Current Agreements

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# Fourth amendment to licensing, co-development and marketing agreement for Entereg (alvimopan)

Adolor
GSK

Jan 30 2009

# Fourth amendment to licensing, co-development and marketing agreement for Entereg (alvimopan)

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| **Companies:** | Adolor<br>GSK |
| **Announcement date:** | Jan 30 2009 |
| **Related contracts:** | Termination of licensing, co-development and marketing agreement for Entereg (alvimopan)<br>Third amendment to licensing, co-development and marketing agreement for Entereg (alvimopan)<br>Second amendment to licensing, co-development and marketing agreement for Entereg (alvimopan)<br>Distribution agreement for Entereg (alvimopan)<br>First amendment to licensing, co-development and marketing agreement for Entereg (alvimopan)<br>Licensing, co-development and marketing agreement for Entereg (alvimopan) (terminated)<br>Fifth amendment to licensing, co-development and marketing agreement for Entereg (alvimopan)<br>First amendment to distribution agreement for Entereg (alvimopan) |



## Details

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| **Announcement date:** | Jan 30 2009 |
| **Start date:** | Jan 30 2009 |
| **Industry sectors:** | Bigpharma<br>Pharmaceutical |
| **Therapy areas:** | Hospital care » Surgery<br>Gastrointestinal » Symptoms » Bowel movement |
| **Technology types:** | Drug delivery<br>Software tools |
| **Deal components:** | Co-development<br>Co-market<br>Co-promotion<br>Licensing<br>Marketing<br>Promotion |
| **Stages of development:** | Phase III |
| **Geographic focus:** | Worldwide |

## Financials

## Termsheet

*Not available.*

## Press Release

*Not available.*

## Filing Data

*Not available.*

## Contract

MENDMENT NO. 4 TO

COLLABORATION AGREEMENT

THIS AMENDMENT NO. 4 TO COLLABORATION AGREEMENT (this “Amendment No. 4”), dated as of January 30, 2009 and effective as of January 1, 2009 (the “Effective Date”), is made by and between ADOLOR CORPORATION, a Delaware corporation and having its principal office at 700 Pennsylvania Drive, Exton, Pennsylvania 19341 (“Adolor”), and GLAXO GROUP LIMITED, a United Kingdom corporation and having its principal office at Glaxo Wellcome House, Berkeley Avenue, Greenford, Middlesex, UB6 0NN, United Kingdom (“GSK”). Adolor and GSK are each sometimes referred to individually as a “Party” and together as the “Parties.”

WHEREAS, Adolor and GSK entered into that certain Collaboration Agreement dated April 14, 2002 (the “Collaboration Agreement”), as amended by Amendment No. 1 to the Collaboration Agreement effective on June 24, 2003 (“Amendment No. 1”), Amendment No. 2 to the Collaboration Agreement effective on December 22, 2004 (“Amendment No. 2”), Amendment No. 3 to the Collaboration Agreement effective on June 9, 2008 (“Amendment No. 3”) and a Notice of Termination for GI Products dated August 29, 2008 (the “Notice”) (the Collaboration Agreement, Amendment No. 1, Amendment No. 2, Amendment No. 3 and the Notice are collectively referred to herein as, the “Agreement”).

WHEREAS, Adolor and GSK desire to amend the Agreement with respect to FTE Requirements for POI Products on and after January 1, 2009, among other things.

NOW, THEREFORE, in consideration of the foregoing premises and the representations, covenants and agreements contained herein, Adolor and GSK, intending to be legally bound, hereby agree as follows:

1. Capitalized terms used herein and not otherwise defined shall have the meanings given to them in the Agreement.

2. Schedule 5.7 to the Agreement is hereby deleted in its entirety.

3. Notwithstanding anything set forth in Section 5.7 of the Agreement, the Parties acknowledge and agree that only the following shall apply with respect to the quantity of Sales Representative FTEs deployed by each Party for POI Product beginning on January 1, 2009:

With respect to POI Product in the United States, the Joint U.S. Marketing Team shall determine the targeted number of total Sales Representative FTEs to be deployed by each Party in the United States during each Calendar Year (“Sales Representative FTE Requirements”); provided, however that during each Calendar Year of the period beginning on January 1, 2009 and continuing through June 30, 2011 (the “Post-Launch Period”), the Sales Representative FTE Requirements for POI Product in the United States shall be, in the aggregate, as follows:

With respect to GSK: A minimum of [**] FTEs, pro rated as applicable.



