

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

FORM 8-K

**CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934**

**January 21, 2020
Date of Report (Date of earliest event reported)**

**JAZZ PHARMACEUTICALS PUBLIC LIMITED
COMPANY**

(Exact name of registrant as specified in its charter)

**Ireland
(State or Other Jurisdiction
of Incorporation)**

**001-33500
(Commission
File No.)**

**98-1032470
(IRS Employer
Identification No.)**

**Fifth Floor, Waterloo Exchange, Waterloo Road, Dublin 4, Ireland
(Address of principal executive offices, including zip code)**

**011-353-1-634-7800
(Registrant's telephone number, including area code)**

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Ordinary shares, nominal value \$0.0001 per share	JAZZ	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

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

Item 2.01 Completion of Acquisition or Disposition of Assets.

As previously disclosed, on December 19, 2019, Jazz Pharmaceuticals Ireland Limited (the “Company”), a subsidiary of Jazz Pharmaceuticals plc (“Jazz Pharmaceuticals”), entered into an exclusive license agreement (the “Agreement”) with Pharma Mar, S.A. (“PharmaMar”) pursuant to which PharmaMar granted to the Company an exclusive license under PharmaMar’s patents and know-how to develop and commercialize lurbinectedin in the United States. The effectiveness of the Agreement was subject to the expiration or early termination of the applicable waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended (the “HSR Act”). The applicable waiting period under the HSR Act expired on January 21, 2020, and the Agreement became effective.

Under the Agreement, PharmaMar is responsible for continuing ongoing clinical trials of lurbinectedin. PharmaMar is also responsible for conducting any post-approval commitment studies that are required by the U.S. Food and Drug Administration with respect to any regulatory approval of lurbinectedin in small cell lung cancer. Under a separate agreement to be executed by the parties within a specified time period, PharmaMar will supply the Company with launch quantities of lurbinectedin drug product and on an ongoing basis will supply the Company with the active pharmaceutical ingredient for lurbinectedin.

Pursuant to the terms of the Agreement, the Company will pay PharmaMar an upfront payment of \$200 million and will be obligated to pay PharmaMar up to \$250 million in regulatory milestone payments based on the achievement of accelerated and/or full regulatory approval of lurbinectedin in small cell lung cancer in the United States within specified timeframes. PharmaMar is also eligible to receive tiered royalties from the high teens percentage up to 30% on net sales of lurbinectedin in the United States, subject to customary royalty reductions, and commercial milestone payments of up to \$550 million once certain sales levels have been achieved in the United States. The Company may also be obligated to pay additional milestone payments upon receipt of regulatory approval of lurbinectedin in additional indications, with any such milestone payments creditable against the Company’s commercial milestone payment obligations.

The term of the Agreement will extend until the latest of: (i) expiration of the last PharmaMar patent covering lurbinectedin in the United States (subject to certain exclusions), (ii) expiration of regulatory exclusivity for lurbinectedin in the United States and (iii) 12 years after the first commercial sale of lurbinectedin in the United States. The Company also has the right to terminate the Agreement at will upon a specified notice period, provided that the effective date of such termination is not within one year of the signing of the Agreement. Either party can terminate the Agreement for the other party’s uncured material breach or bankruptcy.

The foregoing summary of certain terms of the Agreement does not purport to be complete and is subject to, and qualified in its entirety by, the full text of the Agreement, a copy of which is filed as Exhibit 2.1 hereto and incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.*(d) Exhibits*

<u>Exhibit Number</u>	<u>Description</u>
2.1*	License Agreement, dated as of December 19, 2019, between Pharma Mar, S.A. and Jazz Pharmaceuticals Ireland Limited
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

* Pursuant to Item 601(b)(2) of Regulation S-K, certain portions of this agreement have been omitted because the omitted portions are both not material and would likely cause competitive harm if publicly disclosed.

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 hereunto duly authorized.

JAZZ PHARMACEUTICALS PUBLIC LIMITED
COMPANY

By: /s/ Neena M. Patil

Name: Neena M. Patil

Title: Senior Vice President and General Counsel

Date: January 22, 2020

[***] = CERTAIN PORTIONS OF THIS AGREEMENT HAVE BEEN OMITTED BECAUSE THE OMITTED PORTIONS ARE BOTH NOT MATERIAL AND WOULD LIKELY CAUSE COMPETITIVE HARM IF PUBLICLY DISCLOSED.

Exhibit 2.1

LICENSE AGREEMENT

THIS LICENSE AGREEMENT (“**Agreement**”) is entered into as of December 19, 2019 (the “**Effective Date**”), by and between **PHARMA MAR, S.A.**, a corporation organized under the laws of Spain, with its principal place of business at 1 Avda. De los Reyes, 28770 - Colmenar Viejo, Madrid, Spain (“**PharmaMar**”), and **JAZZ PHARMACEUTICALS IRELAND LIMITED**, a corporation organized under the laws of Ireland, with its principal place of business at Fifth Floor, Waterloo Exchange, Waterloo Road, Dublin 4, Ireland (“**Jazz**”). PharmaMar and Jazz are sometimes referred to herein individually as a “**Party**” and collectively as the “**Parties**”.

RECITALS

WHEREAS, PharmaMar is a specialty biopharmaceutical company that is developing lurbinctedin (Zepsyre®) and owns or controls patent rights and know-how relating thereto;

WHEREAS, Jazz is a biopharmaceutical company with expertise in the development, marketing, and commercialization of pharmaceutical products; and

WHEREAS, Jazz desires to obtain from PharmaMar, and PharmaMar is willing to grant to Jazz, among others, an exclusive license to commercialize lurbinctedin in the United States, on the terms and subject to the conditions set forth herein.

AGREEMENT

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

1. DEFINITIONS

1.1 “Accounting Standards” means (a) with regard to Jazz, U.S. Generally Accepted Accounting Principles (GAAP) or (b) with regard to PharmaMar, International Financial Reporting Standards (IFRS); in either case, consistently applied throughout the organization of a particular entity and its Affiliates.

1.2 “Act” means the United States Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§301 et seq., as amended from time to time.

1.3 “Additional Indication” means an Indication other than SCLC.

1.4 “**Additional Indication Pivotal Trial**” has the meaning provided in Section 4.2(b).

1.5 “**Additional Indication Pivotal Trial Budget**” has the meaning provided in Section 4.2(b).

1.6 “**Additional Indication Pivotal Trial Development Plan**” has the meaning provided in Section 4.2(b).

1.7 “**Additional Indication Regulatory Milestone**” has the meaning provided in Section 8.5.

1.8 “**Additional Indication Regulatory Milestone Payments**” has the meaning provided in Section 8.5.

1.9 “**Adverse Safety Impact**” has the meaning provided in Section 3.4(b).

1.10 “**Affiliate**” means, with respect to any Entity (including a Party to this Agreement), any other Entity controlled by, controlling, or under common control with such Entity. For the purposes of this definition, the term “control” (including, with correlative meanings, the terms “controlled by” and “under common control with”) means the possession, directly or indirectly, of more than 50% of the outstanding voting securities of a corporation or comparable equity interest in any other type of Entity, or otherwise having the power to direct the management and policies of such Entity.

1.11 “**Annual Commercialization Plan**” means the plan for Commercialization of the Licensed Product in the Territory for each Calendar Year during the Term as required by Section 7.5, that contains the details for the Commercialization activities to be conducted with respect to the Licensed Product that are required by Section 7.5.

1.12 “**Annual Sales Forecast Plan**” or “**ASFP**” has the meaning provided in Section 7.8(a)(i).

1.13 “**Anti-Corruption Laws**” means the U.S. Foreign Corrupt Practices Act, as amended, the Organization for Economic Co-operation and Development (OECD) Convention on combating bribery of foreign public officials in international business transactions, and any other applicable anti-corruption laws.

1.14 “**Applicable Laws**” means the applicable provisions of any and all national, supranational, regional, state and local laws, treaties, statutes, rules, regulations, administrative codes, guidances, ordinances, judgments, decrees, directives, injunctions, orders, permits of or from any court, arbitrator, regulatory authority or governmental agency or authority having jurisdiction over or related to the subject item, including the Act, Anti-Corruption Laws and Export Control Laws. Applicable Laws shall also include all applicable legal requirements to pharmaceutical industry.

1.15 “**ASFP Term**” means the [***] starting after [***].

1.16 “Atlantis Trial” means the phase III randomized clinical trial of lurbinectedin (PM01183)/doxorubicin (DOX) versus cyclophosphamide (CTX), doxorubicin (DOX) and vincristine (VCR) (CAV) or topotecan as treatment in patients with SCLC who failed one prior platinum-containing line to determine whether there is a difference in Overall Survival (OS) between lurbinectedin (PM01183)/doxorubicin (DOX) and a control arm consisting of best investigator’s choice between CAV or topotecan and to analyze progression-free survival (PFS) by an Independent Review Committee (IRC); such clinical trial has the ClinicalTrials.gov Identifier: NCT02566993.

1.17 “Atlantis Development Plan” has the meaning provided in Section 4.1(a)(i)

1.18 “Best Knowledge” means, in respect of a Party, that such Party’s [***].

1.19 “Bulk Vials” means units of Licensed Product in the final dosage form containing the Licensed API as an active ingredient, in primary packaging but without secondary packaging, all meeting the specifications therefore as described in the Quality Agreement.

1.20 “Business Day” means a day other than a Saturday, Sunday or bank or other public holiday in Dublin, Ireland or Madrid, Spain.

1.21 “Calendar Quarter” means each successive period of three (3) calendar months commencing on January 1, April 1, July 1 and October 1, except that the first Calendar Quarter of the Term shall commence on the Effective Date and end on the day immediately prior to the first to occur of January 1, April 1, July 1 or October 1 after the Effective Date, and the last Calendar Quarter shall end on the last day of the Term.

1.22 “Calendar Year” means each successive period of twelve (12) calendar months commencing on January 1 and ending on December 31, except that the first Calendar Year of the Term shall commence on the Effective Date and end on December 31 of the year in which the Effective Date occurs and the last Calendar Year of the Term shall commence on January 1 of the year in which the Term ends and end on the last day of the Term.

1.23 “Change of Control” means, with respect to an Entity, (a) the sale to a Third Party of all or substantially all of the assets of such Entity relating to this Agreement, in one or a series of related transactions to which such Entity is a party; or (b) the acquisition of control of such Entity by a Third Party by means of any transaction or series of related transactions to which such Entity is a party (i) wherein such Third Party acquires more than fifty percent (50%) of the voting equity securities of such Entity or (ii) that is a merger, acquisition or consolidation of such Entity by or with such Third Party in which the voting securities of such entity outstanding immediately prior thereto cease to represent at least fifty percent (50%) of the combined voting power of the surviving entity immediately after such merger, reorganization or consolidation.

1.24 “Clinical Trial” means any clinical study involving the administration of a Licensed API or Licensed Product to a human subject for the purpose of evaluating the safety, efficacy, performance or other characteristic of such Licensed API or Licensed Product, including all Medical Affairs Clinical Trials.

1.25 “Combination Product” means a Licensed Product that is sold in a finished dosage form containing Licensed API in combination with one or more Other Actives.

1.26 “Commercialization Activities” has the meaning provided in Section 7.1.

1.27 “Commercialize” means to undertake those activities traditionally undertaken in the pharmaceutical industry to commercially exploit the Licensed Products, including, without limitation, pre-launch and launch activities, pricing and reimbursement activities, marketing, promoting, detailing, distributing, offering for sale and selling the Licensed Products, reporting of adverse events in patients, and interacting with regulatory or other authorities regarding any of the foregoing. **“Commercialization”** shall have a correlative meaning.

1.28 “Commercially Reasonable Efforts” means, with respect to the efforts to be expended by a Party to develop, register and commercialize any Licensed Product, [***], taking into account [***]. Without limiting the foregoing, to the extent it is commercially reasonable to do so, commercially reasonable efforts will [***].

1.29 “Committee” means the JDC, JCC or any Working Group, as applicable.

1.30 “Committee Dispute” has the meaning provided in Section 3.4(a).

1.31 “Competing Program” has the meaning provided in Section 2.4(c).

1.32 “Complete Response Letter” means a response from the FDA following acceptance by the FDA of the filing of an NDA for a particular Licensed Product indicating that the Regulatory Approval of such NDA is delayed or conditioned upon additional information becoming available or additional activities being performed for such Licensed Product.

1.33 “Confidential Information” has the meaning provided in Section 11.1.

1.34 “Confidentiality Agreement” means the Confidential Disclosure Agreement between Jazz and PharmaMar dated [***], as amended.

1.35 “Control” or **“Controlled by”** means, with respect to any Patent Rights, Information or other intellectual property rights, the possession by a Party of the ability (whether by ownership, license or other right, other than pursuant to a license granted to such Party under this Agreement) to grant access to, or a license or sublicense of, such Patent Rights, Information or other intellectual property rights without violating the terms of any agreement or other arrangement with any Third Party.

1.36 “Co-Promotion Agreement” has the meaning provided in Section 7.9(b).

1.37 “Co-Promotion Option” has the meaning provided in Section 7.9(a).

1.38 “CPI” means (a) with respect to Jazz, the [***] and (b) with respect to PharmaMar, [***].

1.39 “CPI Adjustment” means the percentage increase or decrease, if any, in the CPI applicable to FTE personnel for the most recent [***] available at the time of budgeting for the [***] for which the adjustment is being made.

1.40 “Defensive Action” has the meaning provided in Section 10.5(a).

1.41 “Detail” means a face-to-face, interactive (including through video-conference, internet, virtual or other similar means that allow for real-time communication and the exchange of visual information) selling presentation for a Licensed Product by a representative of a Party’s sales force to an eligible HCP in the Jazz Territory in accordance with Applicable Law during which time the Promotion Message involving the Licensed Product is presented [***] and, in each case, the Promotional Message is [***], *provided that* the following shall not constitute Details: [***]. For the avoidance of doubt, NAMs, reimbursement specialists and MSLs do not Detail the Licensed Product.

1.42 “Develop” means to undertake those activities reasonably related to planning and undertaking research and preclinical development activities and clinical trials to obtain a regulatory approval from the FDA in a Licensed Indication, including filing for regulatory approval in the U.S. and interacting with the FDA. **“Development”** shall have a correlative meaning. For clarity, Develop shall not include those research and preclinical development activities and those clinical trials intended to obtain a regulatory approval from Regulatory Authorities other than US Regulatory Authorities such as the EMA and other Regulatory Authorities in the PharmaMar Territory. In addition, “Develop” does not include Medical Affairs Studies.

1.43 “Development Costs” means, with respect to the SCLC Post-Approval Commitment Studies, the sum of [***] and as accounted for by Jazz (or its Affiliates) in accordance with Jazz’s Accounting Standards.

1.44 “Dollar” means a U.S. dollar, and “\$” shall be interpreted accordingly.

1.45 “Drug Conjugate” means any composition of matter wherein a product is linked or attached to a targeting moiety, including, without limitation, an antibody, protein, RNA, DNA or similar construct.

1.46 “Enforcement Action” has the meaning provided in Section 10.4(b)(i).

1.47 “Enforcing Party” has the meaning provided in Section 10.4(b)(iii).

1.48 “Entity” means any corporation, general partnership, limited partnership, limited liability partnership, joint venture, estate, trust, company (including any limited liability company or joint stock company), firm or other enterprise, association, organization or entity.

1.49 “European Union” means all countries that are officially recognized as member states of the European Union at any particular time. For clarity, European Union for the purposes of this Agreement shall at all times include the United Kingdom even if the United Kingdom exits the European Union prior to or during the Term.

1.50 “Expanded Access Programs” or “EAP” means those programs that allows the use of an authorized medicine before Regulatory Approval is obtained for patients in the Territory who have a disease with no satisfactory authorized therapies and who cannot enter a Clinical Trial and that are intended to facilitate the availability to patients of new treatment options under development.

1.51 “Executive Officers” means with respect to PharmaMar, its [***], and with respect to Jazz, [***].

1.52 “Export Control Laws” means: (a) all applicable U.S. laws and regulations relating to sanctions and embargoes imposed by OFAC; (b) all applicable U.S. export control laws, including the Arms Export Controls Act (22 U.S.C. Ch. 39), the International Emergency Economic Powers Act (50 U.S.C. §§ 1701 et seq.), the Trading With the Enemy Act (50 U.S.C. app. §§ 1 et seq.), the Export Administration Act of 1979 (50 U.S.C. app. §§ 2401 et seq.), International Boycott Provisions of Section 999 of the U.S. Internal Revenue Code of 1986, and all rules, regulations and executive orders relating to any of the foregoing, including but not limited to the International Traffic in Arms Regulations (22 C.F.R. §§ 120 et seq.), the Export Administration Regulations (15 C.F.R. §§ 730 et. seq.), and the regulations administered by the Office of Foreign Assets Controls of the United States Department of the Treasury; and (c) all export controls imposed on any Licensed Product by any country or organization or nations within the jurisdiction of which a Party operates or does business.

1.53 “FDA” means the U.S. Food and Drug Administration, or any successor Regulatory Authority thereto in the U.S. having substantially the same function.

1.54 “Finished Product” means single finished dosage form of Licensed Product consisting in already-to-sell pack including immediate packaging cartons, labels and package leaflet of the Licensed Product and any unique identifiers that are required to be inserted in the packaging components of the Product under Applicable Laws, which are approved by Regulatory Authorities of the Jazz Territory.

1.55 “First Commercial Sale” means the first sale of a Licensed Product for which revenue has been recognized by Jazz or its Affiliates or Sublicensees for use or consumption by the general public of such Licensed Product after Regulatory Approval (and pricing or reimbursement approval, if legally required for such sale) for such Licensed Product has been obtained; provided, however, that the following shall not constitute a First Commercial Sale:

- (a) any [***];
- (b) any use of such Licensed Product in [***] ; and
- (c) [***].

1.56 “Full Approval” shall mean that the Licensed Product (a) has received Regulatory Approval from the FDA in a subsequent filing, after submission and approval under the Subpart H regulations or their equivalents, without the FDA requiring any further confirmatory clinical trials to be conducted or (b) has received Regulatory Approval from the FDA without the FDA requiring any further confirmatory clinical trials to be conducted.

1.57 “**FTE**” means the equivalent of a full-time employee’s work time over a 12-month period (including normal vacations, sick days and holidays).

1.58 “**FTE Costs**” means, for a given period, the FTE Rate multiplied by the number of FTEs in such period utilized in connection with a particular activity.

1.59 “**FTE Rate**” means a rate of [***] per FTE; provided that, starting January 1, 2021, such rate shall be subject to an annual CPI Adjustment (as of January 1 of a given Calendar Year).

1.60 “**GCP**” means current good clinical practices, as set forth in 21 C.F.R. Parts 50, 54, 56, 312 and 314 and as interpreted by relevant ICH guidelines; in each case, as amended from time to time.

1.61 “**Generic Product**” means, with respect to a particular Licensed Product sold by Jazz or any of its Affiliates or Sublicensees in the Jazz Territory, a pharmaceutical product sold by a Third Party (other than a Sublicensee or any other Third Party in a chain of distribution originating from Jazz or any of its Affiliates or Sublicensees) in the Jazz Territory: (a) that contains Licensed API (and, if applicable, the same Other Active(s) as such Licensed Product); and (b) has received Regulatory Approval from the relevant Regulatory Authority in such country in reliance on the Regulatory Approval for such Licensed Product in the Jazz Territory.

1.62 “**GLP**” means current good laboratory practices, as set forth in 21 C.F.R. Part 58 and as interpreted by relevant ICH guidelines; in each case, as amended from time to time.

1.63 “**GMP**” means the current good manufacturing practices and standards for the production of drugs and finished pharmaceuticals, as set forth in 21 C.F.R. Parts 210 and 211 and as interpreted by relevant ICH guidelines; in each case, as amended from time to time.

1.64 “**Governmental Authority**” means any court, agency, department, authority or other instrumentality of any national, supra-national, state, county, city or other political subdivision.

1.65 “**HCPs**” means healthcare professionals or healthcare providers.

1.66 “**HSR Act**” means the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, and the rules and regulations promulgated thereunder, or foreign equivalent thereof under Applicable Law.

1.67 “**HSR Clearance**” means, as pertaining to this Agreement, the expiration or termination of all applicable waiting periods and requests for information (and any extensions thereof) under the HSR Act.

1.68 “**HSR Clearance Date**” means the [***] the Parties have actual knowledge that all applicable waiting periods under the HSR Act with respect to the transactions contemplated

under this Agreement have expired or have been terminated, *provided that* such date shall be extended by [***] if (a) PharmaMar notifies Jazz on or within [***] prior to such date of the occurrence of any Material Adverse Effect or (b) PharmaMar was obligated pursuant to Section 16.13 to notify Jazz on or within [***] prior to such date of the occurrence of any Material Adverse Effect; and *further provided that* Jazz has not terminated this Agreement pursuant to Section 16.13 prior to such date or extension thereof.

1.69 “HSR Filing” means (a) filings by Jazz and PharmaMar with the United States Federal Trade Commission and the Antitrust Division of the United States Department of Justice of a Notification and Report Form for Certain Mergers and Acquisitions (as that term is defined in the HSR Act) with respect to the matters set forth in this Agreement, together with all required documentary attachments thereto, or (b) equivalent filings with applicable Governmental Authorities having jurisdiction over requests for HSR Clearance.

1.70 “ICC Rules” has the meaning provided in Section 15.2(a).

1.71 “ICH” means the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use.

1.72 “IMRC” has the meaning provided in Section 7.8(a)(ii).

1.73 “IND” means an investigational new drug application, clinical study application, clinical trial exemption, or similar application or submission filed with or submitted to a Regulatory Authority in a jurisdiction that is necessary to commence human clinical trials in such jurisdiction, including any such application filed with the FDA pursuant to 21 C.F.R. Part 312.

1.74 “Indication” means a specific disease, disorder or condition which is recognized by Regulatory Authorities of Jazz Territory as a disease, disorder or condition.

1.75 “Information” means any and all tangible and intangible (a) techniques, technology, practices, trade secrets, inventions (whether patentable or not), methods, knowledge, know-how, skill, experience, test data and results (including pharmacological, toxicological and clinical test data and results), analytical and quality control data, results or descriptions, software and algorithms, and (b) compositions of matter, cells, cell lines, assays, animal models and physical, biological or chemical material; that, in each case, are not in the public domain.

1.76 “Invention” means any invention, whether or not patentable, made conceived, created, generated or first reduced to practice (together with all intellectual property rights therein) in the course and as a result of the conduct of activities conducted pursuant to this Agreement

1.77 “Investigator Sponsored Studies” or **“ISS”** means those Medical Affairs Studies involving the Licensed API or the Licensed Product which are not sponsored by a Party, its Affiliates, Sublicensees or its Third Party Partners, but by an investigator, an institution or any other Third Party sponsor even if such Studies are supported by such Party by providing the Licensed Products as study drug and/or by providing financial support and/or otherwise.

1.78 “Jazz Generic Inventions” has the meaning provided in Section 10.1(e).

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- 1.79 “**Jazz Generic Patents**” means any Patent Right claiming a Jazz Generic Invention.
- 1.80 “**Jazz License**” has the meaning provided in Section 2.1
- 1.81 “**Jazz Know-How**” means solely any Information Controlled during the Term by Jazz or any of its Affiliates that [***]. For clarity, Jazz Know-How does not include [***].
- 1.82 “**Jazz Patents**” means any Patent Right that is Controlled by Jazz or its Affiliates and Sublicensees during the Term that claims [***]. For clarity, Jazz Patents shall include [***].
- 1.83 “**Jazz Proprietary Component**” has the meaning provided in Section 10.1(d).
- 1.84 “**Jazz Prosecuted Patents**” has the meaning provided in Section 10.2(c).
- 1.85 “**Jazz Solely Invented Specific Combination Inventions**” means any Specific Combination Invention conceived, created or first reduced to practice solely by or on behalf of Jazz, its Affiliates or Sublicensees.
- 1.86 “**Jazz Solely Invented Specific Inventions**” means any Specific Invention conceived, created or first reduced to practice solely by or on behalf of Jazz, its Affiliates or Sublicensees
- 1.87 “**Jazz Specific Combination Inventions**” has the meaning provided in Section 10.1(d).
- 1.88 “**Jazz Standard Trade Dress and Style**” has the meaning provided in Section 10.9(e)
- 1.89 “**Jazz Technology**” means Jazz Patents and Jazz Know-How.
- 1.90 “**Jazz Territory**” means the U.S.
- 1.91 “**Joint Generic Inventions**” has the meaning provided in Section 10.1(e).
- 1.92 “**Joint Patents**” means Joint Specific Combination Patents and Joint Generic Patents.
- 1.93 “**Joint Specific Combination Invention**” has the meaning provided in Section 10.1(d).
- 1.94 “**Joint Specific Combination Patent**” means any Patent Right claiming a Joint Specific Combination Invention.
- 1.95 “**Joint Generic Patent**” means any Patent Right claiming a Joint Generic Invention.
- 1.96 “**JDC**” has the meaning provided in Section 3.1.

1.97 “JCC” has the meaning provided in Section 3.1.

1.98 “Licensed API” means (a) that composition of matter with the chemical structure identified more specifically in **Exhibit A**, otherwise known as lurbinectedin (PM1183); (b) any [***]; (c) any pro-drug, metabolite or degradant of any of the foregoing; or (d) any salt, free acid or base, crystal, co-crystal, hydrate, anhydrous form, solvate, ester, polymorph, isomer, regioisomer or stereoisomer (including enantiomer and diastereoisomer) of any of the foregoing.

1.99 “Licensed Indication” means the prevention, treatment, mitigation or cure of any disease, indication or medical condition, including cancer, whether as monotherapy or in combination with other drugs or biologics.

1.100 “Licensed Product” means any pharmaceutical product containing or comprising a Licensed API as an active ingredient (whether or not as the sole active ingredient) in a form suitable for administration to a human.

1.101 “Licensed Product Data” means any and all results of research, preclinical studies, including *in vitro* and *in vivo* studies, clinical trials and other testing of Licensed API or Licensed Product conducted by or on behalf of a Party or any of its Affiliates (or in the case of PharmaMar, its Third Party Partners) to the extent Controlled by such Party either before or during the Term, and any and all other data generated by or on behalf of a Party related to the development, manufacture or commercialization of Licensed API or Licensed Product, including safety data, biological, chemical, pharmacological, toxicological, pharmacokinetic, clinical, CMC, analytical, quality control, and other data, results and descriptions and, if requested, raw data associated with the conduct of any Clinical Trial for the Licensed API or Licensed Product (including the SCLC Post-Approval Commitment Studies); provided however that, except for that data that is necessary for Jazz to carry out its regulatory and quality obligations as the holder of the NDA for the Licensed Product, Licensed Product Data shall not include any data or Information which is included in any section of the DMF other than Section S of Module 3 of the NDA and is not otherwise publicly available.

1.102 “Major Tumour” means the following indications: (a) [***] and (b) any other [***], in each case of (a) and (b), with a population of over [***], as determined in accordance with Section 5.5(c)(iii). Notwithstanding the foregoing, the Parties agree that none of the following are Major Tumours: [***]. For the avoidance of doubt, [***] shall not be deemed a Major Tumour.

1.103 “Material Adverse Event” shall mean [***].

1.104 “Medical Affairs” means any and all processes and activities directed to interacting with physicians, healthcare professionals and other medical stakeholders with respect to the utilization, research and other medical (but not Commercialization) activities for a pharmaceutical product (including the Licensed Product), including: Medical Affairs Studies, Investigator Sponsored Studies; medical and scientific information; responding to external inquiries or complaints; medical education; health economics and outcomes research (HECOR, HEMAR); speaker programs; advisory boards; grants, fellowships and sponsorships; drug safety; local country government affairs; deployment of field-based medical science liaisons (MSLs);

medical doctors in the field (separate from medical science liaisons); publications; medical communications; field medical education; registries; advocacy support; and slide libraries/kits, reprints and publication planning. For clarity, Medical Affairs excludes any Clinical Trial that is (a) intended for use as a basis for obtaining Regulatory Approval (including for an additional indication or other label expansion or otherwise) or (b) a SCLC Post-Approval Commitment Study or other confirmatory trial requested by Regulatory Authorities.

1.105 “Medical Affairs Studies” means any studies conducted within a country of the Territory after the granting of the Regulatory Approval of the Product in such country including ISS sponsored by an investigator or institution (and not in the name of either Party) under whose supervision such study is being conducted and Clinical Trials sponsored by a Party; provided that Medical Affairs Studies shall exclude any such Clinical Trial which is (a) sponsored by a Party and conducted pursuant to a Regulatory Filing held in the name of a Party and whose primary purpose is to support a Regulatory Filing for the expansion or other modification of the label claims for such Product and (b) a SCLC Post-Approval Commitment Study or other confirmatory trial requested by Regulatory Authorities.

1.106 “MSL” means, with respect to a Party, a medical science liaison employed by a Party or any of its Affiliates to perform activities with respect to a Licensed Product.

1.107 “NAM” means an account manager responsible for seeking coverage, coding and reimbursement of a Product by payers and managed market plans, including national account managers and regional account managers.

1.108 “NDA” means: (a) in the United States, as applicable, a New Drug Application (as more fully described in 21 CFR Part 314.50, et seq., or its successor regulation) or a Biologics License Application (as more fully described in 21 CFR Part 601, et seq., or its successor regulation), filed with the FDA, or any successor application to either of the foregoing; or (b) in any other country or group of countries, the equivalent application or submission for approval to market a pharmaceutical product filed with the governing Regulatory Authority in such country or group of countries.

1.109 “NDA Approval” shall mean a Regulatory Approval by the FDA, whether under the Subpart H regulations or their equivalents or not, to market and/or promote a Licensed Product.

1.110 “Net Sales” means, with respect to any Licensed Product, the [***] by Jazz and its Affiliates and Sublicensees for sales of such Licensed Product in the Licensed Indication in the Jazz Territory to unaffiliated Third Parties, less the following deductions [***]:

- (a) [***];
- (b) [***];
- (c) [***];
- (d) [***];

-
- (e) [***];
 - (f) [***];
 - (g) tariffs, taxes, custom duties and other governmental charges [***]) levied on or measured by [***];
 - (h) [***]; and
 - (i) [***].

Notwithstanding the foregoing, amounts received or invoiced by Jazz or its Affiliates or Sublicensees for the sale of Licensed Products among Jazz and its Affiliates and Sublicensees shall not be included in the computation of Net Sales hereunder. Net Sales shall be determined from the books and records of the Selling Party and its Affiliates maintained in accordance with Accounting Standards consistently applied.

Notwithstanding the foregoing, "Net Sales" shall not include [***]. Further, [***], shall be disregarded in determining Net Sales.

Net Sales for a Combination Product in a country shall be calculated as follows:

(i) If the Licensed Product and Other Active(s) each are sold separately in such country, Net Sales will be calculated by multiplying the total Net Sales (as described above) of the Combination Product by the fraction $A/(A+B)$, where A is the public or list price in such country of the Licensed Product sold separately in the same formulation and dosage, and B is the (sum of the) public or list price(s) in such country of the Other Active(s) sold separately in the same formulation and dosage, during the applicable Calendar Year.

