ] of the [ \* ] in the [ \* ] by the [ \* ];
- and
- (b) [ \* ] to take into account [ \* ] in the [ \* ] of the [ \* ] and [ \* ] as a result of [ \* ] in the [ \* ]. HPA acknowledges and agrees that it will co-operate in good faith with OPi [ \* ] to [ \* ] which [ \* ] shall be [ \* ]
- 3.2.2 on such other terms and conditions as are set out in Schedule 2.
- The standard terms and conditions of business of neither party shall have any effect in respect of the supply or purchase of Product.
- 3.3 OPi shall order from HPA [ \* ] the Product (as specified in Schedule 2) and OPi shall pay for the actual quantity of Product complying with the terms of this Agreement and supplied by HPA. HPA shall ensure that it supplies [ \* ] the Product. It is acknowledged by the Parties that any delay in transferring the Marketing Authorisations of the Product could impact negatively the Sales of the Product expected by OPi. Both Parties thus undertake to use all reasonable endeavours to timeously transfer the Marketing Authorisations to OPi.
- 3.4 [ \* ] following the Effective Date OPi shall order [ \* ] the Product (the “Initial Order”). HPA shall supply such quantity of Product [ \* ] following receipt of the Initial Order and OPi shall purchase the Initial Order in accordance with the terms of this Agreement.
- 3.5 OPi shall maintain sufficient levels of the Product in stock at all times throughout the term of this Agreement in order to meet the following [ \* ] sales demand based on the forecast provided by OPi pursuant to paragraph 3.1 of Schedule 2. HPA shall maintain such levels of the Organism and other ingredients, excipients and packaging required and set aside appropriate Manufacturing and other facilities necessary to Manufacture the Product at all times throughout the term of this Agreement as may be reasonably expected to be necessary in order to meet the forecasts and orders [ \* ] provided by OPi from time to time pursuant to this Agreement. The forecasts for the [ \* ] shall be binding on both parties as specified in Clause 3.1 of Schedule 2.
- 3.6 If at any time HPA and OPi shall agree to change or add to the Specification or definitions in Schedule 1 they shall be amended accordingly to reflect such changes together if necessary with the price per Vial provided for in Schedule 2.
- 3.7 HPA shall in good faith make available to OPi all information reasonably required to enable OPi to verify the amount of [ \* ] or [ \* ] under [ \* ].
- 3.8 The parties shall enter into and perform their respective obligations as set out in the Technical Agreement, the form of which is specified in Schedule 5. To the extent that there is any conflict between any of the provisions of the Technical Agreement and the other terms of this Agreement then the other terms of this Agreement shall prevail.

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#### 4. ROYALTIES

- 4.1 In consideration of the assistance and services hereby agreed to be rendered and of the licence hereby granted, OPi shall both during the term of this Agreement in respect of all the Product sold by OPi and after the termination of this Agreement in respect of any stocks of the Product held by OPi at the date of termination and sold on or after such date by OPi pay to HPA in addition to any other sums payable hereunder a royalty equal to [ \* ] per cent of the Net Sales for sales up [ \* ], [ \* ] per cent for sales between [ \* ] and [ \* ], [ \* ] per cent for sales between [ \* ] and [ \* ] and [ \* ] per cent for sales over [ \* ] in anyone Minimum Calculation Year. To the extent that OPi is required by applicable law to deduct any amounts from such royalty payable by way of withholding or other tax, it shall make such deduction, pay the appropriate amount of tax deducted to the appropriate taxation authorities and provide HPA with an appropriate certificate of tax deduction.
- 4.2 Within [ \* ] after the end of each Quarter OPi shall furnish to HPA a written statement setting out Net Sales of Product in such Quarter and the amount that will be payable at the end of the relevant Minimum Calculation Year by OPi by way of royalties in respect thereof in such Quarter. The statement for the last Quarter in any Minimum Calculation Year shall include details of all amounts payable by OPi by way of royalties in respect of that Minimum Calculation Year. Following receipt thereof, HPA shall provide to OPi an invoice in respect of such royalties. Within [ \* ] of the date of such invoice, OPi will make payment (less any income tax OPi is required by statute to deduct) in favour of HPA for the amount due to HPA in respect of the preceding Minimum Calculation Year.
- 4.3 Information as to the Net Sales and the quantities of Product sold or otherwise distributed or provided by OPi, the identity of the countries within the Territory to which such sales or other distributions or provisions have been made and the quantity and Net Sales in respect of such sales or other distributions or provisions of Product made within each such country and such other information as may be requested by HPA shall be furnished to HPA by OPi by [ \* ] each year in respect of the preceding Minimum Calculation Year.
- 4.4 A sale of the Product shall be deemed to have been made on the earliest of (i) [ \* ] following the date shown as the date of the invoice relating to such sale, or (ii) [ \* ] following the date of delivery of the Product, or (iii) the date of receipt of payment in respect of such Product. Any invoice made or income or sums received in whole or in part in foreign currency shall be converted to sterling for the purpose of calculating the royalties by reference to the average of the middle market exchange rate of National Westminster Bank plc during the relevant Quarter.
- 4.5 OPi shall at all times during the continuance of this Agreement keep at its usual place of business all proper books of account and other records of sales or other distributions or provisions of the Product by OPi (including details of the countries within the Territory to which such sales or other distributions or provisions have been made) and royalties due on Net Sales to HPA and shall make true and complete entries therein at the earliest

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practical opportunity of all the particulars necessary or convenient to substantiate the information required by the written statements hereinbefore mentioned and HPA and/or its authorised representative shall have reasonable access following prior written notice to OPi's books of account and other records in order to determine the accuracy of the said statements and/or to determine or ascertain whether the amounts payable to HPA pursuant to this Agreement have been paid to it.

4.6 If [ \* ] the [ \* ] under [ \* ] are [ \* ] the [ \* ] as set out in [ \* ], OPi may elect to [ \* ] which [ \* ] under [ \* ] is [ \* ] the [ \* ] specified in [ \* ], in which event such [ \* ] with the [ \* ] will be [ \* ] the [ \* ] in accordance with the provisions of [ \* ]. Any [ \* ] by OPi in respect of any [ \* ] shall be [ \* ] so as to be taken into account when [ \* ] in the [ \* ]. The [ \* ] can be [ \* ] the [ \* ] but not [ \* ].

4.6.1 If during the term of this Agreement OPi shall fail (a) to make payment in accordance with the provisions of clause 4.2 of this Agreement following the end of each Minimum Calculation Year [ \* ], or (b) to [ \* ] as provided in [ \* ] in any Minimum Calculation Year, HPA may at its option:

(a) as its sole and exclusive remedy [ \* ] on [ \* ] written notice to OPi (provided always that in the event of [ \* ] OPi accepts that [ \* ] under the terms of this Agreement to [ \* ] which is in compliance with the provisions of this Agreement [ \* ]); or

(b) as its sole and exclusive remedy [ \* ] on [ \* ] written notice to OPi;

4.6.2 It is acknowledged by HPA that OPi sales forecasts are based on an average selling price of [ \* ]. OPi undertakes to use its best endeavours to reach such Average Selling Price, and HPA will, at OPi's cost, provide OPi with all reasonable assistance in its negotiations with the Pricing Authorities.

## 5. UNDERTAKINGS

5.1 Subject to HPA's compliance with its obligations under Clauses 5.2 and 5.8, OPi hereby undertakes with HPA that:

5.1.1 OPi will at its own cost:

(a) transfer as soon as reasonably practicable following the Effective Date into its own name such of the Marketing Authorisations in such countries of the Territory (except the United Kingdom) as OPi may specify;

(b) vary, obtain, maintain or renew (as appropriate) the Marketing Authorisations (except for that granted for the United Kingdom) as OPi may require from time to time during the term of this Agreement;

(c) as soon as reasonably practicable following the transfers in paragraph (a) above and during the term of this Agreement use its best endeavors to market, sell and distribute the Product (or procure the same by its distributors) in the [ \* ] subject always to the limitations imposed by the relevant Marketing Authorisations in such countries and applicable law;

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- (d) as soon as reasonably practicable following the transfers in paragraph (a) above and during the term of this Agreement use its reasonable endeavors to market, sell and distribute the Product (or procure the same by its distributors) in all such other countries within the Territory subject always to the limitations imposed by the relevant Marketing Authorisations in such countries and applicable law;

In relation to the United States of America it is acknowledged by the parties that the existing Treatment IND may not be transferable or renewable but OPi undertakes to use its best endeavors to ensure appropriate Marketing Authorisation is obtained in OPi's name for the United States of America to enable the Product to be supplied as widely as possible in the United States of America based on the current Dossier. HPA shall provide all reasonable assistance to OPi in respect of the obtaining of such Treatment IND.

- 5.1.2 OPi will supply to HPA from time to time such evidence of OPi's fulfillment of the undertaking specified in Clause 5.1.1 as may be reasonably requested by HPA;

## 5.2 In respect of the Marketing Authorisations

- 5.2.1 HPA hereby Undertakes to provide to OPi free of charge within [ \* ] following execution of the Agreement the Dossier which supports the current Marketing Authorisation in the United Kingdom, the various available modules of the Common Technical Document of the Product and any recent correspondence relating to the Product between HPA and the MHRA. HPA hereby undertakes to provide (or procure the provision by [ \* ]) timeously to OPi free of charge the Dossiers and all other information or data in HPA's or [ \* ] possession or control as is reasonably required by OPi in order for OPi to transfer into its own name, vary, obtain, maintain or renew (as appropriate) the Marketing Authorisations specified by OPi under Clause 5.1.1. Where any Regulatory Agency requires HPA or [ \* ] to complete any documentation HPA undertakes to do (or undertakes to procure that [ \* ] does) so as soon as reasonably possible. In relation to the Marketing Authorisation for the United Kingdom, HPA undertakes to maintain and renew the Marketing Authorisation and as soon as reasonably possible to vary the Marketing Authorisation to specify OPi as the distributor for the Product. HPA hereby undertakes to provide (or procure the provision by [ \* ]) timeously to OPi free of charge all information relating to the pharmacovigilance of the Product (including but not limited to source document, CIOMS forms and PSUR) as well as appropriate line listing covering the period from the last PSUR to the date of transfer of the last licence in HPA's or [ \* ] possession or control. Subject to the agreement of [ \* ], HPA hereby undertakes to ensure (or procure the provision by [ \* ]) that the pharmacovigilance database of the Product will be transferred to OPi [ \* ] within [ \* ] after transfer of all registrations held for the product in the respective territories.

