# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

## FORM 8-K/A

(Amendment No. 1)

Current Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event Reported): January 30, 2015

## THERAVANCE BIOPHARMA, INC.

(Exact Name of Registrant as Specified in its Charter)

Cayman Islands (State or Other Jurisdiction of Incorporation) 0001-36033 (Commission File Number) Not Applicable (I.R.S. Employer Identification Number)

PO Box 309 Ugland House, South Church Street George Town, Grand Cayman, Cayman Islands KY1-1104 (650) 808-6000

(Addresses, including zip code, and telephone numbers, including area code, of principal executive offices)

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 (see General Instruction A.2. below):
☐ 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))

#### EXPLANATORY NOTE

This Form 8-K/A is filed as an amendment to the Theravance Biopharma, Inc. (the "Company") Current Report on Form 8-K filed with the Securities and Exchange Commission on February 2, 2015 (the "Original Filing"). The sole purpose of this amendment is to file as exhibits to this Form 8-K/A copies of the Commercialization Agreement and Purchase Agreement (each as defined below) that were described in Item 1.01 of the Original Filing. Except as supplemented below, no other changes have been made to the Original Filing.

#### Item 1.01. Entry into a Material Definitive Agreement.

As previously reported on the Original Filing, on January 30, 2015 (i) Theravance Biopharma R&D, Inc. a Cayman Islands exempted company and wholly-owned subsidiary of the Company entered into a Development and Commercialization Agreement (the "Commercialization Agreement") with Mylan Ireland Limited, a limited company organized and existing under the laws of Ireland, and (ii) the Company entered into an Ordinary Share Purchase Agreement (the "Purchase Agreement") with Mylan, Inc., a publicly-traded Pennsylvania corporation.

The descriptions of the terms and conditions of the Commercialization Agreement and the Purchase Agreement in the Original Filing are qualified in their entirety by reference to the Commercialization Agreement and the Purchase Agreement, copies of which are attached as Exhibits 10.1 and 10.2 to this Current Report on Form 8-K/A and are incorporated herein by reference.

The information in this Item 1.01 above supplements, but does not replace the information in Item 1.01 of the Original Filing.

#### Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
10.1	Development and Commercialization Agreement by and between Theravance Biopharma R&D, Inc. and Mylan Ireland Limited, dated January 30, 2015*
10.2	Ordinary Share Purchase Agreement by and between Theravance Biopharma, Inc. and Mylan Inc., dated January 30, 2015

<sup>\*</sup> Confidential treatment has been requested from the Securities and Exchange Commission as to certain portions of this exhibit.

#### SIGNATURE

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

## THERAVANCE BIOPHARMA, INC.

Date: April 24, 2015 By: <u>/s/ Renee D. Gala</u>

Renee D. Gala

Senior Vice President and Chief Financial Officer

### EXHIBIT INDEX

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<sup>\*</sup> Confidential treatment has been requested from the Securities and Exchange Commission as to certain portions of this exhibit.

#### DEVELOPMENT AND COMMERCIALIZATION AGREEMENT

This Development and Commercialization Agreement ("Agreement") dated January 30, 2015 (the "Effective Date") is made by and between THERAVANCE BIOPHARMA R&D, INC., a Cayman Islands exempted company having its principal office at Ugland House, South Church Street, George Town, Grand Cayman, Cayman Islands E9 KY1-1104 ("THERAVANCE"), and MYLAN IRELAND LIMITED, a limited company organized and existing under the laws of Ireland with its offices at South Bank House, Barrow Street, 6<sup>th</sup> Floor, Dublin 4, Ireland ("MYLAN"). THERAVANCE and MYLAN may be referred to, individually, as a "Party" or, together, as the "Parties."

#### RECITALS

WHEREAS, THERAVANCE has discovered and is currently developing the proprietary long-acting muscarinic compound identified as TD-4208 for the treatment of respiratory disorders; and

WHEREAS, MYLAN and THERAVANCE desire to establish a broad collaboration for the development and commercialization of TD-4208 in a nebulized form, both as a standalone monotherapy and in combination or co-formulation with other chemically distinct and therapeutically active compounds.

NOW, THEREFORE THERAVANCE and MYLAN, intending to be legally bound, hereby agree as follows:

#### ARTICLE 1

#### DEFINITIONS

For purposes of this Agreement, the following initially capitalized terms, whether used in the singular or plural, shall have the following meanings:

Section 1.01 "Adverse Drug Experience" means any of: an "adverse drug experience/reaction," a "life-threatening adverse drug experience," a "serious adverse drug experience," or an "unexpected adverse drug experience," in each case as defined in the Federal Food Drug and Cosmetic Act, or any comparable experience, response or reaction associated with a pharmaceutical product that is reportable to Governmental Authorities in jurisdictions outside of the United States pursuant to applicable Laws.

Section 1.02 "Affiliate" of a Person means any other Person, whether de jure or de facto, that directly or indirectly controls, is controlled by, or is under common control with such Person for so long as such control exists, where "control" means the decision-making authority to control the management of such other Person whether by ownership,

contract or otherwise; and, further, where such control shall be presumed to exist where a Person owns more than fifty percent (50%) of the equity (or such lesser percentage which is the maximum allowed to be owned by a foreign corporation in a particular jurisdiction) having the power to vote on or direct the affairs of any Person.

- Section 1.03 "API Compound" means the active pharmaceutical ingredient compound of TD-4208, prior to the commencement of secondary manufacturing.
- Section 1.04 "Approval Batch" means any validation, confirmation or scale-up batch of Licensed Product in the Field manufactured in support of Marketing Authorization.
- Section 1.05 "Breaching Party" shall have the meaning set forth in Section 13.02.
- Section 1.06 "Business Day" means any day on which banking institutions in New York, New York are open for the conduct of normal banking business.
- Section 1.07 "Calendar Quarter" means for each Calendar Year, each of the three-month periods ending on March 31, June 30, September 30 and December 31.
- Section 1.08 "Calendar Year" means, for the first calendar year, the period commencing on the Effective Date and ending on December 31 of the calendar year during which the Effective Date occurs, and, thereafter during the Term, each successive period beginning on January 1 and ending twelve (12) consecutive calendar months later on December 31.
- Section 1.09 "cGMP" shall mean the Laws that apply to the manufacture of pharmaceuticals for administration to humans in the Territory or any country or jurisdiction therein, including: (a) the principles detailed in the U.S. Current Good Manufacturing Practices, including 21 C.F.R. Parts 210 and 211, (b) the current principles and guidelines of good manufacturing practices for medicinal products as set out in EU Directive 2003/94/EC, and (c) the principles detailed in the ICH Q7A guidelines.
- Section 1.10 "Change of Control Conflict Company" means any Person listed on Exhibit H or an Affiliate of such Person.
- Section 1.11 "China" means the People's Republic of China, including the Hong Kong Special Administrative Region, the Macao Special Administrative Region and Taiwan.
- Section 1.12 "China Notice" shall have the meaning set forth in Section 2.07.
- Section 1.13 "China Notice Date" shall have the meaning set forth in Section 2.07(a).
- Section 1.14 "China RFN" shall have the meaning set forth in Section 2.07.
- Section 1.15 "Claim" means all charges, complaints, actions, suits, proceedings, hearings, investigations, claims and demands.

- Section 1.16 "CMC" shall have the meaning set forth in Section 4.01.
- Section 1.17 "Combination Licensed Product" means any pharmaceutical composition or product that contains TD-4208 as an active ingredient that is packaged or formulated in combination with one or more other therapeutically active agents.
- Section 1.18 "Commercialization" means any and all activities directed to marketing, advertising, promoting, distributing (including storing, transporting), detailing and otherwise offering for sale and selling Licensed Product, regardless of whether such activities occur prior to or after receipt of Marketing Authorization (including medical support planning) of such Licensed Product, including exporting or importing Licensed Product (to the extent applicable) for such purposes, conducting health economic studies and Phase 4 Studies, market research, and regulatory affairs and interactions with Governmental Authorities in support of the foregoing. For clarity, Commercialization includes any and all (a) Co-Promotion activities and (b) activities with respect to pricing, discounting, reimbursement and patient access for Licensed Product through all private and public channels. When used as a verb, "Commercialize" means to engage in Commercialization.
- Section 1.19 "Commercial Budget" means the budget included as part of each Commercialization Plan, as updated annually for each Calendar Year or otherwise by the Parties in accordance with this Agreement, setting forth the anticipated spending required for executing the Commercialization Plan.
- Section 1.20 "Commercialization Plan" means the comprehensive sales and marketing plan for a Licensed Product in the Field in the Territory described in Section 5.01.
- Section 1.21 "Commercialization Plan Outline" means that outline attached hereto as Exhibit E that sets forth the elements to be included in each Commercialization Plan.
- Section 1.22 "Competitive Product" shall have the meaning set forth in Section 5.06(a).
- Section 1.23 "Confidential Information" means all secret, confidential or proprietary information, data or know-how (including MYLAN Know-How and THERAVANCE Know-How), whether provided in written, oral, graphic, video, computer or other form, provided by one Party or its Affiliates (the "Disclosing Party") to the other Party or its Affiliates (the "Receiving Party") pursuant to this Agreement or generated pursuant to this Agreement, including information relating to the Disclosing Party's existing or proposed research, development efforts, patent applications, business or products, the terms of this Agreement and any other materials that have not been made available by the Disclosing Party to the general public. Confidential Information shall not include any information or materials that the Receiving Party can document with competent written proof:
- (a) were already known to the Receiving Party (other than under an obligation of confidentiality), at the time of disclosure to the Receiving Party hereunder;

- (b) were generally available to the public or otherwise part of the public domain at the time of its disclosure to the Receiving Party hereunder;
- (c) became generally available to the public or otherwise part of the public domain after its disclosure or development, as the case may be, and other than through any act or omission of the Receiving Party (or its Affiliate or Third Party acting under its authority) in breach of such Party's confidentiality obligations under this Agreement;
- (d) were disclosed to the Receiving Party, other than under an obligation of confidentiality, by a Third Party who (to the knowledge of the Receiving Party) had no obligation to the Disclosing Party not to disclose such information to others; or
- (e) were independently discovered or developed by or on behalf of the Receiving Party without the use of, or reference to, the Confidential Information belonging to the other Party.

Notwithstanding the foregoing exceptions (a)-(e), inclusive, specific aspects of Confidential Information shall not be deemed to be within the foregoing exceptions when such exceptions apply only to more general information or when the relevant specific aspects are identified using Confidential Information.

- Section 1.24 "Consensus" means, in the framework of the governance provisions set forth in Article 3 herein, agreement between the relevant representatives from each Party, with each Party's representatives on the applicable committee having, collectively, one vote, in each case as reflected in final written minutes of the applicable committee or other writing executed or acknowledged by an appropriate representative from each Party.
- Section 1.25 "COPD" shall have the meaning set forth in Section 1.45.
- Section 1.26 "Co-Promotion Agreement" shall have the meaning set forth in Section 5.03(c).
- Section 1.27 "Cost of Goods Sold" or "COGS" means (a) with respect to Licensed Product manufactured by MYLAN or its Affiliates, the [\*\*\*] and (b) with respect to Licensed Product purchased by MYLAN or its Affiliates from a Third Party, MYLAN or its Affiliate's [\*\*\*], together in the case of (a) and (b) with [\*\*\*], and together in the case of (b) with other costs [\*\*\*] and allocable to such [\*\*\*] in accordance with GAAP, including costs of [\*\*\*]. For clarity, COGS shall include such costs with respect to [\*\*\*]. In the event that any Licensed Product in the Field comprising Approval Batches are not sold commercially, the Parties will share the costs of such Approval Batches as follows: [\*\*\*] by MYLAN and [\*\*\*] by THERAVANCE.
- Section 1.28 "Cost Overrun" shall have the meaning set forth in Section 4.02(d).
- Section 1.29 "Country" means any sovereign entity generally recognized internationally as a nation (including all territories, protectorates and possessions thereof). For purposes of Patent-related activities under Article 12, Country shall also

<sup>\*\*\*</sup>CERTAIN INFORMATION HAS BEEN OMITTED AND FILED SEPARATELY WITH THE COMMISSION. CONFIDENTIAL TREATMENT HAS BEEN REQUESTED WITH RESPECT TO THE OMITTED PORTIONS.

include member states, regions or territories that would be covered by a single patent application or patent pursuant to patent treaties, regional patent offices or patent organizations, including the Patent Cooperation Treaty (PCT), the European Patent Organization (EPO) and the Eurasian Patent Organization.

- Section 1.30 "Creditable Taxes" shall have the meaning set forth in Section 6.06(c).
- Section 1.31 "Date of Termination" shall have the meaning set forth in Section 14.02.
- Section 1.32 "Development" or "Develop" means any and all preclinical and clinical drug development activities (other than Phase 4 Studies), including: test method development and stability testing, toxicology, formulation, process development, conducting clinical trials, development-stage manufacturing and clinical supply, scale up of the proposed commercial manufacturing process, current Good Manufacturing Practices audits conducted with respect to product intended for use in clinical studies, current Good Clinical Practices audits, current Good Laboratory Practices audits, analytical method transfer and validation, manufacturing process validation, cleaning validation, quality assurance/quality control development, statistical analysis and report writing, preclinical and clinical studies, regulatory filing preparation, submission, prosecution and approval, and regulatory affairs related to the foregoing and all other activities necessary or otherwise requested or required by a Regulatory Authority as a condition or in support of obtaining Marketing Authorization, in each case other than Phase 4 Studies and any of the foregoing activities to the extent associated with Phase 4 Studies. When used as a verb, "Develop" means to engage in Development. For clarity, Development excludes all activities comprising Commercialization.
- Section 1.33 "Development Annual Fully Burdened FTE Rate" means the amount THERAVANCE attributes during the Term to support one Full Time Equivalent performing work under the Development Plan, which on the Effective Date is [\*\*\*]. Such amount may be increased by the average of the percentage increase, if any, in each of (i) salaries reported for the current fiscal year by Radford Surveys<sup>TM</sup> Quarterly Salary Increase Trend Survey (QSIT)—Biotechnology Edition Base Salary Increase Analysis for Exempt Employees (Current Fiscal Year Actual (Undiluted) Overall Increases Combined) and (ii) Consumer Price Index, for All Urban Consumers for the San Francisco Bay Area, as published by the U.S. Department of Labor, Bureau of Labor Statistics, in the then current reported year over the immediately preceding reported year (or in the case of the first such increase, the Effective Date), on January 1, 2016 and annually thereafter during the Term. Otherwise the Development Annual Fully Burdened FTE Rate shall not be increased without the prior written consent of MYLAN.
- Section 1.34 "Development Budget" means a part of the Development Plan for the entire Development project for the Licensed Product in the Field in the Territory and for each Calendar Year, capturing the anticipated spending required for executing the Development Plan.
- Section 1.35 "Development Expenses" means the costs incurred by THERAVANCE in connection with the Development of the Licensed Product in the Field. These expenses

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will be comprised only of (a) THERAVANCE's actual external costs for the performance of the Development activities set forth in the Development Plan and (b) THERAVANCE's Development Annual Fully Burdened FTE Rate attributable to the time THERVANCE FTEs devoted to the performance of the Development activities set forth in the Development Plan. For clarity, (i) filing fees (including PDUFA fees) associated with any NDA or MAA ("Filing Fees") shall be Development Expenses, (ii) the costs of Approval Batches for the U.S. shall be COGS (and not Development Expenses), and (iii) [\*\*\*] of the costs of Licensed Product comprising Approval Batches for the ROW Countries that is not actually sold shall be borne by THERAVANCE.

- Section 1.36 "Development Plan" shall have the meaning set forth in Section 4.01.
- Section 1.37 "Diligent Efforts" means the carrying out of obligations with respect to the Development, manufacture and Commercialization of Licensed Products in the Field in a sustained commercially reasonable manner consistent with the efforts a Party devotes (or would devote) to a product of similar market potential, profit potential and strategic value resulting from its own research efforts, based on conditions then prevailing; provided that, at a minimum, Diligent Efforts requires that: (i) each Party assign responsibility for such obligations to specific employee(s) who are held accountable for progress and monitor such progress on an on-going basis; (ii) each Party set, monitor and seek to achieve such obligations; and (iii) each Party make and implement decisions and allocate resources designed to advance progress with respect to such objectives. For clarity, (a) Diligent Efforts shall be evaluated on a country-by-country basis based on all factors relevant to such country (including size of market, availability of alternative treatments, pricing strategies, likelihood of gray-market goods, applicable Law and the likelihood of obtaining a Marketing Authorization and (b) it is acknowledged that efforts would be reduced with respect to a product from and after the launch of a generic equivalent thereof.
- Section 1.38 "Disclosing Party" shall have the meaning set forth in Section 1.23.
- Section 1.39 "Divest" and "Divestiture" shall have the meaning set forth in Section 5.06(b).
- Section 1.40 "DMF" means a drug master file submitted to the FDA, (or comparable document set submitted to any regulatory authority in the Territory, including the EMA).
- Section 1.41 "Effective Date" shall have the meaning set forth in the preamble to this Agreement.
- Section 1.42 "EMA" means the European Medicines Authority.
- Section 1.43 "EU" means, collectively, the Countries of the European Union.
- Section 1.44 "FDA" means the United States Food and Drug Administration and any successor agency thereto.

- Section 1.45 "Field" means the treatment of chronic obstructive pulmonary disease ("COPD"), asthma, cystic fibrosis and other respiratory diseases and conditions in humans via any and all nebulized inhalation product presentations. For the avoidance of doubt, the term "Field" excludes the treatment of chronic obstructive pulmonary disease, asthma, cystic fibrosis and other respiratory diseases and conditions in humans via any delivery mechanism *other than* a nebulized inhalation product presentation (such as in a metered dose inhaler or dry powder inhaler). For purposes of this definition, "treatment" means, with respect to a particular indication, the cure, reduction, mitigation, prevention, slowing or halting the progress of, or other management of such indication or its symptoms.
- Section 1.46 "First Commercial Sale" means with respect to a particular Licensed Product in the Field, the first shipment of commercial quantities of such Licensed Product sold to a Third Party by a Party, its Affiliates and/or their sublicensees and/or distributors after receipt of Marketing Authorization for such Licensed Product in the Field. Sales for test marketing, sampling and promotional uses, named patient programs, clinical trial purposes or emergency or similar uses shall not be considered to constitute a First Commercial Sale.
- Section 1.47 "Force Majeure Event" shall have the meaning set forth in Section 15.03.
- Section 1.48 "FTE" or "Full-Time Equivalent" means the contribution of time equivalent to one (1) year of a full-time employee proficient in the performance of duties assigned to such employee under the Development Plan. One Full-Time Equivalent may be comprised of a single employee's time, or percentages of multiple employees' time which, together, equal 100%. The portion of an FTE year devoted by an employee to duties under the Development Plan shall be determined by dividing the number of full days during any twelve-month period devoted by such employee to such duties by the total number of working days during such twelve-month period.
- Section 1.49 "GAAP" shall have the meaning set forth in Section 6.03.
- Section 1.50 "Governmental Authority" means any court, tribunal, arbitrator, agency, department, legislative body, commission, official or other instrumentality of (i) any government of any Country or supra-national body or (ii) a federal, state, province, county, city or other political subdivision thereof, in each case having authority over the activities hereunder.
- Section 1.51 "Hatch-Waxman Certification" shall have the meaning set forth in Section 12.04.
- Section 1.52 "Hold Separate Transaction" shall have the meaning set forth in Section 5.06(b).
- Section 1.53 "Housemark" means the corporate name and logo of MYLAN or THERAVANCE or any of their respective Affiliates, together with any derivative marks of such name or logo, as identified by one Party to the other from time to time for inclusion on the Labeling for the Licensed Products in the Field.

- Section 1.54 "IND" means an investigational new drug application as defined under the Federal Food, Drug and Cosmetic Act.
- Section 1.55 "Indemnified Party" shall have the meaning set forth in Section 11.03(a).
- Section 1.56 "Indemnifying Party" shall have the meaning set forth in Section 11.03(a).
- Section 1.57 "Invention" means any discovery or new technical idea (whether patentable or not) made (i.e., invented, created or otherwise developed) during the Term that is related to TD-4208 or a Licensed Product as a result of research, manufacturing, Development or Commercialization of the Licensed Products pursuant to this Agreement.
- Section 1.58 "Joint Invention" means an Invention made jointly by an employee or agent of THERAVANCE or its Affiliates and an employee or agent of MYLAN or its Affiliates.
- Section 1.59 "Joint Invention Patents" means all Patents claiming Joint Inventions. Joint Invention Patents include those Patents that may be set forth under "Joint Invention Patents" in Exhibit B after the Effective Date through an update to Exhibit B under Section 2.06.
- Section 1.60 "Joint Product Committee" or "JPC" shall have the meaning set forth in Section 3.02(b).
- Section 1.61 "Joint Steering Committee" or "JSC" shall have the meaning set forth in Section 3.01(a).
- Section 1.62 "Labeling" means any and all labels, labeling, packaging package inserts and outserts, labels for Samples, and Promotional Materials for the Licensed Product in the Field in the Territory.
- Section 1.63 "Laws" means all federal, state, local, and international equivalent laws, statutes, rules, regulations and guidances of Governmental Authorities, including, as applicable: (i) the Federal Food, Drug and Cosmetic Act, as amended, and the regulations promulgated pursuant thereto; (ii) standards for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials, including but not limited to standards and guidances promulgated by the International Conference on Harmonization and the Declaration of Helsinki; (iii) the Clinical Laboratory Improvement Amendments of 1988; (iv) applicable privacy laws, including the Health Insurance Portability and Accountability Act of 1996; and (v) ordinances and other pronouncements of any Governmental Authority having the binding effect of law.
- Section 1.64 "Licensed Product(s)" means any pharmaceutical composition or product that contains TD-4208 as an active ingredient, alone or in combination or co-formulation with other chemically distinct and therapeutically active compounds. For clarity, Licensed Products include Stand Alone Licensed Products and Combination Licensed Products.

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- Section 1.65 "Litigation Condition" shall have the meaning set forth in Section 11.03(b).
- Section 1.66 "Long Acting Muscarinic Antagonist" or "LAMA" means an inhaled agent that selectively binds muscarinic acetylcholine receptors, blocking or inhibiting M3 muscarinic acetylcholine receptor activity, and has a duration of action sufficient to require dosing no more than twice per day for the treatment of respiratory disorders in humans. LAMAs include tiotropium, glycopyrrolate/glycopyrronium, umeclidinium, aclidinium, oxitropium and dexpyrronium.
- Section 1.67 "Losses" means any and all damages (including all incidental, consequential, statutory and treble damages), awards, deficiencies, settlement amounts, defaults, assessments, fines, dues, penalties, costs, fees, liabilities, obligations, taxes, liens, losses, lost profits and expenses (including court costs, interest and reasonable fees of attorneys, accountants and other experts), in each case awarded to Third Parties and required to be paid to Third Parties with respect to a Claim by reason of any judgment, order, decree, stipulation or injunction, or any settlement entered into in accordance with the provisions of this Agreement, together with all documented out-of-pocket costs and expenses incurred by the Indemnified Party in complying with any judgments, orders, decrees, stipulations and injunctions that arise from or relate to a Claim of a Third Party.
- Section 1.68 "MAA" means a marketing authorization application or any amendments or supplements thereto submitted to the EMA in the EU. For purposes of this Agreement, the term "MAA" shall also mean any comparable marketing authorization or approval filings in the other ROW Countries in the Territory.
- Section 1.69 "Manufacturing Cost" means, with respect to Licensed Product, the fully allocated direct and indirect costs incurred by MYLAN or its Affiliates determined in accordance with GAAP and consistent with MYLAN's internal accounting practices, consistently applied, for the manufacture of Licensed Product (provided that any such indirect costs are reasonably allocable to such Licensed Product), which costs may include:
- (a) the cost of materials (including API Compound), components, supplies and other resources directly or indirectly consumed, in each case including freight, insurance, shipping, packaging and other similar costs associated with acquiring such items;
- (b) labor (including salaries, wages and current period employee benefits), including management salary and benefits allocable to the manufacture of Licensed Product;
- (c) the net cost or credit of any value-added taxes or duties actually paid or utilized (and not reimbursed or reimbursable) on account of such Licensed Product;
- (d) Third Party costs for the manufacture of Licensed Product, including facilities fees, transportation costs, customs, duty and transit insurance costs;

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- (e) manufacturing variances (including expired raw materials and finished goods, scrap, maintenance costs and batches that do not conform to the applicable specifications) incurred in the manufacture of Licensed Product;
- (f) costs for quality control/assurance (including the costs of quantities destroyed in quality control testing) of such Licensed Product, including the costs of inspection, rejection and return of components, materials or services; and
- (g) other costs reasonably allocable to the manufacture of Licensed Product, including allocable occupancy, idle capacity (based on planned capacity for the Licensed Product in the Field consistent with the Development Plan or Commercialization Plan), depreciation and amortization, allocable facilities costs, general and other overhead.

For clarity, Manufacturing Cost shall exclude corporate overhead and any other costs not allocable to the manufacture of the Licensed Products hereunder.

- Section 1.70 "Marketing Authorization" means, with respect to a Country, the regulatory authorization required to market and sell Licensed Product in such Country as granted by the relevant Governmental Authority, including any such pricing, labeling or reimbursement approvals.
- Section 1.71 "Milestone" shall have the meaning set forth in Section 1.02(a) of Exhibit F.
- Section 1.72 "MYLAN Invention" means an Invention invented solely or jointly by an employee or agent of MYLAN or its Affiliates (excluding Joint Inventions).
- Section 1.73 "MYLAN Know-How" means all information directly relating to TD-4208 or Licensed Products in the Field, including all data, records, and regulatory filings relating to TD-4208, API Compound or a Licensed Product in the Field, which is necessary or useful for THERAVANCE to perform its obligations or exercise its rights under this Agreement, and which, during the Term, is (a) produced by MYLAN or any of its Affiliates or comes into their possession and control pursuant to this Agreement, (b) disclosed by MYLAN to THERAVANCE hereunder, or (c) used by or on behalf of MYLAN in its manufacture of API Compound or Licensed Product in the Field and, in each case (a), (b) and (c), is owned by, or licensed to, MYLAN (with the right to sublicense in accordance with this Agreement). MYLAN Know-How does not include any MYLAN Patents (other than the information contained in unpublished Patents). MYLAN Know-How shall exclude any information licensed to MYLAN for which it (a) requires consent from any Third Party and such consent is not obtained after using Diligent Efforts to do so or (b) requires any payment to a Third Party as a result of the grant or exercise of any license by or under authority of THERAVANCE or its Affiliates, unless in the case of (b), THERAVANCE agrees in writing to reimburse (and actually reimburses) MYLAN in advance for all amounts payable to such Third Party as a result of such grant or exercise and timely provides any additional information required by MYLAN's agreement with such Third Party in connection therewith.

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- Section 1.74 "MYLAN Patents" means all Patents (excluding Joint Invention Patents) filed and owned by or licensed (with the right to grant sublicenses in accordance with this Agreement) to MYLAN or its Affiliates that claim a MYLAN Invention or a method of manufacture used by or on behalf of MYLAN in its manufacture of API Compound or Licensed Product in the Field hereunder. MYLAN Patents include those Patents set forth under "MYLAN Patents" in Exhibit B after the Effective Date through an update to Exhibit B under Section 2.06. MYLAN Patents shall exclude any Patents licensed to MYLAN for which it (a) requires consent from any Third Party and such consent is not obtained after using Diligent Efforts to do so or (b) requires any payment to a Third Party as a result of the grant or exercise of any license by or under authority of THERAVANCE or its Affiliates, unless in the case of (b), THERAVANCE agrees in writing to reimburse (and actually reimburses) MYLAN in advance for all amounts payable to such Third Party as a result of such grant or exercise and timely provides any additional information required by MYLAN's agreement with such Third Party in connection therewith.
- Section 1.75 "MYLAN Product Trademarks" means any and all Trademarks and trade dress that MYLAN (or its Affiliates) may use, file to register or otherwise select and control in accordance with the terms of this Agreement, in each case for use on the Licensed Product(s) in the Field in the Territory during the Term. For clarity, "MYLAN Product Trademark" excludes any MYLAN Housemark but includes any other MYLAN corporate branding scheme (e.g. font color, type and size and related graphics) used on the Licensed Product(s) in the Field in the Territory during the Term.
- Section 1.76 "NDA" means a new drug application or supplemental new drug application or any amendments thereto submitted to the FDA under the Federal Food, Drug and Cosmetic Act.
- Section 1.77 "Net Sales" means the gross amount invoiced for the sale of Licensed Product in the Field by a Party, its Affiliates and/or their sublicensees to a Third Party, less the following: (a) cash, trade, prompt payment, quantity and other discounts actually given; (b) refunds, rebates, chargebacks, retroactive price adjustments, sales deductions, shelf stock or floor stock adjustments, billing errors, rejected goods, expired product, product recalls, and any other allowances actually given which effectively reduce the gross selling price; (c) credits and allowances for damaged goods and product returns; and (d) credits, charge-backs, discounts, rebates, reimbursements, fees and other allowances provided to distributors, wholesalers, pharmacies, selling agents (excluding sales representatives of a Party or any of its Affiliates), group purchasing organizations, and managed care entities, buying groups, health insurance carriers/agencies, government institutions/agencies, health care organizations and other institutions or customers; (e) freight, insurance and handling costs (to the extent not paid by the Third Party customer); and (f) sales tax, VAT and other taxes, duties or government charges levied on or measured by the billing amount, as adjusted for rebates or refunds, that are borne by the selling Party and that are not refundable and to the extent non-creditable. Net Sales shall exclude Samples distributed in the usual course of business. No individual deduction may be taken more than once in calculating Net Sales.

- Section 1.78 "Non-Neb Field" means the treatment of chronic obstructive pulmonary disease, asthma, cystic fibrosis and other respiratory diseases and conditions in humans via any delivery mechanism *other than* a nebulized inhalation product presentation.
- Section 1.79 "Non-Neb Notice" shall have the meaning set forth in Section 2.08.
- Section 1.80 "Non-Neb Notice Date" shall have the meaning set forth in Section 2.08(a).
- Section 1.81 "Officers" shall have the meaning set forth in Section 3.01(f).
- Section 1.82 "Operating Expense" means the sum of all costs incurred by the Parties or their Affiliates in connection with the Commercialization of Licensed Products in the Field in the U.S. in accordance with the Commercial Budget in the Commercialization Plan, including the following costs (i) advertising and promotion costs (including sales force costs, detailing and e-tailing; costs of developing and producing Promotional Materials, and marketing vendor costs; and costs of communications to healthcare providers, pharmacy and prescription benefit managers and formularies), (ii) medical affairs costs (including post-approval commitments and Phase 4 Studies other than those requested or required by a Regulatory Authority as a condition or in support of obtaining Marketing Authorization to the extent they are conducted prior to obtaining approval of the first NDA for the first Licensed Product in the Field), healthcare and consumer educational program costs, (iii) market research costs, and (iv) general administrative costs attributable to the Licensed Products in the Field. For clarity, no individual costs will be counted more than once and all Operating Expenses will be approved as a part of the Commercial Budget; provided that Commercialization expenses for the Licensed Products in the U.S. that are otherwise agreed by the Parties in writing outside of the Commercial Budget shall nevertheless be Operating Expenses shared by the Parties in accordance with Section 5.03(b) and Exhibit F.
- Section 1.83 "Operating Profit (Loss)" means Net Sales less the following: (i) COGS, (ii) Operating Expense and (iii) Shared Expenses.
- Section 1.84 "Patents" means patents and patent applications, including (a) provisional applications, continuation applications, continuations-in-part, divisional applications, Patent Cooperation Treaty applications and all patents issuing from such applications, (b) utility patents, design patents, reexaminations, reissues, registrations, confirmations, revalidations, certificates of addition, utility models and petty patents, and (c) extensions or restorations of terms thereof, supplementary protection certificates or any other such right, anywhere in the world.
- Section 1.85 "Patent Infringement Claim" shall have the meaning set forth in Section 12.03(a).
- Section 1.86 "Patent Infringement Notice" shall have the meaning set forth in Section 12.03(b).