(ii) If the Licensed Product is sold independently of the Other Active(s) in such country, but the public or list price of the Other Active(s) cannot be determined, Net Sales will be calculated by multiplying the total Net Sales (as described above) of such Combination Product by the fraction A/C , where A is the public or list price in such country of such Licensed Product sold independently and C is the public or list price in such country of the Combination Product.

(iii) If the Other Active(s) are sold independently of the Licensed Product therein in such country, but the public or list price of such Licensed Product cannot be determined, Net Sales will be calculated by multiplying the total Net Sales (as described above) of such Combination Product by the fraction $[1-B/C]$, where B is the (sum of the) public or list price(s) in such country of the Other Active(s) and C is the public or list price in such country of the Combination Product.

(iv) If the public or list price of such Licensed Products and the Other Active(s) cannot be determined, Net Sales will be calculated by multiplying the total Net Sales (as described above) of such Combination Product by a fraction [***]. If [***].

1.111 “OFAC” means the U.S. Department of Treasury’s Office of Foreign Assets Control (or its successor office or other body having substantially the same function).

1.112 “Other Active” means any active pharmaceutical ingredient other than Licensed API.

1.113 “Patent Rights” means (a) all national, regional and international patents and patent applications filed in any country of the world, including without limitation provisional patent applications, (b) all patent applications filed either from such patents and patent applications or from a patent application claiming priority from either of these, including any continuation, continuation-in-part, division, provisional, converted provisional and continued prosecution applications, or any substitute applications, (c) any patent issued with respect to or in the future issued from any such patent applications including utility models, petty patents and design patents and certificates of invention, and (d) any and all extensions or restorations by existing or future extension or restoration mechanisms, including revalidations, reissues, reexaminations and extensions (including any supplementary protection certificates and the like) of the foregoing patents or patent applications.

1.114 “Patent Term Extensions” has the meaning provided in Section 10.3.

1.115 “Person” means any individual, Entity or Governmental Authority.

1.116 “PharmaMar Generic Inventions” has the meaning provided in Section 10.1(e).

1.117 “PharmaMar Know-How” means (a) all Information Controlled by PharmaMar or its Affiliates as of the Effective Date or during the Term that [***]. PharmaMar Know-How does not include [***].

1.118 “PharmaMar Patents” means (a) all Patent Rights Controlled by PharmaMar or its Affiliates as of the Effective Date or during the Term that claim [***]. PharmaMar Patents shall include [***]. **Exhibit B** shall be updated no less frequently than [***] by PharmaMar during the Term to include all PharmaMar Patents (except for Joint Specific Combination Inventions for which Jazz shall provide with updates of such **Exhibit B** no less frequently than [***] during the Term).

1.119 “**PharmaMar Prosecuted Patents**” has the meaning provided in Section 10.2(b).

1.120 “**PharmaMar Technology**” means the PharmaMar Patents and the PharmaMar Know-How.

1.121 “**PharmaMar Territory**” means all countries and jurisdictions in the world other than the Jazz Territory.

1.122 “**Pivotal Trial**” means: (a) a human Clinical Trial that would satisfy the requirements for a Phase 3 study as defined in 21 CFR § 312.21(c) (or any amended or successor regulations); or (b) any other human Clinical Trial that the applicable Regulatory Authority has agreed [***], is sufficient to form the primary basis of an efficacy claim in an NDA submission, regardless of whether the sponsor of such trial characterizes or refers to such trial as a “Phase 3,” “Phase 2b” or “Phase 2b/3” trial (or otherwise) in the applicable protocol, on clinicaltrials.gov, or in any other context.

1.123 “**Pivotal Trial Costs**” means, with respect to a given Joint Additional Indication Pivotal Trial, the sum of [***], in each case, in accordance with the applicable Joint Additional Indication Pivotal Trial Budget and as accounted for by each Party (or its Affiliates, Sublicensees or Third Party Partners) in accordance with such Party’s Accounting Standards.

1.124 “**Positive Results**” means, for an Additional Indication Pivotal Trial, (a) that [***] and (b) for an Additional Indication Pivotal Trial not being a Phase 3 study, that [***].

1.125 “**Product Trademarks**” has the meaning provided in Section 10.9(a).

1.126 “**Promotion Message**” means the set of messages and communications prepared by Jazz intended to promote the use and/or prescribing of the Licensed Product.

1.127 “**Proposed Additional Indication Pivotal Trial**” has the meaning provided in Section 4.2(a).

1.128 “**Prosecution and Maintenance**” has the meaning provided in Section 10.2(b).

1.129 “**PV Agreement**” has the meaning provided in Section 5.11.

1.130 “**Regulatory Approval**” means all approvals from the relevant Regulatory Authority in a given country necessary to market and sell a pharmaceutical product in such country, including pricing and reimbursement approvals if required for marketing or sale of such product in such country.

1.131 “**Regulatory Authority**” means any country, federal, supranational, state or local regulatory agency, department, bureau or other governmental or regulatory authority having the administrative authority to regulate the development or marketing of pharmaceutical products in any country or other jurisdiction.

1.132 “Regulatory Exclusivity” means marketing or manufacturing exclusivity conferred by the applicable Regulatory Authority in a country or jurisdiction on the holder of a Regulatory Approval for a pharmaceutical product in such country or jurisdiction, including, by way of example and not of limitation, regulatory data exclusivity, orphan drug exclusivity, new chemical entity exclusivity and pediatric exclusivity.

1.133 “Regulatory Filing” means any and all INDs, NDAs, drug dossiers or drug master files filed, requests for orphan designation, and Regulatory Approvals and orphan designations obtained, with respect to Licensed API or Licensed Product, including all amendments, supplements, annual reports and the like filed with or otherwise provided to the applicable Regulatory Authority.

1.134 “Regulatory Milestone” has the meaning provided in Section 8.4.

1.135 “Regulatory Milestone Payment” has the meaning provided in Section 8.4.

1.136 “Remedial Action” has the meaning provided in Section 5.9.

1.137 “Royalty Term” has the meaning provided in Section 8.7(b).

1.138 “Sales Force” means, with respect to a Party, its sales organization, including field based sales representatives that [***].

1.139 “Sales Milestone” has the meaning provided in Section 8.6.

1.140 “Sales Milestone Payment” has the meaning provided in Section 8.6.

1.141 “SCLC” means small cell lung cancer.

1.142 “SCLC Initial Indication” shall mean the treatment of SCLC as second or subsequent treatment line in monotherapy or in combination with doxorubicin.

1.143 “SCLC Post-Approval Commitment Studies” has the meaning provided in Section 4.1(b).

1.144 “Specific Combination Invention” has the meaning provided in Section 10.1(c).

1.145 “Specific Inventions” has the meaning provided in Section 10.1(b).

1.146 “Sublicensee” means a Third Party sublicensee under the Jazz License, whether such Third Party’s sublicense was granted to it directly by Jazz or its Affiliate or indirectly through one or more tiers of sublicense.

1.147 “Supply Agreement” has the meaning provided in Section 6.1.

1.148 “Supply Failure” has the meaning to be set forth in the Supply Agreement.

1.149 “Term” has the meaning provided in Section 13.1.

1.150 “**Territory**” means (a) the Jazz Territory in the case of Jazz and (b) the PharmaMar Territory in the case of PharmaMar.

1.151 “**Third Party**” means an Entity other than Jazz or PharmaMar or an Affiliate of Jazz or PharmaMar.

1.152 “**Third Party Partner**” means a Third Party to whom PharmaMar, pursuant to a written or other legally binding agreement, grants any right to Develop and/or Commercialize the Licensed API or the Licensed Product in any jurisdiction in the PharmaMar Territory in each case, for so long as such agreement is in effect. For clarity, Third Party Partner shall exclude any Third Party subcontracted by PharmaMar (or its Affiliates or Third Party Partners) solely to perform any Development, manufacturing or Commercialization activities on PharmaMar’s (or its Affiliate’s or Third Party Partner’s) behalf such as CROs, CMOs, CSOs and logistic subcontractors. As of the Effective Date, existing Third Party Partners are set forth on Exhibit C.

1.153 “**Title 11**” has the meaning provided in Section 16.3(a).

1.154 “**Trademark**” means any trademark, trade name, service mark, service name, brand, domain name, trade dress, logo, slogan or other indicia of origin or ownership in, including registrations and applications therefor as well as any unregistered rights therein and the goodwill and activities associated with each of the foregoing.

1.155 [***] has the meaning provided in Section 10.8.

1.156 “**U.S.**” means the United States of America, including its possessions and territories.

1.157 “**Valid Claim**” means a claim contained in (a) an issued and unexpired patent which has not been held unenforceable, unpatentable or invalid by a decision of a court or other governmental agency of competent jurisdiction, unappealable or unappealed within the time allowed for appeal, and which has not been admitted to be invalid or unenforceable through abandonment, reissue, disclaimer or otherwise or (b) a patent application that has not been irretrievably cancelled, withdrawn or abandoned and that has been pending for less than [***]. If a claim of a [***], then it shall [***].

1.158 “**Working Group**” has the meaning provided in Section 3.5.

2. LICENSE GRANTS

2.1 Jazz License.

(a) Exclusive License Grant to Jazz. Subject to the terms and conditions of this Agreement, PharmaMar hereby grants to Jazz an exclusive (even as to PharmaMar, except as expressly set forth in subsection (vii) below and in Section 2.3), royalty-bearing license, with the right to sublicense through multiple tiers in accordance with Section 2.1(c), under the PharmaMar Technology (i) to Commercialize Licensed Products under the Product Trademarks in the Licensed Indications in the Jazz Territory; (ii) to conduct Medical Affairs activities in the Jazz Territory;

(iii) to Develop Licensed Products in Jazz Territory; (iv) to conduct research and preclinical development activities in the Jazz Territory; (v) to conduct SCLC Post-Approval Commitment Studies and Joint Additional Indications Pivotal Trials in the PharmaMar Territory; (vi) to use and import the Licensed API or Bulk Vials of Licensed Products supplied by PharmaMar to manufacture, have manufactured, use and import Licensed Products for use in accordance with this Section 2.1 in the Jazz Territory and the PharmaMar Territory; and (vii) solely in the event of a Supply Failure, a co-exclusive (solely with PharmaMar and its Affiliates and authorized Third Party manufacturers) license to, within and without the Jazz Territory, to manufacture and have manufactured Licensed API, Bulk Vials and Licensed Products and to import Licensed API, Bulk Vials and Licensed Products into the Jazz Territory, but only for use otherwise in accordance with this Section 2.1. PharmaMar's retained co-exclusive right shall include the right to, within and without the Jazz Territory, manufacture, have manufactured, import and export Licensed API, Bulk Vials and Licensed Products for any use in the PharmaMar Territory otherwise authorized by this Agreement.

(b) Non-Exclusive License Grant to Jazz. In addition to Section 2.1(a), and subject to the terms and conditions of this Agreement, PharmaMar hereby grants to Jazz a non-exclusive, royalty-bearing license, with the right to sublicense through multiple tiers in accordance with Section 2.1(c), under the PharmaMar Technology (i) to conduct research and preclinical development activities in the PharmaMar Territory; (ii) to conduct Jazz Additional Indication Clinical Trials [***]; and (iii) to conduct Joint Additional Indication Pivotal Trials in the PharmaMar Territory (the licenses in Section 2.1(a) and Section 2.1(b) collectively, the "**Jazz License**").

(c) Sublicensing. Jazz shall have the right to grant sublicenses through multiple tiers, under any or all of the rights granted in the Jazz License (i) to its Affiliates and to Third Party contractors or service providers (including contract manufacturing organizations) [***] and (ii) to Third Parties that are not contractors or service providers [***]. Any sublicense granted by Jazz under the Jazz License shall be in writing and shall be consistent with the relevant terms and conditions of this Agreement. [***].

2.2 PharmaMar License.

(a) Exclusive License Grant to PharmaMar. Subject to the terms and conditions of this Agreement, Jazz hereby grants to PharmaMar an exclusive (even as to Jazz), royalty-free license, with the right to sublicense through multiple tiers in accordance with Section 2.2(c), under the Jazz Technology (i) to commercialize Licensed Products in the PharmaMar Territory; (ii) to conduct Medical Affairs activities in PharmaMar Territory; (iii) to develop Licensed Products in the PharmaMar Territory; and (iv) to conduct research and preclinical development activities in the PharmaMar Territory.

(b) Non-exclusive License Grant to PharmaMar. Jazz hereby grants to PharmaMar a non-exclusive, royalty-free license, with the right to sublicense through multiple tiers in accordance with Section 2.2(c), under Jazz Technology, (i) to conduct Atlantis Trial and SCLC Post-Approval Commitment Studies in the Jazz Territory; (ii) to conduct PharmaMar Additional Indication Clinical Trials in the Jazz Territory; (iii) to conduct research and preclinical development activities in the Jazz Territory; and (iv) to manufacture, have manufactured, use and

import Licensed API (solely in the event of a Supply Failure) and Licensed Products for use in accordance with the rights granted in Section 2.2(a) and Section 2.2(b)(i) – (iii) in the Jazz Territory and in the PharmaMar Territory (the licenses in Section 2.2(a) and Section 2.2(b) collectively, the “**PharmaMar License**”).

(c) **Sublicensing.** Subject to Section 2.8, PharmaMar shall have the right to grant sublicenses through multiple tiers, under any or all of the rights granted in the PharmaMar License [***] to Affiliates, Third Party Partners and Third Party contractors or services providers (including contract manufacturing organizations), provided that sublicenses under Jazz Technology other than [***]. Any sublicense granted by PharmaMar under the PharmaMar License shall be in writing and shall be consistent with the relevant terms and conditions of this Agreement. [***]. PharmaMar shall keep Jazz reasonably informed regarding any Third Party Partner’s use of any sublicensed Jazz Technology that it otherwise becomes aware of in the ordinary course, it being understood that PharmaMar shall have no independent duty of inquiry with respect to such uses.

2.3 Reservation of Rights.

(a) Notwithstanding the exclusivity of the Jazz License, PharmaMar retains for itself (and/or, solely with respect to subsection (ii) and (iii), its Affiliates and Third Party Partner(s)), (i) the right under the PharmaMar Technology to file an NDA application for the Licensed Product for the SCLC Initial Indication and to interact with the FDA with respect thereto, each in accordance with Section 5.1; (ii) the exclusive right under the PharmaMar Technology to manufacture and have manufactured the Licensed API in Jazz Territory and in PharmaMar Territory (subject to Jazz’s right to manufacture and have manufactured the Licensed API in the Jazz Territory and in the PharmaMar Territory in the event of a Supply Failure); (iii) the non-exclusive right under PharmaMar Technology to manufacture and have manufacture the Licensed Product in the Jazz Territory and in PharmaMar Territory for the sole purposes of (x) conducting development activities (including Clinical Trials, research and preclinical development) for Licensed Products in the PharmaMar Territory and those Development activities PharmaMar is entitled to conduct in the Jazz Territory in accordance with Section 4.1, 4.2 or 4.3, (subject to Section 3.4(b) if applicable), (y) conducting its Commercialization activities for Licensed Products in the PharmaMar Territory and (z) selling Licensed API or Licensed Products, as applicable, to Jazz in accordance with the terms of the Supply Agreement; and (iv) the right under the PharmaMar Technology to (A) complete the Atlantis Trial in accordance with Section 4.1(a) and (B) conduct the development activities (including clinical trials, research and preclinical development) for Licensed Products that PharmaMar is entitled to conduct in the Jazz Territory in accordance with Section 4.1, 4.2 or 4.3 (subject to Section 3.4(b) if applicable).

(b) Notwithstanding the exclusivity of the PharmaMar License, Jazz retains for itself (and/or its Affiliates and Sublicensees), (i) the right under the Jazz Technology to manufacture and have manufacture Licensed API (in this case solely in the event of a Supply Failure) and Licensed Product in the Jazz Territory and in PharmaMar Territory for the sole purposes of (x) conducting development activities (including Clinical Trials, research and preclinical development) for Licensed Products in the Jazz Territory and those Development activities Jazz is entitled to conduct in the PharmaMar Territory in accordance with Section 4.2 or

4.3, (subject to Section 3.4(b) if applicable) and (y) conducting its Commercialization activities for Licensed Products in the Jazz Territory, (ii) the right under the PharmaMar Technology to conduct the development activities (including clinical trials, research and preclinical development) for Licensed Products that Jazz is entitled to conduct in the PharmaMar Territory in accordance with Section 4.2 or 4.3, (subject to Section 3.4(b) if applicable), and (iii) the right under the Jazz Technology to conduct research and preclinical development activities in the PharmaMar Territory.

(c) PharmaMar reserves to itself (and/or its Third Party Partner(s)), all other rights not expressly granted to Jazz pursuant to this Agreement, including: (i) the right to conduct development activities of the Licensed API and Licensed Product in the PharmaMar Territory, (subject to Section 3.4(b) if applicable), (ii) the right to Commercialize Licensed Products in the PharmaMar Territory and (iii) the right to conduct Medical Affairs activities in the PharmaMar Territory. Jazz reserves to itself (and/or its Affiliates, Sublicensees and licensees), all other rights in the Jazz Technology not expressly granted to PharmaMar pursuant to this Agreement.

2.4 Negative Covenants.

(a) **By PharmaMar.** PharmaMar hereby covenants that, until the [***], neither it nor its Affiliates will, directly or indirectly (including with or through any Third Party licenses): [***], *provided, that* the foregoing covenants [***] shall (x) not prohibit PharmaMar from fulfilling its obligations to Jazz under the Agreement or from filing an NDA application for the Licensed Product for the SCLC Initial Indication and (y) not apply to [***]. For clarity, [***].

(b) **By Jazz.** Jazz hereby covenants that, until the [***], neither it nor its Affiliates will, directly or indirectly (including with or through Third Party licenses): [***], *provided, that* the foregoing covenants [***] shall (A) not prohibit Jazz from Developing, manufacturing or Commercializing Licensed Products pursuant to the Jazz License or fulfilling its obligations to PharmaMar under this Agreement and (B) not apply to [***]. For clarity, [***].

(c) **Exceptions for Mergers and Acquisitions.** In the event that a Third Party becomes an Affiliate of a Party after the Effective Date through merger, acquisition, consolidation or other similar transaction, and, as of the closing date of such transaction, such Third Party is engaged in the research, development or commercialization of a product that, if further developed, manufactured or commercialized by such Party, would cause such Party to be in breach of its exclusivity obligations set forth in Section 2.4(a) or Section 2.4(b), as applicable (a “**Competing Program**”), then:

(1) if such transaction results in a Change of Control of a Party, then such new Affiliate [***]; *provided, that* such new Affiliate [***]; and

(2) if such transaction does not result in a Change of Control of a Party, then such Party and its new Affiliate will [***] from the closing date of such transaction to wind down or complete the Divestiture of such Competing Program, and [***]; *provided, that* [***]. “**Divestiture**” means [***].

2.5 No Implied Licenses. Except as explicitly set forth in this Agreement, neither Party shall be deemed by estoppel or implication to have granted the other Party any license or other right to any Patent Rights or other intellectual property of such Party. ALL RIGHTS WITH RESPECT TO TECHNOLOGY OR INTELLECTUAL PROPERTY RIGHTS THAT ARE NOT SPECIFICALLY GRANTED HEREIN ARE RESERVED TO THE OWNER OF SUCH TECHNOLOGY OR INTELLECTUAL PROPERTY RIGHTS.

2.6 Technology Transfer. Promptly after Jazz's request, but in any event within [***], PharmaMar shall disclose to Jazz all existing PharmaMar Know-How which is [***]. Thereafter, on an ongoing basis, PharmaMar shall also disclose to Jazz all additional PharmaMar Know-How generated after the Effective Date [***]. For clarity, [***], PharmaMar shall [***]. Without limiting the generality of the foregoing, PharmaMar shall provide to Jazz true and complete copies of all written, graphic or electronic embodiments of Licensed Product Data within the PharmaMar Know-How. The PharmaMar Know-How shall be transferred to Jazz in a format to be agreed upon by the Parties, such agreement not to be unreasonably withheld and facilitated, where useful, by face to face technical exchange meetings or meetings at PharmaMar's contract manufacturing sites. With respect to any of the foregoing that is in a language other than English, PharmaMar shall also provide Jazz with English translations thereof.

2.7 [***], Jazz acknowledges and agrees that [***]— even if supported in any manner by PharmaMar, its Affiliates or its Third Party Partners — shall [***]. In addition, Jazz acknowledges and agrees that PharmaMar shall [***]. For clarity, nothing in this Agreement shall prevent PharmaMar (and its Affiliates and Third Party Partners) to [***] and Jazz agrees that if such occurs it shall not, by itself, be deemed a [***]. For further clarity, PharmaMar shall not have the right [***]. In addition, Jazz shall not have the right to [***].

2.8 Third Party Partner Licenses in [*].**

(a) The Parties agree that notwithstanding any other provisions of this Agreement, within [***], Jazz shall, as set forth below, [***]. Therefore PharmaMar agrees that with respect to [***], PharmaMar shall not [***]. For clarity, PharmaMar shall be entitled to disclose to [***] any Licensed Product Data obtained from Clinical Trials conducted by Jazz, and [***] shall be entitled to use such Licensed Product Data in its Territory as may be reasonable necessary or useful for the development, manufacturing or commercialization of the Licensed API and Licensed Product in [***], including to support the filings and prosecuting of Regulatory Filings and obtaining and maintaining Regulatory Approvals in [***]. Furthermore, PharmaMar shall be entitled to provide [***] with (a) sufficient rights of reference and use regarding any Licensed Product Data, and Regulatory Filings, Regulatory Approvals and material communications in Jazz Territory to the extent such rights are necessary for [***] and (b) true and complete copies of any Regulatory Filings, Regulatory Approvals and material communications with Regulatory Authorities in Jazz Territory with respect to the Licensed Product.

(b) In addition, and with regard to [***], PharmaMar shall not [***], in each case, to [***]. Without limiting the provisions of Section 2.8(a), the foregoing obligations under this Section 2.8(b) shall also apply to [***], except to the extent PharmaMar has [***].

(c) If PharmaMar discloses or grants any rights to [***] with respect to any Jazz Technology, then at Jazz's request and PharmaMar's expense, PharmaMar shall take reasonable action to prevent or limit the possibility of such disclosure or grant from or of having an adverse effect on Jazz's rights under this Agreement or with respect to such Jazz Technology.

(d) For clarity, Jazz acknowledges and agrees that [***].

2.9 Right of Negotiation. In the event that development, manufacturing or Commercialization of Licensed Products by [***] (or its Affiliates or [***]), misappropriates any Know-how and/or infringe any Patents Rights that are Controlled by [***] but are not included in the [***], then at [***] request, the Parties will negotiate in good faith regarding the terms for [***] to grant a non-exclusive, royalty-bearing, sublicensable license to [***] under such Know-How or Patent Right for the development, manufacture and commercialization of Licensed API and Licensed Products [***] is entitled to conduct under this Agreement; upon reaching agreement regarding such terms, the Parties shall either enter into a separate license agreement or amend this Agreement to reflect such terms.

3. GOVERNANCE

3.1 Joint Development Committee

(a) **Formation and Role.** Within [***] after the Effective Date, the Parties shall establish a Joint Development Committee (the "JDC") to coordinate, oversee, review and discuss the Parties' activities with respect to the Development and registration of Licensed Products in the Licensed Indication in the Jazz Territory and the PharmaMar Territory. For that purpose and to the extent reasonably necessary, the JDC will:

(i) discuss and approve any amendments to the Atlantis Development Plan;

(ii) prepare, discuss and approve the SCLC Post-Approval Commitment Studies Development Plan (and the SCLC Post-Approval Commitment Studies Budget if applicable);

(iii) prepare, discuss and approve the Proposed Additional Indication Pivotal Trial Development Plan and Proposed Additional Indication Pivotal Trial Budget;

(iv) review and approve the protocols for any Proposed Additional Indication Pivotal Trial of Licensed Product to be performed by Jazz and/or PharmaMar in the Jazz Territory or the PharmaMar Territory;

(v) prepare, discuss and approve changes to any Joint Additional Indication Pivotal Trial Development Plan or Joint Additional Indication Pivotal Trial Development Budget;

(vi) prepare, discuss and approve changes to Additional Indication Pivotal Trial Development Plan for an Additional Indication Pivotal Trial that is not a Joint Additional Indication Pivotal Trial;

(vii) [***], share information about and discuss such PharmaMar Additional Indication Clinical Trial;

(viii) [***], share information about and discuss such Jazz Additional Indication Clinical Trial that Jazz intends to conduct;

(ix) review, discuss and approve Jazz's conduct of a Jazz Additional Indication Clinical Trial in [***];

(x) at each JDC meeting, review and discuss material research and preclinical development activities by either Party or their respective Affiliates with respect to the Licensed API and Licensed Product in the Jazz Territory and the PharmaMar Territory;

(xi) discuss about the regulatory strategy for the Licensed Product in Jazz Territory and in the EMA;

(xii) serve as the principal means by which: (i) Jazz keeps PharmaMar reasonably informed regarding Jazz's Development and registration plans, efforts and results with respect to Licensed Products,; and (ii) PharmaMar keeps Jazz reasonably informed regarding (A) PharmaMar's performance of its obligations under Section 4.1 of this Agreement and (B) PharmaMar's development and registration plans, efforts and results with respect to Licensed Products;

Licensed Indications; (xiii) share information regarding the global development and regulatory strategy with respect to Licensed Product in the

(xiv) establish such Working Groups as it deems necessary to achieve the objectives and intent of this Agreement;

(xv) perform such other duties as are specifically assigned to the JDC in this Agreement or the Supply Agreement; and

Product; (xvi) determine appropriate wind-down procedures for any Expanded Access after the first NDA Approval for the Licensed

Each Party shall be responsible for ensuring that, at all times, its representatives on the JDC act reasonably and in good faith in carrying out their respective responsibilities hereunder.

(b) **Members.** Each Party shall initially appoint up to [***] representatives to the JDC, each of whom will be an officer or employee of the applicable Party having sufficient seniority within such Party to make decisions arising within the scope of the JDC's responsibilities. The JDC may change its size from time to time by mutual consent of its members, and each Party may replace its representatives at any time upon written notice to the other Party. Each Party shall appoint one of its representatives to the JDC to co-chair the meetings of the JDC (each, a

“**Co-Chair**”). The role of the Co-Chairs shall be to coordinate and prepare the agenda (which agenda shall include all matters requested by a JDC representative from either Party), convene and preside at the meetings of the JDC ensuring the orderly conduct of the JDC meetings and to ensure the preparation of meeting minutes, but the Co-Chairs shall have no additional powers or rights beyond those held by other JDC representatives.

(c) **Meetings.** The JDC shall meet as deemed necessary by the JDC members, but at least [***] for so long as either Party or their Affiliates (or any Third Party Partner) is conducting clinical development of any Licensed Product. JDC meetings may be conducted in person, by teleconference or videoconference at times and places to be determined by the JDC members. Unless otherwise agreed by the Parties, all in-person meetings of the JDC shall be held on an alternating basis between PharmaMar and Jazz facilities. A reasonable number of additional representatives of a Party may attend meetings of the JDC in a non-voting capacity. Each Party shall bear its own expenses of participating in meetings of the JDC.

(d) **Minutes.** Each Party, on an alternative basis, shall be responsible for preparing definitive minutes of each JDC meeting. The Party in charge of the minutes shall circulate a draft of the minutes of each meeting to all members of the JDC for comments within [***] after such meeting. Such minutes shall document all actions and decisions approved by the JDC at such meeting, including the approval of the Development Plan or any amendment thereto, which shall be attached to the minutes as an exhibit. The Parties shall promptly discuss any comments on such minutes and finalize the minutes no later than the date of the next JDC meeting.

3.2 Joint Commercialization Committee.

(a) **Formation and Role.** Within [***] after PharmaMar’s exercise of its Co-Promotion Option, if any, the Parties shall establish a Joint Commercialization Committee (the “**JCC**”) to coordinate, oversee, review and discuss the Parties’ activities with respect to the promotion of Licensed Products in the Licensed Indication in the Jazz Territory. For that purpose and to the extent reasonably necessary, the JCC will:

(i) prepare, discuss and approve a plan for the Commercialization of Licensed Products in the Licensed Indication in the Jazz Territory (the “**Co-Promotion Plan**”);

(ii) coordinate the Party’s performance of the Co-Promotion Plan;

(iii) serve as the principal means by which each Party keeps the other Party reasonably informed regarding such Party’s efforts and results with respect to marketing and promotion of Licensed Products in the Jazz Territory pursuant to the Co-Promotion Plan; and

(iv) perform such other duties as are specifically assigned to the JCC in this Agreement or the Co-Promotion Agreement.

Each Party shall be responsible for ensuring that, at all times, its representatives on the JCC act reasonably and in good faith in carrying out their respective responsibilities hereunder.

(b) **Members.** Upon formation of the JCC, each Party shall initially appoint up to [***] representatives to the JCC, each of whom will be an officer or employee of the applicable Party having sufficient seniority within such Party to make decisions arising within the scope of the JCC's responsibilities. The JCC may change its size from time to time by mutual consent of its members, and each Party may replace its representatives at any time upon written notice to the other Party. Each Party shall appoint one of its representatives to the JDC to co-chair the meetings of the JDC (each, a "**Co-Chair**"). The role of the Co-Chairs shall be to coordinate and prepare the agenda (which agenda shall include all matters requested by a JCC representative from either Party), convene and preside at the meetings of the JCC ensuring the orderly conduct of the JCC meetings and to ensure the preparation of meeting minutes, but the Co-Chairs shall have no additional powers or rights beyond those held by other JCC representatives.

(c) **Meetings.** The JCC shall meet as deemed necessary by the JCC members, but at least [***] for so long as either Party is co-promoting Licensed Product in the Jazz Territory. JCC meetings may be conducted in person by teleconference or videoconference at times and places to be determined by the JCC members. Unless otherwise agreed by the Parties, all in-person meetings of the JDC shall be held on an alternating basis between PharmaMar and Jazz facilities. A reasonable number of additional representatives of a Party may attend meetings of the JCC in a non-voting capacity. Each Party shall bear its own expenses of participating in meetings of the JCC.

(d) **Minutes.** Each Party, on an alternative basis, shall be responsible for preparing definitive minutes of each JDC meeting. The Party in charge of the minutes shall circulate a draft of the minutes of each meeting to all members of the JCC for comments within [***] after such meeting. Such minutes shall document all actions and decisions approved by the JCC at such meeting, including the approval of the Co-Promotion Plan or any amendment thereto, which shall be attached to the minutes as an exhibit. The Parties shall promptly discuss any comments on such minutes and finalize the minutes no later than the date of the next JCC meeting.