[ \* ] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

- 5.2.2 HPA warrants that the Common Technical Document, Module 3 reflects the current manufacturing process of the Product.
- 5.2.3 HPA agrees that the sale of Product in countries where a Marketing Authorisation exists will be limited until such Marketing Authorisation has been transferred to OPi and that any delay in obtaining the various Marketing Authorisations could impact OPi actual sales compared to its non-binding forecasts.
- 5.3 OPi hereby undertakes to [ \* ] and [ \* ] pursuant to sub clauses 5.1 and 5.2 above during the term of this Agreement.
- 5.4 OPi hereby undertakes to provide HPA with such forecasts and updates hereto as detailed in Schedule 2, Clause 3.1.
- 5.4 Where, notwithstanding the parties' respective efforts under this Clause 5 it is or becomes commercially unviable to transfer into OPi's name or vary, obtain, maintain or renew (as appropriate) any Marketing Authorisations in any particular country in the Territory, the parties shall refer the matter to the Joint Management Team for resolution but neither party shall be deemed to be in breach of this Agreement solely by reason thereof.
- 5.5 OPi shall at its own cost undertake or procure the undertaking of an optimum dosage and dose regimen trial and such other Phase IV clinical trials on such terms as may be agreed between the parties from time to time and in connection therewith HPA will supply to OPi free of charge [ \* ] of Product for use by OPi in such clinical trials during the period of [ \* ]. The dates and quantities of such supply shall be [ \* ] and [ \* ] or, as otherwise agreed between the parties from time to time (such agreement not to be unreasonably withheld or delayed). HPA shall also make available to OPi during such [ \* ] period a further quantity of [ \* ] Product (having a shelf-life remaining of [ \* ]) free of charge for clinical trials, subject to the availability of Product in stock held by HPA. Notwithstanding anything contained in this sub clause OPi may elect at any time to carry out any clinical trials at its own cost as it may determine.
- 5.6 OPi and HPA will at frequent intervals and where necessary at meetings of the Joint Management Team discuss Marketing Authorisation matters and Regulatory Agency submissions and approvals in the Territory.
- 5.7 HPA acknowledges that OPi will market, sell and distribute products other than the Products and that nothing contained in Clause 5.1 will prevent OPi from the development, marketing, sale or distribution of such other products.
- 5.8 HPA hereby undertakes with OPi that from the Effective Date and during the term of this Agreement it will at all times:

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- 5.8.1 at the written request of OPi apply to obtain and maintain in the name of HPA the registration of such of the Intellectual Property as is reasonably capable of protection by registration in the Territory and is identified in OPi's written request provided that OPi shall reimburse HPA in respect of all reasonable external or out-of-pocket costs incurred in complying with this obligation. Neither OPi nor HPA hereby make any representation that any such registration shall be granted or if granted shall be valid;
- 5.8.2 ensure that the contracts of engagement of its agents, employees, consultants and contractors are consistent with the terms of this Agreement and HPA shall subject to the provisions of Clause 9.4, 9.5 and 9.6 indemnify OPi against all losses, damages, expenses and costs which may be incurred by OPi as a result of any third party claims arising directly from a failure by any of HPA's agents, employees, consultants or contractors to perform their obligations under any contract of engagement with HPA concerning the Product;
- 5.8.3 not waive performance of any obligations of any agent, employee, consultant or contractor of HPA or amend the terms of any contract of engagement with any of them without the prior written consent of OPi if to do so would directly or indirectly prejudice the terms of this Agreement or the performance by any party of its obligations under this Agreement.
- 5.8.4 Provide such information as is consistent with the standards of the pharmaceutical industry and as may be reasonably necessary for OPi to negotiate prices under the UK Pharmaceutical Price Regulation Scheme.
- 5.9 OPi shall not waive performance of any obligations of any distributor of OPi or amend the terms of any distribution agreement granted pursuant to Clause 2.1 if to do so would directly or indirectly prejudice the terms of this Agreement or the performance by any party of its obligations under this Agreement.
- 5.10 In the event of a recall of the Product:
  - 5.10.1 the provisions of the Technical Agreement shall apply; and
  - 5.10.2 to the extent that HPA is responsible for the recall, whether due to a breach of its obligations in respect of the Manufacture of the Product or otherwise HPA shall subject to the provisions of Clause 9.4, 9.5 and 9.6 indemnify OPi against all losses liabilities and costs and expenses suffered or incurred by OPi or any OPi Group Company or a consequence thereof; and
  - 5.10.3 the extent that OPi is responsible for the recall, whether due to a breach of its obligations in respect of the sale and distribution of the Product or otherwise OPi shall subject to the provisions of Clause 9.4, 9.5 and 9.6 indemnify HPA against all losses liabilities and costs and expenses suffered or incurred by HPA as a consequence thereof.

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6. **JOINT MANAGEMENT TEAM**

- 6.1 The parties undertake to establish a Joint Management Team to be made up of 4 representatives from each of HPA and OPi, as nominated from time to time in writing. A nominated representative may by notice in writing appoint a deputy to attend a meeting in his place.
- 6.2 The Joint Management Team will meet as frequently as the Joint Management Team shall deem necessary but in any event not less than [ \* ] in each Minimum Calculation Year during the term of this Agreement. Meetings can be held at HPA's offices or such other venue as the Joint Management Team may reasonably determine.
- 6.3 A resolution in writing signed by all the members of the Joint Management Team shall be as valid and effectual as if it had been passed at a meeting of the Joint Management Team duly convened and held. Any such resolution may be sent by electronic communication and may consist of several documents in the like form each signed by one or more members.
- 6.4 Any member (including any deputy) of the Joint Management Team may participate in a meeting by means of a conference telephone, video link or similar communications equipment whereby all persons participating in the meeting can hear each other and participation in such meeting shall be deemed to constitute presence in person at such meeting.
- 6.5 Resolutions required at a meeting of the Joint Management Team shall require unanimity of all the members attending the meeting. No resolutions on matters regarding funding shall be passed unless notice of the proposed resolution has been sent to all members of the Joint Management Team in advance with the agenda for the meeting.
- 6.6 The Joint Management Team shall be responsible for ensuring that accurate minutes are taken at each meeting and for providing copies thereof to each member.
- 6.7 The Joint Management Team shall be the key body for communicating between the parties in relation both to day-to-day and significant matters or events relating to this Agreement. The Parties acknowledge that in relation to the business of the Joint Management Team, the HPA representatives will have primary responsibility for matters relating to Manufacture of the Product and the OPi representatives will have primary responsibility for matters relating to regulatory issues and the sale, marketing and distribution of the Product. The Joint Management Team will be responsible for proposing to the parties, for the final decision by the parties, the Joint Management Team's written recommendations or requests in relation to:
- 6.7.1 any matters that require the agreement of the parties pursuant to the terms of this Agreement;

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- 6.7.2 any matters arising which could adversely impact on any Marketing Authorisation, the Manufacture, the timely supply of Product, the timely purchase of Product;
  - 6.7.3 the cost of Manufacturing the Products and in particular opportunities to achieve efficiencies and reductions in costs;
  - 6.7.4 marketing strategy for the Products and the Manufacturing strategy;
  - 6.7.5 possible work in support of securing Market Authorisations for the Product;
  - 6.7.6 any unexpected or unplanned events which could impact on the obligations or rights of the parties under this Agreement; and
  - 6.7.7 such other matters as the members of the Joint Management Team may reasonably consider appropriate.
- 6.8 If the Joint Management Team is unable to reach unanimity in relation to any matter any member thereof may notify the Chief Executive Officer of OPi and the Director of the Centre for Emergency Preparedness and Response of HPA.
- 6.9 Nothing in this Clause shall prevent or restrict the parties from reaching any agreement in relation to any matter which is different from that recommended by the Joint Management Team, but the parties undertake to take the views of the Joint Management Team into account when considering any matter relating to this Agreement.

## 7. **CONFIDENTIALITY**

- 7.1 OPi acknowledges that HPA is the owner and shall retain ownership of the Organism, the Know-how and the Intellectual Property and that neither OPi nor any distributor of OPi shall acquire any right, title or interest therein save for the licence granted hereunder. In the event that OPi [ \* ] or [ \* ] or [ \* ], HPA shall be entitled to [ \* ] on notice in writing to OPi. HPA acknowledges that OPi is the owner and shall retain ownership of the OPi Know How.
- 7.2 OPi acknowledges that the Know-how with which it is furnished pursuant to this Agreement (in particular pursuant to HPA's obligation under Clause 10) is furnished in circumstances imparting an obligation of confidence and agrees to keep the Know-how secret and confidential and to respect HPA's proprietary rights therein and not at any time during the continuance of this Agreement for any reason whatsoever to disclose or permit to be disclosed the Know-how to any third party save as provided by Clause 7.3 without HPA's prior written consent provided that the Know-how may be disclosed insofar as such disclosure is necessary to any distributor or prospective distributor under any distribution agreement if that distributor or prospective distributor has undertaken confidentiality obligations the same as those set out in Clause 7, and provided further that OPi may disclose the Know-how on a confidential basis to any relevant Regulatory Agency.