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- Section 1.87 "Patent Resolution Issue" shall have the meaning set forth in Section 12.02(h).
- Section 1.88 "Person" means any natural person, corporation, general partnership, limited partnership, limited liability company, joint venture, sole proprietorship or other business organization or entity.
- Section 1.89 "Phase 2 Clinical Trial" means a study in humans of the safety, dose ranging and efficacy of a product, which is prospectively designed to generate sufficient data (if successful) to commence a Phase 3 Clinical Trial or to file for accelerated approval, or otherwise consistent with the requirements of U.S. 21 C.F.R. §312.21(b) or its foreign equivalents.
- Section 1.90 "Phase 3 Clinical Trial" means a study in humans of the efficacy and safety of a product, which is prospectively designed to demonstrate statistically whether such product is effective and safe for use in a particular indication in a manner sufficient to file for Marketing Authorization, or otherwise consistent with the requirements of U.S. 21 C.F.R. §312.21(c) or its foreign equivalents.
- Section 1.91 "Phase 3 Safety Study" means that certain Phase 3 Clinical Trial of the Licensed Product in the Field planned to be conducted by THERAVANCE as of the Effective Date pursuant to Protocol No. 0128, entitled "A 52-week parallel group safety study of TD-4208 in COPD."
- Section 1.92 "Phase 4 Study" means any clinical trial of a Licensed Product conducted after receipt of Marketing Authorization in the approved indication, which is required to maintain such Marketing Authorization or otherwise useful for Commercializing such Licensed Product.
- Section 1.93 "Post-Approval Development Expenses" shall have the meaning set forth in Section 4.02(c).
- Section 1.94 "Preliminary Development Plan" shall have the meaning set forth in Section 4.01.
- Section 1.95 "Promotional Materials" means the written, printed, audio, video, graphic, or electronic advertising, promotional, public relations, educational and communication materials for marketing, advertising and promotion of Licensed Products in the Field in the Territory. For clarity, the term "Promotional Materials" does not include the official product label for the Licensed Product in the Field in the Territory, which is approved by the relevant Government Authority in connection with its approval of an MAA for such Licensed Product.
- Section 1.96 "Public Announcement Matters" shall have the meaning set forth in Section 9.04.
- Section 1.97 "Publications Policy" shall have the meaning set forth in Section 9.03.

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- Section 1.98 "Receiving Party" shall have the meaning set forth in Section 1.23.
- Section 1.99 "Recording Party" shall have the meaning set forth in Section 6.08.
- Section 1.100 "Regulatory Authority" means any Governmental Authority responsible for granting Marketing Authorizations for a pharmaceutical or healthcare product in the Territory.
- Section 1.101 "Regulatory Filings" means any submission made to a Regulatory Authority with respect to the Licensed Product, including any IND, NDA, Marketing Authorization Application, any submission to a regulatory advisory board, and any supplement or amendment to any of the foregoing.
- Section 1.102 "Reverted Country" shall have the meaning set forth in Section 4.03(d).
- Section 1.103 "RFN" shall have the meaning set forth in Section 2.08.
- Section 1.104 "ROW" or "Rest of World" means worldwide but excluding the U.S. and China.
- Section 1.105 "ROW Recall Costs" shall have the meaning set forth in Section 7.02.
- Section 1.106 "Samples" means Licensed Product packaged and distributed as a complimentary trial for use by patients in the Field in the Territory after having obtained Marketing Authorization.
- Section 1.107 "Shared Expenses" means Post-Approval Development Expenses, U.S. Recall Costs, and Enforcement Damages.
- Section 1.108 "SPCs" shall have the meaning set forth in Section 12.02(g).
- Section 1.109 "Stand Alone Licensed Product" means any pharmaceutical composition or product Developed under this Agreement that contains TD-4208 as the sole active ingredient (i.e. no combination or co-formulation with any other chemically distinct and therapeutically active compound).
- Section 1.110 "Step-In Rights" shall have the meaning set forth in Section 12.02(d).
- Section 1.111 "Sublicensee Improvement" shall have the meaning set forth in Section 2.04.
- Section 1.112 "Supplied Licensed Product" shall have the meaning set forth in Section 14.02(a)(vii).
- Section 1.113 "Taxes" shall have the meaning set forth in Section 6.06(a).
- Section 1.114 "TD-4208" means the chemical compound known as TD-4208, together with all analogs, salts, esters, complexes, chelates, polymorphs, hydrates, isomers, stereoisomers, crystalline and amorphous forms, prodrugs, solvates, metabolites and

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metabolic precursors (whether active or inactive), and other structural derivatives thereof. The structure of TD-4208 is shown in Exhibit A.

- Section 1.115 "Technology Transfer Package" means all THERAVANCE Confidential Information and THERAVANCE Know-How relating to the Licensed Product, including all information regarding the API Compound and formulated Licensed Product in the Field and methods of manufacturing the same, analytical methods, specifications, batch records, batch testing and release results, results and reports of all pre-formulation studies, reports summarizing development pharmaceutics, vendor information, validation documentation, other quality management system documentation supporting manufacture and release, results and reports of all non-clinical, pre-clinical and clinical studies, adverse event data, patent information, regulatory documentation and filings, and regulatory correspondence.
- Section 1.116 "Term" means, on a Licensed Product-by-Licensed Product basis and on a Country-by-Country basis, the period from the Effective Date until the later of (a) the expiration or termination of the last Valid Claim of a THERAVANCE Patent covering any Licensed Product in the Field, or (b) thirteen (13) years from First Commercial Sale anywhere in the Territory, unless this Agreement is terminated earlier in accordance with ARTICLE 13.
- Section 1.117 "Territory" means worldwide, excluding China; provided that upon reversion, a Reverted Country shall no longer be included within the Territory.
- Section 1.118 "THERAVANCE Invention" means an Invention invented solely or jointly by an employee or agent of THERAVANCE or its Affiliates (excluding Joint Inventions).
- Section 1.119 "THERAVANCE Know-How" means all present and future information relating to TD-4208, API Compound or a Licensed Product, including all data, records, and Regulatory Filings relating to TD-4208, API Compound or a Licensed Product or THERAVANCE Invention, which is necessary or useful for MYLAN to perform its obligations or exercise its rights under this Agreement, and which is in THERAVANCE's or any of its Affiliates' possession or control and is or becomes owned by, or is licensed (with the right to sublicense) to, THERAVANCE or its Affiliates. THERAVANCE Know-How does not include any THERAVANCE Patents (other than the information contained in unpublished Patents), nor any THERAVANCE drug discovery research plans, strategies, tools, methods or processes for products other than Licensed Products in the Field.
- Section 1.120 "THERAVANCE Patents" means all present and future Patents (excluding Joint Invention Patents) owned by or licensed to THERAVANCE or its Affiliates that claim the compound, compositions, or any method of making or using, TD-4208 or a Licensed Product or the THERAVANCE Know-How, including Patents claiming THERAVANCE Inventions. THERAVANCE Patents include those Patents set forth under "THERAVANCE Patents" in Exhibit B as of the Effective Date (or added through an update to Exhibit B under Section 2.06), and any and all Patents issuing from

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applications claiming common priority thereto. For purposes of clarity, "THERAVANCE Patents" includes any and all patents issuing, either from continuation or divisional applications, that claim priority to the following provisional applications: [\*\*\*].

- Section 1.121 "Third Party" means a Person who is not a Party or an Affiliate of a Party.
- Section 1.122 "Third Party Claim" shall have the meaning set forth in Section 11.03(a).
- Section 1.123 "Trademarks" shall have the meaning set forth in Section 2.05(a).
- Section 1.124 "Transfer Date" shall have the meaning set forth in Section 7.01(a).
- Section 1.125 "U.S." means the United States and its territories and possessions.
- Section 1.126 "Upfront Payment" shall have the meaning set forth on Exhibit F.
- Section 1.127 "Valid Claim" means an issued patent claim that has not: (i) expired; (ii) been held unenforceable, unpatentable or invalid by a decision of a court or other Governmental Authority of competent jurisdiction, which decision is unappealable or unappealed within the time allowed for appeal; or (iii) been admitted to be invalid or unenforceable through reissue, reexamination or disclaimer.
- Section 1.128 "VAT" means Value Added Tax in Ireland or any similar tax which may be imposed in the Territory and "VATCA" means the Irish Value Added Tax Consolidation Act 2010.
- Section 1.129 "Withholding Party" shall have the meaning set forth in Section 6.06(a).
- Section 1.130 Interpretation. The captions and headings to this Agreement are for convenience only, and are to be of no force or effect in construing or interpreting any of the provisions of this Agreement. Unless specified to the contrary, references to Articles, Sections or Exhibits mean the particular Articles, Sections or Exhibits to this Agreement and references to this Agreement include all Exhibits hereto. Unless context clearly requires otherwise, whenever used in this Agreement: (i) the words "include" or "including" shall be construed as incorporating, also, "but not limited to" or "without limitation;" (ii) the word "or" shall have its inclusive meaning of "and/or;" (iii) the word "notice" shall require notice in writing (whether or not specifically stated) and shall include notices, consents, approvals and other written communications contemplated under this Agreement; (iv) the words "hereof," "herein," "hereunder," "hereby" and derivative or similar words refer to this Agreement (including any Exhibits); (v) provisions that require that a Party, the Parties or any committee hereunder "agree," "consent" or "approve" or the like shall require that such agreement, consent or approval be specific and in writing, whether by written agreement, approved meeting minutes, letter or otherwise; (vi) words of any gender include the other gender; and (vii) words using the singular or plural number also include the plural or singular number, respectively; (viii) references to any specific law, or article, section or other division

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thereof, shall be deemed to include the then-current amendments thereto or any replacement thereof.

#### ARTICLE 2 RIGHTS AND OBLIGATIONS

- Section 2.01 <u>License Grants from THERAVANCE to MYLAN</u>. Subject to the terms of this Agreement, THERAVANCE hereby grants to MYLAN, and MYLAN accepts:
- (a) an exclusive license under the THERAVANCE Patents and THERAVANCE Know-How and THERAVANCE and its Affiliates' interests in any Joint Invention Patents to Develop Licensed Product in the Field worldwide for Commercialization in the Territory;
- (b) an exclusive license under the THERAVANCE Patents and THERAVANCE Know-How and THERAVANCE and its Affiliates' interests in any Joint Invention Patents to Commercialize Licensed Products in the Field in the Territory;
- (c) an exclusive license under the THERAVANCE Patents and THERAVANCE Know-How and THERAVANCE and its Affiliates' interests in any Joint Invention Patents to make and have made (i) API Compound for incorporation into Licensed Products in the Field and (ii) Licensed Products in the Field, in each case worldwide for purposes of Developing such Licensed Products for, and Commercializing such Licensed Product in, the Field in the Territory;
- (d) a non-exclusive license to use THERAVANCE's Housemarks to the extent included on the Labeling of the Licensed Products in the Field, solely for purposes of manufacturing Licensed Products in the Field and Commercializing the Licensed Products in the Field in the Territory; and
- (e) an exclusive license to otherwise exploit the THERAVANCE Patents and THERAVANCE Know-How and any Joint Invention Patents in connection with and within the scope of the licenses set forth in Sections 2.01(a)-(c) above.

Notwithstanding the foregoing, THERAVANCE and its Affiliates retain their rights under the THERAVANCE PATENTS and THERAVANCE KNOW-HOW and Joint Invention Patents to (x) Develop the Licensed Products in the Field for the Territory in accordance with the Development Plan, (y) manufacture the Licensed Products in the Field for purposes of clinical trials of the Licensed Products in the Field to be conducted in accordance with the Development Plan, and (z) Commercialize the Licensed Products in the Field in the U.S. in accordance with the Commercialization Plan, in each case solely in accordance with and pursuant to this Agreement. For clarity, THERAVANCE and its Affiliates retain all rights under the THERAVANCE PATENTS and THERAVANCE KNOW-HOW and THERAVANCE and its Affiliates' interests in and to any Joint Invention Patents to make and have made API Compound and Licensed Products and to Develop and Commercialize Licensed Product, in each case (a) worldwide outside the Field (subject to the RFN) and (b) outside the Territory in the Field (subject to the China RFN).

- Section 2.02 <u>License Grants from MYLAN to THERAVANCE</u>. Effective only upon the existence of any MYLAN Patent and/or MYLAN Know-How, and subject to the terms of this Agreement, MYLAN hereby grants to THERAVANCE, and THERAVANCE accepts:
- (a) an exclusive license under the MYLAN Patents and MYLAN Know-How and MYLAN and its Affiliates' interests in any Joint Invention Patents to conduct the Development activities for the Licensed Products in the Field in the Territory as set forth in the Development Plan in accordance with this Agreement;
- (b) an exclusive license under the MYLAN Patents and MYLAN Know-How and MYLAN and its Affiliates' interests in any Joint Invention Patents to conduct the Commercialization activities for the Licensed Products in the Field in the U.S. as set forth in the Commercialization Plan in accordance with this Agreement;
- (c) an exclusive license under the MYLAN Patents and MYLAN Know-How and MYLAN and its Affiliates' interests in any Joint Invention Patents to Develop Licensed Product in the Field and Commercialize Licensed Products in the Field, in each case in China (to the extent that MYLAN does not obtain exclusive rights to Develop and Commercialize Licensed Products in the Field in China pursuant to Section 2.07) and in any Reverted Countries;
- (d) an exclusive license under: (i) the MYLAN Patents and MYLAN Know-How and MYLAN and its Affiliates' interests in any Joint Invention Patents solely to make and have made anywhere in the world formulated Licensed Products in the Field (including API Compound for incorporation into such Licensed Products in the Field) for purposes of Developing and Commercializing Licensed Products in the Field (A) in China (if MYLAN does not obtain exclusive rights to Develop and Commercialize Licensed Products in the Field in China pursuant to Section 2.07) and (B) in any Reverted Country(ies) and (ii) the MYLAN Patents to the extent claiming Improvements and MYLAN Know-How comprising Improvements and MYLAN and its Affiliates' interest in any Joint Invention Patents to the extent claiming Improvements solely to make and have made anywhere in the world API Compound for incorporation into Licensed Products outside of the Field for purposes of Developing and Commercializing Licensed Product outside of the Field worldwide. For such purposes and purposes of Section 14.02(b)(i)(C), "Improvements" means any and all MYLAN Inventions comprising the composition or a method of manufacture of the API Compound; and
- (e) a non-exclusive license to use the Trademarks, the MYLAN Product Trademarks and MYLAN's Housemarks, in each case to the extent included on the Labeling of Licensed Products in the Field, solely for purposes of Commercializing the Licensed Products in the Field in the U.S. in accordance with the Commercialization Plan.

Notwithstanding the foregoing, MYLAN and its Affiliates retain their rights under the MYLAN Patents and MYLAN Know-How and Joint Invention Patents to (x) Develop

and manufacture the Licensed Products in the Field for the Territory in accordance with this Agreement, (y) Commercialize the Licensed Products in the Field in accordance with this Agreement, in each case (x) and (y) including by granting Affiliates and Third Parties rights and licenses thereunder to the same extent that MYLAN is permitted to grant sublicenses under the THERAVANCE Patents and THERAVANCE Know-How as set forth in Section 2.04 and as set forth in Section 2.03(b), and (z) develop, manufacture and commercialize any other product anywhere in the world, subject to the terms and conditions of this Agreement, including Section 5.06. The exclusive licenses granted to THERAVANCE pursuant to this Section 2.02 shall be exclusive, on a Licensed Product-by-Licensed Product and Country-by-Country basis, until the earliest of (i) the expiration of the last Valid Claim within the MYLAN Patents claiming such Licensed Product in such Country, (ii) the last Valid Claim within the THERAVANCE Patents claiming such Licensed Product in such Country and (iii) the expiration of the Term, and thereafter shall be non-exclusive for the remaining portion of the Term, if any. For clarity, MYLAN retains all rights under the MYLAN Patents, MYLAN Know-How and MYLAN and its Affiliates' interests in the Joint Invention Patents not expressly granted herein, including all rights thereunder to develop, manufacture and commercialize products other than Licensed Products, subject to the terms and conditions of this Agreement, including Section 5.06. Notwithstanding anything herein to the contrary, the licenses granted to THERAVANCE pursuant to this Section 2.02 shall not include the right to exercise the MYLAN Patents, the MYLAN Know-How, or MYLAN and its Affiliates' interests in the Joint Invention Patents with respect any active ingredient other than TD-4208 or with respect to any delivery device that may be formulated, packaged or sold together with TD-4208 as part of a Licensed Product.

#### Section 2.03 <u>Licenses to Third Parties</u>.

- (a) Without limiting MYLAN's rights under Sections 2.07 and 2.08, the licenses granted to MYLAN under Section 2.01 shall not prevent THERAVANCE from granting:
- i. licenses to Third Parties under the THERAVANCE Patents and THERAVANCE Know-How and THERAVANCE and its Affiliates' interests in any Joint Invention Patents to Develop Licensed Products in the Territory outside the Field;
- ii. licenses to Third Parties under the THERAVANCE Patents and THERAVANCE Know-How and THERAVANCE and its Affiliates' interests in any Joint Invention Patents to Commercialize Licensed Products in the Territory outside the Field;
- iii. licenses to Third Parties under the THERAVANCE Patents and THERAVANCE Know-How and THERAVANCE and its Affiliates' interests in any Joint Invention Patents to make and have made API Compound and formulated Licensed Products in the Territory outside the Field; and
- iv. licenses to Third Parties under the THERAVANCE Patents and THERAVANCE Know-How and THERAVANCE and its Affiliates' interests in any

Joint Invention Patents to Develop Licensed Product outside of the Territory (other than Licensed Products in the Field for the Territory) and Commercialize Licensed Products outside of the Territory in or outside of the Field.

- (b) The licenses granted to THERAVANCE under Section 2.02 shall not prevent MYLAN from granting:
- i. licenses to Affiliates or Third Parties under the MYLAN Patents, MYLAN Know-How and MYLAN and its Affiliates' interests in Joint Invention Patents to Develop Licensed Products in or for the Territory in the Field;
- ii. licenses to Affiliates or Third Parties under the MYLAN Patents, MYLAN Know-How and MYLAN and its Affiliates' interests in Joint Invention Patents to Commercialize Licensed Products in the Territory in the Field; and
- iii. licenses to Affiliates or Third Parties under the MYLAN Patents, MYLAN Know-How and MYLAN and its Affiliates' interests in Joint Invention Patents to make and have made API Compound and formulated Licensed Products in or for the Territory in the Field.
- Sublicensing and Subcontracting. Either Party may sublicense or subcontract its rights to Develop, manufacture or Commercialize the Section 2.04 Licensed Product in the Field in whole or in part to one or more of its Affiliates, provided that the rights sublicensed or subcontracted to such Affiliate shall automatically terminate if such Affiliate ceases to be an Affiliate of such Party. Each Party may also sublicense or subcontract any of its rights to Develop, manufacture or Commercialize the Licensed Product in the Field, in whole or in part, to one or more Third Parties, provided, however, that any such sublicense of Commercialization in the U.S. to be granted to a Third Party by either Party shall require the prior written consent of the other Party. Notwithstanding the foregoing, THERAVANCE shall not sublicense its rights or obligations under this Agreement to Develop the Licensed Products in the Field to a Third Party, but it may subcontract its Development responsibilities, solely in accordance with the Development Plan. Each Party shall contractually require all of its sublicensees and subcontractors to comply with all applicable terms and conditions of this Agreement, and each Party shall remain fully responsible for the compliance by such sublicensees and subcontractors with the applicable terms and conditions of this Agreement as if such sublicensees and subcontractors were such Party hereunder. Each Party shall secure appropriate covenants, obligations and rights from any such sublicensee and subcontractor to enable such Party to comply with its obligations under this Agreement, including with respect to intellectual property rights and confidentiality obligations. Without limiting the foregoing, THERAVANCE shall obligate any subcontractor of its Development responsibilities hereunder to assign all Inventions and other intellectual property rights resulting from such Development activities to THERAVANCE, so that they may be licensed to MYLAN in accordance with Section 2.01 and this Agreement. The license granted to THERAVANCE under Sections 2.02(c) and (d) shall include the right to grant sublicenses; provided that any such sublicensee shall be obligated to grant THERAVANCE a corresponding sublicensable license under any new discovery or

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technical idea related to TD-4208 or a Licensed Product after the date such sublicense is granted and any improvements to the API Compound or its manufacture, made by or on behalf of such sublicensee, and any Patents claiming such discoveries, ideas or improvements (collectively, "Sublicensee Improvements"), and THERAVANCE's rights in and to such Sublicensee Improvements shall be included in the THERAVANCE Patent Rights and THERAVANCE Know-How and subject to the licenses granted to MYLAN in Section 2.01.

#### Section 2.05 <u>Trademarks and Housemarks</u>.

- (a) Trademarks. The Licensed Products in the Field shall be Commercialized in the Territory under trademarks (such trademarks, other than the Parties' Housemarks, the "Trademarks") and trade dress approved by the JSC. The Parties acknowledge and agree that the Trademarks and trade dress for the Licensed Products in the Territory in the Field under this Agreement shall be consistent with MYLAN's corporate branding and related policies. For clarity, collectively, such Trademarks and trade dress comprise the MYLAN Product Trademarks. Prior to any such proposed Trademark(s) or trade dress being submitted to the JSC, the JPC (with MYLAN taking the lead) shall be responsible for undertaking their selection. MYLAN shall exclusively own all Trademarks and all goodwill associated therewith, and shall be responsible for the procurement, filing and maintenance of trademark registrations for such Trademarks and all costs and expenses related thereto. MYLAN shall also exclusively own all trade dress and copyrights associated with the Licensed Product in the Territory in the Field. Except as provided in Section 14.02(b)(v), nothing herein shall create any ownership rights of THERAVANCE in and to the Trademarks or the copyrights and trade dress associated with the Licensed Product in the Territory in the Field, and THERAVANCE shall assign and hereby assigns to MYLAN any and all rights, title and interest in and to such Trademarks (including associated goodwill), copyrights and trade dress that may be held by THERAVANCE or its Affiliates. In the event that THERAVANCE desires to utilize the Trademarks with respect to the Commercialization of Licensed Products in the Field in China or any Reverted Country, it may provide MYLAN with notice of such desire, in which case the Parties will discuss the terms and conditions on which MYLAN would license the Trademarks to THERAVANCE for such purposes pursuant to a separate trademark license agreement.
- (b) <u>Housemarks</u>. Each Party acknowledges the goodwill and reputation that has been associated with the other Party's Housemarks over the years, and shall use such Housemarks in a manner that maintains and promotes such goodwill and reputation and is consistent with the owner's trademark guidelines. In using the other Party's Housemarks (and, with respect to THERAVANCE, the MYLAN Product Trademarks) pursuant to the licenses granted in Sections 2.01 and 2.02 above, each Party shall (i) take reasonable precautions and actions to protect the goodwill and reputation that has inured to the other Party's Housemarks and MYLAN Product Trademarks, and (ii) refrain from doing any act that is intended, and use Diligent Efforts to refrain from doing any act that is reasonably likely, to impair the reputation of such Housemarks and MYLAN Product Trademarks.

- Section 2.06 <u>Updates to Exhibit B.</u> During the Term, Exhibit B shall be updated by the Parties at least quarterly to reflect any (i) additional THERAVANCE Patents first filed after the Effective Date, (ii) MYLAN Patents first filed after the Effective Date, and (iii) Joint Invention Patents first filed after the Effective Date.
- Section 2.07 MYLAN Right of First Negotiation for Development and Commercialization in the Field in China. Beginning on the Effective Date and ending on [\*\*\*] MYLAN shall have a first right of negotiation (the "China RFN") to enter into a mutually agreed collaboration arrangement (under this Agreement or otherwise) with THERAVANCE to pursue the Development and Commercialization of Licensed Products in the Field in China. After the Effective Date and until [\*\*\*] should THERAVANCE determine to pursue Development of Licensed Products in the Field in China, itself or with a Third Party, it will provide MYLAN with written notice thereof (the "China Notice"). For clarity, if THERAVANCE determines to pursue Development of Licensed Products in the Field in China itself, it shall provide MYLAN with the China Notice prior to commencing clinical trials of the Licensed Product in the Field in or for China.
- (a) Within thirty (30) days of the date on which MYLAN receives the China Notice (such date of receipt, the "China Notice Date"), MYLAN will notify THERAVANCE in writing as to whether or not it is exercising its China RFN. If MYLAN exercises its China RFN, the Parties have a further ninety (90) days to negotiate and sign a definitive agreement or a definitive amendment to this Agreement governing the Development and Commercialization of the Licensed Products in the Field in China.
- (b) If MYLAN does not exercise its China RFN within thirty (30) days of the China Notice Date or if the Parties are unable, despite negotiating in good faith, to negotiate and sign a definitive agreement or a definitive amendment to this Agreement for Development and/or Commercialization of Licensed Products in the Field in China during such ninety (90)-day period (or such longer period as the Parties may agree), THERAVANCE will be entitled to pursue all Development and Commercialization of Licensed Products in China both in and outside the Field and alone or with a Third Party and, except as expressly set forth herein, MYLAN will have no other legal or financial claim to TD-4208 in China.
- Section 2.08 MYLAN Right of First Negotiation for Non-Nebulized Development and Commercialization Opportunity.
- (a) If by [\*\*\*] MYLAN shall have a first right of negotiation ("RFN") to enter into a mutually agreed collaboration arrangement (under this Agreement or otherwise) with THERAVANCE to pursue the Development and/or Commercialization of Licensed Product in the Non-Neb Field. Under the RFN, should THERAVANCE determine to pursue Development of Licensed Products in the Non-Neb Field itself or with a Third Party, it will provide MYLAN with written notice thereof (the "Non-Neb Notice"). For clarity, if THERAVANCE determines to pursue Development of Licensed Products in the Non-Neb Field itself, it shall provide MYLAN with the Non-Neb Notice prior to commencing clinical trials of the Licensed Product in the Non-Neb Field.

<sup>\*\*\*</sup>CERTAIN INFORMATION HAS BEEN OMITTED AND FILED SEPARATELY WITH THE COMMISSION. CONFIDENTIAL TREATMENT HAS BEEN REQUESTED WITH RESPECT TO THE OMITTED PORTIONS.

- (b) Within thirty (30) days of the date that MYLAN receives the Non-Neb Notice (such date of receipt, the "Non-Neb Notice Date"), MYLAN will notify THERAVANCE in writing as to whether or not it is exercising its RFN with respect to the Non-Neb Field. If MYLAN exercises its RFN, the Parties have a further ninety (90) days to negotiate and sign a definitive agreement or a definitive amendment to this Agreement.
- (c) If MYLAN does not exercise its RFN within thirty (30) days of the Non-Neb Notice Date or if the Parties are unable, despite negotiating in good faith, to negotiate and sign a definitive agreement or a definitive amendment to this Agreement for Development and/or Commercialization of Licensed Products in the Non-Neb Field within such ninety (90)-day period, THERAVANCE will be entitled to pursue all Development and Commercialization of Licensed Products in the Non-Neb Field on a worldwide basis alone or in combination with a Third Party and MYLAN will have no other legal or financial claim to Licensed Products in the Non-Neb Field, except as expressly set forth herein. In the event that THERAVANCE enters into an agreement granting a Third Party the right to Develop or Commercialize Licensed Product in the Non-Neb Field under Section 2.08(a) or pursuant to this Section 2.08(c), and subsequently decides to Develop Licensed Product for an indication or with respect to a territory or dosage form or delivery form within the Non-Neb Field that was not included in the rights granted to such Third Party, THERAVANCE shall provide MYLAN with notice of such decision and the RFN shall apply with respect to such indication, territory, dosage form or delivery form in the Non-Neb Field.
- Section 2.09 No Other Licenses. For the avoidance of doubt, other than as expressly set forth in this Agreement, nothing in this Agreement is intended to or shall be construed to grant either Party any rights or licenses under the intellectual property or with respect to the products of the other Party.

## ARTICLE 3 GOVERNANCE OF DEVELOPMENT AND COMMERCIALIZATION OF LICENSED PRODUCT

#### Section 3.01 <u>Joint Steering Committee.</u>

- (a) <u>Purpose</u>. The Parties hereby establish a joint steering committee (the "Joint Steering Committee" or "JSC") (i) to determine the overall strategic direction for this collaboration between the Parties and (ii) to coordinate the Parties' activities hereunder through the Term of the Agreement.
- (b) Members; Officers. The JSC shall consist of up to eight (8) members, an equal number of whom shall be designated by each of MYLAN and THERAVANCE and each of whom shall be an employee of the designating Party with appropriate expertise. The initial members of the JSC are set forth on Exhibit C. Each Party's representation on

the JSC will include individuals with responsibility for a broad range of functions important to the successful Development and Commercialization of the Licensed Product in the Field at the applicable stage in the life cycle of the Licensed Products. Each of MYLAN and THERAVANCE may replace any or all of its representatives on the JSC at any time upon written notice to the other Party. While it is expected that each JSC member attend each JSC meeting, each Party may designate a substitute to temporarily attend and perform the functions of one or more of such Party's JSC members at any meeting of the JSC. MYLAN and THERAVANCE each may, on advance written notice to the other Party, invite non-member employee representatives of such Party to attend meetings of the JSC, which invitees shall not have the right to vote in JSC decisions. The attendance of members of or any representatives to the JSC who are not employees of the applicable Party shall be subject to the prior written consent of the other Party, not to be unreasonably withheld, refused, conditioned or denied. The JSC shall be chaired on an annual rotating basis by a JSC representative of either THERAVANCE or MYLAN, as applicable, with THERAVANCE providing the first such chairperson. The Party that does not appoint the chairperson shall appoint a secretary of the JSC, who shall be a representative of such other Party and who shall serve for the same annual term as such chairperson.

- (c) <u>Responsibilities</u>. The JSC shall perform the following functions:
  - i. Oversee the Development and Commercialization of the Licensed Product in the Field pursuant to the terms of this Agreement;
- ii. Review and approve the Development Plan, the Development Budget, the Commercialization Plan and the Commercial Budgets, and any material amendments and annual updates to each of the foregoing, as set forth in more detail in this Agreement and subject to Section 3.01(e)(ii);
- iii. At each meeting of the JSC, review actual, forecast and budgeted Net Sales for the year-to-date, as available, and for the remainder of the then-current Calendar Year;
- iv. Review the progress of the JPC under the Development Plan and Commercialization Plan, including against the Development Budget and Commercial Budget, respectively;
  - v. Review and approve the Trademarks in accordance with Section 2.05;
- vi. Review and discuss the life cycle management of, and intellectual property protection for, the Licensed Products in the Field in the Territory;
  - vii. Review and approve operational and other matters referred to the JSC by the JPC for decision;
- viii. Review, approve, and monitor regulatory strategy and activities for the Licensed Product in the Territory in the Field in accordance with ARTICLE 7;

- ix. Review the status of all preclinical and clinical studies conducted on Licensed Products in the Territory in the Field and any results therefrom, including patient accrual to trials vs. plan;
- x. Provide a forum to discuss any recall, market withdrawals or any other corrective action with respect to the Licensed Product in the Field in the Territory, in accordance with and subject to Section 7.05;
- xi. Provide a forum for THERAVANCE to provide MYLAN with updates regarding the Development and Commercialization of Licensed Products outside of the Field and outside of the Territory that are reasonably likely to be material to the Development or Commercialization of Licensed Product in the Field hereunder, including material safety events or findings, updates or changes in requirements from Regulatory Authorities applicable to Licensed Product with respect to study requirements or otherwise, and timing or sites for clinical trials that may compete for enrolment with any studies included in the Development Plan, (which updates shall be provided to the JSC in a timely manner) and for the Parties to coordinate such activities with the activities under this Agreement as appropriate. For clarity, such updates shall be THERAVANCE's Confidential Information, subject to the protections of Article 9;
- xii. Provide a forum for MYLAN to provide THERAVANCE with updates regarding the Development and Commercialization of a generic Competitive Product in the Field in the Territory that are reasonably likely to be material to the Development or Commercialization of Licensed Product in the Field hereunder, including with respect to timing of Regulatory Filings and timing or sites for clinical trials that may compete for enrolment with any studies anticipated or underway for Licensed Product (which updates shall be provided to the JSC in a timely manner). For clarity, such updates shall be MYLAN's Confidential Information, subject to the protections of Article 9.
  - xiii. In accordance with Section 3.01(f), resolve disputes or disagreements within the scope of the JSC's authority; and
- xiv. Have such other responsibilities as may be assigned to the JSC pursuant to this Agreement or as may be mutually agreed upon by the Parties from time to time.
- (d) Meetings. The JSC shall meet at least twice during every Calendar Year, and more frequently (i) as mutually agreed by the Parties or (ii) as required to resolve disputes, disagreements or deadlocks in the JPC, on such dates, and at such places and times, as such Parties shall agree; provided that the Parties shall endeavor to have the first meeting of the JSC within thirty (30) days after the Effective Date. The JSC shall arrange to meet in person or convene otherwise to assess and approve, as applicable, any Development Plan or Commercialization Plan submitted to JSC in each Calendar Year so that such plans will be reviewed and approved, or objections will be submitted, in accordance with this Agreement within thirty (30) days following submission to the JSC.