3.3 Limitation of Committee Authority. Each Committee shall only have the powers expressly assigned to it in this Agreement, and such powers shall be subject to the terms and conditions of this Agreement. Without limiting the foregoing, no Committee will have the power to (a) modify or amend the terms and conditions of this Agreement; (b) waive either Party's compliance with the terms and conditions of under this Agreement; or (c) determine any such issue in a manner that would conflict with the express terms and conditions of this Agreement.

3.4 Decision-Making and Dispute Resolution.

(a) **Decision-Making.** Each Committee will attempt to reach decisions by consensus, with the Jazz representatives having collectively one vote and the PharmaMar representatives having collectively one vote. Each Committee's decision-making authority shall be limited to those matters expressly delegated to it in this Agreement. If, after reasonable discussion and good faith consideration of each Party's view on a particular matter before a Committee, the representatives of the Parties cannot reach an agreement as to such matter within [***] after such matter was brought to such Committee for resolution (each, a "**Committee Dispute**"), such disagreement shall be escalated to the Executive Officers for resolution within [***], who shall confer in good faith on the resolution of the issue. Any final decision mutually agreed to by such Executive Officers shall be conclusive and binding on the Parties.

(b) Final Decisions. If the Executive Officers are not able to agree on the resolution of any such Committee Dispute within [***] after such issue was first referred to them, then the following shall apply:

(i) Jazz shall have final decision-making authority for all matters relating to the Commercialization of Licensed Products in the Licensed Indication in the Jazz Territory;

(ii) Jazz shall have final decision-making authority for all matters relating to its, its Affiliates' and Sublicensees' conduct of preclinical and research development activities in the Jazz Territory and/or the PharmaMar Territory;

(iii) Jazz shall have final decision-making authority for all matters relating to the Development of Licensed API or Licensed Product conducted in the Jazz Territory (except for the conduct of the Atlantis Trial, PharmaMar Additional Indication Clinical Trials, Additional Indication Pivotal Trials, Joint Additional Indication Pivotal Trials and preclinical and research development activities conducted by PharmaMar, its Affiliates and Third Party Partners), and for all matters relating to the conduct of Jazz Additional Indication Clinical Trials in the PharmaMar Territory provided that PharmaMar shall have final decision making authority with respect to whether to permit or not the conduct of a Jazz Additional Indication Clinical Trial outside [***] in PharmaMar Territory;

(iv) To the extent Jazz performs the SCLC Post-Approval Commitment Studies pursuant to Section 4.1(b), Jazz shall have final decision-making authority for all matters relating to the conduct of such SCLC Post-Approval Commitment Studies in the Jazz Territory and the PharmaMar Territory, including with respect to the SCLC Post-Approval Commitment Studies Plan and SCLC Post-Approval Commitment Studies Budget and any amendments thereto (as long as such activities and such plan are consistent with and do not exceed FDA requirements);

(v) PharmaMar shall have final decision-making authority for all matters relating to the development of Licensed API or Licensed Product conducted in the PharmaMar Territory (except for the conduct of Joint Additional Indication Approval Studies, Jazz Additional Indication Clinical Trials in [***] and preclinical and research development activities conducted by Jazz, its Affiliates and Sublicensees) and for all matters relating to the conduct of PharmaMar Additional Indication Clinical Trials in the Jazz Territory;

(vi) PharmaMar shall have final decision-making authority for all matters relating to the conduct of the Atlantis Trial, including any amendment to the Atlantis Development Plan;

(vii) PharmaMar shall have final decision-making authority for all matters relating to the conduct of Additional Indication Pivotal Trials (and for clarity, excluding the conduct of Joint Additional Indication Pivotal Trials);

(viii) Except to the extent Jazz performs the SCLC Post-Approval Commitment Studies in accordance with Section 4.1(b), PharmaMar shall have final decision-making authority for all matters relating to the conduct of the SCLC Post-Approval Commitment Studies in the Jazz Territory and the PharmaMar Territory;

(ix) PharmaMar shall have final decision-making authority for all matters relating to its, its Affiliates' and Third Party Partners' conduct of preclinical and research development activities in the Jazz Territory and/or the PharmaMar Territory;

provided, that, if a Party reasonably believes, based on regulatory and scientific evidence typically relied upon by the pharmaceutical industry, that any Development activity proposed by the other Party (whether or not such proposed activity is subject to the JDC's final decision making authority) would [***] (an "**Adverse Safety Impact**"), such Party shall have the right to either (A) prevent the other Party from exercising its final decision-making authority set forth in Section 3.4(b)(ii), Section 3.4(b)(iv), Section 3.4(b)(vi) or Section 3.4(b)(vii), as applicable, to approve the conduct of any such Development activity or (B) impose additional conditions on the conduct of such Development activity that are [***], which right shall not be subject to further review or approval by the JDC. In the event any Party disputes the other Party's determination of any Development activity having potentially an Adverse Safety Impact, the Parties shall submit the proposed Development activity to an independent Third Party or committee (such as an investigator review board in the case of an Adverse Safety Impact relating to [***]) to be appointed by both Parties jointly for determination of the existence or not of a potential Adverse Safety Impact. Determination by such independent Third Party shall be binding to the Parties.

Nothing in this Section 3.4(b) shall relieve a Party who has or exercises any 'final decision-making authority' set forth herein of any contractual obligation to the other Party, including, without limitation any obligation to exercise Commercially Reasonable Efforts.

(c) **Neither Party Final Decisions.** Neither Party shall have final decision-making authority for any matter relating to the conduct of a Joint Additional Indication Pivotal Trial, including any Additional Indication Pivotal Trial Development Plan or Additional Indication Pivotal Trial Budget for such Clinical Trial and any such decisions shall require the mutual consent of the Parties. In the absence of mutual agreement of the Parties with respect to any such matter, the status quo in the then-current Additional Indication Pivotal Trial Development Plan or Additional Indication Pivotal Trial Budget shall prevail.

(d) **Development and Commercialization Meetings.** During the Term, unless the Parties mutually agree otherwise, the Parties will have meetings at least once each Calendar Year, to discuss any other issue the Parties may consider regarding Development and Commercialization of the Licensed Products in each Party's Territory, including sharing information regarding Jazz's Annual Commercialization Plan and information regarding commercialization and marketing strategies of each Party in its Territory. Such meetings may be conducted in person at times and places to be determined by the Parties. Alternatively, the Parties may meet by means of teleconference, videoconference or other similar communications equipment. Each Party shall bear its own expenses of participating in meetings.

3.5 Working Groups. From time to time, the JDC or the JCC may establish and delegate duties to other committees, sub-committees or directed teams (each, a “**Working Group**”) on an “as-needed” basis to discuss best practices, oversee particular projects or activities, such as regulatory or clinical activities, which delegation shall be reflected in the minutes of the meetings of the JDC. Each such Working Group shall be constituted and shall operate as the JDC or JCC, as applicable, determines and shall report to the JDC or JCC, as applicable. Each Working Group and its activities shall be subject to the oversight, review and approval of the JDC or JCC, as applicable. In no event shall the authority of the Working Group exceed that specified for the JDC in Section 3.1(a) or the JCC in Section 3.2(a), as applicable. Any disagreement between the designees of PharmaMar and of Jazz on a Working Group shall be referred to the JDC or JCC, as applicable, for resolution.

3.6 Alliance Manager. Each Party shall designate an employee (“**Alliance Manager**”) to facilitate communications between the Parties or the JDC (including coordinating the exchange of Information of each Party as required under this Agreement) and to act as the primary liaison between the Parties or the JDC with respect to such other matters as the Parties may mutually agree in order to maximize the efficiency of the exchange of Information, it being understood that the exchange of Information will require the cooperation and efforts of personnel from each Party in addition to the Alliance Manager. Either Party may replace its respective Alliance Manager at any time with prior written notice to the other Party.

4. DEVELOPMENT

4.1 PharmaMar Responsibility. Without limiting the generality of Section 4.4, PharmaMar shall have the obligations set forth in this Section 4.1.

(a) Atlantis Trial.

(i) Responsibility. PharmaMar shall have the sole responsibility for, and shall conduct and complete, the Atlantis Trial at its sole expense in accordance with the current referenced protocols and development plans attached hereto as **Exhibit D** (the “**Atlantis Development Plan**”).

(ii) Material Changes; Suspension or Termination. PharmaMar shall promptly propose to the JDC any material changes it wishes to make to the Atlantis Development Plan, and after discussion and approval by the JDC, such plan shall be amended to address them unless Jazz believes in good faith that such amendment is likely to have an Adverse Safety Impact, in which case the terms of the proviso in Section 3.4(b) shall apply. PharmaMar may suspend or terminate the Atlantis Trial after discussion at the JDC, but without obtaining approval from the JDC, if there is [***] (a “**Safety Reason**”) or such suspension or termination is required by a Regulatory Authority or investigational review board. If Jazz disputes the existence of a Safety Reason, the Parties shall submit the dispute to an independent Third Party or committee (such as an investigator review board) to be appointed by both Parties jointly for determination of the existence or not of such Safety Reason. Determination by such independent Third Party shall be binding to the Parties.

(b) SCLC Post-Approval Commitment Studies.

(i) PharmaMar shall be solely responsible for conducting, on Jazz's behalf and at PharmaMar's sole expense, any post-approval commitment studies that are required by the FDA with respect to any Regulatory Approval by the FDA of a Licensed Product for the SCLC Initial Indication, including any drug-drug interaction studies or hepatic impairment studies required by the FDA (collectively, "**SCLC Post-Approval Commitment Studies**") in accordance with a development plan which shall include a clinical trial design, protocol and timing that satisfies the FDA's requirements to be reviewed, discussed and approved by the JDC. Upon approval by the JDC, such plan shall be deemed the "**SCLC Post-Approval Commitment Studies Development Plan**". JDC approval shall not be required with regard to design, protocol and timeline of those SCLC Post-Approval Commitment Studies whose protocol has been submitted to FDA prior to the Effective Date of this Agreement. The JDC shall incorporate any comments of Jazz to the extent such comments are consistent with FDA requirements. Jazz shall conduct and be responsible, at its expense, for regulatory communications with the FDA regarding the SCLC Post-Approval Commitment Studies once Regulatory Approval by the FDA for Licensed Product in the SCLC Initial Indication has been transferred to Jazz pursuant to Section 5.2.

(ii) If PharmaMar is not [***], then Jazz shall have the right, exercisable upon written notice to PharmaMar, to conduct such SCLC Post-Approval Commitment Studies itself at PharmaMar's expense. In such event, Jazz shall prepare a proposed SCLC Post-Approval Commitment Studies Development Plan and a proposed budget for such SCLC Post-Approval Commitment Studies, including the number of FTEs to conduct such activities (the "**SCLC Post-Approval Commitment Studies Budget**"), which shall be reviewed, discussed and approved by the JDC. In such event, PharmaMar shall reimburse Jazz for one hundred percent (100%) of the Development Costs incurred in accordance with and up to [***] of the SCLC Post-Approval Commitment Studies Budget, as set forth in Section 8.3. Any amendment to SCLC Post-Approval Commitment Studies Budget shall be reviewed, discussed and approved by the JDC, with such approval by PharmaMar's members of the JDC not to be unreasonably withheld (it being understood that an example of unreasonably withholding approval would be to not approve an amendment to the SCLC Post-Approval Commitment Studies Budget if the SCLC Post-Approval Commitment Studies Development Plan is amended by JDC in a manner that implies a change, from the assumptions or the protocol which were taken into account at the time the initial SCLC Post-Approval Commitment Studies Budget was approved, for the purposes of fulfilling any FDA requirement with regard to such SCLC Post-Approval Commitment Studies).

(c) **No Additional Obligations.** Except as set forth in this Section 4.1 with respect to the Atlantis Trial and the SCLC Post-Approval Commitment Studies, PharmaMar shall have no further obligation to conduct any pre-clinical or clinical Development activities with respect to any Licensed Products.

4.2 Additional Indication Pivotal Trial

(a) **Proposed Additional Indication Pivotal Trial.** If PharmaMar wishes to conduct a Pivotal Trial for an Additional Indication that (i) is initiated [***] and (ii) such Pivotal Trial is sufficient to support the filing of an NDA with the FDA, as evidenced by an agreement with or statement from the FDA on a Special Protocol Assessment procedure or equivalent, or

other guidance or minutes issued by the FDA (each, a “**Proposed Additional Indication Pivotal Trial**”), then PharmaMar shall present to Jazz’s representatives at the JDC the proposed design of such Proposed Additional Indication Pivotal Trial, including the proposed protocol and budget for such study. The JDC shall discuss such Proposed Additional Indication Pivotal Trial at its next meeting, and PharmaMar shall provide, within [***] days after such JDC meeting (or such longer period of time as agreed upon in writing by the Parties), any additional information reasonably requested by Jazz’s JDC representatives prior to or during such JDC meeting.

(b) Additional Indication Pivotal Trial. If by the [***] day after the JDC meeting at which a particular Proposed Additional Indication Pivotal Trial is discussed (or such longer period of time as agreed upon in writing by the Parties) under to Section 4.5(a), Jazz has not notified PharmaMar that it believes that such Proposed Additional Indication Pivotal Trial is likely to have an Adverse Safety Impact, then such Proposed Additional Indication Pivotal Trial will be deemed an “**Additional Indication Pivotal Trial**” and the JDC shall review and approve a protocol for such Additional Indication Pivotal Trial and such approved protocol and the proposed budget for such Additional Indication Pivotal Trial shall be deemed an “**Additional Indication Pivotal Trial Development Plan**” and an “**Additional Indication Pivotal Trial Budget**”, respectively.

(c) Pivotal Trial Costs. On an Additional Indication Pivotal Trial-by-Additional Indication Pivotal Trial basis, within [***] days of the JDC’s approval of the applicable Additional Indication Pivotal Trial Development Plan and Additional Indication Pivotal Trial Budget, Jazz shall have the right to elect to either:

(i) have Jazz and PharmaMar share [***] all costs incurred to conduct such Additional Indication Pivotal Trial in accordance with Section 8.2 (any such Additional Indication Pivotal Trial, a “**Joint Additional Indication Pivotal Trial**” and the Additional Indication Pivotal Trial Development Plan and Additional Indication Pivotal Trial Budget therefor, a “**Joint Additional Indication Pivotal Trial Development Plan**” and “**Joint Additional Indication Pivotal Trial Budget**”, respectively); or

(ii) have PharmaMar pay [***] of all costs incurred to conduct such Additional Indication Pivotal Trial, in which case Sections 5.3(c)(ii) and 8.5 shall apply.

(d) Material Changes; Suspension or Termination.

(i) Each Party shall promptly inform the JDC of any material changes it wishes to make to a Joint Additional Indication Pivotal Trial and Joint Additional Indication Pivotal Trial Budget. All changes to any Joint Additional Indication Pivotal Trial Development Plan or Joint Additional Indication Pivotal Trial Budget and all suspensions or terminations of any Joint Additional Indication Pivotal Trial shall be by mutual agreement of the Parties’ representatives to the JDC.

(ii) PharmaMar shall promptly inform the JDC of any material changes it wishes to make to an Additional Indication Pivotal Trial that is not a Joint Additional Indication Pivotal Trial and the JDC shall review, discuss and approve any amendment to the Additional Indication Pivotal Trial Development Plan in accordance with Section 3.4. PharmaMar may

suspend or terminate an Additional Indication Pivotal Trial that is not a Joint Additional Indication Pivotal Trial after discussion at the JDC, but without obtaining approval from the JDC, if there is a Safety Reason or such suspension or termination is required by a Regulatory Authority or investigational review board.

(iii) Notwithstanding anything to the contrary in Section 4.2(d)(i), after transfer of Regulatory Approval and the associated Regulatory Filings to Jazz pursuant to Section 5.2, as the holder of the IND in the Jazz Territory, Jazz may require PharmaMar to suspend or terminate an Additional Indication Pivotal Trial in the Jazz Territory after discussion at the JDC, but without obtaining approval from the JDC, if there is a Safety Reason or such suspension or termination is required by a Regulatory Authority or investigational review board.

(iv) If any Party disputes the other Party's alleged Safety Reason, the Parties shall submit the dispute to an independent Third Party or committee (such as an investigator review board) to be appointed by both Parties jointly for determination of the existence or not of such Safety Reason. Determination by such independent Third Party shall be binding to the Parties.

(e) **PharmaMar Additional Indication Clinical Trial becomes a Pivotal Trial After Initiation.** In the event any PharmaMar Additional Indication Clinical Trial becomes a Pivotal Trial after Initiation of such Clinical Trial, then such PharmaMar Additional Indication Clinical Trial shall thereafter be deemed an Additional Indication Pivotal Trial and PharmaMar shall provide prompt written notice thereof to Jazz. Such written notice shall include a copy of the protocol for such Clinical Trial. Within [***] days of such notification, PharmaMar shall provide to Jazz a complete accounting of all Pivotal Trial Costs (as such term is modified *mutatis mutandis* to apply to such Clinical Trial) incurred to date and a proposed plan and budget for all additional activities and anticipated costs for conducting the remainder, if any, of such Clinical Trial for review and approval by the JDC (such plan after such approval be deemed an Additional Indication Pivotal Trial Development Plan and such accounting, together with the proposed budget, shall after such approval be deemed an Additional Indication Pivotal Trial Development Budget). Notwithstanding the timing set forth in Section 4.2(c), within [***] days of the JDC's approval of the Additional Indication Pivotal Trial Development Budget for any such Additional Indication Pivotal Trial pursuant to this Section 4.2(e), Jazz shall have the right to elect to either:

(i) [***] all Pivotal Trial Costs incurred to conduct such Additional Indication Pivotal Trial in accordance with Section 8.2 as set forth in Section 4.2(c)(i), in which case (1) PharmaMar shall include in the next Reconciliation Report pursuant to Section 8.2 [***] of all Pivotal Trial Costs incurred in connection with such Additional Indication Pivotal Trial as of such election, (2) such Additional Indication Pivotal Trial shall be deemed to be a Joint Additional Indication Pivotal Trial, (3) such Additional Indication Pivotal Trial Plan shall be deemed to be a Joint Additional Indication Pivotal Trial Plan and (4) such Additional Indication Pivotal Budget shall be deemed to be a Joint Additional Indication Pivotal Budget; or

(ii) have PharmaMar pay one hundred percent (100%) of all costs incurred to conduct such Additional Indication Pivotal Trial as set forth in Section 4.2(c)(ii).

4.3 Other Development Rights.

(a) Except with respect to the Atlantis Trial, the SCLC Post-Approval Commitment Studies and the Additional Indication Pivotal Trials addressed under Sections 4.1 and 4.2, each Party shall be entitled to conduct in its Territory any research and pre-clinical, clinical or other Development activities, including, without limitation, the conduct of Clinical Trials and Pivotal Trials with respect to Licensed API or Licensed Product for the purposes of obtaining or expanding Regulatory Approval of Licensed Product in its Territory at its sole responsibility and cost and without any prior approval by the JDC, but (i) with prior discussion by the JDC with respect to any Jazz Additional Indication Clinical Trial and PharmaMar Additional Indication Clinical Trial and (ii) with the JDC being informed of any other Clinical Trials.

(b) In addition, each Party shall be entitled to conduct any research and preclinical development activities in the other Party's Territory at its sole discretion and expense and shall keep the other Party, through the JDC, regularly informed about such development activities provided however that no prior approval of those activities by the JDC would be required for its conduct.

(c) Jazz shall be entitled to conduct Clinical Trials (other than Medical Affairs Clinical Trials) in Additional Indications other than Additional Indication Pivotal Trials within the [***] ("**Jazz Additional Indication Clinical Trials**"), provided that prior to initiation of any Jazz Additional Indication Clinical Trials, Jazz will inform the JDC about such intended Jazz Additional Indication Clinical Trials for review and discussion by the JDC provided that, except as set forth in Section 3.4(b), Jazz shall have final decision making about Jazz Additional Indications Clinical Trials in [***]. Except as provided herein for research and preclinical Development activities in the PharmaMar Territory and for Jazz Additional Indication Clinical Trials in [***], Jazz shall have no other right to conduct Development activities in the PharmaMar Territory. PharmaMar shall ensure that any Third Party Partner agreement entered into after the Effective Date includes the right for Jazz and its Affiliates and Sublicensees to conduct Jazz Additional Indication Clinical Trials in such Third Party Partner's territory in a manner consistent with the terms of this Agreement, provided however that such rights may be subject to such Third Party Partner's prior written consent on a Clinical Trial by Clinical Trial basis provided that such Third Party Partner's Clinical Trials in the Jazz Territory are subject to Jazz's prior written consent.

(d) PharmaMar shall be entitled to conduct Clinical Trials (other than Medical Affairs Clinical Trials) in Additional Indications other than Additional Indication Pivotal Trials in the Jazz Territory ("**PharmaMar Additional Indication Clinical Trials**") provided that prior to initiation of any PharmaMar Additional Indication Clinical Trials, PharmaMar will inform the JDC about such intended PharmaMar Additional Indication Clinical Trials for review and discussion by the JDC provided that, except as set forth in Section 3.4(b), PharmaMar shall have final decision making about PharmaMar Additional Indications Clinical Trials in the PharmaMar Territory. For clarity, PharmaMar Additional Indication Clinical Trials shall include any Pivotal Trial in an Additional Indication which is [***]. Except as provided herein for research and preclinical Development activities and for PharmaMar Additional Indication Clinical Trials in the Jazz Territory, PharmaMar shall have no other right to conduct Development activities in the Jazz Territory.

4.4 Performance Standards. Each Party shall conduct, or have conducted, all Licensed API and Licensed Product Development, manufacture and registration activities performed by it or on its behalf in good scientific manner and in compliance with all Applicable Laws and, as applicable, GLP, GCP and/or GMP.

4.5 Exchange of Data. On an ongoing basis during the Term, each Party shall disclose to the other Party all Licensed Product Data generated by such Party or its Affiliates (or in the case of PharmaMar, its Third Party Partners or in the case of Jazz, its Sublicensees). Each Party and its Affiliates shall have the right to use the Licensed Product Data disclosed by the other Party, for the purpose of obtaining and maintaining Regulatory Approval within its respective Territory of Licensed Products in the Licensed Indications. Subject to Section 2.8, PharmaMar shall have the right to sublicense [***] such right to use such Licensed Product Data to its Third Party Partners in the PharmaMar Territory if and only if such Third Party Partners are obligated to share all Licensed Product Data generated by them or on their behalf with Jazz for Jazz's and its Affiliates' use in the Jazz Territory at no cost to Jazz.

5. REGULATORY

5.1 Initial SCLC NDA.

(a) Responsibility. PharmaMar, through its Affiliate based in the U.S., shall (i) submit an NDA for the Licensed Product in the SCLC Initial Indication under the Subpart H regulations or their equivalent (the "**Initial SCLC NDA Filing**") and (ii) be responsible for prosecuting such Initial SCLC NDA Filing until such time as the FDA grants NDA Approval. Notwithstanding the foregoing, if the FDA issues a Complete Response Letter or a refusal to file with respect to the Initial SCLC NDA Filing, Jazz shall have the right, in its sole discretion and exercisable upon written notice to PharmaMar, to assume responsibility for responding to such Complete Response Letter or refusal to file, as applicable, and continuing to prosecute the Initial SCLC NDA Filing. Upon any such election by Jazz, PharmaMar shall promptly transfer the Initial SCLC NDA Filing to Jazz and shall, at the request of Jazz, cooperate with and provide assistance to Jazz with respect to such efforts. In the event Jazz does not elect to have the Initial SCLC NDA Filing transferred to Jazz, PharmaMar shall remain responsible for responding to such Complete Response Letter or refusal to file, as applicable, and shall use Commercially Reasonable Efforts to perform all activities required or reasonably useful to obtain NDA Approval for the Licensed Product for the SCLC Initial Indication as soon as possible after such Complete Response Letter or refusal to file, as applicable.

(b) Initial SCLC NDA Cooperation. Jazz shall have the right to participate in PharmaMar's internal discussions regarding regulatory strategy for the SCLC Initial Indication and to participate in all substantive discussions, communications and meetings with the FDA regarding the SCLC Initial Indication or the Initial SCLC NDA Filing. Without limiting the generality of the foregoing, PharmaMar shall provide Jazz with drafts of proposed Regulatory Filings with respect to the Initial SCLC NDA Filing reasonably in advance of submission to the FDA and Jazz shall have the right to review and comment on such Regulatory Filings prior to submission to the FDA. PharmaMar shall [***]. PharmaMar shall promptly provide Jazz with copies of all correspondence received from the FDA with respect to the Initial SCLC NDA Filing. Jazz, at PharmaMar's request, shall use Commercially Reasonable Efforts to assist PharmaMar with respect to the Initial SCLC NDA Filing by providing access to its internal and external experts and reviewing the filing for technical compliance with the electronic filing requirements of the FDA.

(c) **Labeling.** Notwithstanding the foregoing in this Section 5.1, Jazz shall have final decision-making authority regarding all discussions with the FDA regarding labelling of the Licensed Product for the SCLC Initial Indication, provided, that (i) if [***], (ii) Jazz notifies PharmaMar that Jazz intends to [***] and (iii) PharmaMar [***], the Parties agree to [***]. If Jazz's [***], then it may exercise its final decision-making authority to implement such choice. If Jazz's [***], then it shall [***]. For the avoidance of doubt, it shall be [***]. The [***] shall be [***]; if the Parties do not [***], then each Party shall [***].

(d) Jazz shall exercise the rights provided for in Sections 5.1(b) and (c) in a prompt manner including, without limitation, exercising its final decision-making authority with respect to labeling within [***] Business Days of PharmaMar's request. Any exercise of Jazz's final decision-making authority under Section 5.1(c) shall include an accurate summary description of Jazz's reasons for such exercise.

(e) **Cooperation.** Without limiting the generality of Section 5.5(b)(i), at Jazz's reasonable request, PharmaMar shall reasonably cooperate and assist Jazz in facilitating launch activities with respect to the Licensed Product in the SCLC Initial Indication in the Jazz Territory, including cooperation and assistance with respect to preparing and submitting any Regulatory Filings relating to labeling, packaging materials and submission of the secondary packaging contractor designated by Jazz and with respect to discussions with the FDA related thereto.

5.2 Transfer of Regulatory Approval. Promptly after receipt of any Regulatory Approval by the FDA for a Licensed Product in the SCLC Initial Indication, PharmaMar shall, transfer and assign to Jazz such Regulatory Approval and all Regulatory Filings for a Licensed Product in the Jazz Territory and shall transfer to Jazz all Licensed Product Data and PharmaMar Know-How not previously transferred to Jazz, except for the DMF, which shall be maintained by and in the name of PharmaMar. For these purposes, Jazz shall promptly submit the required Regulatory Filings to the FDA for such transfer, documenting Jazz's commitment to agreements, promises, and conditions made by PharmaMar in the NDA or IND and the effective date of the change in ownership of the Regulatory Approval. Cost of such transfer shall be borne by both Parties equally. After transfer of the Regulatory Approval to Jazz pursuant to this Section 5.2 on a NDA Approval that is not a Full Approval, Jazz shall use Commercially Reasonable Efforts to achieve the next Regulatory Milestone that is based on Full Approval.

5.3 Additional Transfer of Regulatory Data. After transfer of the Regulatory Approval to Jazz, PharmaMar will provide completed clinical study reports (CSRs) and submission-ready analysis datasets to Jazz for any of the studies supporting the Regulatory Approval by the FDA for a Licensed Product in the SCLC Initial Indication (including the Atlantis Trial and the SCLC Post-Approval Commitment Studies) promptly after such reports and datasets are available. In addition, PharmaMar will also provide to Jazz, prior to database lock for cross-trial comparison of the Atlantis Trial, the pre-specified statistical analysis plan for cross-trial comparison of the treatment arm of the Atlantis Trial with the monotherapy data from PharmaMar's Clinical Trial known as PM1183-B-005-14 (i.e. the "basket trial"), which comparison will be submitted to the FDA to support the granting of Full Approval.

5.4 Expanded Access Program. Jazz acknowledges that PharmaMar has entered into a master service agreement and a related work order with [***] effective on [***], a copy of which has been provided to Jazz prior to the Effective Date of this Agreement, under which [***] is providing PharmaMar with services related to the set up and delivery of an EAP for the Licensed Product in the Jazz Territory in the SCLC Indication (“**EAP Agreement**”). Jazz shall have the right to choose between: (i) having the EAP Agreement assigned by PharmaMar to Jazz; in which case, Jazz shall assume PharmaMar’s post-assignment obligations under the EAP Agreement, including payment of any service fees and other expenses due to Bionical Inc. after the assignment date; provided however that PharmaMar would remain responsible for the supply of the Licensed Product under the EAP Agreement at Jazz’s expense solely until the time Jazz is able to supply the Licensed Product for EAP itself or (ii) having PharmaMar terminate the EAP Agreement in accordance with the EAP Agreement provisions, in which case PharmaMar shall retain all obligations under the EAP Agreement. Jazz shall notify PharmaMar of its decision regarding the EAP Agreement within [***] from the HSR Clearance Date. For clarity, Jazz acknowledges and agrees that the existence of EAP Agreement shall not, by itself, be deemed a breach by PharmaMar of the exclusive rights and licenses granted to Jazz pursuant to this Agreement or of any representation, covenant or any other provision of this Agreement.

5.5 Jazz Territory.

(a) Regulatory Responsibility in the Jazz Territory. Except as for the DMF and any development activity PharmaMar is entitled to conduct in the Jazz Territory under its own IND, after transfer to Jazz of a Regulatory Approval by the FDA for a Licensed Product in the SCLC Initial Indication pursuant to Section 5.2 or after Jazz’s election to assume responsibility for responding to such Complete Response Letter pursuant to Section 5.1(a), Jazz:

- (i) shall have the sole right to prepare and file for all Regulatory Approvals for Licensed Products in the Licensed Indication in the Jazz Territory;
- (ii) shall have the sole right to communicate with the FDA with respect to Licensed Products in the Licensed Indication;
- (iii) shall use Commercially Reasonable Efforts to obtain pricing and reimbursement approvals for each Licensed Product in the Licensed Indication, to the extent required by Applicable Law in the Jazz Territory;
- (iv) shall be solely responsible for conducting pricing and reimbursement negotiations in the Jazz Territory for each Licensed Product in the Licensed Indication; and
- (v) shall own all Regulatory Filings (including Regulatory Approvals) for each Licensed Product in the Licensed Indication in the Jazz Territory.

(b) Cooperation.