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- 7.3 OPI shall take all reasonable steps to ensure that each of its agents, employees, consultants and contractors or prospective contractors having access to the Know-how is made aware that the same is secret and confidential and shall obtain from each of them enforceable written undertakings that they shall not during the continuance of this Agreement make any disclosure thereof.
- 7.4 HPA shall take all reasonable steps to ensure it does not during the continuance of this Agreement disclose or transfer to third parties any part of the Know-how or the OPI Know How otherwise than as may be disclosed or transferred in accordance with the provisions of this Agreement and shall obtain from its agents, employees, consultants and contractors having access to the Know-how or OPI Know How enforceable written undertakings that they shall not during the continuance of this Agreement make any transfer or disclosure thereof.
- 7.5 Neither OPI nor HPA shall (without the written consent of the other) during the continuance of this Agreement or for a period of [ \* ] following the expiration or termination of this Agreement make any disclosure or use of information relating to the business or affairs of the other party which is stated in writing by the other party to be confidential, except as otherwise expressly permitted under this Agreement.
- 7.6 Without prejudice to Clause 7.5, OPI and HPA shall each ensure that all of its agents, employees, consultants and contractors having access to the information specified in Clause 7 are made aware that the same is secret and confidential and shall be bound by undertakings of confidentiality (whether in their contracts of employment or otherwise) not to make any disclosure or use of such information but to keep the same confidential.
- 7.7 Each of OPI and HPA (the “First Party”) shall at its own expense give all reasonable assistance required by the other (the “Other Party”) to prevent any improper disclosure or use of the Know-how or the OPI Know How or the information specified in Clause 7.5 by any agents, employees, consultants and contractors of the First Party and the First Party shall be directly responsible to the Other Party for any such improper disclosure or use thereof.
- 7.8 The obligations of confidence referred to in this Clause 7 shall not extend to any information which:
- 7.8.1 is or shall become generally available to the public otherwise than by reason of a breach by OPI or HPA (as the case may be) (“the Recipient”), or any distributor of OPI or any agents, employees, consultants or contractors of OPI or HPA of the provisions of this Clause 7;
  - 7.8.2 is known to the Recipient or any distributor of OPI and is at its free disposal prior to its receipt from HPA or OPI (as the case may be) (the “Disclosing Party”);

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7.8.3 is subsequently disclosed to the Recipient or any distributor of OPi without obligations of confidence by a third party owing no such obligations in respect thereof,

7.8.4 is developed by the Recipient independently of the Disclosing Party.

7.9 The obligations of the parties under this clause shall survive the expiration or termination of this Agreement for whatever reason except where otherwise specified in this Clause 7.

## 8. INTELLECTUAL PROPERTY

8.1 HPA hereby warrants and represents:

8.1.1 the Product, the Know-how, the Dossier and the Intellectual Property (including for the avoidance of doubt the Trademarks) were each developed by HPA (or its predecessor) without reliance upon or licence from any third party and HPA requires no third party approval or consent to enter into and comply with the obligations of this Agreement;

8.1.2 as far as HPA is aware there is no reason why the Marketing Authorisations cannot be transferred into OPi's name or varied, obtained or renewed as contemplated by this Agreement;

8.1.3 as far as HPA is aware all information or data in respect of the Intellectual Property and the Product provided to OPi by HPA in writing was when given and remains at the date hereof true and accurate in all material respects;

8.1.4 as far as HPA is aware there are no claims, disputes, proceedings or litigation active, pending or threatened against HPA concerning the Product, the Manufacture, the Know-how, the Dossier or the Intellectual Property;

8.1.5 as far as HPA is aware there is no unauthorised use of the Intellectual Property or the Know-how; and

8.1.6 the Intellectual Property including for the avoidance of doubt the Trademark, the Know-how and Manufacture, marketing, sale or distribution of the Product in the Territory does not and will not infringe any rights of any third party.

Where a Warranty refers to the knowledge or awareness of HPA, HPA is deemed to have the knowledge of HPA's Chief Executive Officer from time to time and of all such employees of HPA with whom OPi has been in contact during the due diligence and negotiation period and the knowledge which such persons should have after due and careful enquiry into the matters referred to.

8.2 Except as expressly incorporated or provided in this Agreement all conditions, warranties, representations and understandings (whether express or implied, statutory or otherwise) with respect to the subject matter of this Agreement are excluded to the extent permitted by law.

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- 8.3 Each of HPA and OPi will immediately bring to the attention of the other:
- 8.3.1 any claim of any third party that the Intellectual Property is invalid or the Know-how is in the public domain; or
  - 8.3.2 any claim that the use of the Intellectual Property or the Manufacture, marketing, sale or distribution of the Product in the Territory infringes any rights of any third party; or
  - 8.3.3 any unauthorised use of the Intellectual Property or the Know-how.

8.4 In the event of:

- 8.4.1 any claim being made or action brought against OPi or any distributor arising out of the matters referred to in Clause 8.3.1 or 8.3.2; or
- 8.4.2 any unauthorised use as is referred to in Clause 8.3.3,

then the parties shall within ten (10) working days of one of them becoming aware of any claim, action or any use which is unauthorised refer the matter to the Joint Management Team and use their reasonable endeavours to agree an appropriate course of action. If both parties consider that action should be taken to protect the Organism, the Know-how, the Intellectual Property or any other intellectual property relating to the Product they shall consult with each other concerning the steps to be taken to pursue such action and take such steps provided that [ \* ], if it considers it necessary to protect the Organism, the Know-how, the Intellectual Property or any other intellectual property relating to the Product, take control of the conduct of any relevant litigation and of the settlement of any such claim or infringement but will inform [ \* ] of the progress of any relevant litigation and consider [ \* ] interests under this Agreement in reaching any settlement of such claim or infringement. The costs of any such action shall be borne equally unless the parties agree otherwise or unless [ \* ] takes control as aforesaid in which case it will bear the costs. If [ \* ] notifies [ \* ] that it does not consider the proposed action to be necessary to protect the Organism, the Know-how, the Intellectual Property or any other intellectual property in the Product [ \* ] shall be entitled to continue the proposed action without further consultation at its own cost. [ \* ] shall not [ \* ] make any admission that may be prejudicial to [ \* ]. [ \* ] shall [ \* ] give all available assistance for the purpose of contesting or supporting any such claim or action. Any amounts recovered shall be shared between HPA and OPi [ \* ].

- 8.5 If [ \* ] does not wish to take any action to protect the Organism, the Know-how, the Intellectual Property or any other intellectual property in the Product, [ \* ] may take such action as it considers appropriate to do so and [ \* ] shall give [ \* ] such reasonable assistance in so doing [ \* ] which are satisfactory to [ \* ] and to [ \* ] in accordance with [ \* ] and [ \* ]. [ \* ] shall not make any admission prejudicial to [ \* ] action under this Clause 8.5 [ \* ].

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## 9. PRODUCT LIABILITY

9.1 HPA shall not be liable to any third parties or to OPi for any claims whatsoever (including but not limited to infringement of intellectual property rights and product liability claims) arising out of or in any way related to:-

9.1.1 the distribution, sale or use of the Product by or on behalf of OPi, its sub contractors, or distributors; or

9.1.2 the actions of OPi or its sub-contractors or distributors or their respective agents or employees; or

9.1.3 any contracts or other commitments made by OPi or its sub-contractors or distributors or their respective agents or employees with any other parties,

and OPi agrees to indemnify HPA against all losses, damages, expenses and costs which may be incurred by HPA as a result of any such claims by third parties arising directly from any matter referred to in this Clause 9.1.

9.2 OPi shall, while this Agreement is in force and for so long after expiry or termination as there is any possibility of a claim against HPA (or its officers or employees), at OPi's cost, keep in force adequate insurance with a reputable insurance company against all risks arising under this Agreement. OPi shall provide HPA with such evidence of insurance cover as HPA may request from time to time and shall procure that the insurance carrier undertakes to give HPA reasonable notice prior to any termination or expiry of the insurance cover.

9.3 HPA warrants that all Product supplied to OPi under this Agreement will conform to the Specification and the Technical Agreement, be manufactured in accordance with GMP, be free from contamination and adulteration, be in compliance with the United Kingdom Marketing Authorisation and the relevant provisions of Schedule 2 and [ \* ]. HPA will in addition use reasonable commercial endeavours to procure that all Product will conform with variations made to the Marketing Authorisations for all countries in addition to the United Kingdom and with any new Marketing Authorisations to be granted for any country in the Territory (subject always to the provisions of Schedule 3).

9.4 The liability of either party to the other in respect of any claim or loss arising from or in relation to this Agreement shall not exceed:

9.4.1 in respect of any claim or series of connected claims, [ \* ]; and

9.4.2 in respect of the aggregate of all claims, [ \* ].

9.4.3 During the [ \* ], the liability either party to the other in respect of any claim or series of connected claims shall not exceed [ \* ].

9.4.4 During the [ \* ], the liability either party to the other in respect of the aggregate value of all claims shall not exceed [ \* ].