<sup>\*\*\*</sup>CERTAIN INFORMATION HAS BEEN OMITTED AND FILED SEPARATELY WITH THE COMMISSION. CONFIDENTIAL TREATMENT HAS BEEN REQUESTED WITH RESPECT TO THE OMITTED PORTIONS.

To the extent any such Development Plan or Commercialization Plan are not approved and need to be reformulated by the JPC, such plans shall be reviewed by the JSC as soon as reasonably practicable after resubmission of same, and in any event within thirty (30) days. Meetings of the JSC that are held in person shall alternate between offices of MYLAN and THERAVANCE, or such other place as the Parties may agree. Meetings the JSC may also be held by means of telecommunications or video conferences as deemed appropriate by the Parties; provided that at least one meeting of the JSC per Calendar Year shall be in person.

#### (e) <u>Decision-Making</u>.

- i. The JSC may make decisions with respect to any subject matter that is subject to the JSC's decision-making authority as set forth in Section 3.01(c). All decisions of the Joint Steering Committee shall be made by Consensus, with each Party acting in good faith to reach Consensus. Prior to each JSC meeting, the JPC shall provide a list of any topics arising in the JPC that require formal review or decision-making by the JSC. Each Party shall retain the rights, powers and discretion granted to it under this Agreement and no such rights, powers or discretion shall be delegated to or vested in the JSC unless such delegation or vesting of rights is expressly provided for in this Agreement or the Parties expressly so agree in writing. The JSC shall not have the power to (A) amend, modify or waive compliance with this Agreement, (B) impose any financial obligation on either Party or its Affiliates or sublicensees, (C) resolve any dispute regarding the existence or amount of any sums payable under this Agreement, or (D) impose on either Party an obligation to allocate such Party or its Affiliate's tangible or intangible resources and assets in a certain manner. For clarity, the JSC shall not have the power to impose the obligations described in (B) and (D) above on a Party, including pursuant to the dispute resolution procedures set forth in Section 3.01(f).
- ii. Notwithstanding anything herein to the contrary, if, in the context of the JSC's review and approval of the Commercialization Plan, THERAVANCE objects, in writing, to one or more elements of a Commercialization Plan (each, an "Objected Element"), then (A) the Parties shall use Diligent Efforts to implement all elements of such Commercialization Plan to the extent they are not Objected Elements, and (B) the Parties shall negotiate in good faith on an expedited basis, with time being of the essence, to revise the Objected Elements in a manner acceptable to the JSC as soon as practicable, including by promptly employing the dispute resolution procedures set forth in Section 3.01(f) as necessary or appropriate to reach resolution quickly. THERAVANCE shall not object to elements of the Commercialization Plan with respect to the ROW Countries unless such element is reasonably likely to have a material adverse effect on the Licensed Product either outside of the Field in the applicable ROW Country or inside the Field in the Territory.

#### (f) <u>Dispute Resolution</u>.

i. If the JSC cannot reach Consensus within thirty (30) days of the matter being brought to the JSC's attention, then such issue shall be referred to the Chief Executive Officer of THERAVANCE and the Chief Executive Officer or President of

MYLAN (collectively, the "Officers") for resolution. The JSC will utilize all resources at its disposal, including the use of Third-Party experts, as reasonably necessary to come to Consensus and agree that the use of the Officers for resolution of any unresolved issues will be on an exceptional basis.

- ii. If the Officers are unable to reach consensus within thirty (30) days of the matter being referred to them, the final decision with respect to any dispute within the scope of the JSC's decision-making authority will be made by a single, mutually acceptable Third Party arbitrator (the "Arbitrator") unless the issue is a Patent Resolution Issue (in which case it will be governed by Section 12.02(h)). Either Party can initiate such arbitration on thirty (30) calendar day's written notice to the other Party. The arbitration shall be conducted by JAMS pursuant to its Streamlined Arbitration Rules & Procedures then in effect, in New York, New York, and shall be subject to the following:
  - (A) Fees. The fees of associated with any such arbitration shall be shared equally by the Parties unless otherwise allocated by the Arbitrator.
  - (B) <u>Confidentiality.</u> The arbitration proceeding shall be confidential. Except as required by Law, no Party shall make (or instruct JAMS or the Arbitrator to make) any public announcement with respect to the proceedings or decision of the Arbitrator without prior written consent of each other Party. The existence of a dispute submitted to arbitration hereunder, and the outcome, shall be kept in confidence by the Parties, their affiliates, their counsel, insurers and re-insurers, accountants and auditors, and any Person necessary to the conduct of the proceeding. The confidentiality obligations shall not apply if (i) disclosure is required by applicable Laws or (ii) to the extent necessary to enforce the rights arising out of the award.
  - (C) <u>Findings of Arbitrator</u>. The decision of the Arbitrator will be final and binding on the Parties. Judgment upon the award may be entered by any court having jurisdiction thereof or having jurisdiction over the relevant Party.
  - (D) <u>Injunctive Relief.</u> Notwithstanding the foregoing, any Party has the right to apply to any court of competent jurisdiction for interim relief necessary to preserve the Party's rights until the Arbitrator is appointed. After appointment of the Arbitrator, the Arbitrator shall have the exclusive jurisdiction to consider applications for interim relief.
- (g) <u>Minutes of JSC Meetings</u>. Definitive minutes of all JSC meetings shall be finalized within thirty (30) days of the meeting to which the minutes pertain as follows:

<sup>\*\*\*</sup>CERTAIN INFORMATION HAS BEEN OMITTED AND FILED SEPARATELY WITH THE COMMISSION. CONFIDENTIAL TREATMENT HAS BEEN REQUESTED WITH RESPECT TO THE OMITTED PORTIONS.

- i. <u>Distribution of Minutes</u>. Within seven (7) days following a committee meeting, the secretary of the JSC shall prepare and distribute to all JSC members draft minutes of the meeting. Such minutes shall provide a list of any issues yet to be resolved, either within the JSC or through the relevant dispute resolution process.
- ii. Review of Minutes. The members of the JSC shall have seven (7) days after receiving such draft minutes to collect comments thereon and provide them to the secretary of the JSC.
- iii. <u>Discussion of Comments</u>. Upon the expiration of such second 7-day period, the Parties shall have an additional fourteen (14) days to discuss each other's comments and finalize the minutes. The secretary and chairperson of the JSC shall sign and date the final minutes. The signature of such chairperson and secretary upon the final minutes shall indicate each Party's assent to the minutes.
- (h) Expenses. Each Party shall be responsible for all travel and related costs and expenses for its members and other representatives to attend meetings of, and otherwise participate in, the JSC.

#### Section 3.02 Joint Product Committee.

- (a) <u>Purpose</u>. The purpose of the Joint Product Committee shall be to prepare the Development Plan and to coordinate and monitor the implementation of the Development Plan in accordance with the Development Budget and the Commercialization Plan in accordance with the Commercial Budget.
- (b) Members; Officers. Within thirty (30) days after the Effective Date, the Parties shall establish a joint product committee (the "Joint Product Committee" or "JPC"), and MYLAN and THERAVANCE shall designate an equal number of representatives, up to a maximum total of eight (8) members on such JPC, with an equal number from each Party. Each of MYLAN and THERAVANCE may replace any or all of its representatives on the JPC at any time upon written notice to the other Party. Such representatives shall be employees of the Parties who have the relevant experience and expertise to complete the activities included in the Development Plan or Commercialization Plan (as the case may be) for the Licensed Product in the Field for the next twelve months. On an occasional basis a Party may designate a substitute employee to temporarily attend and perform the functions of such Party's JPC member at any meeting of the JPC. MYLAN and THERAVANCE each may invite non-member employees representatives of such Party to attend meetings of the JPC. The attendance of members of or any representatives to the JPC who are not employees of the applicable Party shall be subject to the prior written consent of the other Party, not to be unreasonably withheld, refused, conditioned or denied. From the Effective Date until the date that is thirty (30) days after the filing of the first NDA for the Licensed Product in the Field in the U.S. the JPC shall be chaired by a representative of THERAVANCE and MYLAN shall appoint a secretary of the JPC, who shall be a representative of MYLAN and

THERAVANCE shall appoint a secretary of the JPC, who shall be a representative of THERAVANCE.

- (c) <u>Responsibilities</u>. The JPC shall perform the following functions:
- (i) Consult with THERAVANCE in the case of the Development Plan and with MYLAN in the case of the Commercialization Plan in connection with such Party's preparing and updating of the Development Plan and Commercialization Plan and their associated budgets in a timely manner (providing any comments within thirty (30) days of the submission thereof by the applicable Party) and submit them to the JSC for review and approval;
- (ii) At an appropriate and regular frequency, review the Development strategy (and, when appropriate, the Commercialization strategy) for the Licensed Product in the Field;
- (iii) Review and discuss whether or not to recommend to the JSC any material amendments or modifications to the Development Plan or the Commercialization Plan;
  - (iv) Coordinate and monitor regulatory strategy and activities for the Licensed Product in accordance with Article 7;
  - (v) Review and recommend to the JSC operational and other decisions for the Development of Licensed Product in the Field;
- (vi) Discuss the state of the markets for Licensed Product and opportunities and issues concerning the Commercialization of the Licensed Product, including consideration of marketing and promotional strategy, marketing research plans, and labeling;
  - (vii) At an appropriate and regular frequency, review the status of all studies conducted on Licensed Product and any results therefrom;
- (viii) At an appropriate and regular frequency, review Net Sales of Licensed Product for the year-to-date, and a current outlook for Net Sales for the remainder of the then-current Calendar Year:
  - (ix) Plan and review all publications described in Section 9.03, and review and approve a publications policy for such publications; and
- (x) Have such other responsibilities as may be assigned to the JPC pursuant to this Agreement or as may be mutually agreed upon by the Parties through the JSC from time to time.

<sup>\*\*\*</sup>CERTAIN INFORMATION HAS BEEN OMITTED AND FILED SEPARATELY WITH THE COMMISSION. CONFIDENTIAL TREATMENT HAS BEEN REQUESTED WITH RESPECT TO THE OMITTED PORTIONS.

- (d) Meetings. The JPC shall meet at least quarterly, and more frequently as the Parties mutually agree on such dates, and at such places and times, as the Parties shall agree; provided that the Parties shall endeavor to have the first meeting of the JPC as a face to face meeting within thirty (30) days after the establishment of JPC. Meetings of the JPC that are held in person shall alternate between the offices of MYLAN and THERAVANCE, or such other place as the Parties may agree and such face to face meetings shall occur no less than twice per year. The remaining meetings may be held by means of telecommunications or video conferences as deemed appropriate.
- (e) <u>Decision-Making</u>. The JPC may make decisions with respect to any subject matter that is subject to the JPC's decision-making authority as set forth in Section 3.02(c); provided that such decisions are consistent with the then-current Development Plan and Commercialization Plan. All decisions of the JPC shall be made by Consensus. If the JPC cannot reach Consensus within ten (10) Business Days after it has first met and attempted to reach such Consensus, the matter shall be referred on the eleventh (11th) Business Day to the JSC for resolution.
- (f) Minutes of JPC Meetings. Definitive minutes of all JPC meetings shall be finalized within thirty (30) days of the meeting to which the minutes pertain as follows:
  - (i) <u>Distribution of Minutes</u>. Within seven (7) days following a committee meeting, the secretary of the JPC shall prepare and distribute to all members of such committee draft minutes of the meeting. Such minutes shall provide a list of any issues yet to be resolved, either within such committee or through the relevant resolution process.
  - (ii) <u>Review of Minutes</u>. The Party members of the JPC shall have seven (7) days after receiving such draft minutes to collect comments thereon and provide them to the secretary of such committee.
  - (iii) <u>Discussion of Comments</u>. Upon the expiration of such second 7- day period, the Parties shall have an additional fourteen (14) days to discuss each other's comments and finalize the minutes. The secretary and chairperson of the JPC shall sign and date the final minutes. The signature of such chairperson and secretary upon the final minutes shall indicate each Party's assent to the minutes.
- (g) <u>Expenses</u>. Each Party shall be responsible for all travel and related costs and expenses for its members and other representatives to attend meetings of, and otherwise participate on, the JPC.
- (h) <u>Sub-Committees</u>. From time to time, the JPC may create sub-committees that will be responsible for assisting the Parties with respect to various Development, manufacturing and/or Commercialization activities undertaken pursuant to this Agreement.

<sup>\*\*\*</sup>CERTAIN INFORMATION HAS BEEN OMITTED AND FILED SEPARATELY WITH THE COMMISSION. CONFIDENTIAL TREATMENT HAS BEEN REQUESTED WITH RESPECT TO THE OMITTED PORTIONS.

Section 3.03 <u>General Guidelines and Initial Coordination Efforts.</u> In all matters related to the collaboration established by this Agreement, the Parties shall strive to balance as best they can the legitimate interests and concerns of the Parties and to realize the economic potential of Licensed Product in the Field.

Section 3.04 Third Party Restrictions on Certain Activities. Prior to the Effective Date, THERAVANCE has entered into an agreement with a Third Party (which agreement has been provided to MYLAN) that restricts THERAVANCE's ability to engage in certain Development and Commercialization activities with respect to certain Combination Licensed Products (the "Restrictions"). The Parties hereby agree that prior to making any Development or Commercialization decision hereunder that may implicate the Restrictions, they will work cooperatively and in good faith to mutually agree on appropriate procedures and course of conduct (which may require, by way of example, amendment of certain provisions of this Agreement) to ensure that THERAVANCE can comply with the Restrictions in a manner which most closely approximates the purpose and economic effect of the Parties' presumed intentions hereunder.

#### **ARTICLE 4**

#### DEVELOPMENT

Section 4.01 Development Plan. The Parties will agree to a comprehensive development plan for Licensed Products in the Field in the Territory (the "Development Plan"), which shall be prepared by the JPC and approved by the JSC, and is designed to generate the preclinical, clinical, chemistry manufacturing and controls ("CMC"), and regulatory data and information required for filing and approval of a U.S. IND application and a U.S. NDA and the foreign equivalent applications for each ROW Country for which the JSC determines to proceed with Development of Licensed Products in the Field (as applicable). A preliminary Development Plan for the initial U.S. Development program for the Licensed Product in the Field and its associated budget will be separately agreed upon by the Parties in writing prior to or at the Effective Date (the "Preliminary Development Plan"). The Parties acknowledge that, although the Phase 3 Clinical Trial of the Licensed Product in the Field for post-acute care of COPD ("PAC Trial") is included in the documents setting forth the Preliminary Development Plan, the inclusion of the PAC Trial or any other Development activities related to post-acute care in the Development Plan to be implemented under this Agreement shall be contingent upon further refinement of the protocol, discussions with the FDA, further cost/benefit analysis and approval by the JSC. Accordingly, as of the Effective Date, THERAVANCE shall not be obligated to perform, and MYLAN shall not be obligated to pay for, the PAC Trial, and any such obligations shall be subject to the foregoing contingencies, including approval by the JSC. The full Development Plan will contain, at a minimum:

(a) a prioritized list of indications for which the Parties intend to seek Marketing Authorization for the Licensed Products in the Field, and timelines for such activities;

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- (b) the configurations of Licensed Product in the Field, including Combination Licensed Product(s), that will be Developed by the Parties for the Territory, and timelines for such Development;
- (c) Protocol synopses that meet the standards for registration of non-clinical, pre-clinical and clinical trials in the Countries in which the Parties intend to conduct the trials of Licensed Product in the Field that are described in such protocols;
- (d) Complete study protocols, including statistical analysis plans, for the non-clinical, pre-clinical studies and clinical trials to be executed by the Parties or their representatives with respect to Licensed Products in the Field, and timelines for the conduct of each such study and trial;
- (e) Regulatory strategy to coordinate submissions of Regulatory Filings, including NDAs and Marketing Authorization Applications, in each of the applicable Countries, and timelines for such submissions;
- (f) Manufacturing strategy for clinical supply and transition and scale up to commercial supply for Licensed Product in the Field in the Territory, including development of a harmonized manufacturing package for registration and approval, and any bridging studies necessary in connection with a change of manufacturer for commercial supply; and
  - (g) A detailed Development Budget setting forth all anticipated Development Expenses by trial and Calendar Quarter.

#### Section 4.02 <u>U.S. Development.</u>

- (a) <u>Development Responsibility and Diligent Efforts.</u> Under the direction of the JSC, THERAVANCE shall have overall responsibility for, and shall use Diligent Efforts in, the performance of all Development activities for the Licensed Product in the Field for the U.S., subject to the terms and conditions of this Agreement. THERAVANCE shall use Diligent Efforts to advance the Licensed Product in the Field through Development in the U.S. in accordance with the Development Plan. Specifically, but without limitation, THERAVANCE will be responsible for the following U.S. Development matters:
  - i. conducting any remaining pharmaceutical science formulation and analytical work and accompanying quality control;
  - ii. conducting any remaining pre-clinical and toxicology studies;
  - iii. conducting clinical trials required to support the first NDA for the Licensed Product in the Field, including pivotal Phase 3 Clinical

Trials;

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- iv. conducting all CMC work, including any activities necessary to support filing and approval of the Commercial manufacturing process, and, unless agreed by the Parties, obtaining supply of Licensed Product in the Field necessary to conduct the Development Plan for the U.S. and support filing of the first NDA for the Licensed Product in the Field;
- v. preparing and filing all U.S. Regulatory Filings necessary to conduct the Development Plan, including any INDs and the first NDA for the Licensed Product in the Field, and executing any activities necessary to include in such filings to support Commercialization of the Licensed Products in the Field;
- vi. leading interactions with FDA and responding to questions from FDA during review of such Regulatory Filings in accordance with Article 7; and
- vii. cooperating to transition to MYLAN (or its Affiliates) activities for which MYLAN has primary responsibility with respect to Licensed Products in the Field.
- (b) MYLAN Assistance. MYLAN will provide technical expertise and advice to support THERAVANCE's conduct of activities under the Development Plan, including with respect to U.S. non-clinical, preclinical and clinical trials of, and Regulatory Filings for, the Licensed Product in the Field, by reviewing and approving such Regulatory Filings in accordance with Section 7 and as otherwise set forth in the Development Plan, which assistance may be provided directly or through MYLAN's vendors or contractors and sub-contractors.
- (c) Development Funding Responsibility. MYLAN shall reimburse THERAVANCE for all Development Expenses actually incurred, in accordance with the Development Budget contained in the Development Plan to Develop the Licensed Product in the Field for the U.S., from January 1, 2015 through first NDA approval for the Licensed Product in the Field in the U.S. MYLAN shall reimburse THERAVANCE on a quarterly basis in arrears for all such Development Expenses within thirty (30) days of receipt of THERAVANCE's invoice therefor. After the approval of the first NDA for the Licensed Product in the Field in the U.S., all Development Expenses incurred by THERAVANCE for the U.S. and all costs actually incurred by MYLAN in connection with the Development of the Licensed Product in the Field for the U.S. in accordance with the Development Budget contained in the then-current Development Plan approved by the JSC ("Post-Approval Development Expenses") will be Shared Expenses. For clarity, any Development Expense incurred by THERAVANCE after approval of the first NDA for the Licensed Product in the Field in the U.S. which is required or requested by FDA as a condition or in support of obtaining such NDA approval shall be Post-Approval Development Expenses.
- (d) <u>Cost Overruns.</u> If THERAVANCE anticipates that its quarterly Development Expenses that are subject to reimbursement hereunder may exceed the corresponding portion of the Development Budget for such Calendar Quarter (a "Cost Overrun"), then, together with its monthly report set forth in Section 1.07(a)(i) of Exhibit

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F, THERAVANCE will promptly give written notice to MYLAN of the anticipated Cost Overrun, including an explanation for such Cost Overrun. Subject to this Section 4.02(c), MYLAN will reimburse THERAVANCE for Cost Overruns in a given Calendar Quarter; provided that such Cost Overrun does not cause, and is not anticipated to cause, THERAVANCE to exceed the Development Budget for such Calendar Year. If such Cost Overruns exceed the Development Budget for such Calendar Year. If such Cost Overruns exceed the Development Budget for such Calendar Quarter by more than [\*\*\*] the Parties shall, upon MYLAN's request, meet promptly to discuss the reasons for such Cost Overruns and their impact on the annual Development Budget. The Cost Overrun mechanism is implemented as a tool to monitor and effectively manage quarterly variations in Development Expenses for timing differences. It does not provide approval to increase the Development Budget. If THERAVANCE determines that projected costs for Development activities under the Development Plan will exceed the approved Development Budget for a given Calendar Year, then THERAVANCE would need to obtain approval from MYLAN to increase the Development Budget prior to incurring such costs, and the allocation of Development costs in excess of the previously approved Development Budget ("Excess Costs") will be subject to the written agreement of the Parties, not to be unreasonably withheld. If the Parties fail to agree with respect to the allocation of Excess Costs, the Parties will share any such Excess Costs equally.

(e) <u>Development Updates</u>. THERAVANCE shall provide MYLAN with written and oral updates regarding U.S. Development of the Licensed Product in the Field at each JPC and JSC meeting (and at least once every Calendar Quarter) at a reasonable level of detail containing at a minimum all information generated as of the date of the report that is or would be required to be included in an IND, NDA or MAA (including by way of example and not limitation: all information regarding the API Compound and formulated dosage form(s) of the Licensed Product in the Field and methods of manufacturing the same, analytical methods, batch records, pre-formulation studies, reports summarizing development pharmaceutics, vendor information, validation documentation, interim and final results from all preclinical and clinical studies, adverse event data, patent information, regulatory documentation and filings, regulatory correspondence and data from nonclinical, preclinical and clinical studies), a summary of incurred and expected Development Expenses against the Development Budget, as well as high-level plans and objectives for the subsequent twelve (12) months.

## Section 4.03 Rest of World Development.

(a) <u>Development Responsibility.</u> During the twenty-four (24)-month period following the Effective Date, the JSC will evaluate, on a Country-by-Country or market-by-market basis, the potential Development of the Licensed Product in the Field for Country(ies) in the ROW. Should the JSC determine to proceed with Development of the Licensed Product in the Field for any Countries in the ROW, then the Parties will use good faith efforts to determine each Party's respective responsibilities to conduct Development under a ROW Development Plan and ROW Development Budget for such Country(ies) to be agreed by the JSC. Once the Parties reach agreement on a ROW Development Plan and ROW Development Budget for a Country in the ROW, then such Country shall become a "ROW Country" for purposes of this Agreement, and each Party will use Diligent Efforts to Develop the Licensed Product in the Field in such ROW

Country(ies) in accordance with such Development Plan and Development Budget. The Parties acknowledge and agree that, if MYLAN proposes to proceed with respect to the Development and Commercialization of Licensed Products in the Field in a particular Country in the ROW and demonstrates to the JSC that proceeding in such Country is commercially reasonable, the JSC shall not withhold its consent to proceed with the Development and Commercialization of the Licensed Products in the Field in such Country.

- (b) <u>Development Funding Responsibility.</u> MYLAN shall pay all Development Expenses incurred or committed to and which are set forth in the Development Budget contained in the Development Plan for all ROW Development hereunder, unless otherwise agreed by the JSC as part of the Development Budget. For clarity, if THERAVANCE has responsibility to conduct any ROW Development activities under the ROW Development Plan, Section 4.02(d) shall apply with respect to ROW Development Expenses associated therewith. THERAVANCE shall reimburse MYLAN for [\*\*\*] of the costs of any Licensed Product in the Field comprising Approval Batches for the ROW Countries that is not actually sold, within thirty (30) days of receipt of MYLAN's invoice therefor.
- (c) Development Updates. The Parties shall provide each other with quarterly written and oral updates regarding all ROW Development of the Licensed Product in the Field at each JPC and JSC meeting (and at least once every Calendar Quarter while such Development is ongoing) at a reasonable level of detail containing at a minimum all information generated as of the date of the report that is or would be required to be included in an IND (or foreign equivalent), MAA (including by way of example and not limitation: all information regarding the API Compound and formulated dosage form(s) of the Licensed Product in the Field and methods of manufacturing the same, analytical methods, batch records, pre-formulation studies, reports summarizing development pharmaceutics, vendor information, validation documentation, interim and final results from all preclinical and clinical studies, adverse event data, patent information, regulatory documentation and filings, regulatory correspondence and data from nonclinical studies), a summary of incurred and expected Development Expenses against the Development Budget, as well as high-level plans and objectives for the subsequent twelve (12) months.
- (d) Reversion of Rights. If, after an evaluation period of not less than one hundred eighty days, MYLAN's representatives to the JSC decline to proceed with Development in a particular Country in the ROW recommended by THERAVANCE, then all such rights and licenses granted to MYLAN in Section 2.01 to Develop and Commercialize the Licensed Product in such Country (each, a "Reverted Country") will revert to THERAVANCE and THERAVANCE will be free to pursue Development and Commercialization of products incorporating TD-4208 in the Field in such Reverted Country with no further obligation to MYLAN, except as expressly set forth in this Agreement.
- (e) <u>Cooperation</u>. THERAVANCE will use Diligent Efforts to ensure that registrational studies for Licensed Products inside and outside the Field are harmonized

with respect to design, conduct and timing to the extent reasonably required to comply with instructions and scientific advice received from Regulatory Authorities and applicable Laws. Where necessary or useful, both Parties will have access to the dossiers and documentation for the Licensed Products and other Regulatory Filings that are controlled by the other Party for the purposes of supporting Regulatory Filings for the Licensed Product in the Field in each Country where it is responsible for Development under this Agreement in accordance with Section 7.03.

- (f) Compensation to MYLAN for Use of Data.
- i. If: (A) MYLAN does not exercise its China RFN within thirty (30) days of the China Notice Date or if the Parties are unable to negotiate and sign a definitive agreement or a definitive amendment to this Agreement for Development and/or Commercialization of Licensed Products in the Field in China in accordance with Section 2.07; (B) THERAVANCE exercises, or permits its Affiliate or any Third Party to exercise, any right under (I) any MYLAN Patent or any manufacturing process within the MYLAN Know-How or (II) any non-clinical, pre-clinical, clinical or manufacturing data that were funded by MYLAN under this Agreement, in each case for purposes of Developing Licensed Product in the Field in China; and (C) THERAVANCE is able to Commercialize Licensed Product in the Field in China, itself or through an Affiliate or Third Party, then THERAVANCE agrees to pay to MYLAN a royalty equal to [\*\*\*] of Net Sales of Licensed Product in the Field in China for the longer of the life of such MYLAN Patents and thirteen (13) years following the First Commercial Sale of Licensed Product in China.
- ii. If THERAVANCE intends to incorporate, or permit its Affiliate or any Third Party to incorporate, any non-clinical, pre-clinical, clinical or manufacturing data intended to be incorporated in any Regulatory Filing in place of data that would otherwise have been required to be incorporated by or on behalf of THERAVANCE, its Affiliate or such Third Party, in each case that was funded by MYLAN under this Agreement ("Data"), in any Regulatory Filing for Licensed Products outside the Field, THERAVANCE shall promptly notify MYLAN and the Parties will negotiate in good faith a percentage [\*\*\*] of the costs incurred by MYLAN to generate such Data for which THERAVANCE shall be obligated to reimburse MYLAN. Such reimbursement shall be made within thirty (30) days of THERAVANCE's receipt of MYLAN's invoice therefor, in U.S. Dollars.
- iii. Notwithstanding anything herein to the contrary, THERAVANCE shall not be permitted to provide any Third Party with access to, or the benefit of, Data, either directly or through a right of use or reference pursuant to Section 7.03 or otherwise, unless such Third Party permits THERAVANCE to provide similar access, and THERAVANCE provides such access (including the right to use and incorporate into Regulatory Filings), to MYLAN with respect to data of a corresponding scope regarding Licensed Product that was funded by such Third Party, to the extent that such data exists.

#### ARTICLE 5

#### COMMERCIALIZATION

- Section 5.01 Commercialization Plan. MYLAN (in consultation with THERAVANCE through the JPC as set forth in this Section 5.01) will prepare a Commercialization Plan for Licensed Product in the Field in the Territory on an annual basis, which is designed to cover all necessary activities directed to the successful Commercialization of Licensed Product in the Field in the Territory during the following three (3) calendar years, as set forth in the Commercialization Plan Outline, and which shall reflect the bounds of operation to accomplish such objective. The Commercialization Plan should contain the depth and detail that are typical for MYLAN's internal commercial plans for similar products. A preliminary Commercialization Plan shall be prepared on or before March 31, 2016, and the Commercialization Plan shall be updated annually thereafter. Once a Commercialization Plan is developed in consultation with THERAVANCE through the JPC, MYLAN will prepare and submit a final draft of each such Commercialization Plan to the JPC for review and comment, which comments MYLAN will consider in good faith, and the JPC shall submit each Commercialization Plan to the JSC within thirty (30) days of its receipt of such final draft from MYLAN for review and approval by the JSC pursuant to Section 3.01(c)(ii).
- Section 5.02 The Commercialization Plan shall contain at a minimum those elements described in the Commercialization Plan Outline, as appropriate to current knowledge at the time.

#### Section 5.03 <u>U.S. Commercialization.</u>

- (a) <u>Joint Responsibility.</u> MYLAN and THERAVANCE shall closely collaborate, with MYLAN having primary responsibility and THERAVANCE complimenting such efforts in accordance with the agreed Commercialization Plan, with respect to, and shall use Diligent Efforts to effect, the Commercialization of the Licensed Product in the Field in the U.S. in compliance with applicable Laws and within the parameters of the then-current Commercialization Plan, all as to be set forth in more detail in the Co-Promotion Agreement. The marketing of the Licensed Product is to be planned and implemented in accordance with the Commercialization Plan that is approved by the JSC, and reviewed and monitored by the JPC. Without limiting the foregoing, the Parties will submit to the JPC representative samples of Promotional Materials from new marketing campaigns for Licensed Product in the Field in the U.S. for review and comment prior to their use in the course of their development. A division of marketing responsibilities in the U.S. between the Parties, with the intent of achieving transparency and reasonably minimizing duplication of efforts, will be defined between the Parties in the Commercialization Plan.
- (b) <u>Cost / Profit Sharing</u>. Operating Profits (Losses) with respect to the Licensed Products in the Field in the U.S. will be shared by the Parties, sixty-five percent (65%) to MYLAN and thirty-five percent (35%) to THERAVANCE, in accordance with Section 1.03 of Exhibit F.

<sup>\*\*\*</sup>CERTAIN INFORMATION HAS BEEN OMITTED AND FILED SEPARATELY WITH THE COMMISSION. CONFIDENTIAL TREATMENT HAS BEEN REQUESTED WITH RESPECT TO THE OMITTED PORTIONS.