(i) Each Party shall, at the other Party's request, provide reasonable assistance with respect to regulatory matters concerning the Licensed Products in the other Party's Territory, including assistance with respect to Regulatory Filings required to obtain or maintain Regulatory Approval for a Licensed Product in the other Party's Territory. Without limiting the generality of the foregoing, PharmaMar shall consult with Jazz and provide Jazz with all CMC documents and information related to Licensed Products and all Licensed Product Data included within the Initial SCLC NDA Filing, except those CMC Information of Licensed API which is included in any section of the DMF other than Section S of Module 3 of the NDA and not otherwise publicly available. In the event that PharmaMar anticipates changes in the manufacture of the Licensed API which may impact the regulatory status of the Licensed Product in the Jazz Territory, the Parties shall review such changes and potential outcomes so Jazz may take the appropriate steps to support the Regulatory Filings. Except as expressly set forth in Section 5.1, with respect to the DMF or manufacture and development activities in the Jazz Territory that PharmaMar is entitled to conduct under this Agreement, or as otherwise expressly requested by Jazz in writing, PharmaMar (i) shall not submit any Regulatory Filings for Licensed Products in the Jazz Territory without the prior written consent of Jazz and (ii) shall not communicate with respect to the Licensed Products with the FDA, unless so required to comply with Applicable Law in the Jazz Territory, in which case PharmaMar shall promptly notify Jazz of such requirement under Applicable Law and, to the extent practicable and permitted under Applicable Law, shall submit any proposed communication to Jazz for prior approval or, if not practicable or permitted, shall provide Jazz with a copy or summary thereof as soon as reasonably practicable thereafter.

(ii) After transfer to Jazz of Regulatory Filings and Regulatory Approvals for a Licensed Product in the SCLC Initial Indication pursuant to Section 5.2 or after Jazz's election to assume responsibility for responding to such Complete Response Letter or refusal to file pursuant to Section 5.1(a), Jazz shall provide PharmaMar with drafts of proposed Regulatory Filings reasonably in advance of submission to the FDA or any other Regulatory Authority and PharmaMar shall have the right to review and comment on such Regulatory Filings prior to submission to Regulatory Authorities. Jazz shall [***]. Jazz shall promptly provide PharmaMar with copies of all material correspondence, Regulatory Filings and Regulatory Approvals received from the Regulatory Authorities with respect to the Licensed Product. To the extent allowed by the Regulatory Authorities, PharmaMar shall have the right to attend and participate with up to [***] representatives in all substantive meetings with the Regulatory Authorities with regard to Licensed Product.

(c) Additional Indications in the Jazz Territory.

(i) In the event that PharmaMar intends to conduct one or more Proposed Additional Indication Pivotal Trial, upon the written request of PharmaMar, in a manner consistent with the guidance and decisions of the JDC, Jazz shall promptly seek FDA guidance to ascertain if such Proposed Additional Indication Pivotal Trial would be a registration trial sufficient to support the filing of a NDA as evidenced by an agreement with or statement from the FDA on a special protocol assessment procedure or equivalent. Additionally, upon the written request of PharmaMar, in a manner consistent with the guidance and decisions of the JDC, Jazz shall seek to hold a pre-NDA meeting with the FDA to discuss the NDA related to the data obtained from an Additional Indication Pivotal Trial. To the extent allowed by the FDA, PharmaMar shall

have the right to attend and participate in such meetings with the FDA. PharmaMar shall be responsible, at its own cost, for preparing all documents and materials reasonably necessary for any such special protocol assessment procedure or pre-IND meeting with the FDA. PharmaMar shall reimburse Jazz's costs and expenses (including FTE Costs) incurred in connection with such activities under this Section 5.5(c)(i) to the extent that, on an FDA interaction-by-FDA interaction basis, such costs do not exceed [***].

(ii) If any Joint Additional Indication Pivotal Trial obtains Positive Results, Jazz shall use Commercially Reasonable Efforts to obtain Regulatory Approval from the FDA for such Additional Indication.

(iii) If any Additional Indication Pivotal Trial (other than a Joint Additional Indication Pivotal Trial) obtains Positive Results and Jazz determines in good faith that it will be profitable for Jazz to Commercialize the Licensed Product in such Additional Indication (which profitability determination shall take into account, without limitation, the probability of obtaining Regulatory Approval and the cost of obtaining Regulatory Approval and making the applicable Additional Indication Regulatory Milestone payment, *provided, that*, the profitability determination shall not take into account any potential loss of sales from a product (other than a Licensed Product) that was being developed or commercialized by Jazz or its Affiliates at the time such Additional Indication Pivotal Trial was Initiated), Jazz shall use Commercially Reasonable Efforts to obtain Regulatory Approval from the FDA for such Additional Indication. Prior to filing an NDA for such Additional Indication, if such Additional Indication is [***], Jazz shall provide written notice to PharmaMar of Jazz's good faith determination whether such Additional Indication is a Major Tumour, which determination shall be based on [***].

(iv) If Jazz determines in good faith that it would not be profitable for Jazz to Commercialize the Licensed Product in such Additional Indication, Jazz shall provide PharmaMar with a detailed information and breakdown of Jazz's calculations for such determination. If PharmaMar disputes whether such non-profitability determination was made by Jazz in good faith, the Parties agree to submit the dispute to [***] for final determination of whether such determination was made by Jazz in good faith or not. Once the IMRC makes such determination, it shall be fully applicable and binding on the Parties.

(v) If Jazz determined that such Additional Indication is not a Major Tumour but PharmaMar believes in good faith, based on the same factors, that such Additional Indication [***] and as a result should be classified as a Major Tumour, then such dispute shall be resolved by an independent Third Party expert experienced in determining treatable patient populations in the U.S. (the "**Expert**") as mutually agreed upon by the Parties. If the Parties cannot agree upon any such Expert within [***] days, then each Party shall propose one expert having such experience and such two proposed experts shall jointly select the Expert. Within [***] days of the selection of the Expert, each party shall submit to the Expert and the other Party such information concerning [***]. The Expert shall determine whether or not such Additional Indication [***] and as a result should or should not be classified as a Major Tumour. The determination of the Expert shall be final and binding on the Parties, absent manifest error.

(vi) If any Additional Indication Pivotal Trial obtains Positive Results and Jazz determines in good faith that it would not be profitable for Jazz to Commercialize the

Licensed Product in such Additional Indication, Jazz shall use Commercially Reasonable Efforts, upon PharmaMar's reasonable request, to include such Additional Indication in the NCCN Guidelines or any equivalent guidelines. In addition, Jazz shall also use Commercially Reasonable Efforts to include an Additional Indication in the NCCN Guidelines or any equivalent guidelines, upon PharmaMar's reasonable request, if PharmaMar conducts a Pivotal Trial in such Additional Indication that does not fulfill the conditions for being a Proposed Additional Indication Pivotal Trial but that obtains Positive Results.

(d) Drug Master File. PharmaMar shall file a Type II drug master file as described in and in accordance with the 21 CFR 314.420 (each, a "DMF") with the FDA for the Licensed API and shall provide the appropriate authorizations to the FDA in order to grant Jazz (or its Affiliates or Sublicensees) the right to reference such DMF. PharmaMar shall be responsible for maintaining such DMF in accordance with Applicable Laws and ensuring that all Licensed Product Data incorporated therein is accurate and current as necessary to support filing and prosecuting the applicable Regulatory Filing and obtaining and maintaining the applicable Regulatory Approval for any Licensed Product hereunder. PharmaMar shall permit Jazz to access, and shall provide Jazz with true and complete copies of, [***]. Except to the extent that the following would require disclosure of the contents of any section of the DMF other than [***], PharmaMar shall (i) provide Jazz with drafts of proposed Regulatory Filings related to such DMF reasonably in advance of submission to the FDA for Jazz's review and comment, (ii) consider Jazz's comments in good faith, and (iii) provide Jazz with copies of all material correspondence received from the FDA with respect to such DMF.

(e) Other PharmaMar Regulatory Filings. With respect to all Regulatory Filings (other than the Initial SCLC NDA Filing) made by PharmaMar with the FDA regarding development activities with regard to Licensed Product in the Jazz Territory that PharmaMar is entitled to conduct under this Agreement, PharmaMar shall provide Jazz with drafts of such Regulatory Filings reasonably in advance of submission to the FDA. Jazz shall have the right to review and comment on such Regulatory Filings prior to submission to the FDA, and PharmaMar shall [***]. PharmaMar shall promptly provide Jazz with copies of all material correspondence received from the FDA with respect thereto.

5.6 PharmaMar Territory.

(a) Regulatory Responsibility in the PharmaMar Territory. PharmaMar shall be responsible for preparing and filing for all Regulatory Approvals for Licensed Products in the Licensed Indication in the PharmaMar Territory and for communicating with all Regulatory Authorities with respect to Licensed Products in the Licensed Indication in the PharmaMar Territory. PharmaMar shall own all Regulatory Filings (including all Regulatory Approvals) for each Licensed Product in the Licensed Indication in the PharmaMar Territory. PharmaMar shall provide Jazz with copies of material Regulatory Filings for Licensed Products in the PharmaMar Territory and material correspondence received from any Regulatory Authority in the PharmaMar Territory related to Licensed Products. To the extent allowed by the applicable Regulatory Authority, Jazz shall have the right to have [***] representatives attend any material meetings with any Regulatory Authority in the PharmaMar Territory relating to Licensed Products. For the avoidance of doubt, notwithstanding Section 5.6 PharmaMar's material Regulatory Filings,

Regulatory Approvals and material correspondence received from Regulatory Authorities shall be deemed solely material Regulatory Filings and Regulatory Approvals filed and/or granted, as applicable, before/by [***] with regard to Licensed Products and material communications with such Regulatory Authorities associated thereto. Such documentation shall be provided in the languages that PharmaMar receives such documentation in, provided, that, if PharmaMar or its Affiliates translates any such documentation, PharmaMar shall also provide such translated versions to Jazz.

(b) Clinical Trials Conducted by Jazz. Upon the written request of Jazz, in a manner consistent with the guidance and decisions of the JDC, PharmaMar shall seek to hold meetings with the [***] to discuss the conduct of any Jazz Additional Indication Clinical Trial and Additional Indication Pivotal Trial of a Licensed Product conducted by Jazz [***]. To the extent allowed by the [***], Jazz shall have the right to attend and participate in all meetings with the [***] related to any Jazz Additional Indication Clinical Trial and Additional Indication Pivotal Trial of a Licensed Product conducted by Jazz [***]. Jazz shall reimburse all of PharmaMar's out-of-pocket costs associated with such activities.

(c) Other Jazz Regulatory Filings. With respect to Regulatory Filings made by Jazz with any Regulatory Authority in the PharmaMar Territory regarding development activities that Jazz is entitled to conduct under this Agreement in PharmaMar Territory, Jazz shall provide PharmaMar with drafts of such Regulatory Filings reasonably in advance of submission to any Regulatory Authority in the PharmaMar Territory. PharmaMar shall have the right to review and comment on such Regulatory Filings prior to submission to Regulatory Authorities in PharmaMar Territory, and Jazz shall [***]. Jazz shall promptly provide PharmaMar with copies of all material correspondence received from Regulatory Authorities of PharmaMar Territory with respect thereto.

5.7 Reporting. Each Party shall keep the other Party informed on an on-going and regular basis regarding its (or its Affiliate's or Third Party Partner's) regulatory strategy, planned regulatory submission and material communications regarding Licensed Products with Regulatory Authorities in [***], as applicable.

5.8 Notification of Threatened Action. Each Party shall immediately notify the other Party of any information it receives regarding any material threatened or pending action, inspection or communication by or from any Third Party, including without limitation a Regulatory Authority, which may materially affect the Development, Commercialization or regulatory status of a Licensed Product in the Licensed Indication, including any issuance of notices of inspections, inspection reports and receipt of compliance violation letters in any country of their respective Territories. Upon receipt of such information, the Parties shall consult with each other and assist each other in gathering and evaluating relevant information related thereto.

5.9 Remedial Actions. Each Party will notify the other Party immediately, and promptly confirm such notice in writing, if it obtains information indicating that the Licensed Product may be subject to any recall, market withdrawal, corrective action or other regulatory action with respect to a Licensed Product taken by virtue of Applicable Laws (a "**Remedial Action**"). The Parties will assist each other in gathering and evaluating such information as is necessary to determine the necessity of conducting a Remedial Action. Each Party shall, and shall

ensure that its Affiliates and Third Party Partners will, maintain adequate records to permit the Parties to trace the manufacture, distribution and use of the Licensed Product. In the event Jazz determines that any Remedial Action with respect to a Licensed Product in the Licensed Indication in the Jazz Territory should be commenced or is required by the FDA, Jazz shall have the right, at its expense, to control and coordinate all efforts necessary to conduct such Remedial Action.

5.10 Rights of Access and Reference to Regulatory Documents.

(a) Jazz hereby grants to PharmaMar (and its Affiliates and Third Party Partners in the PharmaMar Territory) the right to access and reference all Regulatory Filings submitted to, and Regulatory Approvals obtained from, the FDA by Jazz or its Affiliates for Licensed Products and to use the Licensed Product Data therein; in each case, solely for the purposes of (i) obtaining and maintaining Regulatory Approvals for Licensed Products in the Licensed Indication in the PharmaMar Territory, (ii) complying with applicable pharmacovigilance and other regulatory requirements with respect to Licensed Products in the PharmaMar Territory and (iii) exercising its rights and performing its obligations under this Agreement. Jazz shall, promptly upon PharmaMar's request, file with the applicable Regulatory Authority(ies) such letters of access or reference as may be necessary to accomplish the intent of this Section 5.10(a).

(b) PharmaMar hereby grants to Jazz (and its Affiliates) the right to access and reference all Regulatory Filings submitted to, and Regulatory Approvals obtained from, any Regulatory Authority in the PharmaMar Territory by PharmaMar (and its Affiliates and Third Party Partners in the PharmaMar Territory) for Licensed Products and to use the Licensed Product Data therein; in each case, solely for the purposes of (i) obtaining and maintaining Regulatory Approvals for Licensed Products in the Licensed Indication in the Jazz Territory, (ii) complying with applicable pharmacovigilance and other regulatory requirements with respect to Licensed Products in the Jazz Territory and (iii) exercising its rights and performing its obligations under this Agreement. PharmaMar shall, promptly upon Jazz's request, file with the applicable Regulatory Authority(ies) such letters of access or reference as may be necessary to accomplish the intent of this Section 5.10(b).

5.11 Safety Data Exchange. Each Party shall be solely responsible, at its own expense, for complying with all applicable regulatory requirements with respect to Licensed Products in such Party's Territory, including all safety reporting to Regulatory Authorities in such Party's Territory. The Parties shall, promptly after the Effective Date (but in any event within [***] days after the Effective Date), negotiate in good faith and enter into a pharmacovigilance/safety data exchange agreement for Licensed Products (the "**PV Agreement**"), which shall set forth standard operating procedures governing the collection, investigation, reporting, and exchange of information concerning adverse drug reactions/experiences. The terms of the PV Agreement shall be sufficient to permit each Party to comply with its regulatory and legal requirements for the management and reporting of safety data regarding such Licensed Products by providing for the exchange of relevant information in appropriate format within applicable timeframes.

6. MANUFACTURING.

6.1 Supply Agreement. Within [***] days of the Effective Date (or such longer period of time as agreed upon by the Parties), the Parties shall execute a supply agreement pursuant to which PharmaMar shall manufacture and supply to Jazz quantities of Bulk Vials for the launch and ongoing supply of Licensed API, in each case in accordance with this Article 6 and such supply agreement, which shall incorporate the terms set forth on **Exhibit E**, including the definition of “**Supply Failure**” which, if triggered, would give Jazz the right under the Jazz License to manufacture or have manufactured Licensed API and to receive a technology transfer to enable such manufacturing (the “**Supply Agreement**”).

6.2 Quality Agreement. PharmaMar and Jazz shall execute a mutually acceptable quality agreement (the “**Quality Agreement**”), which shall be attached to the Supply Agreement, that allocates roles and responsibilities to each Party with respect to quality control and regulatory compliance with respect to the manufacture and supply of Finished Product, Bulk Vials and Licensed API under the Supply Agreement.

6.3 Technology Transfer. Promptly after signing the Supply Agreement, to the extent [***], PharmaMar shall, [***], commence a technology transfer to a Third Party contract manufacturer [***] of all Information, including PharmaMar Know-How, which is reasonably necessary or is otherwise used in the manufacture and supply of Licensed Product for the Jazz Territory from the Licensed API to be supplied by PharmaMar (or its designee) pursuant to the Supply Agreement.

6.4 Launch Responsibilities. Jazz shall be responsible for secondary manufacturing of the Finished Product, including the product required for the initial launch of the Licensed Product in the Jazz Territory in a timely manner from Bulk Vials supplied by PharmaMar pursuant to Supply Agreement. Jazz shall be responsible to prepare, file and obtain, at its sole expense, any Regulatory Approval necessary to perform secondary packaging manufacturing activities of Bulk Vials supplied by PharmaMar at the secondary packager designated by Jazz as well as to obtain Regulatory Approvals required for packaging materials for the Licensed Product with Jazz trade dress once the initial Regulatory Approval of the Licensed Product in SCLC Initial Indication has been transferred to Jazz, pursuant to Section 5.2.; at Jazz’s request, PharmaMar shall file the Regulatory Filings prepared by Jazz, and obtain such Regulatory Approvals, before such transfer but in this case solely to the extent that the filing and obtaining any such required Regulatory Filing and Regulatory Approvals for secondary packaging site and Jazz packaging materials do not interfere with Initial SCLC NDA Filing review and evaluation by the FDA.

In order for Jazz to comply with its obligations under the first sentence of Section 7.3 and hereunder, PharmaMar shall reasonably cooperate with and assist Jazz in establishing a viable program for a rapid launch, which shall include PharmaMar importing into the Jazz Territory Bulk Vials of Licensed Product to be purchased by Jazz and delivery of such Bulk Vials to the secondary packager designated by Jazz prior to first Regulatory Approval for the Licensed Product.

7. COMMERCIALIZATION

7.1 Commercialization in the Jazz Territory. Subject to Section 7.9, Jazz shall have the exclusive right to conduct, and be solely responsible for all aspects of, the Commercialization of Licensed Products in the Licensed Indication in the Jazz Territory, including: (a) developing and executing a commercial launch and pre-launch plan, (b) negotiating with applicable Governmental Authorities regarding the price and reimbursement status of Licensed Products, (c) marketing and promotion, (d) booking sales and distribution and performance of related services, (e) handling all aspects of order processing, invoicing and collection, inventory and receivables, (f) providing customer support, including handling medical queries, and performing other related functions, and (g) conforming its practices and procedures to Applicable Laws relating to the marketing, detailing and promotion of Licensed Products in the Jazz Territory (collectively, the “**Commercialization Activities**”). Subject to Section 7.9, as between the Parties, Jazz shall bear all of its costs and expenses incurred in connection with such commercialization activities in the Jazz Territory.

7.2 Commercialization in the PharmaMar Territory. As between the Parties, PharmaMar will have the exclusive right to conduct, and be solely responsible for all aspects of, the Commercialization of Licensed Products in the Licensed Indication in the PharmaMar Territory, including the Commercialization Activities, and PharmaMar shall bear all of its costs and expenses incurred in connection with such commercialization activities in the PharmaMar Territory.

7.3 Commercial Diligence. Jazz shall commence Commercialization of the Licensed Product in the Jazz Territory as soon as practical after receipt of the Regulatory Approval for a Licensed Product for the SCLC Initial Indication in the Jazz Territory. After such receipt of Regulatory Approval, Jazz shall use Commercially Reasonable Efforts to Commercialize such Licensed Product in the Jazz Territory.

7.4 Sales Force. Jazz shall provide incentives consistent with Jazz’s standards to its Sales Force involved in the Commercialization of the Licensed Product in the Jazz Territory. Jazz is responsible for the recruitment and training of its Sales Force for the Jazz Territory. Jazz shall periodically provide training to its Sales Force including training in relation to Applicable Law and codes of practice applicable to Sales Force activities. Jazz shall be responsible of preparing any training materials for its Sales Force training.

7.5 Annual Commercialization Plan.

(a) Jazz shall have the sole and final authority to determine the Annual Commercialization Plan. The initial Annual Commercial Plan will be prepared and presented to PharmaMar no later than [***] months prior to the expected First Commercial Sale of the Licensed Product in the Jazz Territory and shall include, to the extent consistent with Jazz’s standard practice for the preparation of commercialization plans for its other products, a comprehensive and, prior to launch, [***]. Thereafter, Annual Commercialization Plan will be updated on a Calendar Year basis before the start of the applicable Calendar Year. Each Annual Commercialization Plan will be shared with PharmaMar for good faith review and discussion and Jazz will respond to one set of reasonable inquiries from PharmaMar, provided that final content of the Annual

Commercialization Plan shall be determined solely by Jazz consistent with its diligence obligations pursuant to Section 7.3. For clarity, the content of Annual Commercialization Plan shall be deemed legally non-binding on Jazz and Jazz may change the Annual Commercialization Plan any time and anyhow as it may consider appropriate provided any such change is consistent with its diligence obligations pursuant to Section 7.3.

(b) The Annual Commercialization Plan will contain, in addition to the content referred subsection (a) above for the first Annual Commercialization Plan, at minimum, the following elements: (i) the [***], (ii) the minimum [***], (iii) high level description of the Licensed Product positioning, [***], (iv) high level description of any training programs to be conducted, (v) high level description of the specifications for the development of marketing materials, (vi) anticipated dates for the commercial launch in the Jazz Territory, (vii) high level description of the general [***], (viii) publication plan, (ix) such other information relating to the Commercialization of the Product in the Territory, as deemed advisable by Jazz, and (x) an annualized sales forecast for the Jazz Territory, measured by units of the Licensed Products forecasted to be sold during the applicable Calendar Year, each of the foregoing (i) through (x) to the extent consistent with Jazz's standard practice for the preparation of commercialization plans for its other products.

7.6 Commercialization Materials.

(a) Each Party shall promptly supply to the other Party at cost with one (1) copy in a format agreeable to both Parties (e.g., paper, electronic or digital), in accordance with such other Party's reasonable requests, of each core form of marketing, advertising and promotional materials, and training manuals for its or its Affiliates' medical and sales representatives, that are necessary or useful with respect to the Commercialization of the Licensed Product (collectively "**Commercialization Materials**") and such other Party (including PharmaMar's Third Party Partners) shall have the right to reproduce, translate, use, directly or indirectly, any such Commercialization Materials in connection with the Commercialization of the Licensed Product. PharmaMar shall use Commercially Reasonable Efforts to obtain from its Third Party Partners and provide Jazz with one (1) copy of all such Commercialization Materials used by such Third Party Partners in PharmaMar Territory, including the right for Jazz to reproduce, translate and use the same in connection with the Commercialization of the Product in the Jazz Territory.

(b) Jazz shall be responsible for preparing, at its own cost, all Commercialization Materials for the launch of the Licensed Product in the Jazz Territory ("**Launch Materials**"), such Launch Materials to be submitted to Regulatory Authorities as may be required by Applicable Law.

7.7 Commercialization Compliance. Each Party undertakes hereby to comply, with regard to all Commercialization Materials (including websites, e-commerce and other Internet uses) and Commercialization activities conducted, with all Applicable Laws in its respective Territory and the Pharmaceutical Research and Manufacturers of America ("**PhRMA**") Code of Pharmaceutical Marketing Practices (the "**PhRMA Code**"). Each Party shall promptly notify the other Party of and provide a copy of any material correspondence or other reports with respect to promotion of the Licensed Product submitted to or received from a Regulatory Authority or other Governmental Authority relating to compliance with Applicable Law in conducting the activities contemplated by this Agreement.

7.8 Annual Sales Performance.

(a) Annual Sales Forecast Plan.

(i) Before the end of each Calendar Year during the ASFP Term, Jazz will submit to PharmaMar a proposed annualized sales forecast for the Jazz Territory, measured by units of the Licensed Products forecasted to be sold during the following Calendar Year for review and approval by PharmaMar, such approval not to be unreasonably withheld (the “**Annual Sales Forecast Plan**” or “**ASFP**”).

(ii) If PharmaMar provides written notice of non-approval of a proposed ASFP within [***] days of receipt of such proposed ASFP from Jazz, then both Parties hereby agree that an independent market research company (“**IMRC**”) will serve as an independent market research company and will determine the ASFP that shall be reasonably achievable by Jazz in the Jazz Territory for such Calendar Year, which shall take into consideration all available market research data and prescription trends as well as other commercially reasonable factors, including the actual volume of Annual Net Sales achieved in previous periods in the Jazz Territory as well as market trends. If PharmaMar does not provide notice of non-approval of a proposed ASFP within [***] days of receipt of such proposed ASFP from Jazz, then such proposed ASFP shall be deemed approved by PharmaMar.

(iii) The Parties hereby agree that they shall jointly appoint [***] as the IMRC in the event PharmaMar provides written notice of non-approval of any proposed ASFP in accordance with the terms of this Section 7.8(a). In the event [***] does not accept any such appointment within [***] days from the communication of its appointment, the Parties hereby agree that each Party shall appoint one independent Third Party market research company and the IMRC shall be appointed by the two selected independent Third Party market research companies.

(iv) Within [***] days of the appointment of the IMRC for a particular Calendar Year, each of the Parties will provide the IMRC with accurate and detailed information and documentation about sales of the Licensed Product for at least the past [***] years and [***] year forecasted sales of the Licensed Product for the Jazz Territory (if such data is available at a given time), and any other information requested by the IMRC, acting in good faith at all times. The IMRC will, within [***] after its appointment, issue a report determining the ASFP for the Jazz Territory that shall be reasonably achievable by Jazz in relation to the Calendar Year in the ASFP Term for which PharmaMar provides written notice of non-approval of any proposed ASFP within [***] days of receipt. Once the IMRC determines the ASFP for the Jazz Territory for a given Calendar Year, such ASFP shall be fully applicable and binding on the Parties with respect to such Calendar Year. Fees and expenses of the IMRC in determining the ASFP shall be borne by PharmaMar.

(b) **Annual Sales Performance.** Jazz shall meet [***] of the ASFP for the Jazz Territory of each Calendar Year during the ASFP Term. Nothing in this Section 7.8(b) shall be construed or understood as releasing Jazz’s diligence obligations pursuant to Section 7.3.

(c) Failure to Achieve Annual Sales Performance Standard In the event Jazz fails to achieve [***] of the ASFP in any Calendar Year during the ASFP Term, then as PharmaMar's sole and exclusive remedy for such failure, the terms of this Section 7.8(c) shall apply, provided Jazz has satisfied its diligence obligations pursuant to Section 7.3. For clarity, any failure to achieve [***] of the ASFP in any Calendar Year during the ASFP Term shall not be deemed a material breach of this Agreement, provided Jazz has satisfied its diligence obligations pursuant to Section 7.3.

(i) In the event that Jazz fails to achieve [***] of the ASFP in any Calendar Year during the ASFP Term and the cause for such failure is not attributable in part to acts or omissions of PharmaMar (including a failure to supply Licensed API or Licensed Product pursuant to the terms of the Supply Agreement) or a Force Majeure, then within [***] days after the end of such Calendar Year, Jazz shall submit to PharmaMar an action plan detailing [***]. Jazz will use Commercially Reasonable Efforts to implement such action plan during the following Calendar Year.

(ii) In the event that Jazz fails to achieve [***] of the ASFP in [***] Calendar Years during the ASFP Term and the cause for each such failure is not attributable in part to acts or omissions of PharmaMar (including a failure to supply Licensed API or Licensed Product pursuant to the terms of the Supply Agreement) or a Force Majeure, then as of the start of the next Calendar Year after such failures and thereafter for [***], the base royalty rate for the first tier under Section 8.7(a) shall be increased from [***] to [***].

(iii) In the event that Jazz fails to achieve [***] of the ASFP in any Calendar Year during the ASFP Term and the cause for such failure is not attributable in part to acts or omissions of PharmaMar (including a failure to supply Licensed API or Licensed Product pursuant to the terms of the Supply Agreement) or a Force Majeure, then PharmaMar shall have [***] months after the end of such Calendar Year for which such failure occurred to elect either (A) to exercise its Co-Promotion Option pursuant to Section 7.9(a) or (B) for the base royalty rate for the first tier under Section 8.7(a) to be increased from [***] to [***] as of the start of the next Calendar Year after such failure and continuing during [***].

7.9 Co-Promotion Option

(a) Option. In the event that either (i) (A) there is a Change of Control of Jazz Pharmaceuticals PLC within [***] years of the Effective Date by a company [***] and (B) at any time during the [***], the [***], and such [***] or (ii) Jazz fails to achieve [***] of the ASFP in any Calendar Year during the ASFP Term and the cause for such failure is not attributable in part to acts or omissions of PharmaMar (including a failure to supply Licensed API or Licensed Product pursuant to the terms of the Supply Agreement) or a Force Majeure, then in each case of (i) or (ii), PharmaMar shall have the option to co-promote the Licensed Product in the Jazz Territory in accordance with this Section 7.9 (the **Co-Promotion Option**). PharmaMar shall have the right, in its sole discretion, to exercise such Co-Promotion Option by delivering to Jazz written notice (x) at any time within [***] months after the end of [***] or (y) [***] months after the end of such Calendar Year for which such failure to achieve [***] of the ASFP in any Calendar Year during the ASFP Term occurred, as applicable based on the triggering event for such Co-Promotion Option, provided that, in each case, PharmaMar is then currently [***].

(b) **Effect of Option Exercise.** Within [***] days after PharmaMar's exercise of its Co-Promotion Option, pursuant to Section 7.9(a), the Parties will execute a joint commercial agreement that sets forth the terms and conditions pursuant to which the Parties will collaborate in promoting the Licensed Products in the Licensed Indications in the Jazz Territory, including the terms set forth on **Exhibit F** (the "**Co-Promotion Agreement**").

7.10 Medical Affairs

(a) **General.** Jazz shall have the sole and final authority to plan, determine and implement Medical Affairs activities in the Jazz Territory at its own cost. Jazz shall share with PharmaMar any annual plan for Medical Affairs activities prepared by Jazz to be conducted in the Jazz Territory in each Calendar Year. Jazz will respond to any reasonable inquiries from PharmaMar provided however those Medical Affairs activities to be conducted in the Jazz Territory shall be determined solely by Jazz in a manner consistent with its standard practice. It is understood by the Parties that Medical Affairs activities will be conducted for that purpose to produce good, objectively valid and reliable scientific evidence relating to the Licensed Product and/or the relevant disease, and not for commercial or promotional purposes. For clarity, content of annual plan Medical Affairs shall be deemed legally non-binding on Jazz and Jazz may change such plan any time and anyhow as it may consider appropriate provided any such change is consistent with its standard practice.

(b) **Exchange of Medical Affairs Studies Information.** Jazz and PharmaMar, respectively, shall provide the other Party with copies of the Information obtained from any and all Medical Affairs Studies conducted in each Party's Territory at no expense to the other Party provided such Information is available. Each Party shall be entitled to use such Information for the development, manufacturing, use or commercialization of the Licensed Product in its Territory and shall be entitled to disclose such Information to any Sublicensees and Third Party Partners for the same purposes in its Territory.

(c) **Medical Information.** Jazz shall be responsible at its own cost for medical information activities with respect to the Licensed Products in the Jazz Territory, including ensuring that adequate medical information is in place where relevant in the Jazz Territory and that all medical information requests are responded by Jazz in connection with the Licensed Product originating in the Jazz Territory. Any medical enquiries which are related to adverse events of Licensed Products shall be managed according to Safety Data Exchange Agreement. On a quarterly basis Jazz shall provide PharmaMar with a report of all medical information requests received and all responses provided to such requests in such quarter. In addition, Jazz shall provide PharmaMar every [***] months during the Term with all standard letters generated by Jazz in the Jazz Territory with regard to the Licensed Product.