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- 9.5 The obligations of OPi under Clauses 9.1 and 9.2 and of HPA under Clause 9.3 and the provisions of this sub-clause and Clauses 9.4 and 9.6 shall survive the expiration or termination of this Agreement for any reason.
- 9.6 Neither party shall have any liability to the other party for any indirect or consequential loss or damage howsoever occurring in contract, tort or otherwise under or in connection with this Agreement for: [ \* ]
- 9.7 Nothing in this Agreement is meant to limit or exclude liability for fraudulent misrepresentation or liability for death or personal injury caused by either party's negligence or any other liability which may not be lawfully excluded. The parties expressly agree that should any limitation or provision contained in this Agreement be held to be invalid under any applicable statute or rule of law it shall to that extent be deemed omitted but if any party thereby becomes liable for loss or damage which would otherwise legally have been excluded such liability shall be subject to the other limitations and provisions set out in this Agreement.
10. **HPA ASSISTANCE**
- 10.1 HPA agrees that in addition to its obligations under Clause 5, it will during the term of this Agreement if requested in writing by OPi use its reasonable endeavors to assist OPi in relation to any matters notified to HPA by OPi and concerning the Product, the Intellectual Property, the Marketing Authorisations or the requirements of any Regulatory Agency. Except as provided in clause 5, to the extent that HPA incurs any costs or expenses (including any reasonable internal costs or expenses) in providing such assistance OPi undertakes to reimburse HPA for such costs or expenses (provided that if any such costs or expenses are or are likely to be more than [ \* ] of forecasted sales of the Product in any Minimum Calculation Year then the provisions of Schedule 3 shall apply).
- 10.2 If HPA or any sub-contractor is inspected by any Regulatory Agency or receives any notice or request from any Regulatory Agency that could or does adversely impact or affect the Manufacture or continuity of supply of the Product, HPA shall notify OPi forthwith and undertakes to keep OPi informed of all relevant correspondence relating thereto. HPA undertakes to ensure that any remedial action or measures required to be taken by any Regulatory Agency in relation to the Manufacture or HPA's or its subcontractor's Manufacturing equipment, facilities or premises are promptly and properly taken.
- 10.3 OPi and HPA agree that if OPi requires in writing that HPA carry out any work in relation to the Product other than that which HPA is strictly obliged to do under this Agreement and HPA agrees in writing to do so then the principles and provisions set out in Schedule 3 shall apply.

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11. **PAYMENT**

11.1 All sums payable by OPi to HPA under this Agreement shall be paid subject to receipt by OPi of an accurate invoice from HPA as follows:

- (a) Product: Within [ \* ] after the date of HPA's invoice.
- (b) Royalties: Within [ \* ] after the date of HPA's invoice.
- (c) Assistance and out of pocket expenses: Within [ \* ] after the date of HPA's invoice.

12. **ASSIGNMENT**

12.1 Without the prior written consent of the other Party, neither Party shall sell, transfer, assign or otherwise dispose of, whether voluntarily or involuntarily this Agreement or any of its rights or duties hereunder; provided, however, that OPi may, without such consent, assign or sub-licence this Agreement and its rights and obligations hereunder to an OPi Group Company or to the purchaser of all or substantially all of its undertaking or assets including its rights under this Licence Agreement. Any attempted assignment or delegation in violation of the preceding sentence shall be void and of no effect. All validly assigned and delegated rights and obligations of the Parties hereunder shall be binding upon and inure to the benefit of and be enforceable by and against the successors and permitted assigns of OPi or HPA, as the case may be. In the event either Party seeks and obtains the other Party's consent to assign or delegate its rights or obligations to the other Party, the assignee or transferee shall assume all obligations of its assignor or transferor under this Agreement.

12.2 This Agreement shall be binding upon and inure for the benefit of any successor of HPA in respect of the activities of HPA or any organisation or entity which results from a reconstruction or reorganisation of HPA, in respect of the activities of HPA, provided however that HPA may only assign its rights and obligations hereunder to any such third party subject to the approval of OPi (such approval not to be unreasonably withheld or delayed). The provisions of this clause 12.2 shall not apply to statutory or other governmental reorganisations of HPA or its business.

12.3 If HPA during the term of this Agreement wishes to cease manufacturing the Product the Parties shall in good faith negotiate a transfer of the Intellectual Property to OPi on reasonable commercial terms so that the manufacture can be continued by OPi. [ \* ].

13. **DURATION AND TERMINATION**

13.1 This Agreement shall commence on the Effective Date and shall continue in full force and effect from the Effective Date for an initial period of ten (10) years (the "Initial Term"), subject to earlier termination in accordance with the terms hereof. Unless terminated to the end of the Initial Term with a notice in writing of [ \* ], the Agreement shall automatically renew for subsequent periods of five (5) years terminable at the end of each five (5) year period with a written notice of [ \* ].

13.2

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13.2.1 HPA may terminate this Agreement forthwith by notice in writing to OPi in the event of any change in control of the OPi Group which results in the OPi Group becoming controlled by a person who or company which is domiciled or has its principal or registered office in a country which is not contained in the following list of countries:

- (a) all Member States of the European Union or European Free Trade Association from time to time and Switzerland;
- (b) the United States of America, Canada, Japan, Australia or New Zealand.

For the purposes of this Clause “control” means the ability to direct the affairs of another whether by means of voting or contractual rights or otherwise and whether directly or indirectly.

13.2.2 OPi undertakes to notify HPA forthwith of any change in control of OPi or the OPi Group.

13.3 Either HPA or OPi may terminate this Agreement forthwith by notice in writing to the other upon the occurrence of any of the following events:-

13.3.1 if the other commits a material breach of this Agreement which in the case of a breach capable of remedy shall not have been remedied within [ \* ] or, in case of non-payment of any amount due under this Agreement, [ \* ] of the receipt by the other of notice identifying the breach and requiring its remedy;

13.3.2 if an extension to the period for the other party to fulfil its obligations pursuant to Clause 16.11 exceeds [ \* ];

13.3.3 if OPi or HPA is unable to pay its debts or enters into liquidation whether compulsory or voluntary (other than for the purposes of effecting a reconstruction or amalgamation in such manner that the company resulting from such reconstruction or amalgamation if a different legal entity shall agree to be bound by and assume the obligations of the relevant party under this Agreement) or compounds with or convenes a meeting of its creditors or has a receiver appointed over all or part of its assets or takes or suffers any similar actions in consequence of a debt or ceases for any reason to carry on the whole or a significant part of its business.

13.3.4 if the aggregate of claims substantiated by either party against the other for losses suffered shall have exceeded the aggregate liability of the other party as set out in clause 9.4.

13.4 Subject to the provisions of clause 13.6 of this Agreement, upon the termination or expiry of this Agreement for whatever cause:

13.4.1 OPi shall at the request of HPA promptly return to HPA or otherwise dispose of as HPA may instruct all documents, drawings, data and other materials

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containing the Know-how which are at that time in the possession of OPi and thereafter OPi shall not make any further use of the Intellectual Property or the Know-how (unless such Intellectual Property or Know-how is no longer protectable) without the prior written consent of HPA. Nothing in this Clause 13.4 shall prevent OPi for a maximum period of [ \* ] following expiry or termination of this Agreement (which period may be extended [ \* ]) from selling any unsold stocks of the Product after the date of expiry or termination subject to the payment of royalties as provided by Clause 4.

- 13.4.2 OPi shall on the expiry of [ \* ] following such termination or expiry of this Agreement (subject to any extension to this period [ \* ]) or on such earlier date or dates as the parties shall agree in writing:
- (a) sell all or such quantities of Product as may be in OPi's possession, custody or control to HPA at the purchase cost of OPi. HPA shall be responsible for the transportation of such quantities to HPA [ \* ]. Delivery of such quantities shall be ex-works and title thereto shall pass to HPA on receipt by OPi of the payment due from HPA hereunder; and/or
  - (b) promptly destroy all remaining stocks of product in OPi's possession, custody or control and provide evidence of such destruction to HPA promptly thereafter (subject to the retention by OPi of samples of Product required for regulatory purposes).
- 13.4.3 At the request of HPA, OPi shall (provided that HPA shall reimburse OPi against reasonable external costs and out of pocket expenses incurred by OPi in complying with this Clause 13.4.3):
- (a) supply [ \* ] and [ \* ] to HPA, and procure the [ \* ] of [ \* ] or [ \* ] or procure the [ \* ] of such [ \* ];
  - (b) supply HPA with such reasonably available information [ \* ] for the Product including [ \* ] related to the Product;
  - (c) supply to HPA all documents and other materials relating to [ \* ] or [ \* ];
  - (d) provide HPA with reasonable assistance [ \* ];
- 13.4.4 HPA shall at the request of OPi promptly return to OPi or otherwise dispose of as OPi may instruct all documents, drawings, data and other materials containing the OPi Know How which are at that time in the possession of HPA and thereafter HPA shall not make any further use of the OPi Know How without the prior written consent of OPi.
- 13.4.5 OPi shall have the option exercisable by notice in writing within [ \* ] to purchase from HPA all existing stocks of Product which is in compliance with

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the terms of this Agreement and held by HPA at the price then applicable pursuant to the terms of this Agreement. In addition to the extent that HPA can complete the Manufacture of any Product which Manufacture has already commenced at the date of such expiry or termination within a period of [ \* ] and such Product when Manufactured shall be in compliance with the terms of this Agreement it shall notify OPi in writing and OPi will have the option exercisable by notice in writing within [ \* ] of purchasing such Product following its Manufacture pursuant to the terms of this Agreement.

13.5 Any termination hereunder shall be without prejudice to any accrued rights and liabilities hereunder and to any obligations expressed to continue in force notwithstanding termination.