(c) <u>Co-Promotion Agreement.</u> Within six (6) months after completion of the first Commercialization Plan pursuant to Section 5.01, the Parties shall engage in good faith negotiations to prepare and execute a definitive co-promotion agreement or similar marketing and distribution agreement describing the co-promotion activities of the Parties for such Licensed Product in the Field in the U.S. (the "Co-Promotion Agreement") consistent with the provisions of this Agreement, the terms and conditions set forth on Exhibit D, and such other terms as the Parties may agree and as are customary in an agreement of that type. The Parties shall work in good faith to ensure that the Co-Promotion Agreement is designed to be tax efficient for each Party. The Parties shall endeavor to execute such Co-Promotion Agreement as soon as possible after commencement of such negotiations and no later than eighteen (18) months prior to the anticipated First Commercial Sale of Licensed Product in the Field in the U.S.

#### Section 5.04 ROW Commercialization.

- (a) MYLAN shall have the sole right and responsibility for, and shall use Diligent Efforts to, Commercialize Licensed Product in the Field in the ROW Countries in compliance with applicable Laws and within the parameters of the then-current Commercialization Plan.
  - (b) MYLAN shall bear all costs and expenses associated with the Commercialization of Licensed Product in the Field in the ROW Countries.
- (c) MYLAN shall have the sole right and responsibility to distribute, sell, record sales and collect payments for Licensed Product in the Field in the ROW Countries.
- (d) MYLAN shall have the sole right and responsibility for establishing and modifying the terms and conditions with respect to Commercialization of Licensed Products in the Field in the ROW Countries, including the price or prices at which Licensed Products will be sold, any discount applicable to payments or receivables, all managed care contracting issues and any other similar matters.
- (e) MYLAN will be responsible for storage, order receipt, order fulfilment, shipping and invoicing of Licensed Products in the Field in the ROW Countries.
- (f) If MYLAN does not use Diligent Efforts to Commercialize a Licensed Product in the Field in accordance with the Commercialization Plan for any particular ROW Country approved by the JSC, then THERAVANCE may provide MYLAN with written notice of such failure, including a description of such failure, and THERAVANCE's desire to the have the rights to Commercialize Licensed Product in the Field in such ROW Country revert to THERAVANCE. Such notice shall reference this Section 5.04(f) and Section 13.02 and shall be a notice of material breach solely with respect to such Country, triggering THERAVANCE's right to terminate this Agreement solely with respect to such ROW Country, subject to the provisions (including the cure and dispute provisions) of Section 13.02. This Section 5.04(f) sets forth

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THERAVANCE's sole remedy in the event that MYLAN fails to use Diligent Efforts to Commercialize a Licensed Product in the Field in accordance with the Commercialization Plan for any particular ROW Country; and THERAVANCE shall not have the right to terminate this Agreement in its entirety pursuant to Section 13.02 based on such failure. Any such ROW Country with respect to which this Agreement is terminated pursuant to this Section 5.04(f) due to MYLAN's failure to use Diligent Efforts shall thereafter be deemed to be a Reverted Country.

# Section 5.05 <u>Labeling</u>.

- (a) <u>U.S.</u> All Labeling for use with the Licensed Product in the Field in the U.S. shall include (unless prohibited by Law) the THERAVANCE Housemark and the MYLAN Housemark, each of which shall be given equal exposure and prominence on such materials (unless prohibited by Law); provided that such obligation shall apply with respect to Promotional Materials only for so long as THERAVANCE is co-promoting the Licensed Product in the Field in the U.S., the Promotional Materials shall include a reference (unless prohibited by Law) to the contribution of the license from THERAVANCE for the Licensed Product (for example, by stating "Licensed from THERAVANCE BIOPHARMA R&D, INC.").
- (b) ROW. All Labeling (other than Promotional Materials) for use with the Licensed Product in the Field in the ROW Countries shall include a reference (unless prohibited by Law) to the contribution of the license from THERAVANCE for the Licensed Product (for example, by stating "Licensed from THERAVANCE BIOPHARMA R&D, INC."). In addition, the THERAVANCE Housemarks and the MYLAN (or its designee's) Housemarks shall both be given exposure and prominence on such materials (unless prohibited by Law) with the THERAVANCE Housemarks being subordinate in size and prominence to the MYLAN (or its designee's) HOUSEMARKS.

## Section 5.06 <u>Commercialization Restrictions.</u>

(a) During the Term, for so long as there is a Licensed Product in the Field being Developed or Commercialized under this Agreement in a particular country in the Territory, neither Party shall Commercialize (itself or through a Third Party) any Long Acting Muscarinic Antagonist product in the Field that is not a Licensed Product (any such product, a "Competitive Product") in such country. Further, during the Term neither Party shall Commercialize a generic Licensed Product in the Field outside of this Agreement. Notwithstanding the foregoing, MYLAN may Commercialize (itself or through an Affiliate or Third Party) a generic Competitive Product in any country in the Territory if a Third Party has launched such generic Competitive Product in such country prior to MYLAN's launch of such generic Competitive Product in such country. MYLAN will pay to THERAVANCE, during the Term, a [\*\*\*] calculated in a manner [\*\*\*] and payable [\*\*\*]. For clarity, the foregoing shall not prevent either Party from Commercializing LAMA products in the Non-Neb Field without any obligation to the other Party. For purposes of the foregoing, a "generic" product shall mean any product that is approved based on a Marketing Authorization Application submitted pursuant to

(a) Section 505(j) of the Federal Food Drug and Cosmetic Act or (b) an equivalent or counterpart of such section addressing approval of substitutable generics under applicable Laws in a jurisdiction outside of the U.S.

Neither Party will be deemed to be in breach of the restrictions set forth in Section 5.06(a) if such Party or any of its Affiliates acquires a Competitive Product through an acquisition of or a merger with the whole or substantially the whole of the business or assets of another Person, so long as such Party (or its Affiliate) (i) enters into a definitive agreement with a Third Party to Divest such Competitive Product in the applicable Country (ies) in the Territory (other than as part of any Hold Separate Transaction) within twenty-four (24) months after the closing of such acquisition or merger, or, if such Divestiture is subject to the terms of a Hold Separate Transaction, within twelve (12) months after the closing of the acquisition or merger, or (ii) discontinues sales of the Competitive Product in the Territory no later than twelve (12) months after the closing of such acquisition or merger. "Hold Separate Transaction" means any "hold separate" transaction (whether through the establishment of a trust or otherwise) involving the proposed sale of a Competitive Product in the applicable Country (ies) in the Territory pursuant to an agreement with any Governmental Authority responsible for antitrust laws. "Divest" or "Divestiture" means, with respect to any Competitive Product, (A) the sale, exclusive license or other transfer of all of the right, title and interest in and to such Competitive Product in the applicable Country(ies) in the Territory, including all technology, intellectual property and other assets relating solely thereto, to an independent Third Party, without the retention or reservation of any rights, license or interest (other than solely an economic interest and customary residual rights in the event of a termination) in such Competitive Product with respect to the applicable Country(ies) in the Territory and (B) the shutdown of activities related to the Competitive Product in the applicable Country(ies) in the Territory such that no technology, intellectual property or other asset relating thereto is used by the applicable Party or its Affiliates and delivery of written confirmation from such Party to the other Party that the Divesting Party and its Affiliates covenant not to use any technology, intellectual property and assets solely relating to such Competitive Product in the applicable Country(ies) in the Territory during the Term.

#### ARTICLE 6

# FINANCIAL PROVISIONS

Section 6.01 Payments. In consideration of the rights and licenses granted to MYLAN hereunder, MYLAN will pay to THERAVANCE the amounts set forth on Exhibit F.

Section 6.02 <u>Equity Investment.</u> Within 15 Business Days after the Effective Date, Mylan Inc. shall purchase newly issued Ordinary Shares of Theravance Biopharma, Inc. at a price per share equal to a 10% premium to the 5-day VWAP prior to announcement of this Agreement for total consideration of thirty million United States Dollars (U.S. \$30,000,000). Such purchase will be made pursuant to the Share Purchase Agreement attached hereto as Exhibit G.

- Section 6.03 <u>U.S. GAAP</u>. All financial terms and standards used in this Agreement for sales or activities occurring in the Territory shall be determined in accordance with United States generally accepted accounting principles, consistently applied ("GAAP").
- Section 6.04 Manner of Payments. All sums due under this ARTICLE 6 and Exhibit F shall be payable in United States Dollars by bank wire transfer in immediately available funds to such bank account(s) as the Party entitled to receive such payments shall designate at least five (5) Business Days in advance.
- Section 6.05 Interest on Late Payments. If either Party shall fail to make a timely payment pursuant to this ARTICLE 6 and Exhibit F, any such payment that is not paid within fifteen (15) days of the date such payment is due under this Agreement shall bear interest, to the extent permitted by applicable Laws, at the average one-month London Inter-Bank Offering Rate (LIBOR) as reported on the day such payment was due in *The Wall Street Journal* (U.S. Internet version at www.wsj.com under the "Market Data" tab), plus three percent (3%) annually, effective for the first date on which payment was delinquent and calculated on the number of days such payment is overdue or, if such rate is not regularly published, as published in such source as the JSC agrees.

#### Section 6.06 <u>Tax Withholding.</u>

- (a) Any taxes, levies or other duties ("Taxes") paid or required to be withheld under the appropriate local tax laws by one of the Parties ("Withholding Party") on account of monies payable to the other Party under this Agreement shall be deducted from the amount of monies otherwise payable to the other Party under this Agreement. The Withholding Party shall secure and send to the other Party within a reasonable period of time proof of any such Taxes paid or required to be withheld by Withholding Party for the benefit of the other Party.
- (the "Treaty") in connection with payments made to an Irish incorporated entity resident in Ireland for purposes of the U.S./Ireland Income Tax Treaty (the "Treaty") in connection with payments rendered under this Agreement will not impose a withholding obligation upon under Section 1442 of the Internal Revenue Code of 1986 as amended. THERAVANCE shall promptly provide MYLAN with Form W-8BEN-E certifying that it is the beneficial owner of the income and a resident of Ireland within the meaning of the Treaty. In the event that MYLAN concludes that it has an obligation to withhold under Section 1442 of the Code or otherwise under the Code or other applicable law with respect to any amount payable under this Agreement, MYLAN shall so notify THERAVANCE in writing, specifying the bases for such conclusion by MYLAN and the amount of Taxes and dates of any such withholding obligation that MYLAN believes it must fulfill.
- (c) If MYLAN or any of its Affiliates is or becomes liable to withhold any taxes from payments made to THERAVANCE or any of its Affiliates hereunder as a result of any assignment or sublicense by MYLAN, then MYLAN shall pay to THERAVANCE an amount equal to the withholding tax MYLAN or its applicable Affiliate owes to the relevant tax authority in excess of the amounts that would have been

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owed absent such assignment or failure; provided always that if THERAVANCE is able to obtain credit for any such taxes withheld ("Creditable Taxes") against any liability to tax either in the year in which the receipt is taxable or any preceding years, THERAVANCE shall reimburse to MYLAN an amount equivalent to the Creditable Taxes. THERAVANCE shall provide MYLAN with such reasonable evidence as MYLAN may reasonably request to determine whether the taxes are creditable against taxes payable by THERAVANCE.

- (d) It is understood and agreed between the Parties that any payments made by one Party to the other Party under this Agreement are exclusive of VAT, which shall be added thereon as applicable. Where VAT is properly added to a payment under this Agreement, the Party making the payment will pay the amount of VAT only on receipt of a valid tax invoice issued in accordance to applicable Laws of the country in which the VAT is chargeable.
  - (i) In the event that THERAVANCE receives a valid VAT Form 56B (or its predecessor, 13B, until its expiration date) from MYLAN, issued in accordance with section 56 VATCA, THERAVANCE agrees that it will not apply VAT to any invoices raised to such MYLAN entities detailed within the form 56B (or 13B, if applicable) for as long as that VAT Form 56B (or 13B, if applicable) remains valid. MYLAN agrees to notify THERAVANCE immediately, should MYLAN cease to satisfy the conditions of section 56 VATCA or should the Form 56B (or 13B, if applicable) become invalid for whatever reason. In the event that MYLAN fails to produce a valid and up to date VAT Form 56B (or 13B, if applicable), VAT shall apply to any invoices from THERAVANCE as normal.
  - (ii) Should additional and irrecoverable VAT become payable under this Agreement as a result of any of the Parties assigning this Agreement, or any obligation hereunder to an Affiliate, the Parties agree that any such additional and irrecoverable VAT shall be borne by the assigning Party. It is agreed between the Parties that the assignment by THERAVANCE to an Affiliate in Ireland shall not come within this provision.
  - (iii) If additional and irrecoverable VAT is properly added to payment made under this Agreement due to no fault of either Party, including as a result of changes in applicable tax Laws the Parties will meet promptly to discuss in good faith approaches to minimising such additional and irrecoverable VAT; provided that if such VAT must be paid, the Parties will share such VAT (or any remaining portion) equally unless otherwise agreed.

(e) To the extent a Party is required to deduct and withhold taxes on any payments to the other Party, such Party shall pay the amounts of such taxes to the proper Governmental Authority in a timely manner and promptly transmit to such other Party an official tax certificate or other evidence of such withholding sufficient to enable such other Party to claim such payments of taxes. Each Party shall provide to the other Party any tax forms that may be reasonably necessary in order for such other Party not to withhold tax or to withhold tax at a reduced rate under an applicable bilateral income tax treaty. Each Party shall take such action as the other Party may reasonably request in order for such party not to withhold tax or to withhold tax at a reduced rate in respect of payments to be made under this Agreement to that other Party. Such action shall include but shall not be limited to, an application or submission to a Revenue Authority or other Governmental Authority seeking confirmation of an exemption, relief, published practice, concession or otherwise in respect of such withholding tax. Each Party shall provide the other with reasonable assistance to enable the recovery, as permitted by applicable Laws, of withholding taxes, VAT, 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 VAT.

Section 6.07 <u>Currency</u>. All amounts contained in a reports provided hereunder shall be expressed in United States Dollars and calculated from any other currency by taking the average of the daily other currency: US\$ exchange rate during the Calendar Quarter used by the applicable Party to prepare its audited financial statements for external reporting purposes; provided that such method complies with GAAP and uses a widely accepted source of published exchange rates.

Section 6.08 Financial Records; Audits. Each Party shall keep, and shall cause its Affiliates and sublicensees to keep, such accurate and complete records of (i) for MYLAN, Operating Profits (Losses) and Royalties, and (ii) for THERAVANCE, Operating Profits (Losses) in the U.S., and Development Expenses in the Territory, and the calculations thereof, as are necessary to determine the amounts due to the other Party under this Agreement and such records shall be retained by each Party or any of its Affiliates or sublicensees (in such capacity, the "Recording Party") for at least the three (3) subsequent Calendar Years to which such expenses or Net Sales relate. During normal business hours and with reasonable advance notice to the Recording Party, such records shall be made available for inspection, review and audit, at the request and expense of the other Party, by an independent certified public accountant, or the local equivalent, appointed by the other Party and reasonably acceptable to the Recording Party for the sole purpose of verifying the accuracy of the Recording Party's accounting reports and payments made or to be made pursuant to this Agreement; provided, however that such audits may not be performed by the other Party more than once per Calendar Year. Such accountants shall be instructed not to reveal to the auditing Party the details of its review, except for (i) such information as is required to be disclosed under this Agreement and (ii) such information presented in a summary fashion as is necessary to report the accountants' conclusions to the auditing Party, and all such information shall be deemed Confidential Information of the Recording Party. All costs and expenses incurred in connection with performing any such audit shall be paid by the auditing Party unless the audit discloses at least a [\*\*\*] shortfall with respect to Net Sales or excess with

respect to expenses, as applicable, in which case the Recording Party will bear the full cost of the audit for such Calendar Year. The auditing Party will be entitled to recover any shortfall in payments due to it (or overpayment made by it, as applicable) as determined by such audit, plus interest thereon calculated in accordance with Section 6.05, or alternatively shall have the right to offset and deduct any such shortfall in payments due to it or overpayment made by it against payments the auditing Party is otherwise required to make to the Reporting Party under this Agreement. The documents from which were calculated the sums due under this ARTICLE 6 shall be retained by each Recording Party during the Term.

#### ARTICLE 7

#### REGULATORY MATTERS

# Section 7.01 Regulatory Matters/Filings in the U.S.

Pre-NDA Approval. Unless otherwise determined by the JSC or as set forth in the Development Plan, THERAVANCE shall be responsible for Regulatory Filings and interactions with Regulatory Authorities for the first Licensed Product in the Field in the U.S. up through the earlier of (i) the date that is ten (10) days after issuance of the first U.S. Marketing Authorization for the Licensed Product in the Field and (ii) the date on which the transfer of such Marketing Authorization (or the Marketing Authorization Application therefor) to MYLAN is complete (such date, the "Transfer Date"), and will use Diligent Efforts to prepare and submit such Regulatory Filings for the Licensed Product in the Field and to seek approval of each such filing submitted for the Licensed Product in accordance with the Development Plan. Without limiting the foregoing, THERAVANCE shall submit the first NDA for the first Licensed Product in the Field to the FDA, and shall assign and transfer (and hereby assigns and transfers, effective upon the Transfer Date) such NDA and the associated Marketing Authorization to MYLAN as soon as practicable after approval, and shall use Diligent Efforts to complete such transfer on or before the date that is ten (10) days after receipt of such Marketing Authorization, in accordance with the Development Plan. Each Party shall promptly submit any and all notices and authorizations to the FDA that are necessary to effect the transfer and acceptance of such Marketing Authorization. THERAVANCE shall provide MYLAN (and its representatives) with access to all pre-clinical, clinical and manufacturing data related to the Licensed Products in the Field, including but not limited to source data and a full copy of the NDA upon transfer to MYLAN. THERAVANCE will use reasonable efforts to obtain from its manufacturer(s) of the API Compound and the Licensed Product in the Field the right for MYLAN to accompany THERAVANCE during its audits of such sites upon provision of reasonable notice or the right to provide the results of any such audit conducted by or on behalf of THERAVANCE to MYLAN, and THERAVANCE will use reasonable efforts to coordinate with MYLAN with respect to the timing of any such audits. THERAVANCE shall (to the extent legally permissible) solicit MYLAN's advice and approval of all material Regulatory Filings for the Licensed Products in the Field, material submissions and correspondence and intended discussions with the U.S. Regulatory Authorities

regarding the Licensed Products in the Field, and shall take into account and incorporate MYLAN's reasonable comments and recommendations with respect thereto. Without limiting the foregoing and for the purpose of facilitating MYLAN's review, THERAVANCE shall submit the NDA for the first Licensed Product in the Field to MYLAN for review and comment, on a rolling basis and as soon as practicable, as individual sections are developed. THERAVANCE shall provide, and MYLAN shall have the opportunity to review, the NDA in accordance with a review process to be developed by the Parties, which process (or in the absence of agreement on a process, THERAVANCE) will ensure that MYLAN has a reasonable period to review certain sections of the NDA, including the preclinical, clinical, CMC and pharmaceutical sciences sections, and will ensure that MYLAN has a reasonable period to review and approve the full NDA prior to submission to the FDA, with the goals of providing all remaining sections of the NDA to MYLAN approximately forty-five (45) days prior to submission and allowing for prompt submission of the NDA to the FDA. In each instance, THERAVANCE shall take into account and incorporate MYLAN's reasonable comments and recommendations with respect to the NDA. The Parties shall cooperate with respect to preparing for and presenting at any meetings of any advisory committee to a Regulatory Authority regarding the Licensed Product in the Field in the U.S., provided that THERAVANCE shall have primary responsibility for leading any FDA advisory committee interactions prior to the Transfer Date. THERAVANCE shall provide to MYLAN in a timely manner (not to exceed twenty-four (24) hours after receipt or submission) copies of all material correspondence received by THERAVANCE from FDA regarding Licensed Product and of the material correspondence and submissions made by THERAVANCE to FDA regarding any Licensed Product. Without limiting the foregoing, MYLAN shall have the right to review and approve all material submissions to Regulatory Authorities regarding preclinical, clinical, CMC, manufacturing processes, or supply chain for the Licensed Product in the Field in the U.S. for which THERAVANCE is responsible for preparing and submitting prior to the Transfer Date. MYLAN shall have primary responsibility with respect to all interactions with and submissions to Regulatory Authorities regarding Promotional Materials, pricing and reimbursement for the Licensed Product in the Field in the U.S. and shall (to the extent legally permissible) solicit THERAVANCE's advice and review of all such material submissions related to the Licensed Products in the Field with the U.S. Regulatory Authorities made prior to the Transfer Date, shall take into account and incorporate THERAVANCE's reasonable comments and recommendations with respect thereto, and allow THERAVANCE to attend and participate in all meetings and scheduled calls between THERAVANCE and Regulatory Authorities regarding Promotional Materials, pricing and reimbursement for the Licensed Product in the Field the U.S. (providing THERAVANCE with reasonable advance notice of each such meeting/call). MYLAN shall also be permitted to attend and participate in all meetings and scheduled calls between THERAVANCE and Regulatory Authorities regarding the Licensed Products in the Field in the U.S., and THERAVANCE shall provide MYLAN with reasonable advance notice of each such meeting/call. With respect to Promotional Materials that MYLAN will generate during the period prior to the Transfer Date that require review and approval by FDA, THERAVANCE will facilitate the transfer of such Promotional Materials and any related correspondence to and from the FDA and MYLAN in a timely

manner (not to exceed two (2) Business Days after receipt from MYLAN or the FDA, as applicable).

Post-NDA Approval. Unless otherwise determined by the JSC or as set forth in the Development Plan, MYLAN shall be solely responsible for Regulatory Filings and interactions with Regulatory Authorities for Licensed Products in the U.S. in the Field from and after the Transfer Date, and will use Diligent Efforts to prepare and submit such Regulatory Filings for the Licensed Products and to seek approval of each such Regulatory Filing submitted for the Licensed Products in accordance with the Development Plan and Commercialization Plan. Except as expressly set forth in Section 7.01(a), MYLAN shall hold all Marketing Authorizations and Regulatory Filings for the Licensed Products in the Field, including all information and documentation used in the Regulatory Filings relating to the Licensed Products in the Field. MYLAN shall provide THERAVANCE (and its representatives) with access to all preclinical, clinical and manufacturing data generated by MYLAN with respect to the Licensed Products in the Field in the U.S. as requested by THERAVANCE and reasonably necessary to exercise its Co-Commercialization rights as set forth in Article 5 and the Co-Promotion Agreement, exercise its licenses under Section 2.02 and fulfill its obligations under applicable Laws with respect thereto. MYLAN will use reasonable efforts to obtain from its manufacturer(s) of the API Compound and the Licensed Product in the Field the right for THERAVANCE to accompany MYLAN during its audits of their manufacturing sites upon provision of reasonable notice or the right to provide the results of any such audit conducted by or on behalf of MYLAN to THERAVANCE, and MYLAN will use reasonable efforts to coordinate with THERAVANCE with respect to the timing of any such audits. MYLAN shall (to the extent legally permissible and time constraints permitting) solicit THERAVANCE's advice and review of all material Regulatory Filings, material correspondence and intended discussions with the U.S. Regulatory Authorities regarding the Licensed Products in the Field (including on matters concerning pricing and reimbursement for the Licensed Product in the Field in the U.S.) and shall take into account and incorporate THERAVANCE's reasonable comments and recommendations with respect thereto. Without limiting the foregoing, MYLAN shall solicit THERAVANCE's review and approval of all Regulatory Filings of which approval is necessary to conduct clinical trials or market the Licensed Products in the Field in the U.S ("Approval Filings"). MYLAN shall provide to THERAVANCE in a timely manner copies of all material correspondence received by MYLAN from FDA regarding Licensed Product and of the material correspondence and submissions made to FDA by MYLAN regarding any Licensed Product in the Field; provided that MYLAN shall provide copies of correspondence regarding Approval Filings within twenty-four (24) hours of receipt or submission, as applicable. For clarity, MYLAN shall provide THERAVANCE with copies of Promotional Materials submitted to FDA as set forth in Section 5.03(a) and with final versions of any Promotional Materials submitted to the FDA, but shall not be obligated to provide THERAVANCE with each iteration of Promotional Materials submitted to and received from the FDA. Notwithstanding anything herein to the contrary, MYLAN shall not be responsible for, or obligated to reimburse THERAVANCE for, any costs or expenses incurred by THERAVANCE in reviewing MYLAN's Regulatory Filings or correspondence with Regulatory Authorities in the Territory, and such costs and expenses shall not be Development Expenses.

THERAVANCE shall also be permitted to attend and participate in all meetings and scheduled calls between MYLAN and Regulatory Authorities in the U.S. regarding the Licensed Product in the Field, and MYLAN shall provide THERAVANCE with reasonable advance notice of each such meeting.

Regulatory Matters/Filings in ROW Countries. Unless otherwise determined by the JSC or as set forth in the Development Plan, MYLAN Section 7.02 shall be solely responsible for Regulatory Filings for, and interactions with Regulatory Authorities with respect to, the Licensed Products in the Field in the ROW Countries and will use Diligent Efforts to prepare and submit such Regulatory Filings for the Licensed Products and to seek approval of each such Regulatory Filing submitted for the Licensed Products in accordance with the Development Plan. MYLAN shall (to the extent legally permissible and time constraints permitting) solicit THERAVANCE's advice and review in advance of all material Regulatory Filings, material correspondence and intended discussions with any Regulatory Authority in the Territory. MYLAN shall provide to THERAVANCE in a timely manner copies of all material correspondence received from any Regulatory Authority in ROW Countries regarding any Licensed Product in the Field and of material correspondence and submissions made by MYLAN to such Regulatory Authority regarding any Licensed Product in the Field. MYLAN shall be fully responsible for bearing all its costs and expense associated with undertaking and completing said regulatory activities with respect to the Licensed Products in the Field in the ROW Countries, except that MYLAN will not be responsible for such costs and expenses for those ROW Countries that revert to THERAVANCE under Section 4.03(d) after such reversion, including but not limited to the costs of preparing, filing and prosecuting Regulatory Filings and comparable applications, fees payable in obtaining and maintaining same, responding to requests for information and additional activities from Regulatory Authorities and preparing for and presenting at any meetings of any advisory committee to a Regulatory Authority, or any other meetings requested by a Regulatory Authority. MYLAN shall not be responsible for the costs incurred by THERAVANCE in the discharge of THERAVANCE's obligations in respect of such activities or for THERAVANCE's costs relating to any ROW Country that reverts to THERAVANCE under Section 4.03(d).

#### Section 7.03 Reference Rights.

(a) Subject to Section 4.03(f), each Party hereby grants to the other Party (and their respective sublicensees or designees) a right of reference to Regulatory Filings owned or controlled by such Party as reasonably necessary to support the other Party's Regulatory Filings made for the following purposes: (1) for MYLAN to Develop, manufacture and Commercialize Licensed Products in the Field in the Territory in accordance with this Agreement, including conducting any bridge programs to support a change in manufacturer and (2) for THERAVANCE to (w) Develop Licensed Products in the Field in the Territory in accordance with this Agreement, (x) file the initial NDA to Commercialize the first Licensed Products in the Field in the U.S. in accordance with this Agreement, (y) Commercialize Licensed Product in the Field in the U.S. under the Co-Promotion Agreement, and (z) Develop, manufacture and Commercialize Licensed

Products (i) in the Field in China and the Reverted Countries and (ii) outside of the Field worldwide. Such rights of reference may include:

- i. the right for MYLAN to reference any and all drug master files (DMFs) referenced in the NDA for the Licensed Product in the Field in the Territory that is filed by THERAVANCE. THERAVANCE will enable right of reference to any and all such DMFs held by its contract manufacturer(s) which are relevant to Licensed Product to the extent that MYLAN elects to continue using such manufacturer for the Development or Commercialization of the Licensed Products in the Field in the Territory or as necessary to bridge to a new manufacturer. Such rights shall apply to DMFs relevant to API Compound and formulated Licensed Product, together with all updates to each of the foregoing; and
- ii. the right to reference any and all trial master files (TMFs) that are relevant to Licensed Products held by each Party or any of its contract research organization(s), together with all updates to each of the foregoing.
- (b) For clarity, the rights of reference set forth in Section 7.03(a)(2)(z) shall be subject to THERVANCE's reimbursement obligations under Section 4.03(f)(ii), and all rights of reference set forth in Section 7.03(a)(2) shall be subject to the limitations set forth in Section 4.03(f)(iii).
- (c) Each Party granting a right of reference pursuant to this Section 7.03 shall file any notices or authorizations with Regulatory Authorities that are necessary to effect the foregoing rights of reference, at the request and expense of the other Party.
- Section 7.04 <u>Drug Safety Information</u>. The Parties will at least 3 (three) months prior to the issuance of the first Marketing Authorization for a Licensed Product in the Field in either the U.S. or the EU, execute a pharmacovigilance agreement detailing their respective obligations for recording, investigating, summarizing, notifying, reporting and reviewing all Adverse Drug Experiences in relation to Licensed Products in the Territory in accordance with applicable Laws. Each Party shall require that its Affiliates (i) adhere to all requirements of applicable Laws which relate to the reporting and investigation of Adverse Drug Experiences, and (ii) keep the JSC apprised on a regular basis of such matters arising therefrom. For clarity, prior to the Transfer Date, THERAVANCE shall be responsible for all reporting of Adverse Drug Experiences in relation to the Licensed Product in the Field in the U.S., and on the Transfer Date such responsibilities shall transfer to MYLAN. Except as set forth in the preceding sentence or as otherwise agreed by the Parties pursuant to the pharmacovigilance agreement, MYLAN shall be responsible for managing pharmacovigilance for Licensed Products in the Field in the Territory.
- Section 7.05 Recalls or Other Corrective Action. Each Party shall, as soon as practicable but in no case later than two (2) Business Days after receipt, notify the other Party of any information received by it that could reasonably form the basis for a recall, market withdrawal or other corrective action of the Licensed Products in the Field, in sufficient detail to allow the Parties to comply with any and all applicable Laws to the

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extent such level of detail is available to the reporting Party. Each Party shall promptly notify the other Party of any material actions to be taken with respect to any recall or market withdrawal or other corrective action related to Licensed Product in the Field prior to such action to permit each Party a reasonable opportunity to consult with the other Party with respect thereto, and upon the request of either Party, the Parties will endeavor to hold a JSC meeting to discuss any recall of the Licensed Product in the Field; provided that any such meeting shall not delay the initiation of any recall. All costs and expenses incurred in accordance with this Section 7.05 with respect to a recall, market withdrawal or other corrective action with respect to the Licensed Products in the Field in the U.S ("U.S. Recall Costs") shall be Shared Expenses, split between the Parties proportionate to share of the Operating Profit (Loss) to which each Party is entitled pursuant to Exhibit F, unless such recall, market withdrawal or other corrective action was solely caused by the material breach of this Agreement or the Co-Promotion Agreement, gross negligence or willful misconduct by the other Party (in which case the other Party shall pay all such costs and expenses). All costs and expenses with respect to a recall, market withdrawal or other corrective action incurred by MYLAN or its Affiliates or sublicensees with respect to Licensed Product in the Field in a ROW Country (other than a Reverted Country) ("ROW Recall Expenses" and, together with "U.S. Recall Costs", "Recall Costs) shall be borne by MYLAN unless such recall, market withdrawal or other corrective action was solely caused by the gross negligence, willful misconduct or material breach of this Agreement by THERAVANCE (in which case THERAVANCE will pay all such costs and expenses). Without limiting Section 3.01(c)(x), all final decisions with respect to any recall, market withdrawals or any other corrective action related to the Licensed Product in the Field in the Territory shall be made by MYLAN as the Marketing Authorization holder. MYLAN will keep THERAVANCE reasonably informed with respect to any recalls, market withdrawals or other corrective action with respect to the Licensed Products in the Field in the Territory and will consider any comments from THERAVANCE with respect thereto in good faith. THERAVANCE will keep MYLAN reasonably informed with respect to any recalls, market withdrawals or other corrective action with respect to the Licensed Products in the Field outside the Territory.