8. FINANCIAL TERMS

8.1 Upfront Payment. Within [***] days after the Effective Date or [***] days after the HSR Clearance Date, whichever occurs later, Jazz shall pay to PharmaMar a one-time, non-refundable upfront payment of two hundred million Dollars (\$200,000,000).

8.2 Pivotal Trial Costs.

(a) **Pivotal Trial Cost Sharing.** In the event Jazz elects pursuant to Section 4.2(c)(i) to share costs for a particular Additional Indication Pivotal Trial, then the Parties shall share all Pivotal Trial Costs for such Joint Additional Indication Pivotal Trial with [***] of such Pivotal Trial Costs. Each Party may propose amendments to Joint Additional Indication Pivotal Trial Budget which shall not be implemented until approved by the JDC, such approval not to be unreasonably withheld (it would be unreasonable not to approve any amendment to the Joint Additional Indication Pivotal Trial Budget if the Joint Additional Indication Pivotal Trial is amended by the JDC in a manner that implies a change to the assumptions or a change in the protocol which were taken into account at the time the initial Joint Additional Indication Pivotal Trial Budget was approved). Each Party shall be responsible for [***] of the Pivotal Trial Costs that it incurs in connection with any Joint Additional Indication Pivotal Trial that [***], except for those [***].

(b) **Pivotal Trial Cost Reports; Reconciliation Report** Within [***] days after the end of each Calendar Quarter during which either Party has incurred any Pivotal Trial Costs, such Party shall submit to the other Party a reasonably detailed written report setting forth the total of such Pivotal Trial Costs incurred by such Party in such Calendar Quarter. Within [***] days before the end of each Calendar Quarter during which either Party has incurred any Pivotal Trial Costs, such Party shall submit to the other Party a good-faith, non-binding estimate of the total of such Pivotal Trial Costs incurred by such Party in such Calendar Quarter. Within [***] days after the end of each such Calendar Quarter, PharmaMar shall provide Jazz with a written report setting forth the net payment due from one Party to the other Party to effectuate the sharing of Pivotal Trial Costs as set forth in this Section 8.2 (the “**Reconciliation Report**”). The Party that is owed money pursuant to the Reconciliation Report shall issue an invoice to the paying Party for the applicable Pivotal Trial Costs promptly after receipt (or delivery, as applicable) of such Reconciliation Report. Any payment owed by one Party to the other Party shall be paid within [***] days following receipt of such invoice.

(c) **Creditable Against Sales Milestone Payments.** All Pivotal Trial Costs paid by Jazz shall be fully creditable against all Sales Milestone Payments due and payable thereafter pursuant to Section 8.6.

8.3 Development Costs for SCLC Post-Approval Commitment Studies. In the event Jazz exercises its right to conduct the SCLC Post-Approval Commitment Studies itself in accordance with Section 4.1(b), then PharmaMar shall be responsible for one hundred percent (100%) of the Development Costs up to [***] of the SCLC Post-Approval Commitment Studies Budget. Within [***] days after the end of each Calendar Quarter during which Jazz has incurred any Development Costs, Jazz shall submit to PharmaMar a reasonably detailed written report setting forth the total of the Development Costs incurred by Jazz in such Calendar Quarter and invoicing PharmaMar for [***] of such Development Costs provided however that Jazz shall be responsible for 100% of the Development Costs that it incurs in connection with any SCLC Post-Approval Commitment Studies that exceed [***], except for those [***]. PharmaMar shall pay any amount due and invoiced hereunder within [***] days after the receipt of the invoice.

8.4 Regulatory Milestone Payments. Within [***] days of the first achievement of each of the milestone events set forth in the table below by Jazz, its Affiliates or Sublicensees

(each, a “**Regulatory Milestone**”), Jazz shall provide PharmaMar with written notice of such achievement and shall pay to PharmaMar the corresponding one-time, non-refundable milestone payment set forth below:

<u>Milestone Event</u>	<u>Milestone Payment</u>
1. [***]	[***]
2. [***]	[***]
3. [***]	[***]
4. [***]	[***]

Each of the foregoing milestone payments (each, a “**Regulatory Milestone Payment**”) shall be payable only one time, for the first achievement of the applicable milestone event.

If Regulatory Milestone #2 is achieved, [***] and [***]. If Regulatory Milestone #1 is achieved, then [***], but Regulatory Milestone #1 is not a pre-requisite for Regulatory Milestone #3 or Regulatory Milestone #4. Regulatory Milestone #3 and Regulatory Milestone #4 are mutually exclusive and cannot both be achieved.

The maximum total of all Regulatory Milestone Payments pursuant to this Section 8.24 is two hundred fifty million Dollars (\$250,000,000), which can be achieved through (a) the achievement of [***], (b) the achievement of [***] or (c) the achievement of [***], which together shall total \$250,000,000.

8.5 Additional Indication Regulatory Milestones. In the event (a) Jazz elects to have PharmaMar fund one hundred percent (100%) of the costs for an Additional Indication Pivotal Trial in accordance with Section 4.2(c)(ii), (b) such Additional Indication Pivotal Trial obtains Positive Results; and (c) Jazz determines in good faith that it will be profitable for Jazz to Commercialize such Licensed Product in the Additional Indication (which profitability determination shall include, without limitation, the cost of obtaining Regulatory Approval and making the applicable Additional Indication Regulatory Milestone payment), then within [***] days of the first achievement for such Additional Indication of the applicable milestone event set forth in the table below by Jazz, its Affiliates or Sublicensees (each, an “**Additional Indication Regulatory Milestone**”), Jazz shall provide PharmaMar with written notice of such achievement and shall pay to PharmaMar the corresponding one-time milestone payment set forth below:

<u>Milestone Event</u>	<u>Milestone Payment</u>
1. [***]	[***]
2. [***]	[***]

For clarity, only one of the foregoing milestone payments (each, an “**Additional Indication Regulatory Milestone Payments**”) shall be payable for each Additional Indication.

All Additional Indication Regulatory Milestone Payments shall be fully creditable against the all Sales Milestone Payments thereafter due and payable pursuant to Section 8.6.

8.6 Net Sales Milestone Payments. Within [***] days of the end of the first Calendar Year in which each of the milestone events set forth in the table below is achieved by Jazz, its Affiliates or Sublicensees (each, a “**Sales Milestone**”), Jazz shall provide PharmaMar with written notice of such achievement and shall, subject to any credits available pursuant to Section 8.2 or Section 8.5, pay to PharmaMar the corresponding one-time, non-refundable milestone payment set forth below:

<u>Milestone Event</u>	<u>Milestone Payment</u>
1. [***]	[***]
2. [***]	[***]
3. [***]	[***]
4. [***]	[***]
5. [***]	[***]

Each of the foregoing milestone payments (each, a “**Sales Milestone Payment**”) shall be payable only one time, for the first achievement of the applicable milestone event. The maximum total of all Sales Milestone Payments pursuant to this Section 8.5 is five hundred fifty million Dollars (\$550,000,000). For clarity, if more than one Sale Milestone Event is achieved in the same Calendar Year, all Sale Milestone Payments corresponding to such Events achieved in such Calendar Year shall be paid by Jazz in aggregate.

8.7 Royalties.

(a) **Royalty Rates.** Jazz shall pay to PharmaMar royalties on incremental aggregate annual Net Sales in the Jazz Territory in each Calendar Year (the “**Licensed Product Royalty**”) at the applicable rate(s) set forth below:

<u>Annual Net Sales in the Jazz Territory</u>	<u>Royalty Rate</u>
[***]	[***]
[***]	[***]
[***]	[***]
[***]	30%

(b) Royalty Term. Royalties under Section 8.7 shall be payable on a Licensed Product-by-Licensed Product basis in the Jazz Territory from First Commercial Sale of such Licensed Product in the Jazz Territory until the latest of (a) expiration of the last Valid Claim of the PharmaMar Patents (excluding Jazz Solely Invented Specific Inventions and Jazz Solely Invented Specific Combination Inventions) in the Jazz Territory covering the composition of matter of the Licensed API contained in such Licensed Product, (b) expiration of Regulatory Exclusivity for such Licensed Product in the Jazz Territory and (c) [***] years after such First Commercial Sale (the “**Royalty Term**”).

(c) Loss of Exclusivity Reduction. On a Licensed Product-by-Licensed Product basis, if, during the Royalty Term for such Licensed Product, one or more Generic Products of such Licensed Product is sold by a Third Party, then as of the month in which such Generic Product was first sold, for the remainder of the Royalty Term for such Licensed Product, Jazz’s royalty payment obligations with respect to Net Sales of such Licensed Product in the Jazz Territory shall be reduced by [***].

(d) Third Party Licenses.

(i) Notice. In the event either Party identifies any item of intellectual property controlled by a Third Party that it considers to be [***] for the manufacture, Development or Commercialization of a Licensed Product (alone or in combination with another composition of matter), it shall notify the other Party in writing and shall provide a reasonably detailed specification of the nature and scope of such item of intellectual property.

(ii) Negotiation of Third Party Licenses. Jazz shall have the right to negotiate the terms and conditions for a license from such Third Party under any intellectual property rights identified under a notice in Section 8.7(d)(i) to the extent applicable to the Jazz Territory and to the extent applicable to the exercise of Jazz’s rights under this Agreement in the PharmaMar Territory. Upon agreement of the material terms of any such license agreement with such Third Party, Jazz shall disclose such material terms to PharmaMar and PharmaMar shall have a period of [***] days to elect whether it would like to negotiate for a worldwide license to such intellectual property rights. In the event PharmaMar provides notice in such [***] day period that it would like to negotiate a worldwide license for such intellectual property right, then PharmaMar shall have [***] days to negotiate a worldwide license agreement for such intellectual property rights with such Third Party. In the event (A) PharmaMar is [***] and (B) the Parties are able to agree upon the allocation of any non-royalty consideration that is not directly related to activities conducted solely by one of the Parties or their respective Affiliates or Sublicensees or Third Party Partners, as applicable, then upon agreement of the Parties that (A) and (B) have both been satisfied, PharmaMar shall have the right to enter into a worldwide license agreement on such agreed upon terms and conditions. If either (x) PharmaMar does not elect to negotiate a worldwide license within such [***] day period, (y) either (A) or (B) above are not satisfied or (z) PharmaMar does not execute a worldwide license agreement with such Third Party within [***] days of

agreement by the Parties that (A) and (B) above have been satisfied, then Jazz shall have the right to execute a license from such Third Party under such intellectual property rights to the extent applicable to the Jazz Territory and to the extent applicable to the exercise of Jazz's rights under this Agreement in the PharmaMar Territory. If PharmaMar enters into a license for such item of intellectual property, for the avoidance of doubt, such intellectual property shall be included in the Jazz License provided for by this Agreement and Jazz shall be responsible (subject to the reduction in (iv) below) for all payments owed under such agreement that are directly related to activities conducted solely by Jazz or its Affiliates or Sublicensees and for the agreed upon allocation of all other payments as agreed upon by the Parties under (B) above.

(iii) **PharmaMar Challenge.** With respect to any intellectual property rights identified under a notice in Section 8.7(d)(i), if PharmaMar provides written notice to Jazz within [***] days of receipt of such notice that it elects to challenge such item of intellectual property, then PharmaMar shall be deemed to have [***] and PharmaMar shall keep Jazz reasonably informed of such challenge. In the event Jazz [***] and PharmaMar [***], then Jazz shall [***].

(iv) **Third Party License Reduction.** For any license to Third Party intellectual property rights that are [***] for the manufacture, Development or Commercialization of Licensed Product entered into by Jazz or PharmaMar or their respective Affiliates pursuant to Section 8.7(d)(ii), Jazz shall have the right to deduct from any royalty that would otherwise have been due pursuant to this Section 8.7 in a particular Calendar Quarter an amount equal to [***] paid by Jazz or its Affiliates for such rights; *provided, that* if such license was entered in to by Jazz pursuant to Section 8.7(d)(ii), with respect to any [***], if the applicable Third Party license relates to [***], then such [***] for such rights shall be [***]; and, *provided, further, that* under no circumstances shall the royalty payments otherwise payable to PharmaMar pursuant to this Section 8.7 for any Calendar Quarter in the absence of this reduction be reduced by more than [***] as a result of this Section 8.7(d). Jazz may carry forward to subsequent Calendar Quarters any deductions that it was not able to deduct as a result of the foregoing provision. In the event that Jazz intends to deduct any amounts pursuant to this Section 8.7(d), it shall provide PharmaMar a copy of the agreement with the applicable Third Party.

(v) Neither Party shall, in any event, enter in a written agreement that admits any infringement of any Third Party intellectual property rights by Jazz or Pharma Mar or its respective Affiliates, Sublicensees or Third Party Partners or invalidity or unenforceability of the PharmaMar Technology, without the prior written consent of the other Party.

9. PAYMENTS; RECORDS; AUDITS

9.1 Royalty Reports and Payments. Royalties under Section 8.7 shall be calculated and reported for each Calendar Quarter during the Royalty Term and shall be paid within [***] days after the end of the Calendar Quarter. Each such payment shall be accompanied or preceded by a report (the "**Royalty Report**"), on a Licensed Product-by-Licensed Product basis, of (a) the amount of gross sales and Net Sales of Licensed Products during the applicable Calendar Quarter, (b) units of Licensed Products sold during the applicable Calendar Quarter, (c) a calculation of the amount of royalty payment due on such sales for such Calendar Quarter, (d) any applicable royalty adjustments under Sections 8.7(c) and 8.7(d), and (e) a revised calculation of the payment due after the application of such adjustments. Upon PharmaMar reasonable request, Jazz shall provide PharmaMar with any further information regarding calculations made in the Royalty Report.

9.2 Manner of Payment. All payments owed by Jazz under this Agreement shall be made by wire transfer in immediately available funds to a bank account designated in writing by PharmaMar. All payment amounts in this Agreement are expressed in Dollars, and all payments hereunder shall be payable in Dollars, except for payment of transfer prices for the supply of the Licensed Products (whether as Bulk Vials or Finished Products as applicable) and Licensed API which shall be expressed and made in Euros according to Supply Agreement.

9.3 Taxes.

(a) Taxes on Income. Each Party shall be solely responsible for the payment of all taxes imposed on its share of income arising directly or indirectly from the efforts of the Parties under this Agreement.

(b) Tax Cooperation. The Parties agree to cooperate with one another and use reasonable efforts to reduce or eliminate tax withholding or similar obligations in respect of royalties, milestone payments, and other payments made by Jazz to PharmaMar under this Agreement. To the extent Jazz is required to deduct and withhold taxes on any payment to PharmaMar, Jazz shall pay the amounts of such taxes to the proper Governmental Authority in a timely manner and promptly transmit to PharmaMar an official tax certificate or other evidence of such withholding sufficient to enable PharmaMar to claim such payment of taxes. PharmaMar shall provide Jazz any tax forms that may be reasonably necessary in order for Jazz not to withhold tax or to withhold tax at a reduced rate under an applicable bilateral income tax treaty. Each Party shall provide the other with reasonable assistance to enable the recovery, as permitted by Applicable Laws, of withholding taxes, value added taxes, or similar obligations resulting from payments made under this Agreement, such recovery to be for the benefit of the Party bearing such withholding tax or value added tax.

9.4 Audits. Jazz and its Affiliates and Sublicensees will maintain complete and accurate records in reasonably sufficient detail to permit PharmaMar to confirm the accuracy of the calculation of Development Costs, royalty payments and Sales Milestone Payments. Each Party and its Affiliates will maintain complete and accurate records in reasonably sufficient detail to permit the other Party to confirm the accuracy of the calculation of Pivotal Trial Costs incurred under this Agreement. Upon reasonable prior notice, such records shall be available during regular business hours for a period of [***] years from the end of the Calendar Year to which they pertain for examination, not more often than once each Calendar Year, by an independent certified public accountant selected by the auditing Party and reasonably acceptable to the audited Party, for the sole purpose of verifying the accuracy of the financial reports furnished by the other Party pursuant to this Agreement. Any such auditor shall enter into a confidentiality agreement with the audited Party and shall not disclose the audited Party's Confidential Information, except to the extent such disclosure is necessary to verify the accuracy of the financial reports furnished by the audited Party or the amount of payments due by one Party to the other Party under this Agreement. Any amounts shown to be owed but unpaid shall be paid together with the interest rate set forth in Section 9.5, and any amounts showed to be overpaid will be refunded, within [***] days from the accountant's report. The auditing Party shall bear the full cost of such audit unless such audit discloses an underpayment or overcharge by the audited Party of more than [***] of the amount due, in which case the audited Party shall bear the full cost of such audit.

9.5 Late Payments. In the event that any payment due under this Agreement is not made when due, the payment shall accrue simple interest from the due date until the date of payment at a per-annum rate of prime (as reported in *The Wall Street Journal* (U.S., Eastern Edition) plus [***] or the maximum rate allowable by Applicable Law, whichever is less.

10. INTELLECTUAL PROPERTY

10.1 Ownership of Inventions.

(a) **PharmaMar Technology.** Nothing in this Agreement shall be deemed to constitute a transfer or assignment of the PharmaMar Technology in existence as of the Effective Date or generated by PharmaMar or its Affiliates or Third Party Partners during the Term. Subject only to the other provisions of this Agreement, PharmaMar Controls and shall continue to Control all aspects of such PharmaMar Technology, including, without limitation, the Prosecution and Maintenance of such PharmaMar Technology without any obligation to Jazz except as provided in Section 10.2.

(b) **Specific Inventions.** As between the Parties and subject to the terms and conditions of this Agreement, all right, title and interest to Inventions directed solely and specifically to Licensed API or Licensed Product or which are not severable from Licensed API or Licensed Product, but excluding Specific Combination Inventions and Joint Specific Combination Inventions, regardless of which Party's, its Affiliates' or sublicensees' or Third Party Partners' personnel conceived or created or first reduced to practice such Invention (collectively, "**Specific Inventions**"), shall be solely owned by PharmaMar. For clarity, all Specific Inventions and intellectual property rights therein shall be included in the PharmaMar Technology and licensed to Jazz pursuant to the Jazz License.

(c) **Specific Combination Inventions.** Notwithstanding the provisions of Section 10.1(b), any Inventions directed solely and specifically to any Licensed API or Licensed Product in combination with any Other Active, other than a Joint Specific Combination Invention, shall be deemed a "**Specific Combination Invention**". Specific Combination Inventions shall be owned by PharmaMar. For clarity, Specific Combination Inventions and intellectual property rights therein shall be included in the PharmaMar Technology and licensed to Jazz pursuant to the Jazz License.

(d) **Joint Specific Combination Inventions** Notwithstanding the provisions of Section 10.1(b), any Inventions directed solely and specifically to any Licensed API or Licensed Product in combination with any Other Active that is covered by Patent Rights owned by or licensed to Jazz or its Affiliates (a "**Jazz Proprietary Component**") shall be deemed a "**Joint Specific Combination Invention**". Joint Specific Combination Inventions shall be jointly owned by PharmaMar and Jazz in both Parties Territories except [***], where Patent Rights covering such Joint Specific Combination Invention shall be solely owned by Jazz ("**Jazz Specific Combination Invention**"). For clarity, PharmaMar's interest in the Joint Specific Combination Inventions and intellectual property rights therein shall be included in the PharmaMar Technology

and licensed to Jazz pursuant to the Jazz License. For further clarity, (i) as between the Parties, Jazz (itself or through its Affiliates or Third Parties) shall have the exclusive right to develop, manufacture and commercialize the Jazz Proprietary Component for all uses, including for use with a Licensed API or Licensed Product in the Jazz Territory and the PharmaMar Territory; (ii) nothing herein shall be deemed as a grant of any right to PharmaMar, its Affiliates or Third Party Partners to any Patent Rights or other intellectual property rights owned by or licensed to Jazz or its Affiliates that claim, cover or relate to the Jazz Proprietary Component and are not Joint Specific Combination Inventions; and (iii) nothing herein shall be deemed a grant of any right to Jazz, its Affiliates or Third Parties acting under its authority to Commercialize any Licensed API or Licensed Product in the PharmaMar Territory.

(e) Generic Inventions. Any Invention that is not a Specific Invention, a Specific Combination Invention or a Joint Specific Combination Invention shall be deemed a "**Generic Invention**". Inventorship of Generic Inventions shall be determined in accordance with the rules of inventorship under U.S. patent laws. Any Generic Invention made, conceived, created, generated or first reduced to practice (i) by the personnel of Jazz or its Affiliates or under any agreement between Jazz or its Affiliates or a Third Party with respect to the Licensed Product, independently from the personnel of PharmaMar, its Affiliates and Third Party Partners, shall be solely owned by Jazz (collectively, "**Jazz Generic Inventions**"); (ii) by the personnel of PharmaMar, its Affiliates or Third Party Partners, independently from the personnel of Jazz and its Affiliates and Third Parties acting on Jazz's or its Affiliate's behalf, shall be solely owned by PharmaMar (collectively, "**PharmaMar Generic Inventions**"); and (iii) by personnel of Jazz, its Affiliates or Third Parties under any agreement between Jazz and an Affiliate or a Third Party with respect to the Licensed Product (on one hand) and PharmaMar, its Affiliates or Third Party Partners (on the other), shall be jointly owned by Jazz and PharmaMar (collectively, "**Joint Generic Inventions**"). For clarity, (x) PharmaMar Generic Inventions and intellectual property rights therein and PharmaMar's interest in the Joint Generic Inventions and intellectual property rights therein shall be included in the PharmaMar Technology and licensed to Jazz pursuant to the Jazz License and (y) Jazz Generic Inventions and intellectual property rights therein and Jazz's interest in the Joint Generic Inventions and intellectual property rights therein shall be licensed to PharmaMar pursuant to the PharmaMar License.

(f) Disclosure of Inventions. Each Party shall promptly disclose to the other Party all Inventions made by such Party to which the other Party has rights hereunder, including any invention disclosures, or other similar documents, submitted to it by its employees, agents or independent contractors describing Specific Inventions, Specific Combination Inventions, Joint Specific Combination Inventions, Jazz Generic Inventions, PharmaMar Generic Inventions or Joint Generic Inventions, and shall promptly respond to reasonable request from the other Party for additional information relating to such Inventions.

(g) Assignment; Further Assurances. Jazz hereby assigns to PharmaMar all right, title and interest in and to any Specific Inventions and Specific Combination Inventions. In addition, each Party hereby assigns to the other Party fifty percent (50%) ownership interest of its right, title and interest in any Joint Specific Combination Invention and Joint Generic Invention, as applicable. In accordance with the foregoing, each Party shall execute and shall have its employees execute (and cause its Affiliates and Third Parties, as applicable, to execute) all

documents necessary to transfer such rights, title and interest in accordance with this Section 10.1(g). Any remuneration for each Party's and its Affiliates' employees' inventions shall be solely borne by such Party.

(h) No Accounting. Except as expressly provided otherwise in this Agreement, neither Party shall have any obligation to obtain any approval of the other Party for, nor pay the other Party any share of the proceeds from or otherwise account to the other Party for, the practice, licensing, assignment or other exploitation of Joint Specific Combination Inventions or Joint Generic Inventions and each Party hereby waives any right it may have under the Applicable Laws of any country to require such approval, sharing or accounting.

10.2 Patent Prosecution and Maintenance.

(a) General. Except to the extent expressly specified to the contrary in this Agreement, as between the Parties, each Party shall retain the right to control the prosecution and maintenance of all intellectual property rights Controlled by such Party at such Party's expense, including the Prosecution and Maintenance of Patent Rights. Prosecution and maintenance costs and expenses shall include any prosecution fees, issue fees, maintenance fees and any fees of patent counsels, lawyers, experts and agents involved in the filing, prosecution and maintenance of such intellectual property rights.

(b) PharmaMar Prosecuted Patents. Except as otherwise provided in this Section 10.2(b), PharmaMar shall have the first right, but not the obligation, to control the preparation, filing, prosecution (including any oppositions, interferences, reissue proceedings, reexaminations and post-grant proceedings) and maintenance (such activities collectively, the "**Prosecution and Maintenance**") of PharmaMar Patents (including Joint Generic Patents but excluding Joint Specific Combination Patents) (collectively, the "**PharmaMar Prosecuted Patents**") on a worldwide basis at its own expense, except for Joint Generic Patents, for which expenses shall be shared equally by the Parties. PharmaMar shall provide Jazz reasonable opportunity to review and comment on material issues regarding such PharmaMar Prosecuted Patents in the Jazz Territory (and solely with respect to the Joint Generic Patents, on a worldwide basis), including providing Jazz with copies of all relevant communications to or from any patent authority in the Jazz Territory regarding such PharmaMar Prosecuted Patents (and solely with respect to the Joint Generic Patents, from any patent authority worldwide), and providing drafts of any material filings or responses to be made to such patent authorities reasonably in advance of the submission of such filings or responses for Jazz's review and comment. PharmaMar shall [***] in connection with the Prosecution and Maintenance of such PharmaMar Prosecuted Patents in the Jazz Territory (and solely with respect to the Joint Generic Patents, on a worldwide basis); *provided however* that PharmaMar shall have the sole and final decision making authority regarding Prosecution and Maintenance of PharmaMar Prosecuted Patents, with no obligation to Jazz whether to file, continue to prosecute, abandon and/or disclaim such Patent Right; *provided further* that if PharmaMar determines in its sole discretion to abandon or not file or maintain a PharmaMar Prosecuted Patents in the Jazz Territory (and solely with respect to the Joint Generic Patents, on a worldwide basis), then PharmaMar shall provide Jazz with written notice of such determination sufficiently in advance (but no later than [***] days prior to the date any abandonment of such PharmaMar Prosecuted Patent would become effective or any date that

would bar patentability) so that Jazz may, at its discretion, assume and control the Prosecution and Maintenance of such PharmaMar Prosecuted Patents at its own expense and in its own name. In the event that Jazz elects to assume the Prosecution and Maintenance of a PharmaMar Prosecuted Patent as provided for in this Section 10.2(b), PharmaMar shall assign and hereby assigns to Jazz its interest in such PharmaMar Prosecuted Patent without further consideration and such Patent shall thereafter cease to be considered a PharmaMar Patent for all purposes of this Agreement. If Jazz determines in its sole discretion to not contribute any further to the Prosecution and Maintenance of a Joint Generic Patent, then Jazz shall provide PharmaMar with written notice of such determination sufficiently in advance so that PharmaMar may, at its discretion, continue to control the Prosecution and Maintenance of such Joint Generic Patent, but at its sole expense or abandon such Joint Generic Patent. In the event that PharmaMar elects to continue at its sole expense the Prosecution and Maintenance of a Joint Generic Patent, Jazz shall assign and hereby assigns to PharmaMar its interest into such Joint Generic Patent without further consideration and such Joint Generic Patent shall be then deemed to be a PharmaMar Patent for the purposes of this Agreement.

(c) **Jazz Prosecuted Patents.** Except as otherwise provided in this Section 10.2(c), Jazz shall have the first right, but not the obligation, to control Prosecution and Maintenance of the Jazz Generic Patents and Joint Specific Combination Patents (collectively, “**Jazz Prosecuted Patents**”) on a worldwide basis at its own expense. Jazz shall provide PharmaMar reasonable opportunity to review and comment on material issues regarding such Jazz Prosecuted Patents in the PharmaMar Territory, including providing PharmaMar with copies of all relevant communications to or from any patent authority in the PharmaMar Territory regarding such Jazz Prosecuted Patents, and providing drafts of any material filings or responses to be made to such patent authorities reasonably in advance of the submission of such filings or responses for PharmaMar’s review and comments. Jazz shall [***] in connection with the Prosecution and Maintenance of such Jazz Patents in the PharmaMar Territory, *provided however* that Jazz shall have the sole and final decision making authority regarding Prosecution and Maintenance of Jazz Prosecuted Patents, with no obligation to PharmaMar whether to file, continue to prosecute, abandon and/or disclaim such Patent Right. Notwithstanding the foregoing, and with regard to any Jazz Generic Patent that is being exploited at any time by PharmaMar, its Affiliates or Third Party Partners in relation to the Licensed API or the Licensed Product, if Jazz determines in its sole discretion to abandon or not file or maintain such Jazz Generic Patent in the PharmaMar Territory, then Jazz shall provide PharmaMar with written notice of such determination sufficiently in advance (but no later than [***] days prior to the date any abandonment of such Jazz Prosecuted Patent would become effective or any date that would bar patentability) so that PharmaMar may, at its discretion, assume and control the Prosecution and Maintenance of such Jazz Generic Patent, at its own expense and in its own name and such Jazz Generic Patent shall be then deemed to be a PharmaMar Patent for the purposes of this Agreement. If Jazz determines in its sole discretion to abandon or not maintain a Joint Specific Combination Invention in the Jazz Territory or the PharmaMar Territory, then Jazz shall provide PharmaMar with written notice of such determination sufficiently in advance so that PharmaMar may, at its discretion, assume and control the Prosecution and Maintenance of such Joint Specific Combination Patent at its sole expense or abandon such Joint Specific Combination Patent. In the event that PharmaMar elects to assume at its sole expense the Prosecution and Maintenance of a Joint Specific Combination Patent, Jazz shall assign and hereby assigns to PharmaMar its interest into such Joint Specific

Combination Patent without further consideration and such Joint Specific Combination Patent shall be then deemed to be a PharmaMar Patent for the purposes of this Agreement. For clarity, any such assignment shall not include an assignment, transfer or license to PharmaMar, its Affiliates or Third Party Partners to any Patent Rights or other intellectual property rights owned by or licensed to Jazz or its Affiliates that claim, cover or relate to any Jazz Proprietary Component.

(d) **Cooperation in Prosecution.** Each Party shall provide the other Party all reasonable assistance and cooperation in the Patent Prosecution and Maintenance efforts provided above in this Section 10, including providing any necessary powers of attorney and executing any other required documents or instruments for such Prosecution and Maintenance consistent with the provisions of this Section 10 above, as well as further actions as set forth below:

(i) The Parties shall respectively Prosecute and Maintain the PharmaMar Prosecuted Patents and Jazz Prosecuted Patents as set forth in this Section 10.2.

(ii) All communications between the Parties relating to the Prosecution or Maintenance of the PharmaMar Prosecuted Patents and Jazz Prosecuted Patents, including copies of any draft or final documents or any communications received from or sent to patent offices or patenting authorities with respect to such Patents, shall be considered Confidential Information of the owner of such Patent (and in case of Joint Patents, Confidential Information of both PharmaMar and Jazz) and subject to the confidentiality provisions of Article 11.