13.6 Following the termination of this Agreement by OPi pursuant to Clause 13.3.1 or Clause 13.3.3 of this Agreement, OPi shall have the right to have the Product Manufactured by a third party and continue to market, sell and distribute the Product throughout the Territory for the remainder of the Initial Term or, in case of termination during an extension period, for the remainder of that period, on such reasonable terms as may be agreed between the parties and subject to OPi continuing to pay Royalties to HPA on the terms set out in Clause 4. In such event OPi shall be deemed to have the right to continue to license the Intellectual Property pursuant to Clause 2.1 and to hold, vary, obtain, maintain or renew (as appropriate) the Marketing Authorisations (except for that granted for the United Kingdom) as OPi may require from time to time. In relation to the Marketing Authorisation for the United Kingdom HPA undertakes to maintain and renew the Marketing Authorisation and continue to specify OPi as the distributor for the Product and OPi will reimburse the costs and expenses of HPA of such maintenance or renewal upon the same terms as are set out in Clauses 5.2 and 5.3 of this Agreement. After the expiry of any period of manufacture by OPi pursuant to this Clause 13.6, the provisions of Clause 13.4 shall apply.

#### 14. **SUPERVENING LAW**

14.1 The rights and obligations of the parties hereto under this Agreement shall be subject to all applicable laws, orders, regulations, directions, restrictions and limitations of governments or other bodies having jurisdiction over the parties hereto.

#### 15. **DISPUTE RESOLUTION, LANGUAGE, LAW AND JURISDICTION**

15.1 This Agreement is written in the English language and the construction validity and performance hereof shall be governed by English law.

15.2 The Parties shall negotiate in good faith and use reasonable efforts to settle any dispute, controversy or claim arising from or related to this Agreement, including any question regarding its existence, validity or termination. In the event that the Parties are unable, within [ \* ], to reach a resolution, such dispute shall be referred to the chief executive officers of OPi and HPA who shall attempt in good faith to reach a resolution of the dispute. If the foregoing procedures fail to achieve a mutually satisfactory resolution within a further [ \* ], then either Party may, by written notice to the other Party, elect to have the matter settled as detailed below.

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- 15.3 In the event of the Parties being unable to solve a dispute by negotiation pursuant to Clause 15.2, the parties shall first seek settlement of that dispute by mediation in accordance with the LCIA Mediation Procedure, which Procedure is deemed to be incorporated by reference into this clause.
- 15.4 If the dispute is not settled by mediation within [ \* ] of the appointment of the mediator, or such further period as the parties shall agree in writing, the dispute shall be referred to and finally resolved by arbitration under the LCIA Rules, which Rules are deemed to be incorporated by reference into this clause. The language to be used in the mediation and in the arbitration shall be English. The governing law of the contract shall be the substantive law of England. Each party shall pay its own costs in respect of any such arbitration.
- 15.5 In any arbitration commenced pursuant to this clause, (i) the number of arbitrators shall be one (1) and (ii) the seat, or legal place, of arbitration shall be London. This Agreement is written in the English language and the construction validity and performance hereof shall be governed by English law.
- 15.6 Nothing in this Clause 15 shall preclude either Party from seeking injunctive relief or any other interim equitable relief concerning a dispute, either prior to or during any arbitration hereunder, if necessary to protect the interests of such Party.

## 16. MISCELLANEOUS

16.1 So far as concerns the Product this Agreement:

16.1.1 supersedes any previous agreement between the parties; and

16.1.2 constitutes the entire understanding of the parties in relation thereto and there are no promises, terms, conditions, duties or obligations whether oral or written, express or implied other than those contained or referred to herein.

16.2 This Agreement shall not be varied or amended or supplemented except by instrument in writing signed by duly authorised representatives of the parties.

16.3 The failure of a party hereto at any time to enforce the terms provisions or conditions of this Agreement shall not be construed as a waiver of the same or of the right of such party to enforce the same.

16.4 Any notice required by this Agreement to be given by either party to the other shall be served by sending the same by fax or registered letter to the address of the party to be served stated at the head of this Agreement or such other address as may be notified by the addressee to the other parties from time to time. All such notices shall be in the English language.

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- 16.5 In proving service of any notice hereunder it shall be sufficient to prove:
- 16.5.1 in the case of a notice sent by registered post, that the envelope containing the notice was properly addressed to the address for notices herein or any substituted address, stamped, registered and posted;
  - 16.5.2 in the case of a notice sent by fax, that it was properly transmitted to the fax number given in Clause 16.7 or any substituted number and the receipt by the sender of a clear transmission report.
- 16.6 Notices shall be deemed served:
- 16.6.1 in the case of a notice sent by post on the next business day following the day of posting;
  - 16.6.2 in the case of a notice sent by fax, at the time the sender's fax machine receives a clear transmission report.
- 16.7 Notices shall be deemed served on the parties by transmission to the following fax numbers or such fax numbers as may be substituted for the purpose by a notice duly served in accordance with the provisions of this Agreement:
- HPA: To the attention of the Director of the Centre for Emergency Preparedness and Response
- Fax number : [ \* ]
- OPI: To the attention of the Chief Executive Officer
- Fax number : [ \* ]
- 16.8 For the purposes of Clause 16.6 "business day" means any day from Monday to Friday during which banks are open for business in the United Kingdom.
- 16.9 Each of the parties hereto undertakes with the others to do, execute, perform or procure to be done executed or performed all such further acts deeds documents and things as such others may reasonably require to give effect to this Agreement.
- 16.10 The relationship between HPA and OPI is that of independent contractors and nothing herein shall nor shall it be construed to constitute either party, the agent, partner or representative or a joint venturer with the other party. Accordingly neither party shall have the power and shall not hold itself out as empowered to act on behalf of the other party or to bind or commit the other party to any liability whatsoever.
- 16.11 Should either party be prevented from or hindered in fulfilling any of its obligations hereunder by reason of war, riot, explosion, fire, flood, strike, or lock-out (other than strike or lock out by its own employees) or shortage of materials the time for fulfilling such obligation shall be extended by a period equal to that during which the cause preventing or hindering the fulfillment of the obligation shall exist.

[ \* ] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

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**SCHEDULE 1**

ORGANISM

*Erwinia* [ \* ].

PRODUCT

L-asparaginase being L-asparaginase amidohydrolase derived from the Organism manufactured so as to meet the approvals necessary for fully licensed or other approved sale as a pharmaceutical in the Territory.

[ \* ] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

## SCHEDULE 2

### 1. QUANTITY OF PRODUCT TO BE PURCHASED

1.1 The quantity of Product to be ordered by OPi from HPA in accordance with Clause 3.3 shall [ \* ] and [ \* ] and [ \* ].

1.2 Any [ \* ] Product purchased by OPi [ \* ] in [ \* ] the [ \* ] shall [ \* ] so as [ \* ] when [ \* ] in [ \* ].

1.3 If the [ \* ] Product ordered by OPi [ \* ] is [ \* ] the [ \* ] (and the [ \* ] Product purchased [ \* ] and [ \* ] shall [ \* ]), OPi shall [ \* ] in the [ \* ] of Product [ \* ] in the [ \* ].

1.4 The initial price per vial of the Product will be unchanged for [ \* ].

The minimum shelf life of supplied Product will be:

- For Product supplied [ \* ]: [ \* ].
- For Product supplied [ \* ]: [ \* ].
- For Product supplied [ \* ]: [ \* ].

### 2. PRICE PER VIAL

2.1 Subject to the provisions of Clause 3.2, the price of Product supplied to OPi in respect of [ \* ] shall be [ \* ].

### 3. TERMS AND CONDITIONS OF SUPPLY

3.1 OPi shall provide HPA with rolling forecasts for the following [ \* ] requirements for the supply of Products, such forecast to be updated [ \* ]. The first [ \* ] of each such forecast and of each [ \* ] update of the forecast shall be binding on OPi and, subject to HPA's order confirmation, on HPA. OPi shall order and HPA shall supply [ \* ] Products forecast during such [ \* ] periods. HPA shall confirm acceptance of the order and the delivery date within [ \* ] of receipt of OPi's order. OPi may request HPA to vary any order following acceptance and HPA shall comply with such request to the extent that this is reasonable. HPA shall use all reasonable endeavours to supply Product ordered by OPi in excess of any forecast but shall not be obliged to so supply.

3.2 The Parties shall use their reasonable endeavours to agree to a timetable for the order and supply of Product in order to ensure that [ \* ].

3.3 Each Batch or quantity of Product supplied to OPi shall be accompanied by a certificate of compliance with the Product specification as contained within the Technical Agreement and release documentation signed by the authorised HPA person and in the form agreed between HPA and OPi provided that such specification may be modified from time to time in accordance with the regulatory requirements as agreed between

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HPA and OPi. OPi shall have the right to reject any Product within a reasonable period of receipt at OPi's facilities (or that of its packing contractor) that does not pass inspection criteria in accordance with the terms of the Technical Agreement and/or the Product identity test. If any such Product is justifiably rejected, HPA shall, in HPA's exclusive choice, promptly replace such Product or provide a credit note for the value of the rejected Product.

3.4 Delivery of each supply of Product to OPi shall be from HPA's pharmaceutical product store and shall be complete and Product shall be adequately packed and stored to prevent any damage or deterioration during transit. Title to and risk for each supply of Product shall pass to OPi when OPi's authorised personnel or authorised sub-contractor have signed acceptance documentation in accordance with procedures agreed between the parties from time to time or when OPi sells the Product to its customers.