With respect to Adolor: A minimum of [**] FTEs, pro rated as applicable; provided, however, that (1) during the period January 1, 2009 through December 31, 2009, Adolor’s Sales Representative FTE Requirements shall be [**] FTEs, pro rated as applicable and (2) at any time during the Post-Launch Period, Adolor may, at its sole discretion, determine to [**] employee FTEs to satisfy its Sales Representative FTE Requirements contained in this paragraph.

During the Post-Launch Period, the Parties also acknowledge and agree that:

1. The Sales Representatives to be deployed by GSK in the United States to Co-Promote POI Product shall be those GSK employees referred to internally by GSK as critical care support “Account Managers,” all of whom shall be hospital based or have hospital system account responsibility. For clarity, GSK will not be obligated to deploy Hospital Account Managers, Oncology Account Managers or Surgical Account Managers, as provided in Amendment No. 2.

2. GSK shall, in its discretion, provide supplemental support to Co-Promote the POI Product in the United States in the form of “Strategic Account Managers” and/or “Kaiser Account Managers” (collectively, the “Special Account Managers”).

3. Adolor shall use commercially reasonable efforts to make up to [**] available to support the Co-Promotion efforts of the GSK Account Managers and Special Account Managers with respect to the POI Product in the United States.

GSK agrees that it shall launch a sales incentive program providing for cash incentive compensation payments to GSK Sales Representatives for sales during the first six (6) months of 2009, in accordance with the program detailed in Exhibit A hereto.

GSK agrees that, with respect to the [**] set aside for distribution by GSK under the GSK 2008 Entereg® Incentive Compensation Plan set forth in Exhibit B to this Amendment No. 4 (the "2008 Program"), GSK will pay in cash to Adolor within [**] days after the end of the first Calendar Quarter of 2009 an amount, to the extent such amount is positive (i.e., greater than zero U.S. dollars (U.S. $0)), equal to the following: (1) the difference between [**] and the aggregate amount distributed by GSK to its Sales Representatives in accordance with the terms of the 2008 Programs, less (2) an amount calculated as the aggregate incentive compensation amount made available by Adolor for distribution to Adolor Sales Representatives for sales and hospital registrations during the Launch Period (the "Adolor Incentive Compensation Plan") less the amount actually distributed by Adolor to the Adolor Sales Representatives in accordance with the Adolor Incentive Compensation Plan.

Period Subsequent to the Post-Launch Period

If for any consecutive twelve (12) month period during the time period beginning on July 1, 2011 and continuing until the earlier of (i) the date that is ten (10) years after First Commercial Sale of the first POI Product in the United States, or (ii) the date of the

[**] Certain information on this page has been omitted and filed separately with the Commission. Confidential treatment has been requested with respect to the omitted portions.



expiration or termination of the last Valid Claim of a Patent Right covering such POI Product in the United States (each twelve (12) month period is referred to herein as the "Post-Launch Year"), Net Sales for the POI Product in the United States for the immediately preceding consecutive twelve (12) month period are [**], the Parties acknowledge and agree that during such Post-Launch Year, the Sales Representative FTE Requirements for POI Product in the United States shall be, in the aggregate, as follows:

With respect to GSK: A minimum of [**] FTEs, pro rated as applicable;

With respect to Adolor: For such Post-Launch Year, a minimum of [**] of the FTEs provided by GSK during the same Post-Launch Year, pro rated as applicable; provided, however that (1) in no event shall Adolor be required to provide [**] during any Post-Launch Year and (2) Adolor may, at its sole discretion, determine to [**] satisfy its Sales Representative FTE Requirements during any Post-Launch Year.