10.3 Patent Term Extensions in the Jazz Territory. The Parties shall coordinate and discuss which of the Patent Rights within the PharmaMar Patents or the Jazz Patents should be selected for patent term extensions (including any pediatric exclusivity extensions as may be available) or supplemental protection certificates or their equivalents in the Jazz Territory (collectively, "**Patent Term Extensions**") with respect to any Licensed Product. Notwithstanding anything to the contrary set forth in Section 10.2, Jazz shall have the right to apply for Patent Term Extensions with respect to any Licensed Product in the Jazz Territory and PharmaMar shall have final decision-making authority with respect to determining which Patent Right is selected for any such Patent Term Extensions in the Jazz Territory. Each Party will cooperate fully with the other in making such filings or actions, for example and without limitation, making available all required regulatory data and other Information and executing any required authorizations to apply for such Patent Term Extension, including PharmaMar appointing Jazz as its agent with respect to any Patent Term Extension of a PharmaMar Patent or Joint Patent in the Jazz Territory. For clarity, the Parties agree that (i) the costs of obtaining a Patent Term Extension in the Jazz Territory (a) within a PharmaMar Patent (other than a Joint Patent) shall be borne by PharmaMar, (b) within a Jazz Patent (other than a Joint Patent) shall be borne by Jazz and (c) within the Joint Patents shall be shared equally by both Parties, and (ii) the costs of obtaining a Patent Term Extension in the PharmaMar Territory shall be borne by PharmaMar.

10.4 Infringement of Patents by Third Parties.

(a) **Notification.** Each Party shall promptly notify the other Party in writing within [***] days (except as expressly set forth below) of becoming aware of any alleged existing or threatened infringement by a Third Party of any of the PharmaMar Patents (including Joint Patents) ("**Infringement**"), including (x) any such alleged existing or threatened Infringement on

account of a Third Party's manufacture, use or sale of Licensed API or Licensed Product, (y) any certification filed in the United States under 21 U.S.C. §355(b)(2) or 21 U.S.C. §355(j)(2) or similar provisions in other jurisdictions in connection with an ANDA (an Abbreviated New Drug Application in the United States or a comparable application for Regulatory Approval under Applicable Law in any country other than the United States) or other NDA for a Licensed Product (a "**Patent Certification**"), and (z) any declaratory judgment action filed by a Third Party alleging the invalidity, unenforceability or non-infringement of any of the PharmaMar Patents (a "**Declaratory Judgment**") ((x)-(z), collectively, "**Competitive Infringement**"); *provided, however*, that each Party shall notify the other Party of any Patent Certification regarding any PharmaMar Patent that it receives, and provide the other Party with a copy thereof, within [***] days of receipt. Each such notification shall include all evidence in such Party's possession demonstrating such Competitive Infringement. No later than [***] days following receipt by one Party from the other of a notice of existing or threatened Competitive Infringement, the Parties shall consult with each other regarding any actions to be taken with respect to such Competitive Infringement.

(b) PharmaMar Patents.

(i) Jazz Territory. Jazz shall have the first right, but not the obligation, to bring (or defend) and control an appropriate suit or other legal action against any Third Party engaged in any Competitive Infringement of any PharmaMar Patents (including Joint Patents) in the Jazz Territory at Jazz's own expense and by counsel of its own choice. If Jazz does not bring a suit or take other reasonable action ("**Enforcement Action**") to abate any Competitive Infringement of any PharmaMar Patent in the Jazz Territory, within [***] days of either Party providing a notice of existing or threatened Competitive Infringement under Section 10.4(a), then after consultation with Jazz regarding its rationale for electing not to bring an Enforcement Action and after reasonably considering such rationale, PharmaMar shall have the right, at its own expense, to commence or defend any such Enforcement Action.

(ii) PharmaMar Territory. PharmaMar shall have the first right, but not the obligation, to bring (or defend) and control any action or proceeding with respect to Competitive Infringement of a PharmaMar Patent (including Joint Patents) in the PharmaMar Territory, at PharmaMar's own expense and by counsel of its own choice. If PharmaMar does not bring an Enforcement Action to abate any Competitive Infringement of any Joint Patent in the PharmaMar Territory or to abate any Declaratory Judgment of a PharmaMar Patent (including Joint Patents) in the PharmaMar Territory, and solely if (A) any Third Party that is a Third Party Partner as of the Effective Date does not exercise any enforcement rights they may have in any country of PharmaMar Territory with respect to any PharmaMar Patent under the terms of the corresponding agreement between PharmaMar and such Third Party Partner (as such terms are in effect as of the Effective Date) within the timelines set forth in such agreement or (B) any Third Party that becomes a Third Party Partner after the Effective Date does not exercise any enforcement rights they may have in its specific licensed country(ies) within the PharmaMar Territory with respect to any PharmaMar Patent under the terms of the corresponding agreement between PharmaMar and such Third Party Partner within the timelines set forth in such agreement, in each case, within [***] days of either Party providing a notice of existing or threatened Competitive Infringement under Section 10.4(a) or within [***] days from PharmaMar notice that

any Third Party Partner in any country of PharmaMar Territory has decided not to bring such an Enforcement Action, then after consultation with PharmaMar regarding its rationale for electing not to bring an Enforcement Action and after reasonably considering such rationale, Jazz shall have the right, at its own expense, to commence or defend any such Enforcement Action. To the extent not inconsistent with the terms of any Third Party Partner agreement existing as of the Effective Date, PharmaMar shall not allow any Third Party Partner to enforce any Joint Patent in the PharmaMar Territory or the Jazz Territory.

(iii) Cooperation. The Party commencing or defending any Enforcement Action pursuant to this Section 10.4 (the **Enforcing Party**) shall keep the other Party reasonably informed of the progress of any such Enforcement Action, and such other Party shall have the right to join, but not to control, such action with counsel of its own choice, at its own expense. In any event, the other Party shall reasonably cooperate with the Enforcing Party, including providing information and materials, at the Enforcing Party's request and expense. In the event that the Enforcing Party is unable to initiate or prosecute such action solely in its own name or it is otherwise advisable in order to obtain an effective remedy, the other Party will join, but not control, at the Enforcing Party's request and expense, such action and will execute all documents necessary for the Enforcing Party to initiate litigation and prosecute and maintain such action. In any case, neither Party shall enter into any settlement or compromise of any action under this Section 10.4 which would in any manner alter, diminish, or be in derogation of the other Party's rights under this Agreement without the prior written consent of such other Party, which shall not be unreasonably withheld.

(c) Recovery. Except as otherwise agreed by the Parties in connection with a cost-sharing arrangement, any recovery realized by a Party as a result of any action or proceeding pursuant to this Section 10.4, whether by way of settlement or otherwise, shall be shared in order as follows:

(i) The Enforcing Party shall recoup all of its costs and expenses incurred in connection with such action;

(ii) If the other Party joined such action at its own expense, then, to the extent possible, the other Party shall recover its costs and expenses incurred in connection with such action; and

(iii) The remainder, if any, shall be [***].

10.5 Infringement of Third Party Rights in the Jazz Territory.

(a) Notice. If any Licensed Product manufactured, used or sold by either Party, its Affiliates, or their respective licensees becomes the subject of a Third Party's claim or assertion of infringement of a Patent Right granted by a jurisdiction in either Party's Territory, the Party first having notice of the claim or assertion shall promptly notify the other Party. In the event that either Party notifies the other that it, or its Affiliates, or their respective licensees have become the subject of a Third Party's claim or assertion of infringement of a Patent Right granted in its Territory (any, a **"Defensive Action"**), the Parties shall agree on and enter into a "common interest agreement" wherein such Parties agree to their shared, mutual interest in the outcome of such

potential dispute, and thereafter, the Parties shall promptly meet to consider the claim or assertion and the appropriate course of action; *provided that* in the event such Third Party also alleges the invalidity, unenforceability or non-infringement of any of the PharmaMar Patents (including Joint Patents), such allegation or claim shall be handled as a Competitive Infringement.

(b) Defense. The Party subject to such Defensive Action shall have the exclusive right to defend and control the defense of any such Defensive Action using counsel of its own choice, at its expense, provided that the provisions of Section 10.4 shall govern the right of such Party to assert a counterclaim of infringement of any PharmaMar Patent (including any Joint Patent). In the event that Jazz is the Party against whom such Defensive Action is brought, if the Third Party Patent Rights are used for the manufacture, use or Commercialization of a Licensed Product in the Jazz Territory, then Jazz will be entitled to withhold up to [***] of royalties otherwise payable with respect to Net Sales of such Licensed Product under Section 8.7(d) and use such withheld royalties to reimburse any and all the legal defense costs, attorneys' fees and liability incurred in such Defensive Action for the period beginning from the date Jazz receives notice of such Defensive Action from the Third Party plaintiff until the date of final non appealable judgment by a court or other body of competent jurisdiction or binding settlement by Jazz of such Defensive Action has been made. Notwithstanding the foregoing, Jazz agrees to withhold only that portion of such royalties as may reasonably be necessary to reimburse amounts in accordance with this Section 10.5. If Jazz is required to pay a royalty or other amount for Third Party Patent Rights that are used for the manufacture, use or Commercialization of a Licensed Product in the Jazz Territory, such amounts may be offset as set forth in Section 8.7(d). The Party in any Defensive Action agrees (i) to keep the other Party reasonably informed of all material developments in connection with any such Defensive Action, (ii) to consult with the other Party regarding the strategy for such Defensive Action and (iii) to [***] input provided by the other Party with respect to the strategy for such Defensive Action.

(c) Each Party shall not settle any Defensive Action that includes any statement that may be used as an admission of invalidity or unenforceability of the PharmaMar Technology or of the Jazz Technology without prior consent of the other Party.

10.6 Patent Oppositions and Other Proceedings

(a) Third-Party Patent Rights. If either Party desires to initiate an opposition, action for declaratory judgment, nullity action, interference, declaration for non-infringement, reexamination or other attack upon the validity, title or enforceability of a Patent Right owned or controlled by a Third Party and having one or more claims that covers the Licensed API or the Licensed Product, or the manufacture, use, sale, offer for sale or importation of the Licensed API or the Licensed Product (except insofar as such action is a counterclaim to or defense of, or accompanies a defense of, a Third Party's claim or assertion of a Competitive Infringement, in which case the provisions of Section 10.4 shall govern), such Party shall so notify the other Party and the Parties shall promptly confer to determine whether to bring such action or the manner in which to settle such action. If the Parties do not agree otherwise, as between the Parties, (i) PharmaMar shall have the sole right to control such actions at its expense with regard to PharmaMar Prosecuted Patents and (ii) Jazz shall have the sole right to control such actions at its expense with regard to Jazz Prosecuted Patents, and the Party so controlling such action shall keep the other Party reasonably informed with respect thereto.

(b) Parties' Patent Rights. If a PharmaMar Prosecuted Patent in the Jazz Territory, or a Joint Generic Patent anywhere in the world, becomes the subject of any proceeding commenced by a Third Party in connection with an opposition, reexamination request, nullity action, interference or other attack upon the validity, title or enforceability thereof (except insofar as such action is brought by the Third Party in an action for Competitive Infringement, in which case the provisions of Section 10.4 shall govern), then PharmaMar shall control such defense at its own cost. If a Jazz Generic Patent in the Jazz Territory, or a Joint Specific Combination Patent anywhere in the world becomes the subject of any proceeding commenced by a Third Party in connection with an opposition, reexamination request, nullity action, interference or other attack upon the validity, title or enforceability thereof (except insofar as such action is brought by the Third Party in an action for Competitive Infringement, in which case the provisions of Section 10.4 shall govern), then Jazz shall control such defense, at its own cost. The controlling Party shall permit the non-controlling Party to participate in the proceeding to the extent permissible under Applicable Law, and to be represented by its own counsel in such proceeding, at the non-controlling Party's expense. If either Party decides that it does not wish to defend against such action, then the other Party shall have the backup right to assume defense of such Third Party action at its own expense.

10.7 Jazz Third Party Agreements. Jazz shall require (and shall cause its Affiliates to require) that any Third Party working in collaboration hereunder is bound by a written agreement containing provisions relating to ownership of Inventions consistent with the terms of Section 10.1 and obligating such Third Party to assign to Jazz (or such Affiliate) all right, title and interest in and to such Inventions developed by such Third Party as a result of any activities relating to Licensed API or Licensed Product to the extent required for Jazz to comply with the terms of Section 10.1. Upon PharmaMar's written request, Jazz shall provide to PharmaMar with a copy of any written agreements entered into by Jazz (or its Affiliates) within [***] days from PharmaMar's request; provided, that Jazz shall have the right to redact confidential information contained in such agreement to the extent disclosure of such terms are not required to verify compliance with the terms of this Agreement.

10.8 [*].** If Jazz (or its Affiliates) [***], PharmaMar shall [***]. Jazz hereby [***]. The [***] arising out of such [***] shall not be [***]. [***] shall be entitled to seek any additional remedies available under Applicable Law or under this Agreement.

10.9 Trademarks.

(a) Selection and Display.

(i) The Parties will consult with each other in good faith regarding the selection or replacement of any product-specific Trademarks for any Licensed Product in the Licensed Indication in the Jazz Territory, and PharmaMar shall have the final approval of all such product-specific Trademarks (collectively, the "**Product Trademarks**"). As of the Effective Date, PharmaMar has decided to use the Trademark Zepsyr® set forth on **Exhibit G** for Licensed Products containing lurbinectedin. For clarity, subject to Section 10.9(e), in addition to the word

mark Zepsyre® (or any alternative word Product Trademark), PharmaMar shall also decide at its sole discretion to use with respect to the Commercialization of any Licensed Product certain distinctive colors, figurative marks, combined word/figurative marks, symbols, images, logotypes or other marks and the manner of use thereof which shall also be deemed Product Trademarks, *provided that* the manner of use of such additional marks is consistent with Jazz Standard Trade Dress and Style and are not already in use or otherwise owned by Jazz. Such Trademark shall be the Product Trademark for such Licensed Products unless the FDA rejects such name. PharmaMar shall be responsible for the costs and expenses of all legal and market research for selection and testing of the proposed Product Trademarks in the Jazz Territory.

(b) In the event Regulatory Authorities in the Jazz Territory do not approve the registration or use of the elected Trademark as Product Trademark for any Licensed Product, PharmaMar shall decide at its sole discretion any alternative Product Trademark for the Licensed Product in the Jazz Territory. PharmaMar shall have final decision-making rights for any such alternative trademark for the Licensed Product (upon prior consultation with Jazz) at the time any alternative Product Trademark is needed in the Jazz Territory.

(c) PharmaMar will keep Jazz informed of all product-specific Trademarks used by PharmaMar and its Third Party Partners for Licensed Products in the PharmaMar Territory.

(d) Jazz shall use Commercially Reasonable Efforts to display the applicable Product Trademark(s) on all packaging materials, labels and marketing materials for the applicable Licensed Product, *provided that* the Parties acknowledge and agree that final packaging and label of each Licensed Product is subject to approval by and in compliance with the FDA.

(e) Licensed Product(s) shall be sold in the Jazz Territory under the trade name of Jazz; provided, that Jazz shall use Commercially Reasonable Efforts to include PharmaMar's name on the packaging materials, labels and marketing materials for Licensed Products. The Trademarks of Jazz, trade dress, style of packaging, prominence of PharmaMar's name and the like with respect to a Licensed Product in the Jazz Territory may be determined by Jazz in a manner that is consistent with Jazz's standard trade dress and style ("**Jazz Standard Trade Dress and Style**"). The ownership and all goodwill from use of Jazz Standard Trade Dress and Style shall vest in and inure to the exclusive benefit of Jazz.

(f) **Grant of License.** Subject to the terms and conditions of this Agreement, PharmaMar hereby grants to Jazz an exclusive license under Product Trademarks (with the right to sublicense according to Section 2.1(c)), for its use, consistent with the usage guidelines provided by PharmaMar of such Product Trademarks in writing, in the Jazz Territory for the Commercialization of Licensed Product(s) in accordance with this Agreement. The ownership and all goodwill from the use of the Product Trademarks shall vest in and inure to the exclusive benefit of PharmaMar.

(g) **Registration of Trade Marks.** PharmaMar (or its designee) shall file, register and maintain at PharmaMar's expense and in PharmaMar's own name (to the extent permitted by Applicable Laws), appropriate registrations for the Product Trademarks in the Jazz Territory. PharmaMar will keep Jazz regularly informed of the progress and status of such filings

and provide Jazz with an opportunity to review and comment on any material draft filings related thereto. PharmaMar shall [***] provided by Jazz with respect to such draft filings.

(h) Enforcement.

(i) If either Party becomes aware of any actual or threatened infringement of any Product Trademark or any registration of a proposed Trademark by a Third Party that is similar to a Product Trademark in the Jazz Territory or the PharmaMar Territory, such Party shall promptly notify the other Party in writing. PharmaMar shall maintain an application and publication watch on the U.S. federal trademark registry for Product Trademark used on the Licensed Product in the Jazz Territory and shall promptly appraise Jazz of any Third Party filings for similar marks.

(ii) Jazz shall have the first right, at its own expense, to initiate infringement proceedings or take other appropriate actions against an infringement of any Product Trademark in the Jazz Territory or take appropriate actions with respect to the registration of a proposed Trademark by a Third Party that is similar to a Product Trademark in the Jazz Territory and/or to defend any actions or proceedings involving the Product Trademarks in the Jazz Territory, as the case may be.

(iii) If Jazz does not initiate proceedings or take other appropriate action within [***] days of [***], then PharmaMar shall be entitled, at its own expense, to initiate infringement proceedings or take other appropriate action against an infringement of a Product Trademark in the Jazz Territory, or to take appropriate actions with respect to the application or registration of a proposed Trademark by a Third Party that is similar to a Product Trademark in the Jazz Territory, or to defend any actions or proceedings involving or affecting a Product Trademark in the Jazz Territory, as the case may be.

(iv) The Party conducting such action shall have full control over the conduct of such action, including settlement thereof; provided, however, that the Party conducting such action may not settle any such action, or make any admissions or assert any position in such action, in a manner that would materially adversely affect the Product Trademarks in the Jazz Territory or the rights or interests of the other Party, without the prior written consent of the other Party, which shall not be unreasonably withheld or delayed.

(v) In any event, the Parties shall keep one another informed of the status of their respective activities regarding any litigation in the Jazz Territory involving a Product Trademark or settlement thereof and shall assist one another and cooperate in any such litigation at the other's reasonable request and expense (including joining as a party plaintiff to the extent necessary and requested by the other Party).

(vi) Jazz and PharmaMar shall recover their respective actual out-of-pocket expenses, or proportionate percentages thereof, associated with any litigation against infringers undertaken pursuant to this Section 10.9(h) or settlement thereof from any resulting recovery made by either Party. Any excess amount of such recovery shall be split [***].

11. CONFIDENTIALITY

11.1 Confidential Information. Except to the extent expressly authorized by this Agreement, each Party agrees that, during the Term, and for [***] years thereafter, such Party (the “**Receiving Party**”) shall keep confidential, and shall not publish or otherwise disclose and shall not use for any purpose other than as expressly provided for in this Agreement, any Information furnished to it by the other Party (the “**Disclosing Party**”) pursuant to this Agreement or the Confidentiality Agreement (collectively, “**Confidential Information**”). The Receiving Party may use Confidential Information only to the extent required to accomplish the purposes of this Agreement. The Receiving Party shall use at least the same standard of care as it uses to protect proprietary or confidential information of its own (but in no event less than reasonable care) to ensure that its, and its Affiliates’, employees, agents, consultants and other representatives (“**Representatives**”) do not disclose or make any unauthorized use of the Confidential Information. The Receiving Party shall promptly notify the Disclosing Party upon discovery of any unauthorized use or unauthorized disclosure of the Disclosing Party’s Confidential Information.

11.2 Exceptions. Confidential Information shall not include any information which the Receiving Party can prove by competent evidence: (a) is now, or hereafter becomes, through no act or failure to act on the part of the Receiving Party in violation of this Article 11, generally known or available; (b) is known by the Receiving Party or any of its Affiliates at the time of receiving such information, as evidenced by its records; (c) is hereafter furnished to the Receiving Party or any of its Affiliates by a Third Party, as a matter of right and without restriction on disclosure; or (d) is independently discovered or developed by the Receiving Party or any of its Affiliates, independently of the activities undertaken by the Receiving Party pursuant to this Agreement and without the use or knowledge of Confidential Information of the Disclosing Party.

11.3 Authorized Disclosure. Notwithstanding the provisions of Section 11.1, the Receiving Party may disclose Confidential Information of the Disclosing Party, including the terms of this Agreement, as expressly permitted by this Agreement, or if and to the extent such disclosure is reasonably necessary in the following instances:

- (a) filing or prosecuting Patent Rights as permitted by this Agreement;
- (b) enforcing such Party’s rights under this Agreement and in performing its obligations under this Agreement;
- (c) prosecuting or defending litigation as permitted by this Agreement, subject to the final paragraph of this Section 11.3;
- (d) complying with applicable court orders, Applicable Laws, rules or regulations, subject to the final paragraph of this Section 11.3;
- (e) as determined in the Receiving Party’s reasonable discretion, the listing rules of any exchange on which the Receiving Party’s securities are traded;

(f) disclosure in Regulatory Filings that the Receiving Party has the right to make under this Agreement;

(g) disclosure to the Receiving Party's Affiliates, to actual or potential Sublicensees and Third Party Partners, and to the Receiving Party's and its Affiliates' and Third Party Partners Representatives who, in each case, have a need to know such information in order for the Receiving Party to exercise its rights or fulfill its obligations under this Agreement, provided, in each case, that any such Affiliate, actual or potential Sublicensee, Third Party Partner or Representative agrees [***]; and

(h) disclosure to Third Parties, including potential Third Party Partners, in connection with due diligence or similar investigations by such Third Parties, and disclosures to potential Third Party investors in confidential financing documents, provided, in each case, that [***].

Notwithstanding the foregoing, in the event the Receiving Party is required to make a disclosure of the Disclosing Party's Confidential Information pursuant to Section 11.3(c) or 11.3(d), it will, except where impracticable, (i) give reasonable advance notice to the Disclosing Party of such disclosure, (ii) use efforts to secure confidential treatment of such information at least as diligent as the Receiving Party would use to protect its own confidential information, but in no event less than reasonable efforts, and (iii) cooperate with any efforts by the Disclosing Party, at the Disclosing Party's request and expense, to secure confidential treatment of such Confidential Information. Disclosure by the Receiving Party of Confidential Information in accordance with any of the foregoing provisions of this Section 11.3 shall not, in and of itself, cause the information so disclosed to cease to be treated as Confidential Information under this Agreement, except to the extent that, by virtue of disclosure by the Receiving Party in full compliance with this Section 11.3, such information becomes generally known or available.

11.4 Publications. Each Party and its Affiliates shall be free to publish, and to authorize Sublicensees and Third Party Partners to publish, the protocol or results of any preclinical study or clinical trial of a Licensed Product conducted by or on behalf of such Party or its Affiliate or Sublicensee, provided that solely with regard to (i) manuscripts, abstracts or other publications of PharmaMar (or its Third Party Partners) regarding Atlantis Trial, SCLC Post-Approval Commitment Studies and any other Clinical Trial conducted in the Jazz Territory, or regarding Clinical Trials sponsored by PharmaMar or its Third Party Partners involving the Licensed Product conducted within [***] and (ii) any manuscripts, abstracts or other publications of Jazz (or its Sublicensees) regarding any Development activities conducted by Jazz or on its behalf in Jazz Territory, SCLC Post-Approval Commitment Studies conducted by Jazz and any other Development activity conducted by Jazz in the PharmaMar Territory, the other Party has a reasonable opportunity not less [***] days for abstracts, posters or other presentation materials and [***] days for all other publications prior to the date of publication to review the proposed publication and provide comments; *provided, that*, with respect to publications by Third Parties that are Third Party Partners as of the Effective Date, PharmaMar shall only have an obligation to provide drafts for review and comment in accordance with this Section 11.4 to the extent such Third Party Partner is obligated to provide PharmaMar with such drafts and Jazz's timeline to review and comment shall be consistent with the timelines set forth in the applicable Third Party

Partner agreement. If such comments involve a redaction of Confidential Information of such reviewing Party, the publishing Party shall [***]. If such comments involve the identification of patentable material in such proposed publication, the publishing Party shall delay publication for up to [***] days until the appropriate Party seeks patent protection for such information. Any such publication shall acknowledge, as appropriate, the contribution of the other Party, its employees, agents and representatives, or if appropriate.

11.5 Public Announcements.

(a) **Press Releases.** The Parties shall make a joint public announcement of the execution of this Agreement in the form attached as **Exhibit H**, which shall be issued at a mutually agreed time after the Effective Date. After release of such press release, neither Party may issue any further press releases without the prior review and approval of the other Party. Notwithstanding the foregoing, each Party shall be free to issue such press releases without the prior review or approval of the other Party, that such Party determines are reasonably necessary to comply with Applicable Laws, including disclosure requirements of the U.S. Securities and Exchange Commission or to Spanish Securities Commission (CNMV-Comisión Nacional del Mercado de Valores), or with the requirements of any stock exchange on which securities issued by such Party is traded. In addition, each Party may make public statements regarding this Agreement in response to questions by the press, analysts, investors or those attending industry conferences or financial analyst calls, so long as the contents of any such public statement or press release do not reveal non-public information about the other Party or the terms of the Agreement.

(b) **Filing of this Agreement.** The Parties shall coordinate in advance with each other in connection with the filing of this Agreement (including redaction of certain provisions of this Agreement) with any securities authority or with any stock exchange on which securities issued by a Party or its Affiliate are traded, and each Party will use reasonable efforts to seek and obtain confidential treatment for the terms proposed to be redacted; provided that each Party will ultimately retain control over what terms are disclosed to any securities authority or stock exchange, as the case may be, to the extent such Party determines, on the advice of legal counsel, that disclosure is reasonably necessary to comply with Applicable Laws, including disclosure requirements of the U.S. Securities and Exchange Commission or foreign counterpart, or with the requirements of any stock exchange on which securities issued by a Party or its Affiliates are traded, and provided further that the Parties will use their reasonable efforts to file redacted versions with any governing bodies which are consistent with redacted versions previously filed with any other governing bodies.

11.6 Inside Information.

(a) The Parties agree that certain Confidential Information disclosed by one Party to the other Party under this Agreement may qualify as inside information of such disclosing Party under Article 226 of the Restated Text of the Spanish Securities Market Law, Article 7 of Regulation (EU) 596/2014 of the European Parliament and of the Council dated April 16th 2014 on market abuse (“**Regulation UE 596/2014**”), or other applicable insider dealing, market abuse or similar law and/or equivalent securities market regulations in the Jazz Territory (such laws, “**Inside Information Regulations**” and such information, “**Inside Information**”). To the extent

required to comply with Inside Information Regulations, each Party agrees that it shall, unless it receives the prior written consent of the other Party:

(i) not make any use whatsoever at any time of any Inside Information of the other Party except as for the purposes set forth in this Agreement;

(ii) disclose the Inside Information of the other Party only to those persons within its organization which need to access to the Information for the purposes set forth in this Agreement;

(iii) preserve the confidentiality of the Inside Information of the other Party, and take all necessary and reasonable precautions to prevent such information from being accessible to any Third Party;

(iv) comply with any and all obligations and prohibitions set forth in the aforementioned Regulation UE 596/2014 and the supplementary Regulations which develop it and in any other equivalent regulations in the Jazz Territory;

(v) not engage or attempt to engage in insider dealing as provided under Regulation UE 596/2014 or under any other equivalent regulations in the Jazz Territory;

(vi) not recommend that another person or entity engage in insider dealing or induce another person or entity to engage in insider dealing as provided under Regulation UE 596/2014 or under any other equivalent regulations in the Jazz Territory; and

(vii) promptly notify the other Party upon becoming aware of evidence or suspicion of any unauthorized use or disclosure of the Inside Information of the other Party.

(b) In case that any Inside Information of a Party is disclosed to the other Party under this Agreement, such disclosing Party shall specify with particularity which information disclosed is classified as Inside Information and such receiving Party shall appoint a person within its organization responsible for such Insider Information and shall provide all required information about such person to the other Party ("**Contact Person**"). Each Party acknowledges that its company and its Contact Person will be included in an insider list under Article 18.1 of Regulation (UE) 596/2014 (or under equivalent regulations in the Jazz Territory) as soon as Inside Information is disclosed to such Party. Each Party acknowledges the legal and regulatory duties entailed and declare they are aware of the sanctions applicable to insider dealing and unlawful disclosure of Inside Information.

(c) Each Party shall keep a list of all the persons to whom Inside Information of the other Party is disclosed with the content and form that requires Regulation (EU) 596/2014 (or equivalent Applicable Laws in the Jazz Territory) and to make such list available to the other Party upon request. Each Party shall take all reasonable steps to ensure that any person included in an insider list acknowledges in writing the legal and regulatory duties entailed as reflected in this Section 11.6 and is aware of the sanctions applicable to insider dealing and unlawful disclosure of inside information.

(d) The obligations, duties and prohibitions listed in this Section 11.6 with regard to each piece of Inside Information shall remain in force as long as the Inside Information continues to be qualified as inside information under Article 7 of Regulation (EU) 596/2014 (or under equivalent regulations in the Jazz Territory).

(e) Notwithstanding anything to the contrary in this Section 11.6, each Party shall be permitted to make any disclosure required by Applicable Law (including pursuant to regulations of any securities authority or stock exchange) and such disclosure shall not constitute a breach of this Section 11.6.

12. REPRESENTATIONS AND WARRANTIES

12.1 Mutual Representations and Warranties. Each Party represents and warrants to the other that, as of the Execution Date and the Effective Date: (a) it is duly organized and validly existing under the laws of its jurisdiction of incorporation or formation, and has full corporate or other power and authority to enter into this Agreement and to carry out the provisions hereof; (b) it is duly authorized to execute and deliver this Agreement and to perform its obligations hereunder, and the person or persons executing this Agreement on its behalf has been duly authorized to do so by all requisite corporate or partnership action; and (c) this Agreement is legally binding upon it, enforceable in accordance with its terms, and does not conflict with any agreement, instrument or understanding, oral or written, to which it is a Party or by which it may be bound, nor violate any material law or regulation of any court, governmental body or administrative or other agency having jurisdiction over it.