3.5 Delivery of each supply of Product shall comply with such other conditions as are agreed between HPA and OPi.

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### SCHEDULE 3

#### HPA'S CHARGES TO OPi FOR ASSISTANCE REQUESTED BY OPi

1. OPi will provide HPA with a written specification of the assistance required for each identified work package required pursuant to this Agreement.
2. HPA will provide OPi with a maximum quotation for each such identified work package within [ \* ] following OPi's request.
3. If a quotation is acceptable to OPi, OPi will issue a written order to HPA for the work at a value up to the maximum quoted.
4. HPA's maximum quotation will become binding on both parties upon HPA's written acceptance of OPi's written order.
5. If the work package to be carried out by HPA is small in scope and cost and OPi and HPA agree, the quotation shall if accepted in writing by OPi become binding on both parties and the price payable by OPi for such work package shall not be varied at any time as the work progresses.
6. If HPA and OPi do not agree to adopt the position set out in paragraph 5 of this Schedule 3 in respect of any work package, as work on each identified work package progresses, HPA will monitor the cumulative actual cost and the expected balance of cost in order to check that the accepted maximum quotation will not be exceeded in total. If the quotation is likely to be exceeded, HPA will consult OPi immediately with a view to either modifying the content of the identified work package in order that the quotation will not be exceeded or to agreeing in writing an increase in the total maximum value of the order agreed in accordance with the procedures set out in paragraphs 4 and 5 of this Schedule 3.
7. In the event that HPA and OPi cannot agree an amendment to the identified work package or to the maximum total cost, OPi will have the option to cancel the original order and to pay HPA only for the costs incurred to date in accordance with Clause 10.1.
8. At completion by HPA of the identified work package specified in the accepted order, HPA will invoice OPi with the actual costs incurred, identifying such costs under the same headings as those shown in HPA's quotation. The invoice value may not exceed the maximum order value agreed in writing between HPA and OPi.
9. Frequency of invoicing will be agreed for each work package but will in no case be at more than [ \* ] intervals.
10. Value Added Tax will be added to each of HPA's invoices as appropriate and decreases or increases in the rate of Value Added Tax will not be deemed a cost decrease or increase for the purposes of this Schedule 3.
11. All work carried out by HPA pursuant to this Schedule 3 will be carried out timeously and using all due care and skill.

[ \* ] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

## SCHEDULE 4

[ \* ]

[ \* ] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

Schedule 5#

# REMOVED BY AMENDMENT

[ \* ] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

## Schedule 6

### List of Countries carrying Erwinase Trademarks.

Table shows present status (May 2005) of ERWINASE rights in view of transfer to Health Protection. Agency  
(1<sup>st</sup> April 2003) from  
Microbiological Research Authority

#### ERWINASE

Country	Country	Country	Country	Country
ALGERIA *	DENMARK	IRELAND*	POLAND	TUNISIA*
ANDORRA *	EGYPT*	ISRAEL*	PORTUGAL*	TURKEY*
ARGENTINA *	ETHIOPIA*	ITALY*	SAUDI ARABIA*	UNITED ARAB EMIRATES*
AUSTRALIA *	FINLAND	JAPAN*	SINGAPORE	UNITED KINGDOM
AUSTRIA	FRANCE *	LATVIA*	SLOVAKIA	UNITED STATES
BENELUX*	GERMANY	MACAO*	SLOVENIA	URUGUAY*
BOSNIA *	GREECE	MACEDONIA	SOUTH AFRICA*	VENEZUELA*
BRAZIL *	HONG KONG	MALAYSIA*	SOUTH KOREA*	VIETNAM*
CANADA*	HUNGARY*	MEXICO*	SPAIN*	YUGOSLAVIA i.e. Serbia and Montenegro
CHILE *	INDIA*	NEW ZEALAND	SWEDEN	
CROATIA*	INDONESIA*	NORWAY	SWITZERLAND	

[ \* ] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

Country	Country	Country	Country	Country
ALGERIA *	DENMARK	IRELAND*	POLAND	TUNISIA*
CYPRUS *	INTERNATIONAL (MADRID PROTOCOL) covers Czech Republic, Poland, Slovakia, Slovenia, Yugoslavia, Macedonia	OMAN*	TAIWAN*	
CZECH REPUBLIC *	IRAN *	PHILIPPINES *	THAILAND*	

\* Denotes transfer from Microbiological Research Association to Health Protection Agency on-going

[ \* ] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

<b>Country</b>
BULGARIA*
ESTONIA
INTERNATIONAL (MADRID PROTOCOL)
LITHUANIA
ROMANIA
RUSSIAN FEDERATION
UNITED KINGDOM

\* Denotes transfer from Microbiological Research Association to Health Protection Agency on-going

[ \* ] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

IN WITNESS whereof this Agreement has been executed by duly authorised officers of the parties hereto and is intended to be and is hereby delivered on the date first above written.

EXECUTED AS A DEED BY ) /s/ Pat Troop, CEO  
THE HEALTH PROTECTION AGENCY ) 22/07/05  
/s/ Michael Hacker, Board Secretary

EXECUTED AS A DEED BY ) /s/ G. Alberici  
OPi SA )

President and Chief Executive Officer G. Alberici

July 20<sup>th</sup>, 2005

[ \* ] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

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**AMENDMENT TO ROYALTY BEARING LICENCE  
AGREEMENT AND SUPPLY AGREEMENT RE ERWINIA-  
DERIVED ASPARAGINASE**

between

**HEALTH PROTECTION AGENCY**

and

**EUSA PHARMA SAS**

[ \* ] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.



This Amendment is made this 22nd day of December 2009

**BETWEEN:**

- (1) HEALTH PROTECTION AGENCY acting through its Centre for Emergency Preparedness and Response (CEPR), Porton Down, Salisbury, Wiltshire, SP4 0JG, UK, (HPA), which expression shall include its successors in title; and
- (2) EUSA Pharma SAS, formerly called OPi SA, whose primary place of business and registered address is at Les Jardins d'Eole, allée des Séquoias, F 69760, Limonest, France (EUSA).

**WHEREAS**

- (1) HPA and EUSA have entered into a Royalty Bearing Licence Agreement and Supply Agreement re Erwinia-Derived Asparaginase (RBLA), dated 22<sup>nd</sup> July, 2005, and a Collaboration Agreement for Strengthening Current Marketing Authorisation and for obtaining an FDA Marketing Authorisation for Erwinia Derived Asparaginase (FDA MA Agreement), dated 13th December 2006;
- (2) HPA and EUSA now wish to amend the RBLA and the Parties agree to be bound by the terms and conditions of the RBLA, as amended herein.
- (3) This Amendment confirms the mutual understanding between HPA and EUSA to amend certain terms and conditions of the RBLA.

NOW IT IS HEREBY AGREED as follows;

**1. DEFINITIONS AND INTERPRETATION**

- 1.1** "Parties" means HPA and EUSA collectively;
- 1.2** Unless stated otherwise in this Amendment, Capitalised Terms in this Amendment shall have the same meaning attributed to them in Clause 1.1 of the RBLA.
- 1.3** References to the singular shall include the plural and vice versa.
- 1.4** References to Clauses and Schedules are to clauses and schedules of either the RBLA or to this Agreement, as stated in the text of this Agreement. The headings to the Clauses in this Agreement are for convenience only and have no legal effect.

2. AMENDMENTS

2.1 Clause 3.2 of the RBLA is deleted in its entirety and replaced with the following:

HPA shall supply the Product to EUSA:

2.1.1 at the price per Vial as determined and revised as follows:

a) at an ex-VAT price per Vial [ \* ], as below;

[ * ]	[ * ]	Supply Price
[ * ]	[ * ]	[ * ]
[ * ]	[ * ]	[ * ]
[ * ]	[ * ]	[ * ]
[ * ]	[ * ]	[ * ]

For the avoidance of doubt, as shown in the table above, there will be [ \* ], or [ \* ], based on the [ \* ] and the [ \* ]. This [ \* ] will be [ \* ] the [ \* ]. Dependant on [ \* ], the specific supply prices for [ \* ] may be [ \* ].

b) the price per Vial will be revised [ \* ], at the [ \* ], which shall be agreed between the Parties and take effect [ \* ], by applying the formula stated in the table in Schedule 1 of this Amendment.

2.1.2 on such other terms and conditions as are set out in Schedule 2 of the RBLA.

The standard terms and conditions of neither Party shall have an effect in respect of the supply or purchase of Product.

2.2 Clause 4.1 of the RBLA is, from 1st April 2010, deleted in its entirety and replaced with the following:

In consideration of the exclusive licence granted to EUSA to market, distribute and sell the Product, on a worldwide basis, EUSA shall pay to HPA an annual royalty payment equal to [ \* ] of Net Sales, recorded in the preceding Minimum Calculation Year.

2.3 Clause 2 of Schedule 2 of the RBLA is deleted in its entirety.

2.4 Clause 3.1 of Schedule 2 of the RBLA is deleted in its entirety and replaced with the following:

EUSA shall provide HPA with rolling forecasts for the following [ \* ] requirements for the supply of Product, such forecast to be updated [ \* ]. The first [ \* ] of each forecast, and of each [ \* ] update of the forecast, shall be binding on EUSA and, subject to HPA's order confirmation, on HPA. The [ \* ] of each forecast may [ \* ]. EUSA shall order and HPA shall supply [ \* ] Product forecast during each [ \* ] period. HPA shall confirm acceptance of the order and the delivery date within [ \* ] of receipt of EUSA's order. HPA shall use all reasonable endeavours to supply Product ordered by EUSA in excess of the forecasts [ \* ] however, HPA shall not be obliged to supply such excess.

All other clauses in Schedule 2 of the RBLA remain unchanged.

3. DURATION AND TERMINATION

3.1 Pursuant to Clause 13.1 of the RBLA, HPA and EUSA have mutually agreed to extend the RBLA beyond the Initial Term for an additional period of 5 years, such that the RBLA now extends to 31st December 2020. All other obligations and conditions in Clause 13 of the RBLA remain unchanged.

4. OTHER MATTERS

It is the intent of the Parties that the terms of this Amendment be read and interpreted as being additive to, and in harmony with, except as expressly set out herein, and not as replacing, or contradicting, the terms and conditions of the RBLA.