Section 7.06 Events Affecting Integrity or Reputation. The Parties shall notify each other promptly of any circumstances of which they are aware and which could impair the integrity and reputation of the Licensed Products in the Field in any material respect, or if a Party receives a threat from any Third Party to deliberately conduct unlawful activity in relation to the Licensed Products in the Field, which circumstances shall include, by way of illustration, tampering with or contamination of the Licensed Products in the Field by any Third Party. In any such circumstances, the Parties shall use Diligent Efforts to limit any damage to the Parties and/or to the Licensed Products in the Field in compliance with applicable Laws. The Parties shall promptly call a JSC meeting to discuss and resolve such circumstances.

#### ARTICLE 8

#### ORDERS, MANUFACTURE AND SUPPLY

### Section 8.01 Orders and Terms of Sale.

- (a) <u>U.S.</u> In the U.S., MYLAN will have responsibility, subject to the Co-Promotion Agreement and the parameters established by the JSC in the Commercialization Plan, for establishing and modifying the commercial terms and conditions with respect to the sale and distribution of Licensed Product in the Field, including matters such as the price at which the Licensed Products will be sold and whether any discounts, rebates or other deductions should be made, paid or allowed. In the U.S., subject to the other terms of this Agreement, MYLAN shall have the sole right to (i) receive, accept and fill orders for Licensed Products in the Field, (ii) control invoicing, order processing and collection of accounts receivable for sales of Licensed Products in the Field, and (iii) record sales of Licensed Products in the Field in its books of account.
- (b) ROW Countries. In the ROW Countries, MYLAN shall have the sole right to (i) receive, accept and fill orders for Licensed Products in the Field, (ii) control invoicing, order processing and collection of accounts receivable for sales of Licensed Products in the Field, (iii) record sales of Licensed Products in the Field in its books of account, and (iv) establish and modify the commercial terms and conditions with respect to the sale and distribution of Licensed Products in the Field, including matters such as the price at which the Licensed Products will be sold and whether any discounts, rebates or other deductions should be made, paid or allowed.

# Section 8.02 Supply of API Compound and Formulated Licensed Product.

(a) <u>Selection of Manufacturer</u>. The Parties shall mutually agree (through the JSC) to the selection of an appropriate source(s) for manufacture and supply of API Compound and formulated Licensed Product in the Field to support Phase 3 Clinical Trials and commercial launch in the Territory, in accordance with this Section 8.02(a). Such manufacturer(s) shall be compliant with cGMP, applicable Laws, appropriate U.S. quality and regulatory standards, and similar requirements in the EU. MYLAN shall have the right to identify the manufacturer for Commercial supply of API Compound and formulated Licensed Product in the Field for the Territory, which may be a MYLAN Affiliate, and submit such manufacturer(s) to the JSC for approval, subject to Exhibit I. THERAVANCE shall have the right to identify the Third Party manufacturer for supply of formulated Licensed Product for Phase 3 Clinical Trials included in the Preliminary Development Plan, and submit such manufacturer(s) to the JSC for approval; subject to Exhibit I. Unless otherwise agreed by the Parties, THERAVANCE shall be responsible for procuring supply of Licensed Product in the Field to support such Phase 3 Clinical Trials from such Third Party manufacturer. Subject to the foregoing sentence, MYLAN shall be responsible for manufacture of API Compound for incorporation into Licensed Product in the Field and formulated Licensed Product in the Field for Development and Commercialization in the Territory, by itself or through one or more Third Parties.

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(b) Transition Assistance. THERAVANCE and its Third Party manufacturers will work actively and collaboratively with MYLAN to assist MYLAN in assuming such manufacturing responsibilities on a timely basis. Promptly after identifying the source of API Compound or formulated Licensed Product in the Field for commercial launch in the Territory, THERAVANCE shall provide MYLAN with a Technology Transfer Package and all reasonable cooperation and assistance to achieve technology transfer of the current manufacturing processes for TD-4208, API Compound and formulated Licensed Product in the Field (including the following processes: manufacturing, analytical methods, release procedures and all other relevant processes). THERAVANCE shall use Diligent Efforts as and to the extent reasonably requested by MYLAN to assist MYLAN at its option to (i) take assignment of THERAVANCE's existing Licensed Product, API Compound or component supply agreements, (ii) negotiate new agreements with THERAVANCE's existing suppliers, and/or (iii) enter into three-way agreements among THERAVANCE, MYLAN, and such suppliers for the transitional period, if required. THERAVANCE's assistance under the foregoing paragraph shall be at no additional charge to MYLAN.

# ARTICLE 9

#### CONFIDENTIAL INFORMATION

Section 9.01 Confidential Information. Each of MYLAN and THERAVANCE shall treat all Confidential Information received from the other Party with the same degree of care it uses to maintain the confidentiality of its own Confidential Information, but in no event less than a reasonable degree of care. Neither Party shall use the Confidential Information of the other Party for any purpose other than to exercise its rights and fulfill its obligations under this Agreement, including (a) preparing, filing, prosecuting and maintaining Patents in accordance with this Agreement, (b) prosecuting and defending litigation, and (c) making Regulatory Filings or communicating with Regulatory Authorities in accordance with this Agreement. Neither Party shall disclose the same to any other Person other than to Third Parties as reasonably necessary to conduct the foregoing activities and to such of its Affiliates, employees, contractors, advisors, counsel or agents (collectively, "Representatives") who have a need to know such Confidential Information to implement the terms of this Agreement or enforce its rights under this Agreement. A Receiving Party shall advise any such Person who receives such Confidential Information of the confidential nature thereof and of the obligations contained in this Agreement relating thereto, and the Receiving Party shall ensure that all such Representatives comply with such obligations as if they had been a Party hereto and shall be liable breach of this Article 9 caused by such Representatives use or disclosure of Confidential Information disclosed to it by such Receiving Party. Except as otherwise provided in Article 14, upon termination of this Agreement, the Receiving Party shall destroy all documents containing, and erase from tapes or other media, the Confidential Information of the Disclosing Party that remain in the Receiving Party's or its agents' possession and provide the Disclosing Party with a certificate of such destruction, except that (A) the Receiving Party shall not be obligated

one copy of the Confidential Information under the control of the legal department of the Receiving Party solely for (i) archival purposes, (ii) ascertaining any continuing obligations hereunder, or (iii) enforcing its rights hereunder. Notwithstanding the foregoing, the Receiving Party also shall be permitted to retain such additional copies of or any computer records or files containing the Confidential Information of the Disclosing Party that have been created solely by the Receiving Party's automatic electronic archiving and back-up procedures, to the extent created and retained in a manner consistent with the Receiving Party's standard archiving and back-up procedures, but not for any other use or purpose. Any retained copy of Confidential Information shall be deemed to be the property of the Disclosing Party, and shall continue to be subject to the provisions of this ARTICLE 9.

### Section 9.02 <u>Permitted Disclosure and Use.</u>

- (a) Notwithstanding Section 9.01, a Party may disclose this Agreement or Confidential Information belonging to the other Party to the extent such disclosure is reasonably necessary to: (i) during the Term, obtain Marketing Authorization of Licensed Product; (ii) enforce the provisions of this Agreement; or (iii) comply with applicable Law. If a Party deems it necessary to disclose Confidential Information of the other Party pursuant to this Section 9.02(a)(i) or (iii), such Party shall (to the extent permitted by applicable Law) give reasonable advance notice of such disclosure to the other Party to permit such other Party sufficient opportunity to object to such disclosure or to take measures to ensure confidential treatment of such information. The Receiving Party will cooperate reasonably with the Disclosing Party's efforts to protect the confidentiality of the information.
- (b) Each Party acknowledges that from time-to-time during the Term the other Party may have a legitimate business need to make a disclosure to a Third Party of Confidential Information in connection with the Development, manufacture or Commercialization of Licensed Product (including, (i) in the case of THERAVANCE, in connection with due diligence or negotiation for an out-license related to the Licensed Product outside the Field or in China, or (ii) in the case of MYLAN, in connection with due diligence or negotiation in connection with a potential Commercialization partner in a ROW Country or a manufacturing source). The Parties agree that in such cases, Confidential Information may be disclosed to such Third Party(ies) for the legitimate business need provided that a customary and reasonable legally binding confidentiality and non-use agreement ("CDA") is entered into with such Third Party that is at least as protective of such Confidential Information as this Article 9.
- Section 9.03 <u>Publications</u>. Each Party shall submit to the JPC for review and approval all proposed academic, scientific and medical publications and public presentations relating to a Licensed Product or any Development activities under this Agreement for review in connection with preservation of related patent rights, and trade secrets to determine whether Confidential Information should be modified or deleted from the proposed publication or public presentation and to ensure compliance with the publications policy adopted by the JPC and approved by the JSC (the "Publications Policy"). Written copies of such proposed publications and presentations shall be

submitted to the JPC no later than ninety (90) days before submission for publication or presentation and the JPC shall provide its comments with respect to such publications and presentations within thirty (30) days of its receipt of such written copy. The review period may be extended for an additional sixty (60) days if a representative of the non-publishing Party on the JPC can demonstrate a reasonable need for such extension including, but not limited to, the preparation and filing of patent applications. By mutual agreement of the Parties, this period may be further extended.

Section 9 04 Public Announcements. Except as may be expressly permitted under Section 9.03 or required by applicable Laws and subject to the final three sentences of this Section 9.04, neither Party will make any public announcement of any information regarding this Agreement or the terms hereof, the Licensed Product in the Field or any Development or Commercialization activities conducted under this Agreement (the "Public Announcement Matters") without the prior written approval of the other Party, which approval shall not be conditioned, delayed, refused or withheld unreasonably; provided however, that neither Party shall be prevented from complying with any duty of disclosure that it may have pursuant to applicable Laws or the rules of any recognized stock exchange so long as the Disclosing Party provides the other Party at least five (5) Business Days prior written notice of such disclosure to the extent practicable and only discloses information to the extent required by applicable Laws or the rules of any recognized stock exchange. Once any statement is approved for disclosure by the Parties or information is otherwise made public in accordance with the preceding sentence, either Party may make a subsequent public disclosure of the contents of such statement without further approval of the other Party. Notwithstanding anything herein to the contrary, MYLAN may inform its customers, suppliers and business contacts of the licensing of the Licensed Products in the Field hereunder in the ordinary course of business. In its press releases and public filings that mention or are regarding any Licensed Product in the Field, MYLAN shall refer to the fact that it has licensed the Licensed Product(s) from THERAVANCE, and THERAVANCE shall refer to the fact that it has licensed the Licensed Product(s) to MYLAN in its press releases and public filings. Within sixty (60) days of the Effective Date, appropriate representatives of the Parties will decide a process and principles for reaching timely consensus on how the Parties will make public disclosure concerning Public Announcement Matters. Notwithstanding the foregoing, but subject to Sections 2.07 and 2.08, respectively, THERAVANCE shall not be required to obtain the prior written approval of MYLAN for any public announcement relating to TD-4208 or Licensed Product in connection with or related to use or intended use in China or outside the Field; provided that such announcement would not reasonably be expected to have a material adverse impact on the Parties activities with respect to the Licensed Product in the Field hereunder.

Section 9.05 <u>Confidentiality of This Agreement</u>. The terms of this Agreement shall be Confidential Information of each Party and, as such, shall be subject to the provisions of this ARTICLE 9.

Section 9.06 <u>Termination Of Prior Confidentiality Agreement</u>. This Agreement supersedes the Confidentiality Agreement between MYLAN and Theravance Biopharma

US, Inc. dated June 2, 2014. The information exchanged under such agreement shall be deemed to have been exchanged under this Agreement.

Section 9.07 <u>Survival</u>. The obligations and prohibitions contained in this ARTICLE 9 shall survive for a period of five (5) years after the expiration or termination of this Agreement.

#### ARTICLE 10

#### WARRANTIES; COVENANTS

Section 10.01 Mutual Warranties. THERAVANCE and MYLAN each warrants to the other as of the Effective Date that:

- (a) Such Party (i) is a company duly organized, validly existing, and in good standing under the applicable Laws of the jurisdiction of its incorporation; (ii) is duly qualified as a corporation and in good standing under the Laws of each jurisdiction where its ownership or lease of property or the conduct of its business requires such qualification, or where the failure to be so qualified would have a material adverse effect on its financial condition or its ability to perform its obligations hereunder or MYLAN's ability to Commercialize the Licensed Products in the Field in the Territory in accordance with this Agreement; (iii) has the requisite corporate power and authority and the legal right to conduct its business as conducted as of the Effective Date and currently contemplated to be conducted pursuant to this Agreement; (iv) has or will obtain all necessary licenses, permits, consents, or approvals from or by, and has made or will make all necessary notices to, all Governmental Authorities having jurisdiction over such Party, to the extent required for the ownership and operation of its business and the performance of its obligations hereunder, where the failure to obtain such licenses, permits, consents or approvals, or to make such notices would have a material adverse effect on its financial condition or its ability to perform its obligations hereunder or MYLAN's ability to Commercialize the Licensed Products in the Field in the Territory; and (v) is in compliance with its charter documents;
- (b) The execution, delivery and performance of this Agreement by such Party and all instruments and documents to be delivered by such Party hereunder (a) are within the corporate power of such Party; (b) have been duly authorized by all necessary or proper corporate action; (c) do not conflict with any provision of the charter documents of such Party; (d) will not, to the best of such Party's knowledge, violate applicable Laws or any order or decree of any court or Governmental Authority; (e) will not violate or conflict with any terms of any indenture, mortgage, deed of trust, lease, agreement, or other instrument to which such Party is a Party, or by which such Party or any of its property is bound;
- (c) This Agreement has been duly executed and delivered by such Party and constitutes a legal, valid and binding obligation of such Party, enforceable against such Party in accordance with its terms, except as such enforceability may be limited by

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applicable insolvency and other Laws affecting creditors' rights generally, or by the availability of equitable remedies; and

- (d) All of its employees and consultants conducting activities under this Agreement have executed agreements or have existing obligations under applicable Laws requiring assignment to such Party of all Inventions made by such individuals during the course of and as the result of their association with such Party, and obligating such individuals to maintain as confidential such Party's Confidential Information.
- Section 10.02 <u>Debarment</u>. MYLAN and THERAVANCE each represents and warrants to the other, and (as applicable) covenants, that neither it nor any of its Affiliates has been debarred or is subject to debarment and neither it nor any of its Affiliates has used or will use in any capacity, in connection with the Development of the Licensed Products or the performance of this Agreement, any Person who has been debarred pursuant to Section 306 of the U.S. Federal Food Drug and Cosmetic Act, or who is the subject of a conviction described in such section. Each Party agrees to inform the other Party in writing promptly if it or any such Person who is performing services hereunder is debarred or is the subject of a conviction described in Section 306, or if any action, suit, claim, investigation or legal or administrative proceeding is pending or, to the best of its knowledge, is threatened, relating to the debarment or conviction of it or any such Person performing services hereunder.
- Section 10.03 <u>Additional THERAVANCE Warranties</u>. THERAVANCE, on behalf of itself and all of its Affiliates, further warrants to MYLAN as of the Effective Date that:
  - (a) an accurate and complete list of all THERAVANCE Patents are set forth in Exhibit B under "THERAVANCE Patents";
- (b) it or its Affiliate, Theravance Biopharma R&D IP LLC, is the sole and exclusive owner of all right, title and interest in and to the THERAVANCE Patents listed in Exhibit B and the THERAVANCE Know-How, all of which are owned free and clear of any liens, charges and encumbrances;
- (c) THERAVANCE has the right to grant MYLAN the licenses under the THERAVANCE Patents and THERAVANCE Know-How set forth in Section 2.01 free and clear of any liens, charges and encumbrances;
- (d) to THERAVANCE's knowledge, the manufacture, use and sale of the forms of TD-4208 and the Licensed Product in the Field that exist as of the Effective Date do not infringe upon any intellectual property rights of any Third Party;
- (e) there are no claims, judgments or settlements against or owed by THERAVANCE or any of its Affiliates relating to THERAVANCE Patents or THERAVANCE Know-How, TD-4208 or the Licensed Products or any past, pending or, to THERAVANCE's knowledge, threatened, claims or litigation relating to THERAVANCE Patents or THERAVANCE Know-How, TD-4208 or the Licensed Products, including any such claims or litigation that alleges that the Development,

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manufacture, use or Commercialization of the Licensed Product infringes, misappropriates or otherwise violates the intellectual property rights of a Third Party;

- (f) There is no litigation pending or threatened by THERAVANCE alleging that a Third Party is or was infringing, misappropriating, or otherwise violating the THERAVANCE Patents, and there has been no such litigation in the past;
- (g) there are no Patents or know-how, other than THERAVANCE Patents or THERAVANCE Know-How, owned or licensed by THERAVANCE or its Affiliates that claim or cover the Development, manufacture or Commercialization of TD-4208 or the Licensed Products in the Field; provided that if THERAVANCE subsequently identifies any such Patents or Know-How they shall automatically be included in the definition of THERAVANCE Patents or THERAVANCE Know-How, as applicable
- (h) there are no interferences, re-examination or re-issue proceeding(s) pending, declared or, to THERAVANCE's knowledge, threatened involving THERAVANCE with the THERAVANCE Patents, nor any re-examination or reissue proceeding concerning such THERAVANCE Patents and, to THERAVANCE's knowledge, the THERAVANCE Patents are valid and enforceable;
- (i) there are no actual or pending, and to THERAVANCE's knowledge, no alleged or threatened, adverse actions, suits, claims, or formal governmental investigations, or settlements or judgments, involving TD-4208 or Licensed Product by or against THERAVANCE or any of its Affiliates in or before any governmental authority. In particular, to its knowledge, there is no pending or threatened product liability action involving the use or administration of a Licensed Product;
- (j) all preclinical and clinical trials of Product that have been conducted by or on behalf of THERAVANCE that have been submitted to any Regulatory Authority in connection with any Licensed Product, have been conducted in compliance in all material respects with applicable Law, including good clinical practices and good laboratory practices, as applicable;
- (k) all Regulatory Filings that have been submitted to a Regulatory Authority by or on behalf of THERAVANCE with respect to Licensed Product were complete and accurate in all material respects on the date filed or furnished (or were corrected in or supplemented by a subsequent filing);
- (I) THERAVANCE has disclosed in writing to MYLAN all currently effective and material agreements relating to TD-4208 or the Licensed Products to which THERAVANCE and/or any of its Affiliates is a party as of the Effective Date (excluding clinical site agreements, clinical investigator agreements and related documentation, and excluding confidentiality or non-disclosure agreements with Third Parties);
- (m) THERAVANCE is not a Party to any in-effect agreement or obliged to any surviving obligation under any expired agreement, in each case pursuant to which THERAVANCE has licensed to a Person rights under the THERAVANCE Patents, THERAVANCE Know-How, or Joint Invention Patents to Develop or Commercialize

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the Licensed Product in the Field in the Territory or that would otherwise limit THERAVANCE's ability to grant MYLAN a license of the scope set forth in Section 2.01, and THERAVANCE will not enter into any such Agreement during the Term; and

(n) the Restrictions shall not limit MYLAN's Development and Commercialization activities within the scope of the licenses granted to it pursuant to Section 2.01.

### Section 10.04 Covenants.

- (a) Each Party hereby covenants and agrees during the Term that it shall carry out its obligations or activities hereunder in accordance with (i) the terms of this Agreement and (ii) all applicable Laws.
- (b) THERAVANCE hereby covenants and agrees that it will not expand the scope of, or otherwise modify, the Restrictions in a manner that will impair the Parties' ability to Develop, manufacture or Commercialize the Licensed Products pursuant to this Agreement without the prior written consent of MYLAN.

Section 10.05 <u>Disclaimer of Warranty</u>. Subject to the specific warranties and representations given under Section 10.01 through and including Section 10.03, nothing in this Agreement shall be construed as a warranty or representation by either Party with respect to the subject matter of this Agreement, including any such warranty or representation (i) that any Licensed Product made, used, sold or otherwise disposed of under this Agreement is or will be free from infringement of Patents, copyrights, trademarks, industrial design or other intellectual property rights of any Third Party, (ii) regarding the effectiveness, value, safety, non-toxicity, patentability, or non-infringement of any patent technology, TD-4208, Licensed Product or any information or results provided by either Party pursuant to this Agreement or (iii) that any Licensed Product will obtain Marketing Authorization. EXCEPT AS OTHERWISE SET FORTH IN THIS AGREEMENT EACH OF THERAVANCE AND MYLAN EXPRESSLY DISCLAIMS ANY AND ALL IMPLIED OR EXPRESS WARRANTIES AND MAKE NO EXPRESS OR IMPLIED WARRANTY, STATUTORY OR OTHERWISE, OF ANY KIND, INCLUDING ANY WARRANTIES OF MERCHANTABILITY OR FITNESS FOR ANY PARTICULAR PURPOSE REGARDING TD-4208, LICENSED PRODUCT, THERAVANCE CONFIDENTIAL INFORMATION, MYLAN CONFIDENTIAL INFORMATION, THERAVANCE PATENTS AND THERAVANCE KNOW-HOW OR MYLAN PATENTS AND MYLAN KNOW-HOW.

#### Section 10.06 Anti-Corruption Laws.

(a) Each Party understands that the other Party is required to and does abide by the United States Foreign Corrupt Practices Act ("FCPA"), the United Kingdom Bribery Act ("UKBA") and any other applicable anti-corruption laws (collectively, the "Anti-Corruption Laws"). Each Party represents and warrants that no one acting on its behalf will give, offer, agree or promise to give, or authorize the giving directly or indirectly, of any money or other thing of value to anyone as an inducement or reward for

favorable action or forbearance from action or the exercise of influence (a) to any governmental official or employee (including employees of government-owned and government-controlled corporations or agencies), (b) to any political party, official of a political party, or candidate, (c) to an intermediary for payment to any of the foregoing, or (d) to any other Person or entity in a corrupt or improper effort to obtain or retain business or any commercial advantage, such as receiving a permit or license.

- (b) Without limiting any other provision in this Section 10.06, either Party may suspend payment to the other hereunder, upon prior written notice, if (i) the other Party becomes subject to an investigation of potential violations of the FCPA or (ii) the other Party, in the reasonable determination of the paying party, fails to comply with the provisions of any Anti-Corruption Laws, including but not limited to the FCPA, and such investigation, or such failure, would reasonably be expected to adversely impact in any significant manner the Commercialization of the Licensed Product in the Field in the Territory.
- (c) Each Party warrants that all Persons acting on its behalf will comply with all applicable Laws in connection with all work conducted hereunder, including but not limited to the Anti-Corruption Laws if any, prevailing in the country(ies) in which it has its principal places of business or performs work hereunder.
- (d) Each Party further warrants and represents that should it learn or have reason to suspect any breach of its covenants in this Section 10.06, it will immediately notify the other Party.
- (e) Each Party may appoint a certified public accounting firm to perform a financial audit to determine whether the other Party is in compliance with the terms of this Section 10.6. Each Party hereby agrees to grant the certified public accounting firm commercially reasonable access to its books, records, systems and accounts to the extent they pertain to transactions covered by this Agreement and are necessary for such purpose.

# Section 10.07 Trade Control Laws.

- (a) Each Party will fully comply with all applicable export control, economic sanctions laws and anti-boycott regulations of the United States of America and other governments, including but not limited to the U.S. Export Administration Regulations (Title 15 of the U.S. Code of Federal Regulations Part 730 et seq.) and the economic sanctions rules and regulations implemented under statutory authority and/or President's Executive Orders and administered by the U.S. Treasury Department's Office of Foreign Assets Control (Title 31 of the U.S. Code of Federal Regulations Part 500 et seq.) (collectively, "Trade Control Laws").
  - (b) Each Party acknowledges and confirms that Trade Control Laws apply to its activities, its employees and Affiliates under this Agreement.

<sup>\*\*\*</sup>CERTAIN INFORMATION HAS BEEN OMITTED AND FILED SEPARATELY WITH THE COMMISSION. CONFIDENTIAL TREATMENT HAS BEEN REQUESTED WITH RESPECT TO THE OMITTED PORTIONS.

- (c) No API Compound or Licensed Product will be directly or indirectly shipped by the other Party to any country subject to U.S. or U.N. economic sanctions without the necessary licenses, even for transfer to non-sanctioned countries.
- (d) Neither Party shall be required by the terms of this Agreement to be directly or indirectly involved in the provision of goods, services and/or technical data that may be prohibited by applicable Trade Control Laws if performed by such Party.
- (e) Each Party hereby represents and warrants that it is not included on any of the restricted Party lists maintained by the U.S. Government, including, but not limited to, the Specially Designated Nationals List administered by the U.S. Treasury Department's Office of Foreign Assets Control; the Denied Persons List, Unverified List or Entity List maintained by the U.S. Commerce Department's Bureau of Industry and Security; or the List of Statutorily Debarred Parties maintained by the U.S. State Department's Directorate of Defense Trade Controls.
- (f) Each Party shall commit to maintaining awareness of the importance of Trade Control Laws throughout its organization. Each Party shall take such actions as are necessary and reasonable to prevent API Compound and Licensed Product from being exported or re-exported to any country, entity and/or individual subject to U.S. trade sanctions, unless prior approval of the other Party, and relevant permission and/or license from the U.S. government has been obtained.
- (g) Each Party will keep accurate and consistent records of all transactions covered by the Trade Control Laws for a minimum of five (5) years from the date of export or re-export; the date of expiration of any applicable license; or, other approval or reliance on any application of license exception or exemption.

#### ARTICLE 11

## INDEMNIFICATION; INSURANCE; LIMITATION OF LIABILITY

Section 11.01 <u>Indemnification by MYLAN</u>. Subject to Section 11.04, MYLAN shall defend, indemnify and hold harmless THERAVANCE, its Affiliates and its and their officers, directors, stockholders, employees, successors and assigns (each, a "THERAVANCE Indemnitee") from and against all Losses resulting from Claims brought by Third Parties against a THERAVANCE Indemnitee to the extent such Claims arise out of (a) MYLAN's or its Affiliates' negligence or willful misconduct in performing any of their obligations, or exercising any of their rights, under this Agreement, (b) a breach by MYLAN (or its Affiliates) of any of their representations, warranties, covenants or agreements under this Agreement, or (c) except to the extent resulting from the activities listed in Section 11.02(c), the Development, manufacture, use, handling, storage, marketing, sale, distribution or other disposition of Licensed Product by MYLAN, its Affiliates, agents, sublicensees or distributors, except in each case to the extent such Claims or Losses result from (x) the negligence or willful misconduct of THERAVANCE or its Affiliates or the breach by THERAVANCE or its

Affiliates of any obligation under this Agreement or (y) the manufacture of the API Compound or Licensed Product by MYLAN or its Affiliate's Third Party manufacturer and MYLAN is not indemnified by such Third Party for such Claims or Losses.

Section 11.02 Indemnification by THERAVANCE. Subject to Section 11.04, THERAVANCE shall defend, indemnify and hold harmless MYLAN, its Affiliates and its and their officers, directors, stockholders, employees, successors and assigns (each, a "MYLAN Indemnitee") from and against all Loss resulting from Claims brought by Third Parties against a MYLAN Indemnitee to the extent such Claims arise out of (a) THERAVANCE's or its Affiliates' negligence or willful misconduct in performing any of their obligations, or exercising any of their rights, under this Agreement, (b) a breach by THERAVANCE (or its Affiliates) of any of their representations, warranties, covenants or agreements under this Agreement, or (c) the Development, manufacture, use, handling, storage, marketing, sale, distribution or other disposition of Licensed Product by THERAVANCE, its Affiliates, agents, sublicensees or distributors, except in each case to the extent such Claims or Losses result from (x) the negligence or willful misconduct of MYLAN or its Affiliates or the breach by MYLAN or its Affiliates of any obligation under this Agreement or (y) the manufacture of the API Compound or Licensed Product by THERAVANCE or its Affiliate's Third Party manufacturer and THERAVANCE is not indemnified by such Third Party for such Claims or Losses.

## Section 11.03 <u>Procedure for Indemnification.</u>

- (a) Notice. Each Party will notify promptly the other in writing if it becomes aware of a Claim (actual or potential) by any Third Party (a "Third Party Claim") for which indemnification may be sought by that Party (the "Indemnified Party") and will give all information in its possession with respect thereto to the other Party (the "Indemnifying Party"). The Indemnified Party shall not make any admission or statement concerning such Third Party Claim. The Indemnifying Party and Indemnified Party shall meet to discuss how to respond to any Third Party Claims. The Indemnifying Party shall not be obligated to indemnify the Indemnified Party to the extent any admission or statement made by the Indemnified Party without the consent of the Indemnifying Party or any failure by such Party to notify the Indemnifying Party of the Claim materially prejudices the defense of such Claim.
- (b) <u>Defense of Claim.</u> The Indemnifying Party shall have the right to control the defense of a Third Party Claim, provided it gives notice to the Indemnified Party of its intention to do so within forty-five (45) days after the receipt of the written notice from the Indemnified Party of the potentially indemnifiable Third Party Claim (the "Litigation Condition"). Subject to compliance with the Litigation Condition, the Indemnifying Party shall retain counsel reasonably acceptable to the Indemnified Party (such acceptance not to be unreasonably withheld, refused, conditioned or delayed) to represent the Parties in the defense or settlement of such Third Party Claim and shall pay the fees and costs of such counsel related to such proceeding. In any such proceeding, the Indemnified Party shall have the right to retain its own counsel, but the fees and expenses of such counsel shall be at the expense of the Indemnified Party. The Indemnified Party shall not settle any Third Party Claim for which it is seeking indemnification without the

prior written consent of the Indemnifying Party. The Indemnified Party shall, if requested by the Indemnifying Party, cooperate in all reasonable respects in the defense of such Claim that is being managed and/or controlled by the Indemnifying Party, at the expense of the Indemnifying Party. The Indemnifying Party shall not, without the written consent of the Indemnified Party (which consent shall not be unreasonably withheld, refused, conditioned or delayed), effect any settlement of such Third Party Claim, unless such settlement includes an unconditional release of the Indemnified Party from all liability to Third Parties with respect to such Third Party Claim.

Section 11.04 <u>Assumption of Defense.</u> Notwithstanding anything to the contrary contained herein, an Indemnified Party shall be entitled to assume its own defense against any Third Party Claim upon written notice to the Indemnifying Party, in which case the Indemnifying Party shall be relieved of liability under Section 11.01 or Section 11.02, as applicable, solely for such Third Party Claim and related Losses, if it had previously satisfied the Litigation Condition.

## Section 11.05 Insurance.

- (a) During the Term of this Agreement and for a period of five (5) years after the termination or expiration of this Agreement, MYLAN shall obtain and/or maintain at its sole cost and expense, product liability insurance (including any self-insured arrangements) in amounts which are reasonable and customary in the pharmaceutical industry for companies of comparable size in the territories where MYLAN has activities, taking into account the nature of those activities. Such product liability insurance or self-insured arrangements shall insure against all liability, including personal injury, physical injury, or property damage arising out of the manufacture, sale, distribution, or marketing of the Licensed Products in the Field by or on behalf of MYLAN in the Territory. MYLAN shall provide written proof of the existence of such insurance to THERAVANCE upon request.
- (b) During the Term of this Agreement and for a period of five (5) years after the termination or expiration of this Agreement, THERAVANCE shall obtain and/or maintain at its sole cost and expense, product liability insurance (including any self-insured arrangements) in amounts which are reasonable and customary in the U.S. pharmaceutical industry for companies of comparable size and activities. Such product liability insurance or self-insured arrangements shall insure against all liability, including personal injury, physical injury, or property damage arising out of the manufacture, sale, distribution, or marketing of the Licensed Product worldwide in and outside of the Field by or on behalf of THERAVANCE. THERAVANCE shall provide written proof of the existence of such insurance to MYLAN upon request.
- (c) Without limiting the foregoing, each Party shall at a minimum maintain a product liability insurance policy with a [\*\*\*] limit in the aggregate. For clarity, MYLAN shall have the right to provide the total limits required under this Section 11.05 by any combination of primary and umbrella/excess coverage and may provide all or part of the required coverage through its insurance captive.