For each Post-Launch Year, if Net Sales for the POI Product in the United States for the immediately preceding consecutive are [**], the Parties will negotiate in good faith the Sales Representative FTE Requirements for the POI Product for the then current Post-Launch Year

Unless otherwise agreed to by the Parties, a Party shall not be required in any Calendar Year after January 1, 2009 to deploy more than the applicable Sales Representative FTE Requirements set forth in this Paragraph 3. with respect to the POI Product and, notwithstanding anything to the contrary in the Agreement, [**] of the Agreement shall not apply to such requirement for agreement.

4. Section 5.8 of the Agreement is hereby amended as follows:

Each Party shall offer Incentive Compensation to its Sales Representatives with respect to the sale of the POI Product in the United States for each Calendar Year during the Post-Launch Period. Such incentive schemes shall be adopted by each Party in a manner consistent with the way in which other incentive schemes are adopted within their respective organizations; provided, however, that: the Incentive Compensation available to be earned for the POI Product by an Account Manager who Details the POI Product shall be [**] of the Incentive Compensation available to be earned by such Account Manager, further provided, however, that (x) GSK will not provide an incentive greater than the Incentive Compensation for the POI Product for any other product detailed by the Account Manager who also Detail the POI Product and (y) in the event that GSK [**] Account Managers who are responsible for Detailing the POI Product, then the Incentive Compensation payable by GSK to Hospital Account Managers shall be no less than [**] of the total Incentive Compensation available to such Hospital Account Managers.

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Each Party shall notify the other Party, prior to the commencement of each Calendar Year during the Term, of the structure, formula and relative competitiveness of each Party's incentive compensation arrangements with respect to the POI Product for its Sales Representatives (having regard to other such arrangements adopted by GSK, Adolor, or other companies in the pharmaceutical industry for a company similar in size and scope to such Party).

5. Notwithstanding anything set forth in Section 6.3.4(b) of the Agreement, GSK and Adolor agree that in the event that [**] of its Sales Representative FTEs (or FTE requirements) as set forth in this Amendment No. 4, then the Defaulting Party's share of the Adolor Product Marketing Contribution shall be [**] that the Defaulting Party's actual number of Sales Representatives FTEs is [**] of the Defaulting Party's Sales Representative FTE Requirements and the other Party's share of the Adolor Product Marketing Contribution shall be [**]. If a Party is a Defaulting Party for the POI Product [**] then the Adolor Product Marketing Contribution shall be [**] for the other Party, by [**]. In the event a

Party fails to deploy at least eighty percent (80%) of its Sales Representative FTE Requirements (or FTE Requirements) in a Calendar Year, that Party shall be [**]

6. GSK agrees that it will pay in cash to Adolor on or before February 27, 2009 an amount equal to eight million four hundred twenty-five thousand U.S. dollars (US$8,425,000) in full and complete satisfaction of its obligations under Section 11.1 of the Agreement.

7. This Amendment No. 4 shall be construed, and the respective rights of the Parties determined, according to the substantive law of the State of Delaware notwithstanding the provisions governing conflict of laws under such Delaware law to the contrary.

8. This Amendment No. 4 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. This Amendment No. 4 may be executed by facsimile signatures, which signatures shall have the same force and effect as original signatures.

9. Except as set forth in this Amendment No. 4, the Agreement shall remain in full force and effect, except that each reference to the "Agreement" or words of like import in the Agreement will mean and be a reference to the Agreement as amended by this Amendment No. 4.

[Signature Page Follows]

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IN WITNESS WHEREOF, duly authorized representatives of the Parties have duly executed this Amendment No. 4 to Collaboration Agreement as of the Effective Date.

GLAXO GROUP LIMITED

By:

/s/ Paul Williamson

Name: Paul Williamson

Title:

For and on behalf of

Edinburgh Pharmaceutical Industries Limited

Corporate Director

ADOLOR CORPORATION

By:

/s/ Michael R. Dougherty

Name: Michael R. Dougherty

Title: President and Chief Executive Officer



EXHIBIT A

[**]

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EXHIBIT B

GSK 2008 Entereg® Incentive Compensation

[**]

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