All other terms and conditions to the RBLA remain unchanged and in full force and effect except to the extent superseded by the terms and conditions of this Amendment.

The RBLA, as modified by this Amendment, contains the entire understanding of the Parties with respect to the Product.

IN WITNESS WHEREOF, the Parties have caused this Amendment to be executed by their duly authorized representatives.

For, and on behalf of, Health Protection Agency:	For, and on behalf of, EUSA Pharma SAS:
Signed: /s/ Miles W. Carroll	Signed: /s/ David Cook
Name: Miles Carroll	Name: David Cook
Title: Interim Director	Title: Director
Date: 18 DEC 2009	Date: 22/12/09

Appendix 1

Principles for determining the [ \* ] Vial price

1. [ \* ] price revision shall take place [ \* ] at the [ \* ]. [ \* ] price revision shall take into account two factors as follows;

(a) the [ \* ] in the [ \* ] the [ \* ]. The [ \* ] in the [ \* ] shall be the [ \* ] of [ \* ];

(b) the [ \* ] of the [ \* ] changes in [ \* ], as [ \* ] the [ \* ].

2. In [ \* ], if the [ \* ], as defined in 1(b), [ \* ] and there is [ \* ] in the [ \* ] the [ \* ], the price [ \* ] shall be calculated as per the formula below, as illustrated by the two examples;

[ \* ]

Where:

[ \* ]

[ * ]	[ * ]	[ * ]	[ * ]	[ * ]
[ * ]	[ * ]	[ * ]	[ * ]	[ * ]
[ * ]	[ * ]	[ * ]	[ * ]	[ * ]
[ * ]	[ * ]	[ * ]	[ * ]	[ * ]
[ * ]	[ * ]	[ * ]	[ * ]	[ * ]
[ * ]	[ * ]	[ * ]	[ * ]	[ * ]

[ \* ] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

3. In [ \* ], if the [ \* ], as defined in 1(b), [ \* ] and there is [ \* ] in the [ \* ] the [ \* ], the price [ \* ] shall be calculated as per the formula below, as illustrated by the two examples;

[ \* ]

Where:

[ \* ]

[ * ]	[ * ]	[ * ]	[ * ]	[ * ]
[ * ]	[ * ]	[ * ]	[ * ]	[ * ]
[ * ]	[ * ]	[ * ]	[ * ]	[ * ]
[ * ]	[ * ]	[ * ]	[ * ]	[ * ]
[ * ]	[ * ]	[ * ]	[ * ]	[ * ]
[ * ]	[ * ]	[ * ]	[ * ]	[ * ]

For clarification, in the event that:

- (i) There is [ \* ] in the [ \* ] the [ \* ], then the percentage price change applied will be [ \* ]; and
- (ii) There is [ \* ] in the [ \* ] the [ \* ], then the principles outlined in 2 and 3 above will continue to apply, such that [ \* ] applied as the formula above.

This Second Amendment is made this 23rd day of March 2012

**BETWEEN**

**(1)Health Protection Agency** of Porton Down, Salisbury, Wiltshire, SP4 0JG, UK (HPA), which expressions shall include its successors in title; and

**(2)EUSA Pharma SAS**, formerly called OPi SA, whose primary place of business and registered address is Les Jardins D'Eole, allée des sequoias F 69760, Limonest, France (EUSA), which expressions shall include its successors in title.

**WHEREAS**

(1)HPA and EUSA have entered into a Royalty Bearing Licence Agreement and Supply Agreement re Erwinia-Derived Asparaginase dated 22 July 2005 (RBLA) as amended by the First Amendment dated 22 December 2009.

(2)HPA and EUSA now wish to further amend the RBLA and the Parties agree to be bound by the terms and conditions of the RBLA, as amended herein.

(3)This Second Amendment confirms the mutual understanding between HPA and EUSA to amend certain terms and conditions of the RBLA.

NOW IT IS HEREBY AGREED as follows:

**1. DEFINITIONS AND INTERPRETATION**

**1.1** "Parties" means HPA and EUSA collectively;

**1.2** Unless stated otherwise in this Second Amendment, terms with initial capitals in this Second Amendment shall have the same meaning attributed to them in Clause 1.1 of the RBLA;

**1.3** References to the singular shall include the plural and vice versa.

**1.4** Reference to Clauses and Schedules are to clauses and schedules of either the RBLA or this Second Amendment, as stated in the text of this Second Amendment. The headings to the Clauses in this Second Amendment are for convenience only and have no legal effect.

[ \* ] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

## 2. AMENDMENTS

2.1 With effect from 21 November 2011 the definition of Minimum Calculation Year, is deleted in its entirety and replaced with the following:

**“Minimum Calculation Year”** shall mean a calendar year.

2.2 With effect from 21 November 2011 clause 3.2 of the RBLA is deleted in its entirety and replaced with the following:

*“3.2 HPA shall supply Product to EUSA*

*3.2.1 ex works Porton Down (Incoterms 2000)*

*3.2.2 on such other terms and conditions as are set out in Schedule 2, as amended from time to time.*

*The standard terms and conditions of business of neither party shall have effect in respect of the supply or purchase of Product.”*

2.3 With effect from 21 November 2011 clause 3.6 of the RBLA is deleted in its entirety and replaced with the following:

*“If at any time HPA and EUSA shall agree to change or add to the Specification or definitions in Schedule 1 they shall be amended accordingly to reflect such changes together if necessary with a change to the compensation rates set out in clause 4.1.1 below. For clarity any change or addition to the Specification and change to the compensation rate shall be agreed in good faith by the Parties. For further clarity HPA will not request a change to the compensation in circumstances where a change to the current agreed Specification has no impact on the HPA.”*

2.4 With effect from 21 November 2011 clause 4.1 of the RBLA is deleted in its entirety and replaced with the following:

**“4.1 PAYMENTS TO BE MADE BY EUSA**

*4.1.1 In consideration of the assistance and services hereby agreed to be rendered and of the licence hereby granted, EUSA shall both during the term of this Agreement in respect of all the Product sold by EUSA and after the termination of this Agreement in respect of any stocks of the Product held by EUSA at the date of termination and sold on or after such date by EUSA pay to HPA in addition to any other sums payable hereunder compensation equal to:*

2.

[ \* ] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

- (1) [ \* ] per cent of the Net Sales when the Net Sales are up to and including [ \* ] in any Minimum Calculation Year;
  - (2) [ \* ] per cent of Net Sales when the Net Sales are over [ \* ] and up to and including [ \* ] in any Minimum Calculation Year;
  - (3) [ \* ] per cent of the Net Sales when the Net Sales are over [ \* ] and up to and including [ \* ] in any Minimum Calculation Year;
  - (4) [ \* ] per cent of the Net Sales over [ \* ] in any Minimum Calculation Year;
- 4.1.2 For clarity once an applicable threshold is reached the relevant compensation rate shall be applied to all cumulative Net Sales in the relevant Minimum Calculation Year backdated to the beginning of the then current Minimum Calculation Year.
- 4.1.3 The compensation will be payable in two parts:
- 4.1.3.1 a price per Vial of [ \* ] (the “Transfer Price”), which is payable for the supply of Product, as invoiced in accordance with clause 11 or as otherwise agreed; and
  - 4.1.3.2 a sum equivalent to a royalty on Net Sales, calculated as set out in clause 4.2.1.
- 4.1.4 The Transfer Price will be amended at the [ \* ] using the following formula:  
new Transfer Price = [ \* ].
- 4.1.5 To the extent that EUSA is required by applicable law to deduct any amounts from such royalty payable by way of withholding or other tax, it shall make such deduction, pay the appropriate amount of tax deducted to the appropriate taxation authorities and provide HPA with an appropriate certificate of tax deduction.”

2.5 With effect from 21 November 2011, clause 4.2 of the RBLA is deleted in its entirety and replaced with the following:

“4.2.1 From April 1st 2012 within [ \* ] after the end of the relevant calendar month, EUSA shall furnish to HPA a written statement (the “Monthly Statement”) in the form set out in Appendix 1 attached to the Second Amendment setting out the monthly aggregate Net Sales for the relevant calendar month and the calendar year to date Net Sales of Product (the “Year to Date Total”), and the monthly

3.

[ \* ] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.



*aggregate Transfer Price paid for Vials of Product sold during that calendar month and the aggregate Transfer Price paid for Vials sold in the calendar year to date.*

4.2.2 *EUSA will apply to the Year to Date Total the applicable compensation rate set out in clause 4.1.1, and calculate the relevant compensation payable on the Year to Date Total (“Year to Date Total Royalty”).*

4.2.3 *From the Year to Date Total Royalty, EUSA will subtract:*

4.2.3.1 *the calendar year to date aggregate Transfer Price for Vials of Product paid by EUSA to HPA for Product sold in the calendar year to date; and*

4.2.3.2 *the aggregate of the Year to Date Total Royalty paid by EUSA to HPA in the preceding months of the then current Minimum Calculation Year; and*

4.2.3.3 *[ \* ] where such Vials are supplied by EUSA to an unconnected third party free of charge during the calendar year to date.*

4.2.4 *If the subtraction in clause 4.2.3 results in a positive sum, EUSA will include details of all amounts payable by EUSA in the Monthly Statement for that Minimum Calculation Year in the calendar year to date. Following receipt of the Monthly Statement, HPA shall provide to EUSA an invoice in respect of such payments. Within [ \* ] of the date of receipt of such invoice, EUSA will make payment (less any withholding or other tax EUSA is required to deduct) in favour of HPA for the amount due to HPA in respect of the preceding calendar month.*

4.2.5 *If the subtraction in clause 4.2.3 results in a negative sum, reflecting that payments made by EUSA to HPA in the calendar year to date exceeded the sums that ought otherwise to have been paid, EUSA may set off such over payments made in that calendar year to date against payments due to be made to HPA in the subsequent calendar months until the over payment has been fully balanced provided that [ \* ]. The [ \* ] can be varied in accordance with Appendix 1 of the First Amendment Agreement, although [ \* ] will [ \* ] instead of [ \* ].”*

4.