12.2 PharmaMar Representations and Warranties. PharmaMar represents and warrants to Jazz that as of the Effective Date:

(a) **Exhibit B** attached hereto contains a true and complete list of the PharmaMar Patents existing as of the Effective Date in the Jazz Territory;

(b) The PharmaMar Patents include all of the Patent Rights owned by or licensed to PharmaMar or its Affiliates that claim or disclose Licensed API or Licensed Product, or the manufacture, use, sale, offer for sale or import of Licensed API or Licensed Product;

(c) PharmaMar (i) has the right to grant the Jazz License; and (ii) except as provided for the EAP Agreement, has not granted to any Third Party any license or other right with respect to Licensed API, Licensed Product or PharmaMar Technology that conflicts with the Jazz License and other rights granted to Jazz herein;

(d) there are no agreements in effect as of the Effective Date between PharmaMar and a Third Party under which rights with respect to the PharmaMar Technology are licensed to PharmaMar;

(e) No Information [***] is necessary for the manufacture, use, sale, offer for sale or importation of any Licensed API or Licensed Product or is otherwise used by PharmaMar, its Affiliates or Third Party Partners in the manufacture, use, sale, offer for sale or import of any Licensed API or Licensed Product as of the Effective Date;

(f) PharmaMar is the sole and exclusive owner of all right, title and interest in and to the PharmaMar Patents;

(g) to PharmaMar's Best Knowledge, the issued and unexpired claims included in the PharmaMar Patents existing as of the Effective Date are valid and enforceable,;

(h) to PharmaMar's Best Knowledge, no reexamination, interference, invalidity, opposition, nullity or similar claim or proceeding is pending or threatened with respect to any PharmaMar Patent;

(i) to PharmaMar's Best Knowledge the manufacture, use, sale, offer for sale or import of Licensed API or Licensed Product does not infringe and would not infringe the patent or other intellectual property rights of any Third Party;

(j) PharmaMar has not received any written notice from any Third Party alleging that the manufacture, use, sale, offer for sale or import of Licensed API or Licensed Product does infringe or would infringe the patent or other intellectual property rights of any Third Party;

(k) there are no judgments or settlements against or owed by PharmaMar (or any of its Affiliates) with respect to the PharmaMar Technology, and PharmaMar is not a Party to any legal action, suit or proceeding relating to the PharmaMar Technology, nor has PharmaMar received any written communication from any Third Party, including, without limitation, any Regulatory Authority or other government agency, threatening such action, suit or proceeding;

(l) PharmaMar has made available to Jazz a list with all material data and Information regarding the Licensed Product currently available to PharmaMar and has provided Jazz with copies of any data or Information requested by Jazz during its due diligence process. Such list was and is complete and accurate and all tangible or recorded information and data provided by or on behalf of PharmaMar to Jazz related to Licensed API or Licensed Product on or before the Effective Date in contemplation of this Agreement was and is true, accurate and complete in all material respects, and PharmaMar has not failed (i) to include in such due diligence list any such information or data related to Licensed API or Licensed Product in its possession and Control that would cause the information and data that has been disclosed to be misleading in any material respect or (ii) to disclose, or failed to cause to be disclosed, any information or data requested by Jazz;

(m) Except with regard to Licensed Product Data obtained from ISS, with respect to patient records and with respect to publication rights under Clinical Trial agreements sponsored by PharmaMar, and with regard to Licensed Product Data obtained from those agreements for the conduct of preclinical and research activities under which no Patent Rights have been obtained as of the Effective Date, PharmaMar has the right to license pursuant to this Agreement all Licensed Product Data currently in existence and will solely own all Licensed Product Data arising from the Atlantis Trial, provided, that for the purposes of this Section 12.2(m) the definition of "Licensed Product Data" shall be deemed to not be limited to results and data that are Controlled by PharmaMar or its Affiliates;

(n) To PharmaMar's Best Knowledge, [***] in its manufacture of Bulk Vials pursuant to the [***], and PharmaMar has the right to transfer and license, to Jazz or its designee in accordance with the terms of this Agreement, the manufacturing process currently being used by [***] to manufacture Bulk Vials;

(o) Except for Licensed API and Licensed Products, PharmaMar and its Affiliates are not developing any compound or product for second line treatment SCLC;

(p) All research, manufacture and development of Licensed API and Licensed Products on or before the Effective Date was conducted in compliance with Applicable Laws;

(q) **Exhibit I** sets forth a complete and accurate list of all Regulatory Filings for Licensed API or Licensed Product in the Jazz Territory filed by PharmaMar or any of its Affiliates or Third Party Partners;

(r) neither PharmaMar nor any of its Affiliates is debarred under the Act or comparable Applicable Laws outside of the United States;

(s) neither PharmaMar nor any of its Affiliates has employed or otherwise used in any capacity, in connection with the development or manufacture of Licensed API or Licensed Product, the services of any person debarred or disqualified under United States law, including 21 U.S.C. §335a, or any foreign equivalent thereof;

(t) Except as for the EAP Agreement, Pharma Mar has not entered into any contract or agreement with any Third Party (including any funding agreement) pursuant to which a Third Party obtained any present or contingent right to commercialize Licensed API or Licensed Product in the Jazz Territory or pursuant to which there are contractual limitations or restrictions on Jazz's right or ability to develop or commercialize Licensed API or Licensed Product in the Jazz Territory; and

(u) Except as for ISS and for those agreements for the conduction of preclinical and research activities under which no Patent Rights have been obtained as of the Effective Date, Pharma Mar has not entered into any contract or agreement with any Third Party (including any funding agreement) pursuant to which a Third Party generated any Information or Patent Rights pertaining to Licensed API or Licensed Products that PharmaMar does not have the right to exclusively license to Jazz pursuant the Jazz License or to otherwise develop or commercialize Licensed API or Licensed Product in the Jazz Territory.

12.3 Jazz Representations and Warranties. Jazz represents and warrants to PharmaMar that as of the Effective Date:

(a) neither Jazz nor any of its Affiliates is debarred under the Act or comparable Applicable Laws outside of the United States; and

(b) to Jazz's Best Knowledge, neither Jazz nor any of its Affiliates Controls any Patent Right that claims the Licensed API or the Licensed Product in the form existing on the Effective Date or the method of manufacturing the Licensed API or Licensed Product used as of the Effective Date.

12.4 PharmaMar Covenants. In addition to any covenants made by PharmaMar elsewhere in this Agreement, PharmaMar hereby covenants to Jazz during the Term, PharmaMar will not grant any Third Party any license or other right with respect to Licensed API, Licensed Product or PharmaMar Technology in derogation of the Jazz License or the rights granted to Jazz hereunder, except in connection with (i) any ISS supported by PharmaMar, its Affiliates or Third Party Partners pursuant to agreements in effect prior to the Effective Date or (ii) any ISS supported by PharmaMar, its Affiliates or Third Party Partners after the Effective Date in PharmaMar Territory, provided that in each case of (i) and (ii), such derogation is limited to the grant by PharmaMar of a license to conduct the Clinical Trial of the Licensed Product that is the subject of such ISS.

12.5 Mutual Covenants. In addition to any covenants made by it elsewhere in this Agreement, each Party hereby covenants to the other Party that:

(a) neither such Party nor any of its Affiliates will employ or use the services of any Person who is debarred or disqualified under United States law, including 21 U.S.C. §335a, or any foreign equivalent thereof, in connection with activities relating to Licensed API or Licensed Product; and in the event that such Party becomes aware of the debarment or disqualification or threatened debarment or threatened disqualification of any Person providing services to such Party or any of its Affiliates with respect to any activities relating to Licensed API or Licensed Product, such Party will immediately notify the other Party in writing and such Party will cease, or cause its Affiliate to cease (as applicable), employing, contracting with, or retaining any such Person to perform any services relating to Licensed API or Licensed Product;

(b) neither such Party nor any of its Affiliates will, in connection with the exercise of such Party's rights or performance of its obligations under this Agreement, directly or indirectly through Third Parties, pay, promise or offer to pay, or authorize the payment of, any money or give any promise or offer to give, or authorize the giving of anything of value to a public official or entity or other Person for purpose of obtaining or retaining business for or with, or directing business to, any Person, including such Party and its Affiliates, nor will such Party or any of its Affiliates directly or indirectly promise, offer or provide any corrupt payment, gratuity, emolument, bribe, kickback, illicit gift or hospitality or other illegal or unethical benefit to a public official or entity or any other Person in connection with the exercise of such Party's rights or performance of such Party's obligations under this Agreement;

(c) neither such Party nor any of its Affiliates (or any of their respective employees and contractors), in connection with the exercise of such Party's rights or performance of such Party's obligations under this Agreement, shall cause the other Party to be in violation of Anti-Corruption Laws or Export Control Laws; and

(d) such Party shall immediately notify the other Party if such Party has any information or suspicion that there may be a violation of Anti-Corruption Laws or Export Control Laws in connection with the exercise of such Party's rights or performance of such Party's obligations under this Agreement.

12.6 Performance by Affiliates and Contractors. The Parties recognize that each Party may perform some or all of its obligations or exercise some or all of its rights under this Agreement through one or more Affiliates, or Third Party contractors; *provided*, in each case, that (a) none of the other Party's rights hereunder are diminished or otherwise adversely affected as a result of such delegation or contracting, and (b) each such Affiliate and Third Party contractor undertakes in writing obligations of confidentiality and non-use regarding Confidential Information and ownership of Inventions which are substantially the same as those undertaken by the Parties pursuant to Article 11 and Section 10.1; and *provided, further*, that such Party shall at all times be fully responsible for the performance and payment of such Affiliate or Third Party Contractor.

12.7 Disclaimer. Except as expressly set forth in this Agreement, EACH PARTY EXPRESSLY DISCLAIMS ANY AND ALL WARRANTIES OF ANY KIND, EXPRESS OR IMPLIED, INCLUDING, WITHOUT LIMITATION, THE WARRANTIES OF DESIGN, MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, VALIDITY OF PATENTS, NON-INFRINGEMENT OF THE INTELLECTUAL PROPERTY RIGHTS OF THIRD PARTIES, OR ARISING FROM A COURSE OF DEALING, USAGE OR TRADE PRACTICES.

13. TERM; TERMINATION

13.1 Term. This Agreement shall commence on the Effective Date (*provided, that* the provisions in Articles 2, 3, 4, 5, 6, 7, 8, 9, and 10 and Sections 12.5, 12.6, 13.2, 13.3, 13.4, 13.5, 13.6 and 16.14 shall not go into effect until the HSR Clearance Date) and, unless earlier terminated pursuant to this Article 13 or Section 16.13, shall remain in effect on a Licensed Product-by-Licensed Product basis, until the expiration of the Royalty Term of such Licensed Product (the "**Term**"). Upon the expiration of the Royalty Term for a Licensed Product, the Jazz License with respect to such Licensed Product shall become royalty-free, fully-paid, irrevocable and perpetual; *provided, that* Jazz shall only have the right to practice the license to the Product Trademarks pursuant to the Trademark License Agreement post expiration of this Agreement in accordance with the terms of Section 13.5(b).

13.2 Unilateral Termination by Jazz. Jazz may terminate this Agreement for any or no reason (a) prior to the First Commercial Sale of a Licensed Product in the Jazz Territory, upon [***] months written notice to PharmaMar and (b) after the First Commercial Sale of a Licensed Product in the Jazz Territory, upon the earlier of (i) completion of any agreed upon transfer of Jazz Technology or Regulatory Filings to PharmaMar pursuant to Section 13.5(c)(i) or (ii) [***] after Jazz's written notice to PharmaMar; *provided, however* that Jazz shall not be entitled to exercise unilateral termination right hereunder that would result in a termination effective date during the [***] from Effective Date of this Agreement.

13.3 Termination for Material Breach.

(a) Breach. Subject to Section 13.3(b), each Party shall have the right to terminate this Agreement upon written notice to the other Party if such other Party materially breaches its obligations under this Agreement and, after receiving written notice from the non-breaching Party identifying such material breach in reasonable detail, fails to cure such material

breach within [***] days from the date of such notice; *provided, that* if such breach is not reasonably capable of cure within such [***]-day period, the breaching Party may submit a reasonable cure plan prior to the end of such [***]-day period, in which case the other Party shall not have the right to terminate this Agreement for so long as the breaching Party is using diligent efforts to implement such cure plan.

(b) Disputed Breach. If the alleged breaching Party disputes in good faith the existence or materiality of a breach specified in a notice provided by the other Party in accordance with Section 13.3(a), and such alleged breaching Party provides the other Party notice of such dispute within such [***] day period, then the non-breaching Party shall not have the right to terminate this Agreement under Section 13.3(a) unless and until the arbitrators, in accordance with Article 15.2, has determined that the alleged breaching Party has materially breached the Agreement and that such Party fails to cure such breach within [***] days following such arbitrators' decision. It is understood and agreed that during the pendency of such dispute, all of the terms and conditions of this Agreement shall remain in effect and the Parties shall continue to perform all of their respective obligations hereunder.

13.4 Termination for Bankruptcy. Either Party may terminate this Agreement in its entirety upon written notice to the other Party in the event that (a) a case is commenced by or against such other Party under applicable bankruptcy, insolvency or similar laws, which case, if commenced against (not by) such other Party, is not dismissed within [***] days of the commencement thereof, (b) such other Party files for bankruptcy, reorganization, liquidation, receivership or similar proceedings, (c) such other Party assigns all or a substantial portion of its assets for the benefit of creditors, (d) a receiver or custodian is appointed for such other Party's business, (e) a substantial portion of such other Party's business is subject to attachment or similar process or (f) anything analogous to any of the events described in the foregoing clauses (a) through (f) occurs under the laws of any applicable jurisdiction.

13.5 Effect of Expiration or Termination.

(a) General. Upon any termination (but not expiration) of this Agreement, all licenses granted to Jazz and PharmaMar under this Agreement shall terminate.

(b) Continued Use of Product Trademarks on Expiration. Upon expiration (but not earlier termination) of this Agreement, Jazz shall have the continued right to Commercialize Licensed Product in the Jazz Territory under the Product Trademarks in accordance with the license granted under this Agreement as long as either (i) the Parties execute an agreement pursuant to which Jazz is obligated to pay PharmaMar a running royalty of [***] of all Net Sales of Licensed Product sold by Jazz and its Affiliates and Sublicensees in the Jazz Territory after expiration of the Agreement for the continued right to use the Product Trademarks or (ii) the Parties are parties to a commercial supply agreement pursuant to which PharmaMar is the [***] supplier of Licensed Product for Jazz in the Jazz Territory. Upon the written request of Jazz, PharmaMar shall negotiate in good faith and execute any such agreement on commercially reasonable terms and conditions.

(c) Termination by PharmaMar Pursuant to Section 13.3 or Section 13.4 or by Jazz Pursuant to Section 13.2. In the event of termination of this Agreement by

PharmaMar pursuant to Section 13.3 or Section 13.4, or by Jazz pursuant to Section 13.2, the following provisions shall apply:

(i) **Regulatory Materials.** Subject to Section 13.5(c)(iii), to the extent permitted by Applicable Laws, Jazz shall promptly but no later than [***] days from termination date, transfer and assign to PharmaMar all Regulatory Filings and Regulatory Approvals for the Licensed Product in the Jazz Territory and PharmaMar Territory at Jazz's sole cost; in addition, Jazz shall promptly provide to PharmaMar a copy of all Regulatory Filings, Regulatory Approvals and other regulatory materials related to the Licensed Product to the extent not previously provided to PharmaMar;

(ii) **Jazz License.** Jazz hereby grants to PharmaMar, effective only in event of such termination, a perpetual non-exclusive, fully paid-up and royalty-free license (except as set forth in Section 13.5(c)(iii)), with the right to grant and authorize sublicenses (subject to Section 2.8), under Jazz Technology which as of the effective date of termination is necessary for, or is being used by Jazz or its Affiliates or Sublicensees or by PharmaMar, its Affiliates and Third Party Partners in, the development, manufacture or commercialization of any Licensed Product (as defined below), to develop, make, have made, use, sell, offer for sale, have sold, import and otherwise exploit the Licensed API and the Licensed Products anywhere in the world;

(iii) **Royalty Obligation.** Solely in the event of termination of this Agreement by Jazz pursuant to Section 13.2 (unless in [***]), the rights granted to PharmaMar pursuant to this Section 13.5(c) shall be subject to the Parties agreeing in good faith within [***] days of the effective date of termination on common and customary non-financial conditions for the grant of such rights, *provided, that* the financial compensation shall be set at a royalty of [***] of Net Sales (applied *mutatis mutandis* to sales by PharmaMar, its Affiliates and (sub)licensees) of Licensed Product sold by PharmaMar, its Affiliates and (sub)licensees in the Jazz Territory;

(iv) **Transition Assistance.** Jazz shall provide at no cost to PharmaMar (subject to Section 13.5(c)(iii)) such assistance as may be reasonably necessary to transfer or transition over a reasonable period of time to PharmaMar, all then-existing commercial contractual arrangements, that is, or are, necessary or reasonably useful for PharmaMar to commence or continue developing, manufacturing or commercializing the Licensed Products, to the extent Jazz is then performing or having performed such activities, including without limitation transferring, upon request of PharmaMar, any agreements or arrangements with Third Party suppliers or vendors to Develop, manufacture, supply, distribute or sell or otherwise commercialize the Licensed Product in the Jazz Territory. To the extent that any contract between Jazz and a Third Party is not assignable to PharmaMar, then Jazz shall reasonably cooperate with PharmaMar to arrange the provision of such services for a reasonable time and service fee after termination;

(v) **Remaining Inventories.** PharmaMar shall have the right to purchase from Jazz any and all of the inventory of Licensed API or Licensed Products held by Jazz as of the effective date of such termination at a price equal to Jazz's actual cost to acquire or manufacture such inventory. Promptly after the effective date of such termination, Jazz shall submit to PharmaMar a list of its remaining inventory of Licensed API and Licensed Products and its acquisition cost. PharmaMar shall notify Jazz whether PharmaMar elects to exercise such right within [***] days after receiving notice from Jazz reporting such inventory as of the effective date

of such termination. If PharmaMar does not exercise such right, Jazz shall not have the right to sell any remaining inventory in the Jazz Territory and Jazz shall destroy immediately such remaining inventory at its sole expense, providing PharmaMar with a certificate of destruction of such inventory; and

(vi) In the event of termination of this Agreement by PharmaMar pursuant to Section 13.3 or Section 13.4, PharmaMar shall have all rights at law or in equity to pursue damages against Jazz for any uncured material breach.

(d) **Termination by Jazz Pursuant to Section 13.3 or Section 13.4.** In the event of termination of this Agreement by Jazz pursuant to Section 13.3 or Section 13.4 the following provisions shall apply:

(i) Jazz shall have all rights at law or in equity to pursue damages against PharmaMar for any uncured material breach.

(ii) effective as of such termination, Jazz shall, and it hereby does, grant to PharmaMar, a right of first negotiation, exercisable within [***] days after expiration, upon commercially reasonable terms and conditions (including payments to Jazz) to be negotiated in good faith by the Parties for up to [***] days from the date of exercise:

(1) to obtain an exclusive, royalty-bearing license, with the right to sublicense through multiple tiers of sublicense, under Jazz Technology which as of the effective date of termination is necessary for, or used by Jazz in, the development, manufacture or commercialization of any Termination Licensed Product (as defined below), solely to Develop, manufacture, have manufactured and Commercialize in the Jazz Territory Licensed Products that are being Developed, manufactured or Commercialized as of the effective date of termination (the "**Termination Licensed Products**"), and to have all such Jazz Technology transferred to PharmaMar; and

(2) to have transferred or assigned to PharmaMar or its designee all Regulatory Filings for Licensed Products in the Licensed Indication in the Jazz Territory held in the name of Jazz or any of its Affiliates.

(iii) PharmaMar shall have the right, but not the obligation, to purchase from Jazz any or all usable inventory of Licensed API and Licensed Product in Jazz's or its Affiliates' possession as of the date of expiration. Such inventory shall be provided at a transfer price equal to Jazz's cost of such inventory (as reflected on Jazz's books and records used to prepare its financial statements), plus freight, insurance, transportation, postage and handling. If PharmaMar elects not to purchase such inventory, Jazz shall have the right to sell in the Jazz Territory such remaining inventory over a period of no greater than [***] months after the effective date of such termination, provided that Jazz shall continue to make royalty payments on such sales in accordance with Section 8.7.

13.6 Remedies in Lieu of Termination. If Jazz would otherwise have the right to terminate this Agreement pursuant to Section 13.3, then Jazz may elect, by written notice to PharmaMar, not to terminate this Agreement on the basis of such material breach and to have no further financial obligations under this Agreement (including under Section 8.2, Section 8.4, Section 8.5, Section 8.6 and Section 8.7).

13.7 Accrued Obligations; Survival. Upon any termination or any expiration of this Agreement, all rights and obligations of the Parties under this Agreement shall terminate, except as expressly provided in this Section 13.7 or elsewhere in this Article 13. Neither expiration nor any termination of this Agreement shall relieve either Party of any obligation or liability accruing prior to such expiration or termination, nor shall expiration or any termination of this Agreement preclude either Party from pursuing all rights and remedies it may have under this Agreement, at law or in equity, with respect to breach of this Agreement. In addition, upon any termination or expiration of this Agreement other than termination pursuant to Section 16.13, the Parties' rights and obligations under Sections 9.4, 9.5, 10.1, 12.7, 13.1, 13.5, 13.7, 13.8, 13.9, 14.1, 14.2, 14.3, 14.4 and Articles 1 (to the extent used in any surviving provisions), 11 (other than Section 11.4 and Section 11.5), 15 and 16 of this Agreement shall survive expiration or any termination of this Agreement. Upon any termination of this Agreement pursuant to Section 16.13, the Parties' rights and obligations under Section 12.7 and Articles 1 (to the extent used in any surviving provisions), 11, 15 and 16 (other than Section 16.14) of this Agreement shall survive.

13.8 Return of Confidential Information. Within [***] days following the expiration or termination of this Agreement, except to the extent that a Party retains a license from the other Party as provided in this Article 13, each Party shall promptly return to the other Party, or delete or destroy, all relevant records and materials in such Party's possession or control containing Confidential Information of the other Party; provided that such Party may keep one copy of such materials for archival purposes only subject to Article 11.

13.9 Damages; Relief. Termination of this Agreement shall not preclude either Party from claiming any other damages, compensation or relief that it may be entitled to hereunder as a result of the other Party's breach of this Agreement.

14. INDEMNIFICATION

14.1 Indemnification by Jazz. Jazz hereby agrees to defend, indemnify and hold harmless PharmaMar, its Affiliates, its and their respective officers, directors, agents, employees, successors and assigns (the "**PharmaMar Indemnitees**"), from and against any and all losses, damages, liabilities, expenses and costs, including reasonable legal expense and attorneys' fees (collectively, "**Losses**"), to which any PharmaMar Indemnitee may become subject as a result of any claim, demand, action or other proceeding by any Third Party (each, a "**Claim**") to the extent such Losses arise out of or relate to: (a) the Development, manufacture, use, handling, storage, import or Commercialization of Licensed API or Licensed Products by or on behalf of Jazz, its Affiliates or Sublicensees; (b) the negligence or willful misconduct of any Jazz Indemnitee; or (c) the breach by Jazz of any warranty, representation, covenant or agreement made by Jazz in this Agreement; except, in each case, to the extent such Losses result from the negligence or willful misconduct of any PharmaMar Indemnitee or the breach by PharmaMar of any warranty, representation, covenant or agreement made by PharmaMar in this Agreement.

14.2 Indemnification by PharmaMar. PharmaMar hereby agrees to defend, indemnify and hold harmless Jazz, its Affiliates and their respective officers, directors, employees, consultants and agents (the “**Jazz Indemnitees**”) from and against any and all Losses to which any Jazz Indemnitee may become subject as a result of any Claim to the extent such Losses arise out of or relate to: (a) the development, manufacture, use, handling, storage, import or Commercialization of Licensed API or Licensed Products by or on behalf of PharmaMar, its Affiliates or licensees in the Jazz Territory or PharmaMar Territory prior to the Effective Date or during the Term; (b) the negligence or willful misconduct of any PharmaMar Indemnitee; or (c) the breach by PharmaMar of any warranty, representation, covenant or agreement made by PharmaMar in this Agreement; in each case except to the extent such Losses result from the negligence or willful misconduct of any Jazz Indemnitee or the breach by Jazz of any warranty, representation, covenant or agreement made by Jazz in this Agreement.

14.3 Indemnification Procedures. In the event a Party (the “**Indemnified Party**”) seeks indemnification under Section 14.1 or 14.2, it shall inform the other Party (the “**Indemnifying Party**”) of a claim as soon as reasonably practicable after it receives notice of the claim (it being understood and agreed, however, that the failure by an Indemnified Party to give notice of a claim as provided in this Section 14.3 shall not relieve the Indemnifying Party of its indemnification obligation under this Agreement except and only to the extent that such Indemnifying Party is actually damaged as a result of such failure to give notice), shall permit the Indemnifying Party to assume direction and control of the defense of the claim (including the right to settle the claim solely for monetary consideration) using counsel reasonably satisfactory to the Indemnified Party, and shall cooperate as requested (at the expense of the Indemnifying Party) in the defense of the claim. If the Indemnifying Party does not assume control of such defense within [***] days after receiving notice of the claim from the Indemnified Party, the Indemnified Party shall control such defense and, without limiting the Indemnifying Party’s indemnification obligations, the Indemnifying Party shall reimburse the Indemnified Party for all costs, including reasonable attorney fees, incurred by the Indemnified Party in defending itself within [***] days after receipt of any invoice therefor from the Indemnified Party. The Party not controlling such defense may participate therein at its own expense. The Party controlling such defense shall keep the other Party advised of the status of such action, suit, proceeding or claim and the defense thereof and shall consider recommendations made by the other Party with respect thereto. The Indemnified Party shall not agree to any settlement of such action, suit, proceeding or claim without the prior written consent of the Indemnifying Party, which shall not be unreasonably withheld, delayed or conditioned. The Indemnifying Party shall not agree to any settlement of such action, suit, proceeding or claim or consent to any judgment in respect thereof that does not include a complete and unconditional release of the Indemnified Party from all liability with respect thereto, that imposes any liability or obligation on the Indemnified Party or that acknowledges fault by the Indemnified Party without the prior written consent of the Indemnified Party. If the Parties cannot agree as to the application of Section 14.1 or 14.2 to any claim, pending resolution of the dispute pursuant to Article 15, the Parties may conduct separate defenses of such claims, with each Party retaining the right to claim indemnification from the other Party in accordance with Section 14.1 or 14.2, as applicable, upon resolution of the underlying claim.

14.4 Limitation of Liability. NEITHER PARTY SHALL BE LIABLE TO THE OTHER FOR ANY SPECIAL, CONSEQUENTIAL, INCIDENTAL, PUNITIVE, OR INDIRECT DAMAGES ARISING FROM OR RELATING TO ANY BREACH OF THIS AGREEMENT, REGARDLESS OF ANY NOTICE OF THE POSSIBILITY OF SUCH DAMAGES. NOTWITHSTANDING THE FOREGOING, NOTHING IN THIS SECTION 14.4 IS INTENDED TO OR SHALL LIMIT OR RESTRICT THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF ANY PARTY UNDER SECTION 14.1 OR 14.2 OR DAMAGES AVAILABLE FOR BREACH OF ARTICLE 11.

14.5 Insurance. Each Party shall procure and maintain insurance, including comprehensive or commercial general liability insurance (including contractual liability and product liability), in amounts that are commercially reasonable in light of the activities and obligations undertaken by such Party pursuant to this Agreement, which amounts shall be consistent with normal business practices of prudent companies similarly situated. It is understood that such insurance shall not be construed to create a limit of either Party's liability with respect to its indemnification obligations under this Article 14 or otherwise. Each Party shall provide the other Party with written evidence of such insurance upon request. Each Party shall provide the other Party with written notice at least [***] days prior to the cancellation or non-renewal of such insurance.

15. DISPUTE RESOLUTION

15.1 Disputes. It is the objective of the Parties to establish procedures to facilitate the resolution of disputes arising under this Agreement in an expedient manner by mutual cooperation and without resort to litigation. In the event of any disputes, controversies or differences which may arise between the Parties out of or in relation to or in connection with this Agreement (other than disputes arising from the JDC or JCC that are subject to the final decision making authority set forth in Section 3.4(b) and other than disputes that are subject to Third Party resolution as set forth in Section 4.1(a)(ii), Section 4.2(d)(iv), Section 5.5(c)(iv), Section 5.5(c)(v) or Section 15.3, each of which shall be resolved as described therein), including, without limitation, any alleged failure to perform, or breach, of this Agreement, or any issue relating to the interpretation or application of this Agreement (each, a "**Dispute**"), then upon the request of either Party by written notice, the Parties agree to meet and discuss in good faith a possible resolution thereof, which good faith efforts shall include at least one in-person meeting between the Parties' respective Executive Officers. If the matter is not resolved within [***] days following the written request for discussions, either Party may then invoke the provisions of Section 15.2.

15.2 Arbitration.

(a) ICC Arbitration. Any Dispute that is not resolved pursuant to Section 15.1 or required to be resolved in accordance with Section 3.4(b), Section 4.1(a)(ii), Section 4.2(d)(iv), Section 5.5(c)(iv), Section 5.5(c)(v) or Section 15.3, except for a dispute, claim or controversy under Section 15.3, shall be finally settled by arbitration in accordance with the Rules of Arbitration of the International Chamber of Commerce ("**ICC Rules**"). The number of arbitrators shall be three (3), of whom each Party shall appoint one (1). The two arbitrators so appointed will select the third and final arbitrator in accordance with the ICC Rules. The seat of arbitration shall be located in New York, New York, United States. The Parties each consent to the personal

jurisdiction of the U.S. federal courts for any case arising out of or otherwise related to this arbitration, its conduct and its enforcement. The language to be used in the arbitral proceedings will be English. Any situation not expressly covered by this Agreement shall be decided in accordance with the ICC Rules.

(b) Decision. The arbitrators shall issue a reasoned opinion following a full comprehensive hearing, no later than [***] months following the selection of the arbitrators as provided for in Section 15.2(a) unless the Parties jointly request an extension or the arbitrators determine, in a reasoned decision that the interest of justice or the complexity of the case requires that such limit be extended.

(c) Award. Any award shall be promptly paid in Dollars free of any tax, deduction or offset; and any costs, fees or taxes incident to enforcing the award shall, to the maximum extent permitted by Applicable Law, be charged against the Party resisting enforcement. Each Party agrees to abide by the award rendered in any arbitration conducted pursuant to this Section 15.2, and agrees that, subject to the Federal Arbitration Act, judgment may be entered in any court of competent jurisdiction and that other courts may award full faith and credit to such judgment in order to enforce such award. The award shall include interest from the date of any damages incurred for breach of this Agreement, and from the date of the award until paid in full, at a rate fixed by the arbitrators.

(d) Costs. Except as set forth in Section 15.2(c), each Party shall bear its own legal fees. The arbitrators shall assess their costs, fees and expenses against the Party losing the arbitration unless they believe that neither Party is the clear loser, in which case the arbitrators shall divide their fees, costs and expenses according to their sole discretion.

(e) Confidentiality. The arbitration proceeding shall be confidential and the arbitrators shall issue appropriate protective orders to safeguard each Party's Confidential Information. Except as required by Applicable Law, no Party shall make (or instruct the arbitrators to make) any public announcement with respect to the proceedings or decision of the arbitrators without prior written consent of the other Party. The existence of any dispute submitted to arbitration, and the award, shall be kept in confidence by the Parties and the arbitrators, except (i) as required in connection with the enforcement of such award, (ii) as otherwise required by Applicable Law or required of a Party to fulfill a legal duty or protect or pursue a legal right, (iii) with the consent of both Parties, (iv) where such information is already in the public domain other than as a result of a breach of this clause, or (v) by order of the arbitrators upon application of a Party.

(f) Survivability. Any duty to arbitrate under this Agreement shall remain in effect and be enforceable after termination of this Agreement for any reason.