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### Section 11.06 <u>Limitation of Liability.</u>

- (a) <u>Consequential Damages Waiver</u>. EXCEPT FOR A BREACH OF ARTICLE 9 OR WITH RESPECT TO INDEMNIFICATION OBLIGATIONS ARISING UNDER THIS ARTICLE 11, NEITHER PARTY SHALL BE LIABLE FOR ANY INDIRECT, CONSEQUENTIAL DAMAGES ARISING OUT OF THIS AGREEMENT, INCLUDING DAMAGES FOR LOST PROFITS OR LOST REVENUES, REGARDLESS OF WHETHER IT HAS BEEN INFORMED OF THE POSSIBILITY OR LIKELIHOOD OF SUCH DAMAGES OR THE TYPE OF CLAIM, CONTRACT OR TORT (INCLUDING NEGLIGENCE).
- (b) <u>Liability Cap.</u> EXCEPT FOR (a) ANY AMOUNTS PAYABLE BY MYLAN TO A THIRD PARTY PURSUANT TO MYLAN'S INDEMNIFICATION OBLIGATIONS UNDER THIS ARTICLE 11 OR (b) WILLFUL MISCONDUCT OR FRAUD BY MYLAN OR ITS AFFILIATES, FOR WHICH THERE SHALL BE NO CAP ON AVAILABLE DAMAGES OR OTHERWISE, IN NO EVENT SHALL MYLAN'S LIABILITY FOR DAMAGES UNDER THIS AGREEMENT EXCEED, IN THE AGGREGATE, [\*\*\*] REGARDLESS OF WHETHER MYLAN HAS BEEN INFORMED OF THE POSSIBILITY OR LIKELIHOOD OF SUCH DAMAGES OR THE TYPE OF CLAIM, CONTRACT OR TORT (INCLUDING NEGLIGENCE).

#### **ARTICLE 12**

#### PATENTS AND INVENTIONS

### Section 12.01 <u>Inventions</u>.

- (a) <u>Disclosure and Determination of Inventorship</u>. Each Party shall promptly disclose to the other Party in writing any Inventions made by it during the Term. The determination of inventorship for such Inventions shall be made in accordance with the patent Laws in the U.S.
- (b) Ownership of Inventions. THERAVANCE shall own all THERAVANCE Inventions and MYLAN shall own all MYLAN Inventions. All Joint Inventions shall be owned jointly by THERAVANCE and MYLAN. Subject to the rights and licenses granted hereunder, each Party may license and otherwise exploit the Joint Inventions and Joint Invention Patents without the consent of, or reporting or accounting to, the other Party and each Party hereby waives any right it may have under the Laws of any jurisdiction to require any such consent, reporting or accounting.
- Section 12.02 <u>Preparation, Prosecution and Maintenance of Patents.</u>
  - (a) <u>Preparation, Prosecution and Maintenance of THERAVANCE Patents.</u>
- i. <u>Responsibility</u>. THERAVANCE shall have the first right, and the obligation to prepare, file and prosecute in a diligent manner (including by conducting interferences, oppositions and reexaminations or other similar proceedings), and maintain

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(by timely paying all maintenance fees, renewal fees, and other such fees and expenses required under applicable Laws) and (subject to Section 12.02(f)) extend all THERAVANCE Patents, in accordance with input from MYLAN as provided herein. THERAVANCE may elect not to prepare, file, prosecute, or maintain THERAVANCE Patents subject to the provisions of Section 12.02(d).

- ii. <u>Abandonment.</u> THERAVANCE shall consult with MYLAN and comply with Section 12.02(d) prior to abandoning any THERAVANCE Patents in the Territory.
- iii. Input. THERAVANCE shall regularly advise MYLAN of the status of all THERAVANCE Patents in the Territory, and shall provide MYLAN with copies of all material documentation concerning THERAVANCE Patents in the Territory, including all correspondence to and from any Governmental Authority. Prior to filing new THERAVANCE Patents, including patent applications claiming THERAVANCE Inventions, or significant prosecution documents relating to THERAVANCE Patents in the Territory, THERAVANCE shall solicit MYLAN's advice on the content of the patent application or prosecution document and THERAVANCE shall take into account and incorporate MYLAN's reasonable comments related thereto, unless (without fault of THERAVANCE) deadlines will not permit such review or MYLAN notifies THERAVANCE that it does not wish to review such documents. In the event of a dispute between the Parties regarding the content of patent applications or prosecution documents, THERAVANCE shall have the final decision-making authority with respect to any action relating to Patents claiming THERAVANCE Inventions or THERAVANCE Patents, subject to the provisions of Section 12.02(d) or Section 12.02(h), although THERAVANCE and MYLAN shall seek to agree on which Countries in the Territory in which THERAVANCE Patents shall be filed and the content of patent applications or prosecution documents.
- iv. <u>Expenses.</u> Subject to a budget to be mutually agreed upon by the Parties and updated periodically, MYLAN will reimburse [\*\*\*] of THERAVANCE's actual out-of-pocket expenses incurred after the Effective Date in filing, prosecution and maintenance of THERAVANCE Patents in the Territory. THERAVANCE shall be responsible for all of THERAVANCE's other expenses relating to THERAVANCE Patents.
  - (b) <u>Preparation, Prosecution and Maintenance of MYLAN Patents.</u>
- i. Responsibility. MYLAN shall have the exclusive right, but not the obligation, to prepare, file, prosecute, maintain and extend MYLAN Patents. MYLAN may elect not to prepare, file, prosecute, maintain or extend MYLAN Patents, subject to Section 12.02(e) solely with respect to the MYLAN Patents that claim solely the Licensed Products in the Field, including the composition, manufacture or use thereof (such MYLAN Patents, the "MYLAN Product Patents").

- ii. <u>Status.</u> MYLAN shall keep THERAVANCE reasonably informed with respect to the status of the MYLAN Patents and shall consult with THERAVANCE and comply with Section 12.02(e) prior to abandoning any MYLAN Product Patent.
- iii. Input. MYLAN shall regularly advise THERAVANCE of the status of all MYLAN Product Patents and, at THERAVANCE's request, shall provide THERAVANCE with copies of all documentation concerning MYLAN Product Patents, including all correspondence to and from any Governmental Authority. Prior to filing patent applications or significant prosecution documents relating to MYLAN Product Patents, MYLAN shall solicit THERAVANCE's advice on the content of the patent application or prosecution document and MYLAN shall take into account THERAVANCE's reasonable comments related thereto, unless (without fault of MYLAN) deadlines will not permit such review or THERAVANCE notifies MYLAN that it does not wish to review such documents. In the event of a dispute between the Parties regarding the content of patent applications or prosecution documents, MYLAN shall have the final decision-making authority with respect to any action relating to MYLAN Product Patents subject to the provisions of Section 12.02(e) or Section 12.02(h), although THERAVANCE and MYLAN shall seek to agree on which Countries in the Territory in which MYLAN Product Patents shall be filed within the priority period and the content of patent applications or prosecution documents with respect to the MYLAN Product Patents.
- iv. <u>Expenses.</u> MYLAN shall be responsible for all of MYLAN's expenses incurred to procure MYLAN Patents in the Territory, including all filing fees, translations, maintenance, annuities, and protest proceedings; provided that THERAVANCE shall reimburse MYLAN for [\*\*\*] of MYLAN's out-of-pocket expenses with respect to the MYLAN Product Patents.
  - (c) <u>Preparation, Prosecution and Maintenance of Joint Invention Patents.</u>
- i. Responsibility. THERAVANCE shall have the first right, and the obligation to prepare, file and prosecute in a diligent manner (including by conducting interferences, oppositions and reexaminations or other similar proceedings), and maintain (by timely paying all maintenance fees, renewal fees, and other such fees and expenses required under applicable Laws) and (subject to Section 2.02(f)) extend all Joint Invention Patents, in accordance with input from MYLAN as provided herein. THERAVANCE may elect not to prepare, file, prosecute, or maintain Joint Invention Patents, subject to the provisions of Section 12.02(d) and Section 12.02(h). The Parties agree to cooperate in the preparation and prosecution of all Joint Invention Patents, including by obtaining and executing necessary powers of attorney and assignments by the named inventors, providing relevant technical reports to the filing Party concerning the Invention disclosed in Joint Invention Patents, and obtaining execution of such other documents which shall be needed in the filing and prosecution of Joint Invention Patents. Any Joint Invention Patents shall be filed in the name of both Parties and shall be owned jointly by THERAVANCE and MYLAN.

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- ii. <u>Abandonment</u>. THERAVANCE must consult with MYLAN, and comply with Section 12.02(d), prior to the abandonment of any Joint Invention Patents.
- iii. Input. THERAVANCE shall regularly advise MYLAN of the status of all Joint Invention Patents and shall provide MYLAN with copies of all material documentation concerning Joint Invention Patents, including all correspondence to and from any Governmental Authority. Prior to filing patent applications claiming Joint Inventions or significant prosecution documents relating to Joint Invention Patents, THERAVANCE shall solicit MYLAN's advice on the content of the patent application or prosecution document and THERAVANCE shall take into account and incorporate MYLAN's reasonable comments related thereto, unless (without fault of THERAVANCE) deadlines will not permit such review or MYLAN notifies THERAVANCE that it does not wish to review such documents.
- iv. <u>Expenses.</u> Subject to a budget to be mutually agreed upon by the Parties and updated periodically, MYLAN will pay [\*\*\*] of THERAVANCE's actual out-of-pockets expenses incurred after the Effective Date to procure Joint Invention Patents, including all filing fees, translations, maintenance, annuities, and protest proceedings. THERAVANCE shall be responsible for all of THERAVANCE's other expenses relating to Joint Invention Patents.
- (d) MYLAN Step-In Rights. If THERAVANCE elects not to prepare and file a patent application claiming a patentable THERAVANCE Invention or Joint Invention or not to prosecute and maintain a THERAVANCE Patent or Joint Invention Patent in any Country in the Territory, THERAVANCE shall give MYLAN written notice thereof at least sixty (60) days prior to allowing any rights to such THERAVANCE Invention, Joint Invention, THERAVANCE Patent, or Joint Invention Patent, as applicable, to lapse or become abandoned or unenforceable, and MYLAN shall thereafter have the right ("Step-In Rights"), at its sole discretion and expense, to prepare and file a patent application or prosecute and maintain, as applicable, the relevant Patent in the relevant Country(ies). MYLAN shall provide THERAVANCE with written notice of its decision to exercise its Step-In Rights within thirty (30) days of receipt of the notice from THERAVANCE regarding its decision not to prepare or file a patent application on a THERAVANCE Invention or a Joint Invention Patent. Within thirty (30) days of the exercise of Step-In Rights by MYLAN for any THERAVANCE Invention or a Joint Invention or THERAVANCE Patent or Joint Invention Patent in any Country, THERAVANCE shall assign all of its rights in and to the applicable Invention and/or the applicable Patent to MYLAN in that Country. Any such assigned THERAVANCE Invention, Joint Invention Patent or THERAVANCE Patent shall thereafter be a MYLAN Invention or a MYLAN Patent in the assigned Country and be licensed in accordance with the terms of this Agreement for no additional consideration.
- (e) Execution of Documents. Each of the Parties shall execute or have executed by its appropriate agents such documents as may be reasonably requested by the other Party to prepare, file, prosecute, maintain or extend any Patents in accordance with this Article 12, and each Party shall cooperate as reasonably requested by the other Party

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with respect to furnishing all information and data in its possession reasonably necessary to prepare, file, prosecute, maintain or extend any Patents in accordance with this Article 12, in each case at the requesting Party's expense.

- (f) THERAVANCE Step-In Rights for MYLAN Product Patents. If MYLAN elects not to prosecute and maintain a MYLAN Product Patent in any Country in the Territory, MYLAN shall give THERAVANCE written notice thereof at least sixty (60) calendar days prior to allowing any rights to the MYLAN Product Patent to lapse or become abandoned or unenforceable, and THERAVANCE shall thereafter have the right, at its sole expense, to prosecute and maintain the MYLAN Product Patent in the relevant Country(ies). THERAVANCE shall provide MYLAN with written notice of its decision to exercise its Step-In Rights from and including thirty (30) calendar days of receipt of the notice from MYLAN regarding its decision not to prosecute or maintain a MYLAN Product Patent. From and including thirty (30) calendar days of the exercise of Step-In Rights by THERAVANCE for any MYLAN Product Patent in any Country, MYLAN will assign all of its rights in and to the MYLAN Product Patent to THERAVANCE in that Country. Any such assigned MYLAN Product Patent shall thereafter be a THERAVANCE Patent in the assigned Country and be licensed in accordance with the terms of this Agreement for no additional consideration.
- (g) Patent Term Extensions. The Parties shall cooperate with each other to obtain patent term extensions or other extensions of patent rights, including if applicable supplementary protection certificates ("SPCs"), for the Licensed Products. The JSC shall determine which Patents the Parties shall endeavor to have extended in the Territory with respect to the Licensed Products in the Field. If the JSC does not agree as to which Patents should be extended in the Territory, then the Parties shall resort to the dispute resolution procedure set forth in Section 3.01(f); provided that in the event that MYLAN requests that THERAVANCE extend a THERAVANCE Patent claiming the composition of TD-4208 with respect to a Licensed Product in the Field, THERAVANCE will cooperate with MYLAN to do so. THERAVANCE shall be responsible for filing all such extensions for THERAVANCE Patents and Joint Invention Patents; and MYLAN shall be responsible for filing all such extensions for MYLAN Patents.
- (h) Patent-Related Dispute Resolution. If the Parties disagree on any preparation, prosecution or maintenance issue for Patents within the scope of this Article 12 which is not specifically addressed and resolved by this ARTICLE 12 (a "Patent Resolution Issue"), the Parties agree to seek guidance and resolution from an independent, mutually acceptable patent attorney as further described in this Section 12.02(h) instead of resorting to the dispute resolution process as described in Section 3.01(f) (if applicable). If the Parties reach an impasse (remaining even after resort to the initial dispute resolution provided for in Section 3.01(f)(i)) as to any Patent Resolution Issue, then they shall submit the Patent Resolution Issue to an experienced patent attorney mutually-acceptable to the Parties, who does not otherwise perform work for either Party or any of its Affiliates, for resolution. The Parties shall engage such attorney within thirty (30) days of either Party notifies the other in writing of a Patent Resolution Issue impasse remaining unresolved after resort to Section 3.01(f)(i). If they cannot agree as to who such attorney shall be within such time period, then the total of two nominees of the

Parties (one from each Party) shall select a third patent attorney who shall be the attorney to resolve the dispute. The Parties shall share equally the expenses incurred for the services of such patent attorney. Within fifteen (15) days of engaging the patent attorney, the Parties shall each submit up to twenty (20) pages of documentation to the patent attorney. Within five (5) Business Days of such submission, the Parties shall convene a meeting with the patent attorney during which each Party may orally present its position on the Patent Resolution Issue for no more than one (1) hour. The Parties shall endeavor to cause the patent attorney to render his or her guidance as to the Patent Resolution Issue within five (5) Business Days of such discussion. Neither Party shall engage in any ex parte communications with the patent attorney. The Parties shall accept and follow the guidance and resolution of the patent attorney absent any fraud in the proceedings.

### Section 12.03 Patent Infringement.

- (a) Infringement Claims by Third Parties. With respect to any and all Claims instituted by Third Parties against THERAVANCE or MYLAN or any of their respective Affiliates for patent infringement based on the manufacture, use, license, marketing, sale, offer for sale or importation of TD-4208 or Licensed Product in the Territory during the Term (a "Patent Infringement Claim"), THERAVANCE and MYLAN will assist one another and cooperate in the defense and settlement of such a Patent Infringement Claim at the other Party's request and expense, including by joining as a party-plaintiff where necessary under applicable Laws. The Party that is subject to the Patent Infringement Claim shall have the exclusive right to defend and control the defense of such Patent Infringement Claim at its own expense, and shall keep the other Party reasonably informed of all material developments in such defense. The defending Party shall not enter into a settlement of a Patent Infringement Claim that would adversely affect or diminish the rights or benefits of the other Party under this Agreement to any material extent without such other Party's consent, not to be withheld, refused, conditioned or delayed unreasonably.
- (b) <u>Patent Infringement Notice</u>. In the event that either Party becomes aware of actual or threatened infringement of a THERAVANCE Patent, MYLAN Patent, or Joint Invention Patent during the Term, that Party will promptly notify the other Party in writing (a "Patent Infringement Notice").
- (c) Infringement of THERAVANCE Patents. THERAVANCE will have the first right but not the obligation to enforce the THERAVANCE Patents against any Third Party. If THERAVANCE elects to pursue such an enforcement action, THERAVANCE shall be solely responsible for the expenses associated with such action. During the Term, in the event that THERAVANCE does not undertake such an enforcement action within ninety (90) days of the Patent Infringement Notice, MYLAN shall be permitted to do so in THERAVANCE's name and, if it elects to undertake such an enforcement action, MYLAN shall be solely responsible for the expenses associated with such action. If a Party is authorized to bring an infringement action under this Section 12.03(c) but the Party is not recognized by the applicable court or other relevant body as having the requisite standing to pursue such action, then the other Party shall, at the enforcing Party's request and expense, join as a party-plaintiff. If THERAVANCE recommends

not to enforce the THERAVANCE Patents in response to a Patent Infringement Notice, and MYLAN elects to pursue such enforcement action by joining THERAVANCE as a party plaintiff, then MYLAN agrees to indemnify and hold harmless THERAVANCE for all Losses incurred by THERAVANCE in such enforcement action.

- (d) Infringement of MYLAN Patents. In the event that either Party becomes aware of actual or threatened infringement of a MYLAN Patent during the Term, that Party will promptly send a Patent Infringement Notice to the other Party. MYLAN will have the first right but not the obligation to enforce the MYLAN Patents against any Third Party. If MYLAN elects to pursue such an infringement action, MYLAN shall be solely responsible for the expenses associated with such action. During the Term, in the event that MYLAN does not undertake such an infringement action with respect to a MYLAN Product Patent within ninety (90) calendar days of the Patent Infringement Notice, THERAVANCE shall be permitted to do so in MYLAN's name and THERAVANCE shall be solely responsible for the expenses associated with such action. If a Party is authorized to bring an infringement action under this section but such Party is not recognized by the applicable court or other relevant body as having the requisite standing to pursue such action, then the other Party shall join as a party-plaintiff at the enforcing Party's expense. If MYLAN recommends not to pursue an infringement action, and THERAVANCE elects to pursue such infringement action by joining MYLAN as a party plaintiff, then THERAVANCE agrees to indemnify and hold harmless MYLAN for all losses and damages arising from the infringement action.
- (e) <u>Infringement of Joint Invention Patents</u>. In the event that either Party becomes aware of actual or threatened infringement of a Joint Invention Patent during the Term, that Party will promptly send a Patent Infringement Notice to the other Party. In such an event, the matter will be handled as provided in Section 12.03(c).
- Section 12.04 Notice of Certification. Each Party shall promptly give notice to the other of its receipt of any certification filed under the "U.S. Drug Price Competition and Patent Term Restoration Act of 1984" as amended or as it may be amended (or its foreign equivalent) claiming that any Patent listed in the Orange Book for a Licensed Product in the Field is invalid or that infringement will not arise from the manufacture, use or sale of the Licensed Product by a Third Party ("Hatch-Waxman Certification"). This Section 12.04 is intended by the Parties to apply to any successor legislation in the U.S. to the "U.S. Drug Price Competition and Patent Term Restoration Act of 1984" and to any counterpart or similar legislation outside the U.S.
- (a) Enforcement of Patent. Notwithstanding anything in this Article 12 to the contrary, THERAVANCE shall have the first right to enforce the THERAVANCE Patents against a Third Party filing a Hatch-Waxman Certification and MYLAN shall have the first right to enforce the MYLAN Patents and the Joint Invention Patents against a Third Party filing a Hatch-Waxman Certification. If THERAVANCE decides to bring an enforcement action against the entity making a Hatch-Waxman Certification, THERAVANCE shall permit MYLAN to join as a party to such action (to the extent permitted by Law) and solicit MYLAN's input and advice, and the Parties shall cooperate with respect to such enforcement action. If MYLAN decides to bring an enforcement

action against the entity making a Hatch-Waxman Certification, MYLAN shall solicit THERAVANCE's input and advice, and the Parties shall cooperate with respect to such enforcement action. The Party with the first right under this Section 12.04(a) to bring an enforcement action against the entity making a Hatch-Waxman Certification shall give notice to the other Party of its decision whether or not to bring such an action within twenty-one (21) days of receipt of notice of such Hatch-Waxman Certification.

- (b) Option. Upon receipt of a notice from the non-enforcing Party of its decision not to enforce the applicable Patents in response to a Hatch-Waxman Certification, the other Party then may, but is not required to, enforce the THERAVANCE Patents, the MYLAN Patents or the Joint Invention Patents, as applicable, against the Third Party that filed the Hatch-Waxman Certification.
- (c) Name of Party. Any enforcement action brought by either Party pursuant to this Section 12.04 shall be brought in the name of THERAVANCE or in the name of MYLAN or jointly in the names of THERAVANCE and MYLAN, as may be required by Law, and each Party shall join as a party-plaintiff as reasonably requested by the enforcing Party to satisfy such requirement.
- (d) Representation of Other Party. If a Party elects to pursue an enforcement action under this Section 12.04, the other Party not bringing suit may be represented in such an action by attorneys of its own choice and at its own expense. The Party bringing suit shall take the lead in and control any such action.
- Section 12.05 <u>Settlement</u>. No settlement or consent judgment or other voluntary final disposition of any enforcement action under this Article 12 that would adversely affect or diminish the rights or benefits of a Party under this Agreement to any material extent may be entered into without the joint written consent of such Party (which consent will not be withheld, refused, conditioned or delayed unreasonably).
- Section 12.06 <u>Assistance</u>. Each Party shall execute any legal papers necessary for the enforcement of the THERAVANCE Patents and Joint Invention Patents under this ARTICLE 12 and shall provide reasonable assistance, in each case as requested by the enforcing Party. Such assistance shall be at the expense of the Party bringing suit on a pass-through basis.
- Section 12.07 <u>Disposition of Recoveries</u>. Any damages, awards, settlement payments or other recoveries resulting from an enforcement action brought by the Parties pursuant to this Article 12 with respect to a THERAVANCE Patent or Joint Invention Patent with respect to infringements in the Field during the Term shall be allocated as follows: (i) the Party bringing the infringement action shall be reimbursed for all expenses incurred in connection with bringing and maintaining the infringement action; (ii) the remainder of the recovery, after payment of expenses, shall be split [\*\*\*] to MYLAN and [\*\*\*] to THERAVANCE. Subject to the Parties' indemnification obligations under Article 11 and except as otherwise set forth in this Article 12, any damages or other losses incurred by the Parties or their Affiliates as a result of an enforcement action brought by the Parties pursuant to this Article 12 ("Enforcement Damages") shall be Shared Expenses.

# ARTICLE 13

#### TERM AND TERMINATION

Section 13.01 <u>Term and Expiration of Term.</u> Except as otherwise mutually agreed to by the Parties, this Agreement shall commence on the Effective Date and shall end upon expiration of the Term, unless terminated earlier as contemplated in this Article 13.

Termination for Material Breach. Either Party may, without prejudice to any other remedies available to it at law or in equity, terminate this Agreement subject to ARTICLE 14 in the event that the other Party (as used in this subsection, the "Breaching Party") shall have materially breached this Agreement or defaulted in the performance of any of its obligations hereunder, and not corrected the situation following notice and an opportunity to cure as provided below. The Breaching Party shall have sixty (60) days of written notice thereof was provided to the Breaching Party by the non-breaching Party to remedy such default (or, if such default cannot be cured within such 60-day period, the Breaching Party must commence actions to cure such default during such 60-day period and thereafter diligently continue such actions). Any such termination shall become effective at the end of such 60-day period unless the Breaching Party has cured any such breach or default prior to the expiration of such 60-day period (or, if such default is capable of being cured but cannot be cured within such 60-day period, the Breaching Party has commenced and diligently continued actions to cure such default provided always that, in such instance, such cure must have occurred within ninety (90) days of written notice thereof being provided to the Breaching Party by the non-breaching Party to remedy such default). In the event that one Party claims that the other Party has materially breached its obligations hereunder, and the Breaching Party (by written notice to the other Party) disputes in good faith such material breach or its failure to cure such breach within the applicable cure period, then such dispute may be submitted to dispute resolution, either pursuant to the procedures set forth in Section 3.01(f) or through litigation or arbitration. In such event, the Party alleging such breach does not have the right to terminate this Agreement pursuant to this Section 13.02, until it has been determined, pursuant to such dispute resolution procedure, that the Breaching Party is in material breach of this Agreement, and such Breaching Party further fails to cure such breach within sixty (60) days after the conclusion of any such procedure. For clarity, in the event of a material breach by MYLAN with respect to a particular ROW Country, THERAVANCE's right to terminate under this Section 13.02 would apply on a Country-by-Country basis as set forth in Section 5.04(f).

Section 13.03 <u>Termination by MYLAN.</u> MYLAN shall have right to the terminate this Agreement, upon one hundred eighty (180) days prior written notice to THERAVANCE, (a) at any time with respect to one or more ROW Countries, or (b) in its entirety in the event that (i) final approval of the first NDA for a Licensed Product in the Field in the U.S. in not received prior to December 31, 2021, (ii) the Development Expenses required to obtain such approval exceed, or are reasonably expected to exceed, those set forth in the Preliminary Development Plan by more than [\*\*\*], or (iii) in the event that MYLAN is required to divest the Licensed Product in the Field by a Governmental Authority (in

which case such termination will only be on a Country-by-Country basis); provided that if such termination is of this Agreement in its entirety, THERAVANCE shall be permitted to wind-down the Development of the Licensed Product in the Field pursuant to the Development Plan or continue such Development, either itself or with a Third Party, and MYLAN shall reimburse THERAVANCE's Development Expenses during the period between MYLAN's notice of termination and the effective date of such termination, not to exceed [\*\*\*]. If THERAVANCE elects to wind-down the Development of the Licensed Product in the Field pursuant to this Section 13.03, THERAVANCE shall promptly cease enrolling any further patients in any ongoing clinical trial, cease dosing subjects in such trials with Licensed Product as soon as reasonably practicable without jeopardizing patient safety, cease incurring additional expenses that have not already been committed to, and mitigate those expenses to which THERAVANCE is already committed to the extent practicable.

Section 13.04 <u>Contemporaneous Termination of China RFN and RFN.</u> The China RFN and RFN shall terminate automatically at the time of any early termination of this Agreement in its entirety under this ARTICLE 13, except for a termination by MYLAN under Section 13.02 for THERAVANCE's material breach.

Section 13.05 Accrued Rights; Surviving Provisions. Termination, relinquishment or expiration of this Agreement for any reason shall be without prejudice to any rights that shall have accrued to the benefit of any Party prior to such termination, relinquishment or expiration. Such termination, relinquishment or expiration shall not relieve any Party from obligations which are expressly or by implication intended to survive termination, relinquishment or expiration of this Agreement, including without limitation Articles 1, 9, 11, 14, and 15 Sections 4.03(f), 6.08, 7.03, 10.05 and 13.05. Except as otherwise expressly provided herein, termination of this Agreement in accordance with the provisions hereof shall not limit remedies that may otherwise be available to the Parties in law or equity.

#### **ARTICLE 14**

# CONSEQUENCES OF TERMINATION

Section 14.01 <u>Termination by Natural Expiry of Term.</u>

- (a) Upon expiration of this Agreement under Section 13.01:
- i. any exclusive license granted under Section 2.01 shall survive and become non-exclusive and all licenses granted by THERAVANCE to MYLAN pursuant to Section 2.01 shall survive and become fully-paid up, perpetual and irrevocable.
- ii. any exclusive license granted under Section 2.02(c) or (d) shall survive and become non-exclusive, fully-paid up, perpetual and irrevocable.

<sup>\*\*\*</sup>CERTAIN INFORMATION HAS BEEN OMITTED AND FILED SEPARATELY WITH THE COMMISSION. CONFIDENTIAL TREATMENT HAS BEEN REQUESTED WITH RESPECT TO THE OMITTED PORTIONS.

- Section 14.02 <u>Termination by THERAVANCE Under Section 13.02</u>. Upon the effective date of termination of this Agreement in its entirety (the "Date of Termination") by THERAVANCE pursuant to Section 13.02:
  - (a) the licenses and rights granted under Section 2.01 and 2.02 shall cease;
  - (b) the Parties will negotiate in good faith the terms and conditions on which MYLAN shall:
- i. grant to THERAVANCE the following non-exclusive, royalty-free licenses, which shall replace those license grants made pursuant to Section 2.02, subject to the surviving terms of this Agreement:
- (A) a license under the MYLAN Patents and MYLAN Know-How and Joint Invention Patents to Develop Licensed Products in the Field worldwide:
- (B) a license under the MYLAN Patents and MYLAN Know-How and Joint Invention Patents to Commercialize Licensed Products in the Field worldwide; and
- (C) a license under: (i) the MYLAN Patents and MYLAN Know-How and Joint Invention Patents solely to make and have made anywhere in the world formulated Licensed Product in the Field and (ii) the MYLAN Patents to the extent claiming Improvements and MYLAN Know-How comprising Improvements solely to make and have made anywhere in the world API Compound for incorporation into Licensed Products for purposes of Developing and Commercializing Licensed Product in or outside the Field worldwide.
- ii. subject to Article 9, destroy all THERAVANCE Know-How and, at THERAVANCE's request and expense, deliver to THERAVANCE a copy of all MYLAN Know-How in written form;
- iii. promptly after THERAVANCE's request and at THERAVANCE's expense, deliver to THERAVANCE at the location specified by THERAVANCE any and all quantities of API Compound and Licensed Product in its possession, power, custody or control, subject always to MYLAN's right to dispose of Licensed Product which is the subject of pre-termination date orders in accordance with clause (vi) below. THERAVANCE shall pay for the quantities thus transferred to it in an amount equal to [\*\*\*] for such quantities;
- iv. commensurate with legislative and regulatory requirements, transfer to THERAVANCE or its nominee all Marketing Authorizations and Regulatory Filings for the Licensed Product in the Field in the Territory, at THERAVANCE's request and expense;
- v. assign, or grant a worldwide, royalty-free exclusive license, to THERAVANCE to use the Trademarks used on the Licensed Product in the Field at the time of such termination for use on such Licensed Product in the Field;

<sup>\*\*\*</sup>CERTAIN INFORMATION HAS BEEN OMITTED AND FILED SEPARATELY WITH THE COMMISSION. CONFIDENTIAL TREATMENT HAS BEEN REQUESTED WITH RESPECT TO THE OMITTED PORTIONS.

- vi. for a period of six (6) months after the Date of Termination, MYLAN has the right to dispose of that part of its inventory of Licensed Product on hand as of the Date of Termination which is the subject of orders for Licensed Product accepted prior to MYLAN's receipt of notice of termination, and, within sixty (60) days of disposition of such inventory pursuant to the fulfillment of such orders, MYLAN will forward to THERAVANCE a final report and pay THERAVANCE its share of Operating Profits (Losses) and/or Royalties due with respect to such Licensed Products in accordance with this Agreement;
- vii. at the request of THERAVANCE, for a period of up to twenty-four (24) months following the Date of Termination, manufacture or supply such API Compound and Licensed Product in the Field, if any, that are being manufactured by or for MYLAN prior to such termination ("Supplied Licensed Product") to THERAVANCE or to THERAVANCE's designee. Such Supplied Licensed Product shall be provided to THERAVANCE at [\*\*\*] in respect of such supply. During said twenty-four (24) month period, MYLAN shall manufacture API Compound and Licensed Product in the Field up to the quantities set forth in the current updated forecast for Licensed Product as of the Date of Termination as set forth in the Commercialization Plan and THERAVANCE shall accept such quantities of API Compound or Licensed Product. MYLAN shall also provide THERAVANCE, at THERAVANCE's request and expense, with reasonable assistance in relation to THERAVANCE's transition a Third Party manufacturer of Licensed Product in the Field.
- (c) Disclosure of Confidential Information. Upon the Date of Termination by THERAVANCE under Section 13.02 or by MYLAN pursuant to Section 13.03, THERAVANCE shall have the right to disclose Confidential Information of MYLAN that is generated pursuant to this Agreement, under customary and reasonable legally binding obligations of confidentiality and non-use, to Third Parties for the purpose of, and solely to the extent necessary for, enabling such Third Parties to evaluate the financial and scientific status of the Licensed Products for the purpose of making an offer to THERAVANCE on the licensing or acquisition of the rights returned to THERAVANCE and the rights licensed to THERAVANCE under this ARTICLE 14, and, if such licensing or acquisition occurs, solely to the extent necessary to exploit or enforce such rights. For clarity, this Section 14.02(c) shall not be deemed to grant THERAVANCE any right or license under any Patent, copyright or trademark of MYLAN.