**[ \* ] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.**

### 3. PAYMENT OF PREVIOUS ROYALTIES DUE

- 3.1 Within [ \* ] of the date of this Second Amendment, EUSA shall provide HPA with a statement of Net Sales made prior to 21 November 2011 to which the previous royalty rate [ \* ] applies. HPA shall produce to EUSA an invoice in respect of such royalties due. Within [ \* ] of the date of receipt of the invoice EUSA shall make payment (less any withholding or other tax EUSA is required to deduct) in favour of HPA for the amount of royalties due to HPA for the period prior to 21 November 2011.
- 3.2 EUSA shall within [ \* ] of this Second Amendment provide to HPA an accurate statement setting out the number of Vials (excluding Product batches 151 and 152) that it held as at 21 November 2011.
- 3.3 Following the date of this Second Amendment, HPA shall, as soon as reasonably practicable, issue an invoice to EUSA [ \* ] in respect of Product batches 151 and 152 which sum shall be paid in accordance clause 11 of the RBLA.
- 3.4 Within [ \* ] of this Second Amendment EUSA will carry out a calculation in accordance with clauses 4.2.1 to 4.2.5 of the RBLA (as amended herein) in respect of Net Sales of Products made in the period from 21 November 2011 to 31 December 2011 and shall notify HPA in writing of the amount due and any sums payable to HPA shall be paid in accordance with clause 11 of the RBLA following receipt of HPA's invoice for the same provided that [ \* ] shall be [ \* ] and [ \* ].
- 3.5 Within [ \* ] EUSA will carry out a calculation in accordance with clauses 4.2.1 to 4.2.5 of the RBLA (as amended herein) in respect of Net Sales of Products made in the period from [ \* ] and shall notify HPA in writing of the amount due and any sums payable to HPA shall be paid in accordance with clause 11 of the RBLA following receipt of HPA's invoice for the same provided that [ \* ] shall be [ \* ] and [ \* ]. Thereafter, EUSA shall furnish HPA with a written Monthly Statement in accordance with clause 4.2.1.

### 4. OTHER MATTERS

It is the intent of the Parties that the terms of the Second Amendment be read and interpreted as being additive to, and in harmony with, and not as replacing, or contradicting the terms and conditions of the RBLA except as expressly set out herein.

All other terms and conditions to the RBLA remain unchanged and in full force and effect except to the extent superseded by the terms and conditions of this Amendment.

5.

[ \* ] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

The RBLA, as modified by this Second Amendment, contains the entire understanding of the Parties with respect to the Product.

IN WITNESS WHEREOF, the Parties have caused this Second Amendment to be executed by their duly authorised representatives.

For, and on behalf of, Health Protection Agency:	For, and on behalf of, EUSA Pharma SAS:
Signed: /s/ Tony Sannia	Signed: /s/ Zoe Evans
Name: Tony Sannia	Name: Zoe Evans
Title: Director	Title: General Counsel
Date: 23 March 2012	Date: 23 March 2012

6.

[ \* ] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

Appendix 1

Aggregate

Period for reporting: \_\_\_\_\_

Monthly Aggregate Net Sales			Year to Date Net Sales		
Country	Vials	Revenue	Country	Vials	Revenue
Country 1	x	y	Country 1	x	y
Country 2	x	y	Country 2	x	y
etc	x	y	etc	x	y
Deductions (as per RBLA Net Sales Definition)		(y)	Deductions (as per RBLA Net Sales Definition)		(y)
<b>Total Net Sales</b>	<b>K</b>	<b>L</b>	<b>Total Net Sales</b>	<b>X</b>	<b>Y</b>
Royalty on Year to date Total (@Z%)					=Y x Z=A
Less: Transfer Price paid calendar Year to date					=X x [ * ] =B

7.

[ \* ] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

Less: Year to Date Total Royalty (C)					C
Less [ * ] for free Product as set out in clause 4.2.3.3 (0)					D
Net amount due to HPA					A minus B minus C minus D

8.

[ \* ] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

This Third Amendment is made this 8th day of August 2012

**BETWEEN**

- (1) **Health Protection Agency** of Porton Down, Salisbury, Wiltshire, SP4 0JG, UK (HPA), which expressions shall include its successors in title; and
- (2) **EUSA Pharma SAS**, formerly called OPi SA, whose primary place of business and registered address is Les Jardins D'Eole, allée des sequoias F 69760, Limonest, France (EUSA)

**WHEREAS**

- (1) HPA and EUSA have entered into a Royalty Bearing Licence Agreement and Supply Agreement re Erwinia-Derived Asparaginase, dated 22 July 2005, as amended 22 December 2009 and 23 March 2012 (RBLA).
- (2) Under the RBLA as originally dated 22 July 2005, the Parties entered into a Sub-Contractor Quality Agreement dated as of 21 July 2005 setting forth the individual responsibilities of the Parties with respect to quality assurance matters and matters related to Good Manufacturing Practices, which quality agreement was attached as Schedule 5 to the original RBLA.
- (3) Since that time, the Parties have entered into two substitute quality agreements with the effect that Schedule 5 no longer reflects the current agreement of the Parties with respect to quality assurance matters and matters related to Good Manufacturing Practices.
- (4) HPA and EUSA now wish to amend the RBLA to remove Schedule 5 which no longer reflects the agreement of the Parties and to provide flexibility to enter into future quality agreements as agreed by the Parties without the need to amend the RBLA each time.
- (5) This Third Amendment confirms the mutual understanding between HPA and EUSA to amend certain terms and conditions of the RBLA and the Parties agree to be bound by the terms and conditions of the RBLA, as amended herein.

NOW IT IS HEREBY AGREED as follows:

1. DEFINITIONS AND INTERPRETATION

- 1.1. "Parties" means HPA and EUSA collectively;
- 1.2. Unless stated otherwise in this Third Amendment, terms with initial capitals in this Third Amendment shall have the same meaning attributed to them in Clause 1.1 of the RBLA;
- 1.3. References to the singular shall include the plural and vice versa.

- 1.4. Reference to Clauses and Schedules are to clauses and schedules of either the RBLA or this Third Amendment, as stated in the text of this Third Amendment. The headings to the Clauses in this Third Amendment are for convenience only and have no legal effect.

## 2. AMENDMENTS

- 2.1. With effect from the Effective Date, Schedule 5 to the RBLA is hereby deleted in its entirety.
- 2.2. With effect from the Effective Date, the definition of 'GMP' shall be deleted in its entirety and replaced with the following:  
*“GMP” shall have the meaning set forth in the Technical Agreement.’*
- 2.3. With effect from the Effective Date, the definition of 'Technical Agreement' shall be deleted in its entirety and replaced with the following:  
*“Technical Agreement” means the quality agreement setting forth the individual responsibilities of the Parties with respect to quality assurance matters and matters related to Good Manufacturing Practices with respect to the Product entered into between the Parties on or about the Effective Date (the “original quality agreement”); provided, however, that the original quality agreement will be superseded by the last to be entered into of any subsequent quality agreement entered into by the Parties setting forth the individual responsibilities of the Parties with respect to quality assurance matters and matters related to Good Manufacturing Practices with respect to the Product.’*
- 2.4. With effect from the Effective Date, the first sentence in Section 3.8 shall be deleted in its entirety and replaced with the following:  
*‘The parties shall enter into and perform their respective obligations as set out in the Technical Agreement.’*

## 3. OTHER MATTERS

It is the intent of the Parties that the terms of the Third Amendment be read and interpreted as being additive to, and in harmony with, and not as replacing, or contradicting the terms and conditions of the RBLA, including without limitation Clause 7, *Confidentiality*, except as expressly set out herein.

The failure of either Party at any time to enforce the terms, provisions or conditions of the RBLA shall not be construed as a waiver of the same or of the right of such Party to enforce the same. All terms and conditions to the RBLA remain unchanged and in full force and effect except to the extent superseded by the terms and conditions of this Third Amendment. For the avoidance of doubt, this Third Amendment, as an integral part of the RBLA, is subject to, and governed by,

the provisions of Clause 15 of the RBLA with respect to governing law, jurisdiction and dispute resolution.

This Third Amendment may be executed in any number of counterparts, each of which when executed shall constitute an original of this Third Amendment, but all the counterparts together shall constitute the same Third Amendment. No counterpart shall be effective until each Party has executed at least one counterpart.

The RBLA, as modified by this Third Amendment, contains the entire understanding of the Parties with respect to the Product.



IN WITNESS WHEREOF, the Parties have caused this Third Amendment to be executed by their duly authorised representatives.

For, and on behalf of, Health Protection Agency:	For, and on behalf of, EUSA Pharma SAS:
Signed: /s/ Justin McCracken	Signed: /s/ Bryan Morton
Name: JUSTIN MCCRACKEN	Name: BRYAN MORTON
Title: CHIEF EXECUTIVE	Title: PRESIDENT
Date: 9 AUGUST 2012	Date: 8 AUGUST 2012

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**CERTIFICATION**

I, Bruce C. Cozadd, certify that:

1. I have reviewed this Amendment No. 1 to the Quarterly Report on Form 10-Q/A of Jazz Pharmaceuticals Public Limited Company; and
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report.

Date: August 9, 2012

By: \_\_\_\_\_ /s/ Bruce C. Cozadd  
**Bruce C. Cozadd**  
**Chairman and Chief Executive Officer**