15.3 Court Actions. Nothing contained in this Agreement shall deny either Party the right to seek injunctive or other equitable relief, including specific performance, from a court of competent jurisdiction in the context of a *bona fide* emergency or prospective irreparable harm, including with respect to any breach of Article 11 or the ownership provisions of Section 10.1 in order to preserve the status quo pending resolution of the Dispute between the Parties under Sections 15.1 and 15.2, and such an action may be filed and maintained notwithstanding any

ongoing discussions between the Parties or any ongoing arbitration proceeding. In addition, either Party may bring an action in any court of competent jurisdiction to resolve disputes pertaining to the validity, construction, scope, enforceability, infringement or other violations of Patent Rights or other intellectual property rights, and no such claim shall be subject to arbitration pursuant to Section 15.2.

16. GENERAL PROVISIONS

16.1 Entire Agreement; Amendments. This Agreement, including the Exhibits hereto, and the Supply Agreement, Safety Exchange Agreement and Quality Agreement sets forth the complete, final and exclusive agreement and all the covenants, promises, agreements, warranties, representations, conditions and understandings between the Parties hereto with respect to the subject matter hereof and supersedes, as of the Effective Date, all prior and contemporaneous agreements and understandings between the Parties with respect to the subject matter hereof, including the Confidentiality Agreement. The foregoing shall not be interpreted as a waiver of any remedies available to either Party as a result of any breach, prior to the Effective Date, by the other Party of its obligations under the Confidentiality Agreement. There are no covenants, promises, agreements, warranties, representations, conditions or understandings, either oral or written, between the Parties other than as are set forth in this Agreement. No subsequent alteration, amendment, change or addition to this Agreement shall be binding upon the Parties unless reduced to writing and signed by an authorized officer of each Party.

16.2 Governing Law. This Agreement shall be governed by and construed in accordance with the laws of the State of New York, USA, excluding its conflicts of laws principles with the exception of sections 5-1401 and 5-1402 of New York General Obligations Law. Subject to Article 15 above, each Party hereby consents to the venue and jurisdiction of state and federal courts located in the State of New York (U.S.).

16.3 Rights in Bankruptcy.

(a) All rights and licenses granted under or pursuant to this Agreement by PharmaMar to Jazz are, for all purposes of Title 11 of the United States Code (“**Title 11**”), licenses of rights to “intellectual property” as defined in Title 11, and, in the event that a case under Title 11 is commenced by or against PharmaMar, Jazz shall have all of the rights set forth in Section 365(n) of Title 11 to the maximum extent permitted thereby. During the Term, PharmaMar shall create and maintain current copies to the extent practicable of all such intellectual property. Without limiting the Parties’ rights under Section 365(n) of Title 11, if a case under Title 11 is commenced by or against PharmaMar, Jazz shall be entitled to a copy of any and all such intellectual property and all embodiments of such intellectual property, and the same, if not in the possession of Jazz, shall be promptly delivered to it (i) before this Agreement is rejected by or on behalf of PharmaMar, within [***] days after Jazz’s written request, unless PharmaMar, or its trustee or receiver, elects within [***] days to continue to perform all of its obligations under this Agreement, or (ii) after any rejection of this Agreement by or on behalf of PharmaMar, if not previously delivered as provided under clause (i) above. All rights of the Parties under this Section 16.3 and under Section 365(n) of Title 11 are in addition to and not in substitution of any and all other rights, powers, and remedies that each Party may have under this Agreement, Title 11, and any other Applicable Laws. Jazz shall have the right to perform the obligations of PharmaMar hereunder with respect to such intellectual property, but neither such provision nor such performance by Jazz shall release PharmaMar from any such obligation or liability for failing to perform it.

(b) The Parties agree that they intend the foregoing Jazz rights to extend to the maximum extent permitted by law and any provisions of applicable contracts with Third Parties, including for purposes of Title 11, (i) the right of access to any intellectual property (including all embodiments thereof) of PharmaMar or any Third Party with whom PharmaMar contracts to perform an obligation of PharmaMar under this Agreement, and, in the case of the Third Party, which is necessary for the Development, Regulatory Approval and manufacture of Licensed Products and (ii) the right to contract directly with any Third Party described in (i) in this sentence to complete the contracted work.

(c) Any intellectual property provided pursuant to the provisions of this Section 16.3 shall be subject to the licenses set forth elsewhere in this Agreement and the payment obligations of this Agreement, which shall be deemed to be royalties for purposes of Title 11.

(d) Notwithstanding anything to the contrary in Article 10, in the event that a case under Title 11 is commenced by or against PharmaMar, Jazz may take appropriate actions in connection with the filing, prosecution, maintenance and enforcement of any PharmaMar Patent Rights in the Jazz Territory licensed to Jazz under this Agreement without being required to consult with PharmaMar before taking any such actions, *provided that* such actions are consistent with this Agreement.

16.4 Assignment. Neither Party may assign or transfer this Agreement or any rights or obligations hereunder without the prior written consent of the other, except that a Party may make such an assignment or transfer without the other Party's consent to its Affiliates or to a Third Party successor to substantially all of the business of such Party to which this Agreement relates, whether in a merger, sale of stock, sale of assets or other transaction. Any permitted assignment shall be binding on the successors of the assigning Party. Any assignment or attempted assignment by either Party in violation of the terms of this Section 16.4 shall be null, void and of no legal effect.

16.5 Force Majeure. Each Party shall be excused from liability for the failure or delay in performance of any obligation under this Agreement by reason of any event beyond such Party's reasonable control, including but not limited to Acts of God, fire, flood, explosion, earthquake, or other natural forces, war, civil unrest, acts of terrorism, accident, destruction or other casualty, any lack or failure of transportation facilities, any lack or failure of supply of raw materials, any strike or organized labor disturbance, or any other event similar to those enumerated above ("**Force Majeure**"). Such excuse from liability shall be effective only to the extent and duration of the event(s) causing the failure or delay in performance and provided that the Party has not caused, in whole or in part, such event(s) to occur. The affected Party shall notify the other Party of such Force Majeure as soon as reasonably practical, and shall promptly undertake all reasonable efforts necessary to cure such Force Majeure.

16.6 Non-Waiver. The failure of a Party to insist upon strict performance of any provision of this Agreement or to exercise any right arising out of this Agreement shall neither

impair that provision or right nor constitute a waiver of that provision or right, in whole or in part, in that instance or in any other instance. Any waiver by a Party of a particular provision or right shall be in writing, shall be as to a particular matter and, if applicable, for a particular period of time and shall be signed by such Party.

16.7 Severability. If any one or more of the provisions contained in this Agreement is held invalid, illegal or unenforceable in any respect, the validity, legality and enforceability of the remaining provisions contained herein shall not in any way be affected or impaired thereby, unless the absence of the invalidated provision(s) adversely affects the substantive rights of the Parties. The Parties shall in such an instance use their best efforts to replace the invalid, illegal or unenforceable provision(s) with valid, legal and enforceable provision(s) which, insofar as practical, implement the purposes of this Agreement.

16.8 Further Actions. Each Party agrees to execute, acknowledge and deliver such further instruments, and to do all such other acts, as may be necessary or appropriate in order to carry out the purposes and intent of this Agreement.

16.9 Notices. Any notice to be given under this Agreement must be in writing and delivered either in person, by internationally-recognized express courier, to the Party to be notified at its address(es) given below, or at any address such Party has previously designated by prior written notice to the other. Notice shall be deemed sufficiently given for all purposes upon the earliest of: (a) the date of actual receipt; or (b) if delivered by express courier, the second Business Day the express courier regularly makes deliveries following deposit.

If to Jazz, to: Jazz Pharmaceuticals Ireland Limited
Fifth Floor, Waterloo Exchange
Waterloo Road, Dublin 4, Ireland
Attention: General Counsel
Fax: [***]

With a copy to:
Jazz Pharmaceuticals, Inc.
3170 Porter Drive
Palo Alto, CA 94304
Attention: General Counsel
Fax: [***]

With a copy to:
[***]
Attention: Legal Department

If to PharmaMar, to: PharmaMar SA
Avda. De los Reyes n° 1
28770 Colmenar Viejo, Madrid
Spain
Attn. Business Development, Director
Fax: [***]
E-mail address: [***]

With a copy to:

PharmaMar SA
Avda. De los Reyes n° 1
28770 Colmenar Viejo, Madrid
Spain
Attn. Legal Director – Business
Email: [***]

16.10 Interpretation. The headings of clauses contained in this Agreement preceding the text of the sections, subsections and paragraphs hereof are inserted solely for convenience and ease of reference only and shall not constitute any part of this Agreement, or have any effect on its interpretation or construction. All references in this Agreement to the singular shall include the plural where applicable. The term “including” or “includes” as used in this Agreement means including, without limiting the generality of any description preceding such term, and the word “or” has the inclusive meaning represented by the phrase “and/or.” Unless otherwise specified, references in this Agreement to any section shall include all subsections and paragraphs in such Section and references in this Agreement to any subsection shall include all paragraphs in such subsection. All references to days in this Agreement shall mean calendar days, unless otherwise specified. Ambiguities and uncertainties in this Agreement, if any, shall not be interpreted against either Party, irrespective of which Party may be deemed to have caused the ambiguity or uncertainty to exist. This Agreement has been prepared in the English language, and the English language shall control its interpretation. In addition, all notices required or permitted to be given hereunder, and all written, electronic, oral or other communications between the Parties regarding this Agreement shall be in the English language.

16.11 Relationship between the Parties. The Parties’ relationship, as established by this Agreement, is solely that of independent contractors. This Agreement does not create any partnership, joint venture or similar business relationship between the Parties. Neither Party is a legal representative of the other Party, and neither Party may assume or create any obligation, representation, warranty or guarantee, express or implied, on behalf of the other Party for any purpose whatsoever.

16.12 No Third Party Rights. The provisions of this Agreement are for the exclusive benefit of the Parties, and no other person or entity shall have any right or claim against any Party by reason of these provisions or be entitled to enforce any of these provisions against any Party.

16.13 HSR Clearance; Termination Upon HSR Denial. If either or each of the Parties reasonably determines that an HSR Filing is required by Applicable Law to consummate the transactions contemplated hereunder, each Party shall, within [***] Business Days of the Effective Date (or such later time as may be agreed to in writing by the Parties), file with the United States Federal Trade Commission and the Antitrust Division of the United States Department of Justice, and/or with any equivalent Governmental Authority in any other country,

as the case may be, any HSR Filing under the HSR Act with respect to the transactions contemplated hereunder. Each Party shall use its respective reasonable best efforts to do, or cause to be done, all things necessary, proper and advisable to, as promptly as practicable, take all actions necessary to make the HSR Filings required of any of the Parties or their respective Affiliates under the HSR Act, to respond promptly to any reasonable requests for additional information from any Governmental Authority, and to obtain all approvals, consents, clearances and/or termination or expiration of any waiting periods required to consummate the transactions contemplated by this agreement. The Parties shall cooperate with one another to the extent reasonably necessary in the preparation of any such HSR Filing. Each Party shall be responsible for its own out-of-pocket costs and expenses associated with any HSR Filing, provided, however, that Jazz shall be solely responsible for any fees (other than penalties that may be incurred as a result of actions or omissions on the part of PharmaMar) required to be paid to any Governmental Authority in connection with making any such HSR Filing hereunder. If the Parties make an HSR Filing hereunder, then this Agreement shall terminate (a) at the election of either Party, immediately upon notice to the other Party, if the U.S. Federal Trade Commission or the U.S. Department of Justice, or an equivalent authority in the European Union or any member state, seeks a preliminary injunction or takes similar action under the Antitrust Laws against any Party to enjoin the transactions contemplated by this Agreement; (b) at the election of either Party, immediately upon notice to the other Party, in the event that the United States Federal Trade Commission or the United States Department of Justice obtains a preliminary injunction under the Antitrust Laws against any Party to enjoin the transactions contemplated by this Agreement; or (c) at the election of either Party, immediately upon notice to the other Party, in the event that the HSR Clearance Date shall not have occurred on or prior to [***] days after the commencement of the HSR waiting period (or [***] after the commencement of the HSR waiting period in the event the Parties [***]). From the period running from the Effective Date and ending on the HSR Clearance Date, PharmaMar shall provide prompt, but in no event less than [***] hours after having actual knowledge thereof, written notice to Jazz of the occurrence of any Material Adverse Event. Within [***] Business Days after (i) Jazz's receipt of such notice or (ii) if PharmaMar fails to provide such written notice, after Jazz becomes aware of the occurrence of any Material Adverse Event, Jazz may terminate this Agreement pursuant to this Section 16.13. For the avoidance of doubt, if Jazz does not provide any such written notice within the two Business Day period provided for herein, any right to terminate this Agreement pursuant to this Section 16.13 on account of a Material Adverse Event shall be deemed to expire.

16.14 Personal Data Protection

(a) General. Both Parties undertake to comply with any Applicable Law regarding protection of personal data, including but not limited to the European General Data Protection Regulation 2016/679 of 8 April 2016 ("GDPR").

(b) Purpose. The Parties acknowledge that personal data of each Party's officers, agents, Affiliates, partners, employees, subcontractors, consultants, customers, partners, investigators, physicians, and authorities' staff may become part of data files property of PharmaMar or Jazz, as appropriate, for the only purpose of managing the contractual relationship between the Parties, including regulatory matters, operational matters and financial relationship derived from this Agreement, control of the execution of the activities to be performed by the

Parties under this Agreement, contact maintenance and compliance with all Applicable Laws, regulations and codes of practices. Both Parties shall be considered independent data controllers (as that term is defined in the GDPR) of such personal data exchanges according to Applicable Law. The Parties do not operate as joint data controllers.

(c) Recipients. The Parties agree that each Party may transfer personal data of the other Party for the same purpose to the respective Affiliates, Sublicensees, Third Party Partners, each Party's subcontractors and to Regulatory Authorities as provided by Applicable Law.

(d) Legitimation of the treatment of personal data. The Parties agree that the legitimation for the collection, processing and transfer of personal data of the other Party is based in the existing contractual relationship under this Agreement and subsequently once purpose for its collection, processing and transfer has been completed, in the need to comply and/or verify compliance with contractual and legal obligations and possible liabilities derived from this Agreement. In the case of opposing the processing of personal data, PharmaMar and/or Jazz would not be able to continue maintaining the Agreement, having to make the necessary modifications or even having to cancel it. The maintenance of contact, even by electronic means, on matters relating to the activities to be performed under the Agreement is based on the legitimate interest respectively of both PharmaMar and Jazz.

(e) Limited storage periods. Subject to Applicable Law, each Party may store personal data of the other Party during the Term of the Agreement and thereafter during the time necessary to assure the compliance with any contractual and legal obligation or as necessary to determine any liability of the Parties derived from the contractual relationship and the processing of personal data. In this regard, financial data will be gathered according to Applicable Laws and regulations in this subject matter - for the time tax and accounting regulations provide such information could be required from Regulatory Authorities, such as tax agencies or courts.

(f) Rights. To the extent a Party receives a request from each of the aforementioned persons in 16.15(b) to exercise his/her rights (including requests of access, rectification, cancellation, portability or/and opposition to his data being processed) under Applicable Law with respect to personal data under the Agreement gathered in PharmaMar or Jazz files, as appropriate, the receiving Party will respond to the extent required under Applicable Law, and each Party shall reasonably cooperate with the other Party to assist the other Party with such required response.

(g) Data Protection Officer. In case of data gathered in PharmaMar files, to execute any of the previously mentioned rights, data subjects must provide written notice in this regard to the Legal Department of PharmaMar to its address at Avda. De los Reyes nº 1, 28770 Colmenar Viejo (Madrid), Spain or by email to dpo@pharmamar.com. Jazz and its staff can access the full information on the privacy and data protection policy on PharmaMar's website www.pharmamar.com.

In case of data gathered in Jazz's files, to execute any of the previously mentioned rights, data subjects must provide written notice in this regard to the Privacy Office of Jazz Pharmaceuticals to its address at 3170 Porter Drive, Palo Alto, CA 94303, U.S., or by email to dpo@jazzpharma.com. PharmaMar and its staff can access the privacy statement on Jazz's website www.jazzpharma.com.

(h) Other Obligations. Likewise, PharmaMar and Jazz, as independent data controllers, compromise to:

(i) reasonably cooperate with the other Party to enable such Party to fulfill its obligations under Applicable Laws;

(ii) have in place appropriate technical and organizational measures to protect the personal data against accidental or unlawful destruction or accidental loss, alteration, unauthorized disclosure or access, and which provide a level of security appropriate to the risk represented by the processing and the nature of the data to be protected;

(iii) subject to Applicable Laws, comply with its secrecy obligations with regard to all personal data gathered in their file; this obligation to remain indefinitely in place after the end of this Agreement;

(iv) all personal involved in this Agreement must be aware of the obligation to confidentiality and security;

(v) have in place procedures so that any third party they authorize to have access to the personal data, including processors, will respect and maintain the confidentiality and security of the personal data;

(vi) process the personal data for purposes described in this Agreement, and have the legal authority to give the warranties and fulfil the undertakings set out in these clauses;

(vii) to the extent a Party receives a request from supervisory authority with respect to personal data for which another Party is also a data controller, the other Party shall reasonably cooperate with the receiving Party's efforts to respond to such a request;

(viii) to the extent a Party needs to conduct a data protection impact assessment ("**DPIA**"), including prior consultation with a supervisory authority, the other Party shall reasonably cooperate with the Party conducting the DPIA to assist with its completion of the DPIA; and

(ix) in the event that for the performance of activities set forth in this Agreement any Party should provide personal data of natural persons to the other Party, such Party providing such personal data should inform, in advance, to such natural person about the processing of such personal data as contemplated by this Agreement.

16.15 Counterparts. This Agreement may be executed in counterparts, each of which shall be deemed an original document, and all of which, together with this writing, shall be deemed one instrument. This Agreement may be executed by facsimile or PDF signatures, which signatures shall have the same force and effect as original signatures.

[Signature page follows.]

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

JAZZ PHARMACEUTICALS IRELAND LIMITED

By: /s/ Patricia Carr
Name: Patricia Carr
Title: Director

PHARMA MAR S.A.

By: /s/ Jose María Fernandez Sousa-Faro
Name: Jose María Fernandez Sousa-Faro
Title: President

[Signature Page to License Agreement]

Exhibit A

Licensed API

[**]

EXHIBIT B

PharmaMar Patents

[**]

EXHIBIT C

Third Party Partners

[**]

EXHIBIT D

Atlantis Trial Development Plan

[**]

EXHIBIT E

- (a) For launch: PharmaMar shall supply Jazz with quantities of Bulk Vials obtained from existing in stock validation lots. Jazz will be [***].
- (b) For all other supply: PharmaMar shall supply Jazz with Licensed API. Jazz will be [***].
- (c) For clarity, [***].
- (d) PharmaMar shall [***].
- (e) Promptly after signing of the Supply Agreement, [***], PharmaMar shall [***].
- (f) Supply price shall be [***].
- (g) All payments of supply prices will be in [***].
- (h) There shall be periodic rolling forecasts with [***].
- (i) [***] shall promptly discuss [***].
- (j) All Licensed API and Bulk Vials supplied by PharmaMar will be [***].
- (k) All [***]. Notwithstanding anything to the contrary, the Parties agree that [***].
- (l) Supply price shall be [***].
- (m) Subject to Section 6.4 of the Agreement, [***]. PharmaMar shall [***].
- (n) Governance structure and decision making for CMC-related activities will be included in the Supply Agreement.
- (o) PharmaMar will [***].
- (p) [***].
- (q) Any purchase order [***] shall be deemed a **'Firm Order'** and shall be [***] and such [***] shall be deemed the **'Delivery Date.'** Additional details of the forecasting and ordering mechanism will be agreed upon in the Supply Agreement.
- (r) Upon [***], the Parties will [***]. The Parties shall [***]. In the event that [***], then such circumstances shall be deemed a **'Supply Failure'**.

-
- (s) As set forth in subsection (o) above, PharmaMar shall [***]. If PharmaMar's [***], then the Parties will [***]. The Parties shall [***]. In the event that [***], then such circumstances shall be deemed a "**Supply Failure**."
 - (t) Upon any Supply Failure (as defined under subsection (r) or (s) above), Pharma Mar shall, [***].

Exhibit F

Co-Promotion Terms

1. [***] will have the right and obligation to provide (a) [***] and (b) [***] (the **‘Co-Promotion Activities’**). The [***] will be agreed upon by the JCC as part of the Co-Promotion Plan. Each Party’s [***] shall be [***].
2. The [***] shall be [***].
3. [***] shall [***] in the Jazz Territory. [***] shall [***] in the Jazz Territory.
4. To [***], [***] will [***] starting on [***] and ending upon [***].
5. Other terms included in this Agreement shall be *mutatis mutandi* applied to the Co-Promotion Agreement to the extent such terms are applicable to a Co-promotion Agreement.

Exhibit G

Product Trademark

[**]

EXHIBIT H

Press Release

PharmaMar and Jazz Pharmaceuticals Sign Exclusive License Agreement for Lurbinectedin in the U.S.

- *Jazz to pay an upfront payment of \$200 million to PharmaMar*
- *Opportunity for Jazz to expand its oncology portfolio with lurbinectedin, a late stage asset in relapsed small cell lung cancer (SCLC)*
- *PharmaMar is also eligible to receive up to \$800 million in potential milestone payments in addition to royalties on net sales*
- *Lurbinectedin New Drug Application (NDA) submitted to FDA in December 2019 with the potential to launch in 2020*
- *Collaboration emphasizes Jazz and PharmaMar's commitments to providing differentiated medicines to patients in areas of high unmet need.*

MADRID and DUBLIN, December 19th, 2019- PharmaMar (MSE:PHM) and Jazz Pharmaceuticals plc (Nasdaq:JAZZ) today announced that PharmaMar and Jazz Pharmaceuticals Ireland Limited have entered into an exclusive license agreement for lurbinectedin in the United States.

Under the terms of this agreement, PharmaMar will receive an upfront payment of \$200 million with potential regulatory milestone payments of up to \$250 million upon the achievement of accelerated and/or full regulatory approval of lurbinectedin by FDA within certain timelines.

PharmaMar is also eligible to receive up to \$550 million in potential commercial milestone payments, as well as incremental tiered royalties on future net sales of lurbinectedin ranging from the high teens up to 30 percent. PharmaMar may receive additional payments on approval of other indications. PharmaMar retains production rights for lurbinectedin and will supply the product to Jazz.

Lurbinectedin was granted orphan drug designation for SCLC by FDA in August 2018. In December 2019, PharmaMar submitted an NDA to FDA for accelerated approval of lurbinectedin for relapsed SCLC, based on data from its Phase 2 basket trial, following positive interactions with FDA.

The lurbinectedin Phase 2 monotherapy basket trial enrolled a total of 105 patients at 39 centers in eight Western European countries in addition to the U.S. The primary endpoint was Overall Response Rate (ORR) as measured by investigator review assessment. Secondary endpoints included Duration of Response, Progression-Free Survival, Overall Survival, and safety. In relapsed SCLC, lurbinectedin showed an ORR of 35.2%, which compares favorably to topotecan's historical ORR of 16.9%¹ by investigator assessment. In addition, lurbinectedin demonstrated a favorable safety, tolerability and administration profile versus historical standard of care.

"We are very pleased with the lurbinectedin agreement with our new U.S. partner Jazz," said José María Fernández Sousa-Faro, PhD, President of PharmaMar. "We are convinced that with Jazz, we have found a partner deeply committed to providing lurbinectedin to patients in the U.S. Lurbinectedin has the potential to become a therapeutic alternative for patients with relapsed small cell lung cancer, who have limited treatment options."

"Lurbinectedin represents a strong strategic fit and an exciting opportunity for Jazz to expand our oncology portfolio with a late stage asset," said Bruce C. Cozadd, Chairman and CEO of Jazz Pharmaceuticals. "We are looking forward to commercializing lurbinectedin in the U.S., as SCLC is an area of significant unmet medical need given limited late-stage treatment options and we believe lurbinectedin may offer patients with relapsed SCLC a meaningful treatment option."

SCLC is a very aggressive cancer that usually is diagnosed with advanced, often metastatic, disease, thus limiting the role of traditional approaches and often posing a worse prognosis when compared to other lung cancers². In the U.S., approximately 10-15% of lung cancers are small cell.² Approximately 30,000 new cases of SCLC are recorded in the U.S. every year³.

Closing of the agreement is subject to expiration or termination of the waiting period under the Hart-Scott-Rodino Act.

PharmaMar Conference Call for Investors and Analysts

PharmaMar management will host a conference call and webcast for investors and analysts on January 9th, 2020, at 14:00 CET (08:00 AM, New York time) as follows. The numbers to connect to the teleconference are 877-407-3102 (from USA or Canada) and +1 201-493-6790

¹ von Pawel et al. *J Clin Oncol* 32:4012-4019

² American Cancer Society, <https://www.cancer.org/cancer/small-cell-lung-cancer/about/what-is-small-cell-lung-cancer.html> (accessed December 17, 2019)

³ SEER Cancer Stat Facts – Lung and Bronchus Cancer, <https://seer.cancer.gov/statfacts/html/lungb.html> (accessed December 17, 2019)

(other countries). Interested parties can also follow the conference call live via the following link:
<https://78449.themediaframe.com/dataconf/productusers/phm/mediaframe/33803/index1.html>

The recording of the teleconference will be available for thirty days and it can be accessed on PharmaMar's website by visiting the [Events Calendar](#) section of the Company's website www.pharmamar.com.

Jazz Pharmaceuticals Conference Call for Investors and Analysts

Jazz Pharmaceuticals will host an investor conference call and live audio webcast on Friday, January 10, 2020 at 8:30 a.m. EST (1:30 p.m. GMT) to discuss the transaction. The live webcast may be accessed from the Investors section of Jazz Pharmaceuticals' website at www.jazzpharmaceuticals.com. Please connect to the website prior to the start of the conference call to ensure adequate time for any software downloads that may be necessary. Investors may participate in the conference call by dialing +1 855 353 7924 in the U.S., or +1 503 343 6056 outside the U.S., and entering passcode 4069667.

A replay of the conference call will be available through January 17, 2020 by dialing +1 855 859 2056 in the U.S., or +1 404 537 3406 outside the U.S., and entering passcode 4069667. An archived version of the webcast will be available for at least one week in the Investors section of Jazz Pharmaceuticals' website at www.jazzpharmaceuticals.com

About Lurbinectedin

Lurbinectedin (PM1183) is a synthetic compound currently under clinical investigation. It is a selective inhibitor of the oncogenic transcription programs on which many tumors are particularly dependent. Together with its effect on cancer cells, lurbinectedin inhibits oncogenic transcription in tumor-associated macrophages, downregulating the production of cytokines that are essential for the growth of the tumor. Transcriptional addiction is an acknowledged target in those diseases, many of them lacking other actionable targets.

About PharmaMar

Headquartered in Madrid, PharmaMar is a biopharmaceutical company, focused on oncology and committed to research and development which takes its inspiration from the sea to discover molecules with antitumor activity. It is a company that seeks innovative products to provide healthcare professionals with new tools to treat cancer. Its commitment to patients and to research has made it one of the world leaders in the discovery of antitumor drugs of marine origin.

PharmaMar has a pipeline of drug candidates and a robust R&D oncology program. It develops and commercializes Yondeli® in Europe and has other clinical-stage programs under development for several types of solid cancers: lurbinectedin (PM1183), PM184 and PM14. With subsidiaries in Germany, Italy, France, Switzerland, Belgium, Austria and the United States. PharmaMar wholly owns other companies: GENOMICA, a molecular diagnostics company; Sylentis, dedicated to researching therapeutic applications of gene silencing (RNAi). To learn more about PharmaMar, please visit us at www.pharmamar.com.

About Jazz Pharmaceuticals

Jazz Pharmaceuticals plc (Nasdaq: JAZZ), a global biopharmaceutical company, is dedicated to developing life-changing medicines for people with limited or no options. As a leader in sleep medicine and with a growing hematology/oncology portfolio, Jazz has a diverse portfolio of products and product candidates in development, and is focused on transforming biopharmaceutical discoveries into novel medicines. Jazz Pharmaceuticals markets Sunosi® (solriamfetol), Xyrem® (sodium oxybate) oral solution, Defitelio® (defibrotide sodium), Erwinaze® (asparaginase *Erwinia chrysanthemi*) and Vyxeos® (daunorubicin and cytarabine) liposome for injection in the U.S. and markets Sunosi, Defitelio® (defibrotide), Erwinaze® and Vyxeos® liposomal 44 mg/100 mg powder for concentrate for solution for infusion in countries outside the U.S. For country-specific product information, please visit <https://www.jazzpharmaceuticals.com/medicines>. For more information, please visit www.jazzpharmaceuticals.com and follow us on Twitter at @JazzPharma.

PharmaMar Legal Statement

This press release does not constitute an offer to sell or the solicitation of an offer to buy securities, and shall not constitute an offer, solicitation or sale in any jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of that jurisdiction.

Jazz Pharmaceuticals “Safe Harbor” Statement under the Private Securities Litigation Reform Act of 1995

This press release contains forward-looking statements, including, but not limited to, statements related to potential accelerated FDA approval of lurbinectedin in the U.S. during 2020; potential regulatory, sales and development milestones under the licensing agreement between Jazz Pharmaceuticals and PharmaMar and related potential future payments by Jazz Pharmaceuticals to PharmaMar; the potential for lurbinectedin to become a therapeutic alternative for patients with relapsed SCLC; Jazz’s potential commercialization of lurbinectedin in the U.S. and its belief that lurbinectedin may offer patients with relapsed SCLC an important therapeutic option; and other statements that are not historical facts. These forward-looking statements are based on Jazz Pharmaceuticals’ current plans, objectives, estimates, expectations and intentions and inherently involve significant risks and uncertainties. Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of these risks and uncertainties, which include, without limitation, risks and uncertainties associated with: the ability to obtain U.S. antitrust clearance for the licensing agreement; Jazz Pharmaceuticals’ ability to achieve the expected benefits (commercial or otherwise) from the license agreement; pharmaceutical product development and clinical success thereof; the regulatory approval process; effectively commercializing any product candidates; and other risks and uncertainties affecting Jazz Pharmaceuticals, including those described from time to time under the caption “Risk Factors” and elsewhere in Jazz Pharmaceuticals plc’s Securities and Exchange Commission filings and reports (Commission File No. 001-33500), including the company’s Quarterly Report on Form 10-Q for the quarter ended September 30, 2019 and future filings and reports by the company. Other risks and uncertainties of which Jazz Pharmaceuticals is not currently aware may also affect the company’s forward-looking statements and may cause actual results and the timing of events to differ materially from those anticipated. The forward-looking statements herein are made only as of the date hereof or as of the dates indicated in the forward-looking statements, even if they are subsequently made available by Jazz Pharmaceuticals on its website or otherwise. Jazz Pharmaceuticals undertakes no obligation to update or supplement any forward-looking statements to reflect actual results, new information, future events, changes in its expectations or other circumstances that exist after the date as of which the forward-looking statements were made.

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EXHIBIT I

Regulatory Filings in Jazz Territory

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