# Section 14.03 <u>Termination by MYLAN Under Section 13.02</u>.

- (a) Upon the Date of Termination of this Agreement by MYLAN pursuant to Section 13.02:
  - i. The licenses and rights granted under Section 2.02 shall cease;
  - ii. THERAVANCE's share of Operating Profits in the U.S. under Section 1.03 of Exhibit F shall be reduced by [\*\*\*];

<sup>\*\*\*</sup>CERTAIN INFORMATION HAS BEEN OMITTED AND FILED SEPARATELY WITH THE COMMISSION. CONFIDENTIAL TREATMENT HAS BEEN REQUESTED WITH RESPECT TO THE OMITTED PORTIONS.

- iii. THERAVANCE's licenses and rights granted to MYLAN under Section 2.01 shall continue, subject to MYLAN's continued obligation to pay Royalties to THERAVANCE under Section 1.04 of Exhibit F at rates equal to [\*\*\*] of the rates set forth therein, for a period that would be the remainder of the Term, had it not been terminated.
- iv. The JSC and JPC shall be disbanded, the Co-Promotion Agreement shall terminate, and THERAVANCE shall no longer have the right to receive any Development or Commercialization reports or other information from MYLAN other than as required to determine the amount of continuing shared Operating Profits and Royalties owed hereunder;
  - Sections 2.07 and 2.08 shall survive; and
- vi. MYLAN shall be entitled to conduct all enforcement against infringement within the scope of the licenses to MYLAN hereunder (treating all recoveries over expenses as Net Sales in the Territory), and THERAVANCE will join as a party plaintiff in any such enforcement action with respect to the THERAVANCE Patents and Joint Invention Patents, at MYLAN's reasonable request and expense.
- (b) <u>Disclosure of Confidential Information</u>. Upon the Date of Termination by MYLAN under Section 13.02, THERAVANCE shall, subject to Article 9, destroy all MYLAN Know-How and deliver to MYLAN a copy of all THERAVANCE Know-How in written form, which MYLAN shall be permitted to use and disclose in accordance with Article 9, including with respect to all rights surviving such termination.

#### **ARTICLE 15**

#### MISCELLANEOUS

Section 15.01 <u>Relationship of the Parties.</u> Each Party shall bear its own costs incurred in the performance of its obligations hereunder without charge or expense to the other except as expressly provided in this Agreement. Neither Party shall have any responsibility for the hiring, termination or compensation of the other Party's employees or for any employee benefits of such employee. No employee or representative of a Party shall have any authority to bind or obligate the other Party for any sum or in any manner whatsoever, or to create or impose any contractual or other liability on the other Party without said Party's approval, except as expressly set forth in this Agreement. For all purposes, and notwithstanding any other provision of this Agreement to the contrary, MYLAN's legal relationship under this Agreement to THERAVANCE shall be that of independent contractor. This Agreement is not a partnership agreement and nothing in this Agreement shall be construed to establish a relationship of co-partners or joint venturers between the Parties.

Section 15.02 <u>Registration and Filing of This Agreement</u>. To the extent, if any, that either Party concludes in good faith that it or the other Party is required to file or register this Agreement or a notification thereof with any Governmental Authority, including the

<sup>\*\*\*</sup>CERTAIN INFORMATION HAS BEEN OMITTED AND FILED SEPARATELY WITH THE COMMISSION. CONFIDENTIAL TREATMENT HAS BEEN REQUESTED WITH RESPECT TO THE OMITTED PORTIONS.

U.S. Securities and Exchange Commission or the U.S. Federal Trade Commission, in accordance with applicable Laws, such Party shall inform the other Party thereof. Should both Parties jointly agree that either of them is required to submit or obtain any such filing, registration or notification, they shall cooperate, each at its own expense, in such filing, registration or notification and shall execute all documents reasonably required in connection therewith. In such filing, registration or notification, the Parties shall request confidential treatment of sensitive provisions of this Agreement, to the extent permitted by Law, and will involve each other in a reasonable fashion to help ensure each Party's confidentiality concerns are addressed to the extent permissible. The Parties shall promptly inform each other as to the activities or inquiries of any such Governmental Authority relating to this Agreement, and shall reasonably cooperate to respond to any request for further information there from on a timely basis.

Section 15.03 Force Majeure. The occurrence of an event which materially interferes with the ability of a Party to perform its obligations or duties hereunder which is not within the reasonable control of the Party affected or any of its Affiliates, not due to malfeasance by such Party or its Affiliates, and which could not with the exercise of reasonable effort have been avoided (each, a "Force Majeure Event"), including an injunction, inability to obtain raw materials, delay or errors by shipping company, fire, accident, riot, civil commotion, act of God, or change in Laws, shall not excuse such Party from the performance of its obligations or duties under this Agreement, but shall merely suspend such obligation to perform during the continuation of the Force Majeure. The Party prevented from performing its obligations or duties because of a Force Majeure Event shall promptly notify the other Party of the occurrence and particulars of such Force Majeure and shall provide the other Party, from time to time, with its best estimate of the duration of such Force Majeure Event and with notice of the termination thereof. The Party so affected shall use Diligent Efforts to avoid or remove such causes of nonperformance and resume performance as soon as is reasonably practicable. Upon termination of the Force Majeure Event, the performance of any suspended obligation or duty shall promptly recommence. The Party subject to the Force Majeure Event shall not be liable to the other Party for any direct, indirect, consequential, incidental, special, punitive, exemplary or other damages arising out of or relating to the suspension or termination of any of its obligations or duties under this Agreement by reason of the occurrence of a Force Majeure Event, provided such Party complies in all material respects with its obligations under this Section 15.03.

Section 15.04 Governing Law. This Agreement shall be construed, and the respective rights of the Parties determined, according to the substantive law of the State of New York notwithstanding the provisions governing conflict of laws under such New York law to the contrary, except matters of intellectual property law which shall be determined in accordance with the intellectual property Laws relevant to the intellectual property in question.

Section 15.05 Assignment. This Agreement may not be assigned by either Party without the prior written consent of the other Party, not to be unreasonably withheld, conditioned or delayed (except with respect to an assignment by THERAVANCE to a Change of Control Conflict Company, in which case MYLAN may grant or withhold its consent in

its sole discretion). Notwithstanding the foregoing, either Party may assign this Agreement (a), in whole or in part, to any of its Affiliates if such Party guarantees the performance of this Agreement by such Affiliate to which this Agreement is assigned in part, or (b) to a successor to all or substantially all of the assets of such Party to which this Agreement relates, whether by merger, sale of stock, sale of assets or other similar transaction or by operation of law; provided that THERAVANCE may only assign this Agreement to a Change of Control Conflict Company pursuant to this clause (b), without the prior written consent of MYLAN, if such Change of Control Conflict Company is (i) a successor to all or substantially all of the assets of THERAVANCE or (ii) a successor to all or substantially all of the assets of THERAVANCE related to TD-4208. This Agreement shall be binding upon, and subject to the terms of the foregoing sentence, inure to the benefit of the Parties hereto, their permitted successors, legal representatives and assigns. Notwithstanding the foregoing, in the event that THERAVANCE is subject to a Change of Control in which a Change of Control Conflict Company is the acquiring party or this Agreement is otherwise assigned to a Change of Control Conflict Company in accordance with this Section 15.05, THERAVANCE shall, within two (2) days after the date that such merger or acquisition closes or the date of such assignment, as applicable, (the "Closing Date"), provide MYLAN with notice of such Change of Control or assignment, and, effective as of the Closing Date, (a) any and all diligence obligations on MYLAN hereunder shall be of no further force and effect, and MYLAN shall not be obligated to submit any further updates to the Commercialization Plan to THERAVANCE or the Change of Control Conflict Company, (b) except as provided in (e) below, neither THERAVANCE nor the Change of Control Conflict Company shall have any further right of input or insight into MYLAN's Commercialization of the Licensed Products in the Field hereunder, (c) MYLAN shall have the right to terminate the Co-Promotion Agreement and THERAVANCE's right (and any right the Change of Control Conflict Company may have) to Commercialize the Licensed Products in the Field in the U.S., (d) MYLAN shall not be obligated to reimburse THERAVANCE or the Change of Control Conflict Company for any Development Expenses incurred after the Closing Date, unless MYLAN requests in writing, after the Closing Date, that THERAVANCE complete the Development activities pursuant to which THERAVANCE incurs such Development Expenses, in which case THERAVANCE shall complete such Development activities; (e) MYLAN shall have no further reporting or record-keeping obligations hereunder with respect to the Development or Commercialization of, and regulatory activities for, the Licensed Products in the Field other than its financial reporting and record-keeping obligations under Exhibit F, and (f) MYLAN shall have no further obligation to disclose to THERAVANCE or the Change of Control Conflict Company the MYLAN Product Trademarks or the MYLAN Know-How hereunder and any MYLAN Know-How developed or reduced to practice after the Closing Date or MYLAN Patents filed after the Closing Date shall not be included within the scope of the licenses granted to THERAVANCE under Section 2.01. For purposes of the foregoing, a "Change of Control" shall mean the acquisition of voting shares of THERAVANCE by a Person that results in such Person holding more than fifty percent (50%) of the voting shares of THERAVANCE. In the event that THERAVANCE is subject to a Change of Control in which the acquiring party is not a Change of Control Conflict Company or otherwise assigns this Agreement in accordance with this Section

15.05 to a Person that is not a Change of Control Conflict Company, this Agreement shall continue in accordance with its terms; provided that, effective upon the Closing Date, MYLAN shall have final decision-making authority with respect to all JSC matters after they are escalated to the Officers pursuant to Section 3.01(f)(i) and such matters shall not go to arbitration in accordance with Section 3.01(f)(ii).

Section 15.06 <u>Notices</u>. All demands, notices, consents, approvals, reports, requests and other communications hereunder must be in writing and will be deemed to have been duly given only if delivered personally, by facsimile with confirmation of receipt, by mail (first class, postage prepaid), or by overnight delivery using a globally recognized carrier, to the Parties at the following addresses:

THERAVANCE: Theravance Biopharma R&D, Inc.

c/o Theravance Biopharma US, Inc.

901 Gateway Boulevard South San Francisco, CA 94080

Facsimile: [\*\*\*]

Attn: Head of Business Development

With a copy to: Legal Department

Theravance Biopharma R&D, Inc. c/o Theravance Biopharma US, Inc.

901 Gateway Boulevard South San Francisco, CA 94080

Facsimile: [\*\*\*]

MYLAN: Mylan Ireland Limited

6th Floor, South Bank House

Barrow Street Dublin 4 Ireland

Attn: Peter McCormick, Director

With a copy to: Mylan Inc.

1000 Mylan Boulevard Canonsburg, PA 15317 Facsimile: (724) 514-1871 Attn: Global General Counsel

or to such other address as the addressee shall have last furnished in writing in accord with this provision to the addressor. All notices shall be deemed effective upon receipt by the addressee.

Section 15.07 Severability. In the event of the invalidity of any provisions of this Agreement, the Parties agree that such invalidity shall not affect the validity of the remaining provisions of this Agreement. The Parties will replace an invalid provision with valid provisions which most closely approximate the purpose and economic effect of the invalid provision. In the event that the terms and conditions of this Agreement are materially altered as a result of the preceding sentences, the Parties shall renegotiate the terms and conditions of this Agreement in order to resolve any inequities. Nothing in this Agreement shall be interpreted so as to require either Party to violate any applicable Laws.

Section 15.08 Amendment; Waiver. Any term or condition of this Agreement may be waived at any time by the Party that is entitled to the benefit thereof, but no such waiver shall be effective unless set forth in a written instrument duly executed by or on behalf of the Party waiving such term or condition. No waiver by any Party of any term or condition of this Agreement, in any one or more instances, shall be deemed to be or construed as a waiver of the same or any other term or condition of this Agreement on any future occasion. Except as expressly set forth in this Agreement, all rights and remedies available to a Party, whether under this Agreement or afforded by law or otherwise, will be cumulative and not in the alternative to any other rights or remedies that may be available to such Party.

Section 15.09 Entire Agreement. This Agreement (including the exhibits and schedules hereto) constitutes the entire agreement between the Parties hereto with respect to the subject matter hereof and supersedes all previous agreements and understandings between the Parties with respect to such subject matter, whether written or oral. No Party has entered into this Agreement in reliance upon any statement, representation, warranty or undertaking made by or on behalf of any other Party other than those expressly set out in this Agreement. This Agreement may be altered, amended or changed only in writing and by making specific reference to this Agreement and signed by duly authorized representatives of THERAVANCE and MYLAN.

Section 15.10 No License. Nothing in this Agreement shall be deemed to constitute the grant of any license or other right to either Party, in respect of any product, patent, trademark, Confidential Information, trade secret or other data or any other intellectual property of the other Party, except as expressly set forth herein.

Section 15.11 <u>Third Party Beneficiaries.</u> None of the provisions of this Agreement shall be for the benefit of or enforceable by any Third Party, including without limitation any creditor of either Party hereto. No such Third Party shall obtain any right under any provision of this Agreement or shall by reasons of any such provision make any Claim in respect of any debt, liability or obligation (or otherwise) against either Party hereto.

Section 15.12 Counterparts. This Agreement may be executed in any two counterparts, each of which, when executed, shall be deemed to be an original and both of which together shall constitute one and the same document.

IN WITNESS WHEREOF, THERAVANCE and MYLAN, by their duly authorized officers, have executed this Agreement.

THERAVANCE BIOPHARMA R&D, INC.

MYLAN IRELAND LIMITED

Director

By: /s/ Brett K Haumann By: /s/ Peter McCormick

Brett K. Haumann Peter McCormick

Senior Vice President, Clinical Development

\*\*\*CERTAIN INFORMATION HAS BEEN OMITTED AND FILED SEPARATELY WITH THE COMMISSION. CONFIDENTIAL TREATMENT HAS BEEN

REQUESTED WITH RESPECT TO THE OMITTED PORTIONS.

# EXHIBIT A

# Chemical Structure of TD-4208

# EXHIBIT B Patents

Version Date: On Execution			
I.	THERAVANCE Patents		
[***]			
II.	MYLAN Patents		
[***]			
III.	Joint Invention Patents		

[\*\*\*]

<sup>\*\*\*</sup>CERTAIN INFORMATION HAS BEEN OMITTED AND FILED SEPARATELY WITH THE COMMISSION. CONFIDENTIAL TREATMENT HAS BEEN REQUESTED WITH RESPECT TO THE OMITTED PORTIONS.

# **EXHIBIT C**Initial JSC Members

MYLAN: [***]	
THERAVANCE: [***]	

<sup>\*\*\*</sup>CERTAIN INFORMATION HAS BEEN OMITTED AND FILED SEPARATELY WITH THE COMMISSION. CONFIDENTIAL TREATMENT HAS BEEN REQUESTED WITH RESPECT TO THE OMITTED PORTIONS.

# EXHIBIT D

#### CO-PROMOTION AGREEMENT TERMS AND CONDITIONS

The Co-Promotion Agreement shall incorporate the terms and conditions described in this <u>Exhibit D</u> below as well as other terms and conditions standard and customary for these types of agreements and consistent with the terms and conditions of the Agreement and the following:

# **Definitions**:

"Co-Promote" means joint conduct of Direct Promotional Activities through MYLAN's and THERAVANCE's respective commercial personnel under the Trademark and MYLAN taking the predominant role and managing General Promotional Activities, distribution and booking sales for the Products in the U.S. "Co-Promoting" and "Co-Promotion" have their correlative meanings.

"Direct Promotional Activities" means, as to be defined in more detail in the Co-Promotion Agreement, (a) those sales and promotional activities generally performed by Sales Representatives in the U.S., including detailing and other similar communications, (b) non-personal promotional activities (e.g., e-detailing, tele-detailing and channel marketing), and (c) medical / health economic marketing and support activities generally performed by Medical Representatives, in each case, (a) — (c), directly to (i) appropriate health care professionals with prescribing or similar authority for the applicable Product or (ii) Persons responsible for overseeing or managing (A) pharmacy or prescription drug benefits, utilization and/or capitation, (B) formulary/preferred drug program inclusion and maintenance, or (C) health outcomes support services and physician/patient advocacy, or, in each case, (A) — (C), similar functions (Persons described in (i) and (ii) collectively, "Responsible Persons").

"General Marketing Activities" means, as to be defined in more detail in the Co-Promotion Agreement, any and all Commercialization activities including marketing and promotional activities and healthcare and consumer educational programs that are standard and customary for products similar to Licensed Products in the U.S., including the following:

- Generating Promotional Materials;
- Conducting market research and acquiring applicable market data;

- Branding
- Working with marketing vendors (e.g., public relations agencies, advertising agencies and medical education agencies) to develop applicable marketing campaigns; and
- Coordinating and implementing (a) publications, journal and magazine advertisements (both paper and electronic) (b) media production; and (c) patient marketing activities (patient education, direct patient marketing, direct to consumer advertising, direct mail, web site development and maintenance and the like).

"Medical Representative" means an individual medical scientific liaison, health economics and outcomes researcher and any individual having similar medical support functions.

"Sales Representative" means an individual sales representative (including a field sales representative, institutional sales representative, pharmacy/trade sales representative or managed care sales representative) and any individual having similar direct sales or marketing functions.

#### General:

Each Party will participate in the Co-Promotion of Licensed Product in the U.S. as set forth in the Commercialization Plan and as described generally below.

<u>Direct Promotional Activities</u>. Unless THERAVANCE provides MYLAN at least twelve (12) months prior notice, that it will not participate in Direct Promotional Activities(1), then each Party will through its Sales Representatives and Medical Representatives (collectively, the "Sales Force"), the number of each will be specified in the Commercialization Plan by Party, be responsible for conducting those Direct Promotional Activities in the U.S. assigned to it in the Commercialization Plan. The Parties shall conduct such activities in accordance with the Commercialization Plan and will coordinate with each other with respect thereto.

Responsibility for Licensed Product details to specific target Responsible Persons will be apportioned to each Party by market segment (including customer segments, including channel, payer, managed care and government affairs), such apportionment will also include prioritization and targets for the number of times

<sup>(1)</sup> In the event that THERAVANCE notifies MYLAN that it will not participate, then from the effective date of such notice, MYLAN shall be solely responsible and have the right to conduct all Direct Promotional Activities and other activities under the Commercialization Plan.

<sup>\*\*\*</sup>CERTAIN INFORMATION HAS BEEN OMITTED AND FILED SEPARATELY WITH THE COMMISSION. CONFIDENTIAL TREATMENT HAS BEEN REQUESTED WITH RESPECT TO THE OMITTED PORTIONS.

specific groups of Responsible Persons will be detailed each year and allocable Sampling programs.

The Parties will coordinate its performance of Direct Promotional Activities with the goal of ensuring coordination and transparency between the Parties, including, sharing marketing intelligence, call lists and the results of such efforts in a reasonably expeditious and detailed manner in order to preserve the relevance and utility thereof.

MYLAN will be responsible for providing professional services and Medical Representatives with respect to and in support of the Direct Promotional Activities for Licensed Product; however, THERAVANCE may provide a mutually agreed number of Medical Representatives.

General Marketing Activities: MYLAN will be responsible for the performance of the General Marketing Activities in the U.S. as set forth in the Commercialization Plan.

Each Party will be responsible for maintaining Samples and records thereof in accordance with application Laws.

#### Reimbursement:

MYLAN will be responsible for establishing and implementing appropriate reimbursement / payer strategies with respect to Licensed Product in the U.S. as set forth in the Commercialization Plan, which may include:

- Obtaining (i) reimbursement coding for Medicare, (ii) coverage and payment by the Veteran's Administration and at Vertical Integrated Service Networks (VISNs), (iii) inclusion on the Federal Supply Schedule, (iv) inclusion on applicable formularies and reimbursement by identified managed care and national private payer accounts; and
- Establishing hotline service mechanism for patient/physician assistance program and a reimbursement hotline for Licensed Product.

#### Hiring:

Each Party will be responsible for recruiting and hiring its own Sales Force for the conduct of activities under the Commercialization Plan. Each Party will be responsible for incentive compensation programs aimed at appropriately incentivizing its Sales Force to effectively promote Licensed Products and otherwise conduct their activities under the Commercialization Plan, provided that the Parties may agree to coordinate such compensation. Each Party will be responsible for

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the actions of its own Sales Force and other personnel and their compliance with applicable Law, MYLAN's Code of Conduct, and otherwise the highest levels of ethical and business conduct. The Sales Force of one Party shall not be considered an employee of the other Party, nor entitled to any compensation or benefits from such other Party.

Training:

MYLAN (in consultation with the JPC) will develop and implement training program(s) for the Parties' Sales Forces. Promptly after such training programs have been developed each Party will ensure that each of its Sales Representatives, Medical Representatives and other related support personnel for Licensed Product complete the applicable training program (as updated from time to time) and pass certain qualification criteria. Accordingly, each Party will allocate time at each of its Sales Force meetings for updated training with respect Licensed Product.

**Promotional Material**:

MYLAN will develop and provide to the Parties' Sales Forces all Promotional Material and other sales materials and aids for use in the promotion and sale of Licensed Product in the Field will be developed in accordance with the applicable guidelines established in the then-current version of the Commercialization Plan and Commercial Budget and subject to the oversight of the

Administrative Services: MYLAN will coordinate administrative services for the Parties' Sales Forces Co-Promotion Activities in the U.S including:

- Territory/market alignment;
- Data management, including: compiling and analyzing Licensed Product sales data, market data (including data relating to competitive sales), and data related to the tracking of the Direct Promotional Activities of the Parties; and
- Sales Force automation matters.

Meetings:

MYLAN and THERAVANCE will jointly participate in and staff all major and regional scientific and trade meetings designated in the Commercialization Plan.

Costs:

Each Party will bear its own costs in conducting activities under the Co-Promotion Agreement, except that certain of such costs will be shared in the context of the sharing of Operating Profits (Losses) under the Agreement.

<sup>\*\*\*</sup>CERTAIN INFORMATION HAS BEEN OMITTED AND FILED SEPARATELY WITH THE COMMISSION. CONFIDENTIAL TREATMENT HAS BEEN REQUESTED WITH RESPECT TO THE OMITTED PORTIONS.

**Reporting:** MYLAN will report on its activities under the Commercialization Plan at each JPC and JSC meeting.

<u>Term</u>: The term of the Co-Promotion Agreement will be coextensive with the Agreement. The Co-Promotion Agreement will be subject

to termination on the same terms as the Agreement.

# **EXHIBIT E**Commercialization Plan Outline

[***]	
***CERTAIN INFORMATION HAS BEEN OMITTED AND FILED SEPARATELY WITH THE COMMISSION. CONFIDENTIAL TREATMENT HAS	BEEN

# EXHIBIT F

#### Financial Exhibit

Section 1.01 <u>Upfront Payment.</u> MYLAN shall pay to THERAVANCE a non-refundable fee of Fifteen Million United States Dollars (U.S. \$15,000,000) (the "Upfront Payment") in partial consideration for the rights and licenses granted to it under this Agreement. MYLAN shall become obligated to pay the Upfront Payment 120 days after the Effective Date.

# Section 1.02 <u>Milestone Payments</u>.

(a) <u>General</u>. In further consideration for the acquisition of license rights under the THERAVANCE Patents, THERAVANCE Know-How and the Joint Invention Patents under Section 2.01, MYLAN shall also pay to THERAVANCE the one-time payments set forth below for the first occurrence of the corresponding Development Milestone or Sales Milestone referred to therein (each, a "Milestone"):

Development Milestones	Amount
[***]	
Sales Milestones	Amount
[***]	

- (b) <u>Payment Only Once for Milestones.</u> For the avoidance of doubt, Milestones are each payable only once, upon first attainment of the relevant milestone, regardless of how many times a Milestone is reached. In the event that more than one Sales Milestones are achieved in a given Calendar Year then the lower Sales Milestone payment for the Stand Alone Licensed Product would be payable for that Calendar Year and the higher Sales Milestone would be payable at the end of the following Calendar Year provided that the higher Sales Milestone is achieved and/or maintained in the following Calendar Year.
- (c) Notification and Payment. In the event of attainment of a Milestone, a Party shall promptly, but in no event more than ten (10) Business Days after the achievement of each such Milestone, notify the other Party in writing of the achievement of same. For each Milestone achieved, MYLAN shall promptly, but in no event more than ten (10) Business Days after receipt of THERAVANCE's invoice therefore, remit payment to THERAVANCE for such Milestone.
- Section 1.03 Operating Profit (Loss) Share in the U.S.
- (a) The Parties shall share the Operating Profits (Losses) from the sale of the Licensed Products in the Field in the U.S as set forth in this Section 1.03. The Parties

expect that Net Sales in the U.S. shall be accounts receivable of MYLAN and MYLAN shall receive payment on account thereof.

- (b) During the Term, MYLAN and THERAVANCE shall split the Operating Profits (Losses), sixty-five percent (65%) to MYLAN and thirty-five percent (35%) to THERAVANCE.
- (c) In the event that both Parties elect to sublicense the Commercialization of the Licensed Products in the Field in the U.S. to a Third Party, all cash consideration received in consideration for the grant of such sublicense will be treated as Net Sales in the U.S. For clarity, any such sublicense must be agreed by both Parties. In the event that one Party sublicenses the Commercialization of the Licensed Products in the Field in the U.S. to a Third Party, the sharing of Operating Profits (Losses) shall, as between the Parties, remain as set forth in Section 1.03(b) of this Exhibit F.
- (d) The sharing of Operating Profits (Losses) set forth in this Section 1.03 shall be reported, calculated and paid in accordance with Section 1.07 below.

# Section 1.04 Payment of Royalties to THERAVANCE on Net Sales in the ROW Countries.

(a) As further consideration for the acquisition of license rights under the THERAVANCE Patents and THERAVANCE Know-How under this Agreement, MYLAN shall pay to THERAVANCE royalties on Net Sales of Licensed Products in the Field in the ROW Countries that either (i) are covered by a Valid Claim within a THERAVANCE Patent or (ii) incorporate the THERAVANCE Know-How, Less ROW Recall Costs ("Adjusted Net Sales"), in the following percentages ("Royalties"):

On the portion of annual Adjusted Net Sales of Licensed Product in the Field in the ROW Countries up to U.S. [\*\*\*]

[\*\*\*]

On the portion of annual Adjusted Net Sales of Licensed Product in the Field in the ROW Countries over U.S. [\*\*\*] and less than U.S. [\*\*\*]:

[\*\*\*]

On the portion of annual Adjusted Net Sales of Licensed Product in the Field in the ROW Countries over U.S. [\*\*\*]:

[\*\*\*]

(b) Notwithstanding the foregoing, the Royalties shall be reduced by [\*\*\*] with respect to Licensed Products that are not covered by a Valid Claim within the THERAVANCE Patents in the Country of sale. For purposes of the foregoing, "cover" means that the manufacture, use, sale or importation of a Licensed Product would infringe a Valid Claim within the THERAVANCE Patents but for the licenses granted to MYLAN herein.

<sup>\*\*\*</sup>CERTAIN INFORMATION HAS BEEN OMITTED AND FILED SEPARATELY WITH THE COMMISSION. CONFIDENTIAL TREATMENT HAS BEEN REQUESTED WITH RESPECT TO THE OMITTED PORTIONS.

# Section 1.05 <u>Duration of Royalty Payments to THERAVANCE</u>.

- (a) <u>Commencement</u>. All royalties payable under Section 6.05(a) shall be paid on a Country-by-Country basis from First Commercial Sale of the Licensed Product in the relevant ROW Country.
- (b) <u>Duration of Royalties</u>; <u>Adjustment of Royalties</u>. Royalty obligations under Section 6.05 shall apply on a Country-by-Country basis, until the later of (i) the expiration or termination of the last Valid Claim of a THERAVANCE Patent or Joint Invention Patent covering the Licensed Product in the ROW Country of sale and (ii) thirteen (13) years from First Commercial Sale of the Licensed Product anywhere in the Territory.

#### Section 1.06 Payments to Third Parties; Combination Products.

- (a) Payments to Third Parties. If MYLAN is required to pay any amounts to a Third Party with respect to the manufacturing, using or selling Licensed Product in a ROW Country based on the intellectual property rights of such Third Party covering such Licensed Product, MYLAN shall be entitled to deduct [\*\*\*] of any such amount paid to such Third Party from the Royalties otherwise due THERAVANCE for such Licensed Product, provided in no event shall such reduction(s) reduce the royalties otherwise payable to THERAVANCE during any Calendar Year by more than [\*\*\*], and provided further than amounts not deducted in accordance with this Section 1.06 shall be carried forward to the following Calendar Year until [\*\*\*] of all such amounts is so deducted.
- (b) Combination Products. For Combination Licensed Products, the Parties shall meet prior to beginning clinical Development of such Combination Licensed Product, and negotiate in good faith appropriate adjustments to the Royalty and share of Operating Profits (Loss) for THERAVANCE to receive, based on the relative value of: 1) the Parties' respective contributions to the Development and Commercialization (including associated expenses) of such Combination Licensed Product; and 2) relative importance and proprietary protection of the Stand Alone Licensed Product and the other active ingredient(s) included in such Combination Licensed Product. In the event the Parties are unable to agree with respect to such adjustments, Operating Profits (Losses) or Royalties, as applicable shall be multiplied by the fraction equal to 1/[the number of active ingredients in such Combination Licensed Product].

# Section 1.07 <u>Reporting and Payment.</u>

(a) Reports.

(i) On or before the tenth (10<sup>th</sup>) day of each month, each Party will provide a written report to the other Party setting forth, with respect to THERAVANCE, the Development Expenses and, with respect to both Parties, the Operating Expenses, Shared Expenses and Patent expenses subject to reimbursement in accordance with Article 12 ("Reimbursable Patent Expenses"), incurred and anticipated to be incurred by such Party during the then-current Calendar Quarter and Calendar Year. Such reports shall compare such amounts to the amounts set forth in the Development Budget or

<sup>\*\*\*</sup>CERTAIN INFORMATION HAS BEEN OMITTED AND FILED SEPARATELY WITH THE COMMISSION. CONFIDENTIAL TREATMENT HAS BEEN REQUESTED WITH RESPECT TO THE OMITTED PORTIONS.

Commercial Budget, respectively, for the corresponding periods. Within fifteen (15) days after the end of each Calendar Quarter during the Term, THERAVANCE shall also provide to MYLAN a written report of its Operating Expenses, Shared Expenses and Reimbursable Patent Expenses incurred for such Calendar Quarter.

- (ii) As soon as is reasonably practical after the end of each Calendar Quarter, MYLAN shall submit to THERAVANCE a written report (each, a "Quarterly Report") setting forth in reasonable detail for such Calendar Quarter (i) Net Sales in the Territory, in the aggregate and on a country-by-country basis, (ii) Royalties owed to THERAVANCE on ROW Net Sales, (iii) COGS for the U.S., (iv) Operating Expenses and Shared Expenses for the Calendar Quarter, incurred by each Party and in the aggregate, (v) Operating Profit (Loss) and each Party's share thereof, (vi) Reimbursable Patent Expenses and each Party's share thereof, and (vii) the amounts due to or from the relevant Party, as well as the computation of each of the foregoing.
- (iii) Subject to Section 1.07(b) below, within fifteen (15) days following submission to THERAVANCE of each Quarterly Report, the Parties shall make any reconciling payments necessary to effect the Royalties owed to THERAVANCE pursuant to Section 1.04 of this Exhibit F, and the sharing of Operating Expense and Operating Profit (Loss) of the Parties set forth in Section 1.03 of this Exhibit F for such Calendar Quarter. For clarity, if the amount of the Operating Profits (Loss) are negative with respect to any Calendar Quarter, the Parties will share such Operating Loss and THERAVANCE will make any necessary payments to MYLAN.
- (iv) The reports required by this Section 1.07 shall be the reporting Party's Confidential Information subject to the protections of Article 9 of the Agreement.
- (b) <u>Disputes.</u> In the event of a dispute regarding any amount reported by a Party or any amount owed under Section 1.07(a) above, the JSC shall promptly meet and negotiate in good faith a resolution to such dispute. In the event that the JSC is unable to resolve such dispute within sixty (60) days after notice by the disputing Party, the Parties will (a) use reasonable, good faith efforts to reach agreement on the appointment of one internationally-recognized independent accounting firm to determine the matter or (b) if the Parties cannot reach agreement on such accounting firm, then the head of the office of the American Arbitration Association in New York City shall choose an internationally-recognized independent accounting firm to make the final determination.
- (c) <u>Efforts to Streamline Reporting</u>. The Parties will cooperate in good faith to develop processes and align the reporting timelines set forth in this Section 1.07 with each Party's internal close calendars and internal and other reporting obligations.

<sup>\*\*\*</sup>CERTAIN INFORMATION HAS BEEN OMITTED AND FILED SEPARATELY WITH THE COMMISSION. CONFIDENTIAL TREATMENT HAS BEEN REQUESTED WITH RESPECT TO THE OMITTED PORTIONS.

# EXHIBIT G

Share Purchase Agreement

(See Attached)

**EXHIBIT H**Change of Control Conflict Companies

# **EXHIBIT I**Approved Manufacturers

The JSC shall not withhold its approval of the following Commercial manufacturers:

[\*\*\*]

The JSC shall not withhold its approval of the following manufacturers for supply of Licensed Product for use in the clinical trials included in the Preliminary Development Plan:

[\*\*\*]

The JSC shall not withhold its approval of the following manufacturers for supply of API for use in the clinical trials included in the Preliminary Development Plan:

[\*\*\*]

Notwithstanding the foregoing, MYLAN shall have the right to conduct a quality inspection of the foregoing manufacturers of the Licensed Product or API Compound or any component of the Licensed Product for use in the clinical trials included in the Preliminary Development Plan in accordance with Section 7.01(a), and the JSC may withhold or withdraw its approval of such manufacturers in the event any such inspection reveals material quality issues.

# THERAVANCE BIOPHARMA, INC.

# ORDINARY SHARE PURCHASE AGREEMENT

January 30, 2015

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# THERAVANCE BIOPHARMA, INC.

#### ORDINARY SHARE PURCHASE AGREEMENT

THIS ORDINARY SHARE PURCHASE AGREEMENT (the "Agreement") is made as of the thirtieth day of January 2015 by and among Theravance Biopharma, Inc., a Cayman Islands exempted company (the "Company"), and Mylan Inc., a Pennsylvania corporation (the "Investor").

WHEREAS, Mylan Ireland Limited, a limited company organized and existing under the laws of Ireland and an indirect wholly-owned subsidiary of Investor, and Theravance Biopharma R&D, Inc., a Cayman Islands exempted company and a wholly-owned subsidiary of the Company, have entered into that certain Development and Commercialization Agreement dated as of the date hereof, pursuant to which, the parties desire to establish a broad collaboration for the global development and commercialization of TD-4208 in a nebulized form both as standalone monotherapy and in combination or coformulation with other chemically distinct and therapeutically active compounds; and

WHEREAS, the Investor and the Company are entering into this Agreement, pursuant to which the Investor shall purchase Ordinary Shares of the Company.

#### THE PARTIES HEREBY AGREE AS FOLLOWS:

- 1. <u>Purchase and Sale of Shares</u>.
  - 1.1 Sale and Issuance of Ordinary Shares.
- (a) On or prior to the Closing (as defined below), the Company shall have authorized the sale and issuance of its Ordinary Shares of a par value of U.S. \$0.00001 each to the Investor (the "Shares" or the "Ordinary Shares"). The Shares shall have the rights, preferences, privileges and restrictions set forth in the Company's Amended and Restated Memorandum and Articles of Association (the "Restated Articles").
- (b) Subject to the terms and conditions of this Agreement, the Investor agrees to purchase at the Closing and the Company agrees to sell and issue to the Investor at the Closing, 1,585,790 Shares at a price per share of \$18.91802, resulting in an aggregate purchase price of Thirty Million United States Dollars (U.S. \$30,000,000.00) (the "Aggregate Purchase Price").
- 1.2 Closing. The purchase and sale of the Shares shall take place at the offices of Theravance Biopharma US, Inc., 901 Gateway Boulevard, South San Francisco, CA 94080. On February 2, 2015, the Investor will initiate an irrevocable wire transfer in the amount of the Aggregate Purchase Price to an account designated in writing by the Company. Immediately upon the Company's receipt of the Aggregate Purchase Price, the purchase and sale of the Shares shall be consummated (which time is designated as the "Closing"). Immediately following the Closing, the Company shall instruct the Company's transfer agent to record Investor's purchase of the Shares on the Company's register of members. As used herein,

"Business Day" shall mean any weekday that is not a day on which banking institutions in the City of San Francisco are authorized or obligated to close.

- 2. Representations and Warranties of the Company. The Company hereby represents and warrants to the Investor that:
- 2.1 <u>Organization, Good Standing and Qualification.</u> The Company is an exempted company with limited liability duly incorporated, validly existing and in good standing under the laws of the Cayman Islands and has all requisite corporate power and authority to (i) execute, deliver and perform its obligations under this Agreement, (ii) to issue and sell the Shares hereunder, (iii) to perform its obligations under the Restated Articles, and (iv) to carry on its business as now conducted and as proposed to be conducted. The Company is duly qualified to transact business and is in good standing in each jurisdiction in which the failure to so qualify would have a material adverse effect on its business or properties.
- 2.2 <u>Authorization</u>. All corporate action on the part of the Company, its officers, directors and shareholders necessary for the authorization, execution and delivery of this Agreement, the performance of all obligations of the Company hereunder, and the authorization, issuance (or reservation for issuance), sale and delivery of the Shares being sold hereunder has been taken or will be taken prior to the Closing, and this Agreement constitutes a valid and legally binding obligation of the Company, enforceable in accordance with its terms, except (i) as limited by applicable bankruptcy, insolvency, reorganization, moratorium, and other laws of general application affecting enforcement of creditors' rights generally and (ii) as limited by laws relating to the availability of specific performance, injunctive relief, other equitable remedies, or general principles of equity.
- 2.3 <u>Valid Issuance of Ordinary Shares</u>. The Shares that are being purchased by the Investor hereunder, when issued, sold and delivered in accordance with the terms of this Agreement and registered on the register of members of the Company for the consideration expressed herein, will be duly and validly issued, fully paid, and nonassessable, and will be free of restrictions on transfer other than restrictions on transfer under this Agreement and under applicable state and federal securities laws. The Shares that are being purchased by the Investor hereunder will not be subject to preemptive rights or rights of first refusal that have not been waived or complied with.
- 2.4 <u>Governmental Consents.</u> No consent, approval, order or authorization of, or registration, qualification, designation, declaration or filing with, any federal, state or local governmental authority on the part of the Company is required in connection with the consummation of the transactions contemplated by this Agreement, except certain post-closing filings as may be required pursuant to federal securities laws and under the "Blue Sky" laws of the various states.
- 2.5 Offering. Subject in part to the truth and accuracy of the Investor's representations set forth in Section 3 of this Agreement, the offer, sale and issuance of the Shares as contemplated by this Agreement are exempt from the registration requirements of any applicable state and federal securities laws, and neither the Company nor any authorized agent acting on its behalf will take any action (including any offering of any securities of the Company

under circumstances which would require the integration of such offering with the offering of any of the Shares to be issued pursuant to this Agreement under the Securities Act (as defined below) and the rules and regulations of the Commission thereunder) hereafter that would cause the loss of such exemption.

- 2.6 <u>Litigation</u>. There is no action, suit, proceeding or investigation pending or, to the Company's knowledge, currently threatened against the Company that questions the validity of this Agreement or the right of the Company to enter into this Agreement or to consummate the transactions contemplated hereby or thereby. The Company is not a party or subject to the provisions of any order, writ, injunction, judgment or decree of any court or government agency or instrumentality.
- 2.7 <u>Compliance with Other Instruments.</u> The execution, delivery and performance of this Agreement and the consummation of the transactions contemplated hereby and thereby will not violate or be in conflict with or constitute, with or without the passage of time and giving of notice, either a default under any statute, rule or regulation applicable to the Company or any instrument, judgment, order, writ, decree or contract or an event that results in the creation of any lien, charge or encumbrance upon any assets of the Company or the suspension, revocation, impairment, forfeiture, or nonrenewal of any material permit, license, authorization, or approval applicable to the Company, its business or operations or any of its assets or properties.
- SEC Reports: Financial Statements. The Company has filed all reports, schedules, forms, statements and other documents required to be filed by the Company under the Securities Act of 1933, as amended (the "Securities Act") or the Securities Exchange Act of 1934, as amended (the "Exchange Act"), including pursuant to Section 13(a) or 15(d) thereof (the foregoing materials being collectively referred to herein as the "SEC Reports"), on a timely basis or has received a valid extension of such time of filing and has filed any such SEC Reports prior to the expiration of any such extension. As of their respective dates, the SEC Reports complied in all material respects with the requirements of the Securities Act and the Exchange Act and the rules and regulations of the Securities and Exchange Commission (the "Commission") promulgated thereunder, as applicable, and none of the SEC Reports, when filed, contained any untrue statement of a material fact or omitted to state a material fact required to be stated therein or necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading. No executive officer of the Company has failed in any respect to make the certifications required of him or her under Section 302 or 906 of the Sarbanes-Oxley Act of 2002. The financial statements of the Company included in the SEC Reports comply in all material respects with applicable accounting requirements and the rules and regulations of the Commission with respect thereto as in effect at the time of filing. Such financial statements have been prepared in accordance with United States generally accepted accounting principles applied on a consistent basis during the periods involved ("GAAP"), except as may be otherwise specified in such financial statements or the notes thereto and except that unaudited financial statements may not contain all footnotes required by GAAP, and fairly present in all material respects the financial position of the Company and its consolidated subsidiaries as of and for the dates thereof and the results of operations and cash flows for the periods then ended, subject, in the case of unaudited statements, to normal, immaterial, year-end audit adjustments. The balance sheet of the Company

contained in the SEC Reports as of September 30, 2014 is hereinafter referred to as the "Company Balance Sheet".

- 2.9 <u>Corporate Documents.</u> The Restated Articles of the Company are in the form as set forth as an exhibit in the SEC Reports.
- 2.10 <u>Capital Stock.</u> The authorized share capital of the Company consists of: (i) 200,000,000 Ordinary Shares and (ii) 230,000 preferred shares, par value \$0.00001 per share (the "<u>Preferred Shares</u>"). At the close of business on January 29, 2015: (i) 32,221,083 Ordinary Shares were issued and outstanding and (ii) no Preferred Shares were issued and outstanding, and since January 29, 2015 there have been no material changes in the information provided pursuant to clauses (i) and (ii) of this sentence. No Ordinary Shares are owned or held by any subsidiary of the Company.
- 2.11 Share Options. As of the close of business on December 31, 2014: (i) not more than 3,962,426 Ordinary Shares were subject to issuance pursuant to outstanding options ("Company Options") under the Company's 2013 Equity Incentive Plan and 2014 New Employee Equity Incentive Plan (collectively, the "Stock Option Plans"), and (ii) 2,216,145 Ordinary Shares were reserved for future issuance under the Stock Option Plans. All Ordinary Shares subject to issuance under the Company Options, upon issuance in accordance with the terms and conditions specified in the instruments pursuant to which they are issuable, would be duly authorized, validly issued, fully paid and nonassessable. There are no commitments or agreements of any character to which the Company is bound obligating the Company to accelerate the vesting of any Company Option solely as a result of the transactions contemplated hereby (whether alone or upon the occurrence of any additional or subsequent events). There are no outstanding or authorized stock appreciation, phantom stock, profit participation or other similar rights with respect to the Company.
- 2.12 <u>Voting Debt.</u> No Voting Debt of the Company is issued or outstanding as of the date hereof. For purposes of this Agreement, the term "<u>Voting Debt</u>" shall mean any bonds, debentures, notes or other indebtedness of the Company or any of its subsidiaries (i) having the right to vote on any matters on which shareholders of the Company may vote (or which is convertible into, or exchangeable for, securities having such right) or (ii) the value of which is any way based upon or derived from capital or voting shares of the Company.
- 2.13 Other Securities. Except as otherwise disclosed in the SEC Reports (as defined herein) filed prior to the date hereof, there are no securities, options, warrants, calls, rights, contracts, commitments, agreements, instruments, arrangements, understandings, obligations or undertakings of any kind to which the Company or any of its subsidiaries is a party or by which any of them is bound obligating the Company or any of its subsidiaries to (including on a deferred basis) issue, deliver or sell, or cause to be issued, delivered or sold, additional shares of capital stock of the Company, Voting Debt or other voting securities of the Company or any of its subsidiaries, or obligating the Company or any of its subsidiaries to issue, grant, extend or enter into any such security, option, warrant, call, right, contract, commitment, agreement, instrument, arrangement, understanding, obligation or undertaking. All outstanding Ordinary Shares, all outstanding Company Options, and all outstanding shares of capital stock of each subsidiary of the Company have been issued and granted in compliance in all material

respects with (i) all applicable securities laws and all other applicable Legal Requirements and (ii) all requirements set forth in applicable material Contracts. For purposes of this Agreement, the term: (A) "Legal Requirements" shall mean any federal, state, local, municipal, foreign or other law, statute, constitution, principle of common law, resolution, ordinance, code, order, edict, decree, rule, regulation, ruling or requirement issued, enacted, adopted, promulgated, implemented or otherwise put into effect by or under the authority of any Governmental Entity; (B) "Contract" shall mean any agreement, contract, subcontract, settlement agreement, lease, binding understanding, instrument, note, option, warranty, purchase order, license, sublicense, insurance policy, benefit plan or legally binding commitment or undertaking of any nature, as in effect as of the date hereof or as may hereinafter be in effect; and (C) "Governmental Entity" shall mean any supranational, national, state, municipal, local or foreign government, any instrumentality, subdivision, court, administrative agency or commission or other governmental authority or instrumentality, or any quasi-governmental or private body exercising any regulatory, taxing, importing or other governmental or quasi-governmental authority.

- 2.14 <u>No Undisclosed Liabilities</u>. Except as set forth in the SEC Reports, neither the Company nor its subsidiaries has any liability, indebtedness, obligation, expense, claim, deficiency, guaranty or endorsement of any type, whether accrued, absolute, contingent, matured, unmatured or otherwise, other than (i) those not required under generally accepted accounting principles to be reflected in the Company Balance Sheet or (ii) those incurred in the ordinary course of business since the Company Balance Sheet.
- 2.15 No Solicitation; No Integration. Neither the Company nor any of its subsidiaries, nor any person acting on its or their behalf, (i) has engaged in any form of general solicitation or general advertising (within the meaning of Regulation D under the Securities Act) in connection with the offer or sale of the Shares, (ii) has, directly or indirectly, made any offers or sales of any security or solicited any offers to buy any security, under any circumstances that would require registration of the Shares under the Securities Act or (iii) has issued any securities which are required to be integrated with the sale of the Shares to the Investor for purposes of the Securities Act or of any applicable shareholder approval provisions under the rules and regulations of Nasdaq, nor will the Company or any of its subsidiaries or affiliates take any action or steps that would require registration of any of the Shares under the Securities Act or cause the offering of the Shares to be integrated with other offerings (other than the other transactions contemplated in this Agreement). Assuming the accuracy of the representations and warranties of the Investor in Article 3 of this Agreement, the offer and sale of the Shares by the Company to the Investor pursuant to this Agreement will be exempt from the registration requirements of the Securities Act.
- 2.16 Absence of Certain Changes or Events. Since the date of the Company Balance Sheet, the Company has conducted its business only in the ordinary course of business and there has not been: (i) any change that would have a material adverse effect on the Company, (ii) any declaration, setting aside or payment of any dividend on, or other distribution (whether in cash, stock or property) in respect of, any of the Company's capital stock, or any purchase, redemption or other acquisition by the Company or any of its subsidiaries of any of the Company's capital stock or any other securities of the Company or any options, warrants, calls or rights to acquire any such shares or other securities of the Company except for repurchases from employees following their termination pursuant to the terms of their pre-existing stock option or purchase agreements, (iii) any split, combination or reclassification of any of the

Company's capital stock, (iv) entry by the Company or any of its subsidiaries into any licensing or other agreement with regard to the disposition of any material intellectual property other than licenses, distribution agreements, advertising agreements, sponsorship agreements or merchant program agreements entered into in the ordinary course of business, (v) any material change by the Company in its accounting methods, principles or practices, except as required by concurrent changes in GAAP or by the Commission, (vi) any material change to the Company's internal controls over financial reporting, (vii) any material revaluation by the Company of any of its assets, including, without limitation, writing down the value of capitalized inventory or writing off notes or accounts receivable other than in the ordinary course of business, (viii) any communication from the Nasdaq Stock Market with respect to the delisting of the Ordinary Shares, (ix) any cancellation by the Company or any of its subsidiaries of any debts or waiver of any claims or rights of material value other than cancellations or waivers solely between the Company and its subsidiaries, (x) any sale, transfer or other disposition outside of the ordinary course of business of any material properties or assets (real, personal or mixed, tangible or intangible) by the Company or any of its subsidiaries, or (xi) any agreement, whether in writing or otherwise, to take any action described in this section by the Company or any of its subsidiaries.

- 2.17 <u>Listing and Maintenance Requirements</u>. The Company is, and has no reason to believe that it will not in the foreseeable future continue to be, in compliance with the listing and maintenance requirements for continued listing of the Shares on Nasdaq. The issuance and sale of the Shares under this Agreement does not contravene the rules and regulations of Nasdaq and no approval of the shareholders of the Company thereunder is required for the Company to issue and deliver to the Investor the Shares contemplated by this Agreement.
  - 3. Representations and Warranties of the Investor. The Investor hereby represents and warrants that:
- 3.1 <u>Authorization</u>. The Investor has full power and authority to enter into this Agreement and this Agreement constitutes a valid and legally binding obligation, enforceable in accordance with its terms except (i) as limited by applicable bankruptcy, insolvency, reorganization, moratorium, and other laws of general application affecting enforcement of creditors' rights generally and (ii) as limited by laws relating to the availability of specific performance, injunctive relief, other equitable remedies, or general principles of equity.
- 3.2 Purchase Entirely for Own Account. This Agreement is made with the Investor in reliance upon the Investor's representation to the Company, which by the Investor's execution of this Agreement the Investor hereby confirms, that the Shares to be received by the Investor will be acquired for investment for the Investor's own account, not as a nominee or agent, and not with a view to the resale or distribution of any part thereof, and that the Investor has no present intention of selling, granting any participation in, or otherwise distributing the same in violation of applicable securities laws. By executing this Agreement, the Investor further represents that the Investor does not have any contract, undertaking, agreement or arrangement with any person to sell, transfer or grant participations to such person or to any third person, with respect to any of the Shares.

- 3.3 <u>Disclosure of Information</u>. The Investor believes it has received all the information it considers necessary or appropriate for deciding whether to purchase the Shares. The Investor further represents that it has had an opportunity to ask questions and receive answers from the Company regarding the terms and conditions of the offering of the Shares and the business, properties, prospects and financial condition of the Company. The Investor acknowledges that it has read the "Risk Factors" section contained in the Company's Quarterly Report on Form 10-Q filed with the SEC on November 12, 2014 and understands the Company's business and recognizes that a purchase of the Shares involves risks and uncertainties. The foregoing, however, does not limit or modify the representations and warranties of the Company in Section 2 of this Agreement or the right of the Investor to rely thereon.
- 3.4 <u>Investment Experience</u>. The Investor is an investor in securities of companies in the development stage and acknowledges that it is able to protect its own interests, can bear the economic risk of its investment, and has such knowledge and experience in financial or business matters that it is capable of evaluating the merits and risks of the investment in the Shares. The Investor also represents that it has not been organized for the purpose of acquiring the Shares.
- 3.5 Accredited Investor. The Investor is an "accredited investor" within the meaning of Rule 501 of Regulation D adopted pursuant to the Act, as presently in effect.
- 3.6 Restricted Securities. The Investor understands that the Shares it is purchasing are characterized as "restricted securities" under the federal securities laws inasmuch as they are being acquired from the Company in a transaction not involving a public offering and that under such laws and applicable regulations such securities may be resold without registration under the Act, only in certain limited circumstances. In this connection, the Investor represents that it is familiar with Rule 144 adopted pursuant to the Act, as presently in effect, and understands the resale limitations imposed thereby and by the Act.
- 4. <u>Interim Covenant.</u> During the period from the date of this Agreement and continuing until the earlier of the termination of this Agreement and the Closing, the Company shall conduct its business in the usual, regular and ordinary course consistent with past practice.
- 5. <u>Conditions of Investor's Obligations at Closing.</u> The obligations of the Investor under subsection 1.1(b) of this Agreement are subject to the fulfillment on or before the Closing of each of the following conditions, the waiver of which shall not be effective against the Investor if it does not consent thereto:
- 5.1 <u>Performance</u>. The Company shall have performed and complied with all agreements, obligations and conditions contained in this Agreement that are required to be performed or complied with by it on or before the Closing.
- 5.2 <u>Representations and Warranties.</u> The representations and warranties of the Company contained in Section 2 shall have been true on and as of the Closing.
- 5.3 Qualifications. All authorizations, approvals, or permits, if any, of any governmental authority or regulatory body of the United States of or any state or foreign country

that are required in connection with the lawful issuance and sale of the Shares pursuant to this Agreement shall be duly obtained and effective as of the Closing.

- 5.4 <u>Proceedings and Documents</u>. All corporate and other proceedings in connection with the transactions contemplated at the Closing and all documents incident thereto shall be reasonably satisfactory in form and substance to the Investor, and they shall have received all such counterpart original and certified or other copies of such documents as they may reasonably request.
- 6. <u>Conditions of the Company's Obligations at Closing</u>. The obligations of the Company to the Investor under this Agreement are subject to the fulfillment on or before the Closing of each of the following conditions by the Investor:
- 6.1 <u>Representations and Warranties.</u> The representations and warranties of the Investor contained in Section 3 shall have been true on and as of the Closing.
- 6.2 Qualifications. All authorizations, approvals, or permits, if any, of any governmental authority or regulatory body of the United States of or any state or foreign country that are required in connection with the lawful issuance and sale of the Shares pursuant to this Agreement shall be duly obtained and effective as of the Closing.

# Miscellaneous.

- 7.1 Covenant Against Transfers. Prior to the nine month anniversary of the Closing, other than pursuant to a transaction or series of related transactions (including mergers, consolidations and other forms of business consolidations) following which continuing shareholders of the Company hold less than 50% of the outstanding voting securities of either the Company, the entity surviving such transaction or any direct or indirect parent entity of such continuing or surviving entity, the Investor agrees that neither it nor any affiliate will (i) lend, offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, or otherwise transfer or dispose of, directly or indirectly, any Shares or any securities convertible into or exercisable or exchangeable for Shares (whether such Shares or any such securities are then owned by the Investor or are thereafter acquired), or (ii) enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of Shares, whether any such transaction described in clause (i) or (ii) above is to be settled by delivery of Shares or such other securities, in cash or otherwise.
- 7.2 Termination. This Agreement may be terminated and the transactions contemplated hereby abandoned at any time prior to the Closing: (a) by mutual written agreement of the Investor and the Company; (b) by the Investor or Company if the Closing shall not have occurred by March 2, 2015; provided, however, that the right to terminate this Agreement under this Section 7.2 shall not be available to any party whose action or failure to act has been a principal cause of or resulted in the failure of the transactions contemplated hereby to occur on or before such date and such action or failure to act constitutes a breach of this Agreement; or (c) by the Investor or Company if ninety days after notice to the other party of any Legal Requirement in effect which would have the effect of making the transactions contemplated hereby illegal or otherwise prohibit or prevent the consummation of the

transactions contemplated hereby and such Legal Requirement having such effect shall remain in effect after the expiration of such ninety day period.

- 7.3 Effect of Termination. If this Agreement is terminated as provided in Section 7.2 hereof, this Agreement shall forthwith become void and there shall be no liability or obligation on the part of the Company or the Investor, or their respective officers, directors, members or shareholders, if applicable; provided, however, that each party hereto and each person shall remain liable for any breaches of this Agreement prior to its termination, and provided, further, that the provisions of this Section 7.3, Sections 7.7 through 7.16, and Section 7.19 shall remain in full force and effect and survive any termination of this Agreement.
- 7.4 Rule 144 Reporting. With a view to making available the benefits of certain rules and regulations of the Commission that may permit the sale of the Shares to the public without registration, the Company agrees to use its commercially reasonable efforts to: (i) make and keep adequate current public information with respect to the Company available in accordance with Rule 144 under the Securities Act and (ii) file with the Commission in a timely manner all reports and other documents required of the Company under the Securities Act and the Exchange Act.
- 7.5 Restrictions on Transfers. Any legend referring to the stock transfer instructions and record notations of the Shares shall be removed if: (i) those securities have been sold pursuant to a registration statement that is then effective under the Securities Act or (ii) the Investor provides the Company with an opinion of counsel reasonably acceptable to the Company to the effect that a sale or transfer of those securities may be made without registration or qualification.
- 7.6 <u>Survival of Warranties</u>. The warranties, representations, covenants and agreements of the Company and the Investor contained in or made pursuant to this Agreement shall survive the execution and delivery of this Agreement and the Closing and shall in no way be affected by any investigation of the subject matter thereof made by or on behalf of the Investor or the Company.
- 7.7 Successors and Assigns. Except as otherwise provided herein, the terms and conditions of this Agreement shall inure to the benefit of and be binding upon the respective successors and assigns of the parties (including transferees of any Shares). Nothing in this Agreement, express or implied, is intended to confer upon any party other than the parties hereto or their respective successors and assigns any rights, remedies, obligations, or liabilities under or by reason of this Agreement, except as expressly provided in this Agreement.
- 7.8 Governing Law. This Agreement shall be governed by and construed in accordance with the law of the State of New York, without regard to the conflicts of laws principles thereof. Any action brought, arising out of, or relating to this Agreement shall be brought in United States District Court of the Southern District of New York. Each party hereby irrevocably submits to the exclusive jurisdiction of said Court in respect of any claim relating to the validity, interpretation and enforcement of this Agreement, and hereby waives, and agrees not to assert, as a defense in any action, suit or proceeding in which any such claim is made that it is not subject thereto or that such action, suit or proceeding may not be brought or is not

maintainable in such courts, or that the venue thereof may not be appropriate or that this agreement may not be enforced in or by such courts. The parties hereby consent to and grant the United States District Court of the Southern District of New York jurisdiction over such parties and over the subject matter of any such claim and agree that mailing of process or other papers in connection with any such action, suit or proceeding in the manner provided in Section 6.8, or in such other manner as may be permitted by law, shall be valid and sufficient thereof.

- 7.9 <u>WAIVER OF JURY TRIAL</u>. EACH OF THE PARTIES HERETO HEREBY IRREVOCABLY WAIVES ANY AND ALL RIGHT TO TRIAL BY JURY IN ANY LEGAL PROCEEDING ARISING OUT OF OR RELATED TO THIS AGREEMENT OR THE TRANSACTIONS CONTEMPLATED HEREBY.
- 7.10 Counterparts. This Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.
- 7.11 <u>Titles and Subtitles</u>. The titles and subtitles used in this Agreement are used for convenience only and are not to be considered in construing or interpreting this Agreement.
- 7.12 Notices. All notices required or permitted pursuant to this Agreement shall be in writing and shall be deemed effectively given: (a) upon personal delivery to the party to be notified, (b) when sent by confirmed electronic mail or facsimile if sent during normal business hours of the recipient, if not, then on the next Business Day or (c) one (1) day after deposit with an internationally recognized overnight courier, specifying next day delivery, with written verification of receipt. All notices and certificates will be addressed to the Company or Investor at the addresses set forth on the signature pages hereto or at such other address as the Company or the Investor may designate by ten (10) days advance written notice to the other parties hereto.
- 7.13 Finder's Fee. The Investor agrees to indemnify and to hold harmless the Company from any liability for any commission or compensation in the nature of a finders' fee (and the costs and expenses of defending against such liability or asserted liability) for which the Investor or any of its officers, partners, employees, or representatives is responsible. The Company agrees to indemnify and hold harmless the Investor from any liability for any commission or compensation in the nature of a finders' fee (and the costs and expenses of defending against such liability or asserted liability) for which the Company or any of its officers, employees or representatives is responsible.
- 7.14 Expenses. Irrespective of whether the Closing is effected, each party shall bear their own costs and expenses incurred with respect to the negotiation, execution, delivery and performance of this Agreement. If any action at law or in equity is necessary to enforce or interpret the terms of this Agreement or the Restated Articles, the prevailing party shall be entitled to reasonable attorney's fees, costs and necessary disbursements in addition to any other relief to which such party may be entitled.

- 7.15 Amendments and Waivers. Any term of this Agreement may be amended and the observance of any term of this Agreement may be waived (either generally or in a particular instance and either retroactively or prospectively), only with the written consent of the Company and the Investor. Any amendment or waiver effected in accordance with this paragraph shall be binding upon each holder of any securities purchased under this Agreement at the time outstanding, each future holder of such securities, and the Company.
- 7.16 Severability. If one or more provisions of this Agreement are held to be unenforceable under applicable law, such provision shall be excluded from this Agreement and the balance of the Agreement shall be interpreted as if such provision were so excluded and shall be enforceable in accordance with its terms.
  - 7.17 <u>Legends</u>. It is understood that the transfer agent's records evidencing the Shares may bear one or all of the following legends:
- (a) "The Shares have not been registered under the Securities Act of 1933, as amended (the "Act"). The Shares may not be sold, transferred or assigned in the absence of an effective registration for these shares under the Act or an opinion of the corporation's counsel that registration is not required under the Act."
  - (b) Any legend required by the laws of any state.
- 7.18 Nasdaq Listing. The Company shall use all commercially reasonable efforts to have the Shares acquired by the Investor at the Closing authorized for listing on Nasdaq.
- 7.19 Entire Agreement. This Agreement, the Development and Commercialization Agreement and the documents referred to herein and therein constitute the entire agreement among the parties and no party shall be liable or bound to any other party in any manner by any warranties, representations, or covenants except as specifically set forth herein or therein.

[Remainder of page intentionally left blank.]

IN WITNESS WHEREOF, the parties have executed this Agreement as of the date first above written.

# THERAVANCE BIOPHARMA, INC.

By: /s/ Rick E Winningham

Rick E Winningham Chief Executive Officer

Theravance Biopharma, Inc. c/o Theravance Biopharma US, Inc. 901 Gateway Boulevard South San Francisco, CA 94080 Attn: Head of Business Development

With a copy to: Theravance Biopharma R&D, Inc. c/o Theravance Biopharma US, Inc. 901 Gateway Boulevard South San Francisco, CA 94080 Attn: Legal Department

SIGNATURE PAGE TO ORDINARY SHARE PURCHASE AGREEMENT

INVESTOR:

MYLAN INC.

By: /s/ Rajiv Malik
Signature of Authorized Person
Name: Rajiv Malik

Title: President

Mylan Inc.

1000 Mylan Boulevard Canonsburg, Pennsylvania 15317 Attn: Head of Global Business Development

With a copy to: 1000 Mylan Boulevard Canonsburg, Pennsylvania 15317 Attn: Global General Counsel

SIGNATURE PAGE TO ORDINARY SHARE PURCHASE AGREEMENT