Current Agreements

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First amendment to co-development and licensing agreement for naproxen and esomeprazole combination for pain

AstraZeneca
Pozen

Sep 06 2007

First amendment to co-development and licensing agreement for naproxen and esomeprazole combination for pain

Companies:	AstraZeneca Pozen
Announcement date:	Sep 06 2007
Related contracts:	Co-development and licensing agreement for Vimovo (naproxen and esomeprazole combination) for pain Amendment to co-development and licensing agreement for naproxen and esomeprazole combination for pain Amendment to co-development and licensing agreement for naproxen and esomeprazole combination for pain Second amendment to co-development and licensing agreement for naproxen and esomeprazole combination for pain

Details

Announcement date:	Sep 06 2007
Start date:	Sep 06 2007
Industry sectors:	Bigpharma Pharmaceutical Drug delivery
Therapy areas:	Central Nervous System » Pain Musculoskeletal » Arthritis » Osteoarthritis Musculoskeletal » Arthritis » Rheumatoid arthritis
Technology types:	Drug delivery Small molecules
Deal components:	Co-development Licensing
Stages of development:	Phase III Formulation
Geographic focus:	Worldwide

Financials

Termsheet

Not available.

Press Release

Not available.

Filing Data

Not available.

Contract

AMENDMENT NO. 1 TO THE COLLABORATION AND LICENSE AGREEMENT

This Amendment No. 1 to the Collaboration and License Agreement (this “Amendment”) is made effective as of September 6, 2007 (the “Amendment Effective Date”) by and between POZEN INC., a Delaware corporation having offices at 1414 Raleigh Road, Suite 400, Chapel Hill, North Carolina (“POZEN”), and ASTRAZENECA AB, a Swedish corporation having an office at SE-431 83, Mölndal, Sweden (“AstraZeneca”). POZEN and AstraZeneca may be referred to herein individually as a “Party,” or collectively as the “Parties.”

RECITALS

A. POZEN and AstraZeneca entered into that certain Collaboration and License Agreement, dated as of August 1, 2006, and effective as of September 7, 2006 (as amended hereby, the “Agreement”).

B. POZEN and AstraZeneca desire to amend the Agreement.

NOW, THEREFORE, in consideration of the mutual promises and covenants hereinafter set forth, the parties hereto agree to amend the Agreement as follows:

Capitalized terms used herein have the respective meanings assigned to them as defined in this Amendment. Other capitalized terms not otherwise defined herein have the meaning ascribed thereto in the Agreement.

ARTICLE 1 - AMENDMENTS

1.1 Amendment to Section 1.77. Section 1.77 of the Agreement is hereby amended and restated to read in its entirety as follows:

""***, ***, ***, and *** Studies" means the ***, ***, ***, and *** Studies described in the U.S. Development Plan, each of which may be referred to individually (e.g., the "*** Study") to describe that particular study in the U.S. Development Plan."

1.2 Amendment to Section 1.82(b). Section 1.82(b) of the Agreement is hereby amended and restated to read in its entirety as follows:

*** Portion for which confidential treatment requested.

"(b) the receipt of notice from the FDA, EMEA or other Regulatory Authority in the EU that successful completion of the Budgeted Development Activities and Core Development Activities would be insufficient to achieve NDA Approval of the Initial POZEN Product without the performance of Additional Development Activities that are not included in the Budgeted Development Activities and that would be reasonably expected, in the aggregate, to either (i) delay the anticipated date of NDA Approval of the Initial POZEN Product by more than *** *** past the dates set forth in the Initial U.S. Development Plan Timeline or for any country of the EU set forth in the Initial ROW Development Plan Timeline, or (ii) require AstraZeneca to spend more than an aggregate of $*** to perform; provided that, the cost of any such Additional Development Activities conducted pursuant to the *** Study or *** Study shall not be counted toward such $*** limit;"

1.3 Amendment to Section 1.104. Section 1.104 of the Agreement is hereby amended and restated to read in its entirety as follows:

“1.104 “TPP Studies” means the studies entitled ***, ***, *** in the U.S. Development Plan.”

1.4 Amendment to Section 2.2.1(a). Section 2.2.1(a) of the Agreement is hereby amended and restated to read in its entirety as follows:

"(a) Membership. In addition to members designated by AstraZeneca, the GPT shall have up to three (3) representatives designated by POZEN, attending, observing and participating in meetings of the GPT at POZEN’s expense, such representatives having the relevant experience and skill appropriate for service on such team. Attendance of POZEN representatives at GPT meetings shall be agenda-driven, as determined in the sole discretion of AstraZeneca. AstraZeneca shall be entitled to have as many representatives serve as members of the GPT as it desires. POZEN may replace its representatives on the GPT at any time upon written notice to AstraZeneca. AstraZeneca shall provide POZEN with office space at its facilities for such representatives to facilitate such participation; provided, that such representatives shall comply with all policies and reasonable restrictions imposed by AstraZeneca and provided to POZEN in writing. Upon prior written consent of AstraZeneca, which consent will not be unreasonably withheld, a reasonable number of employees, consultants, representatives or advisors of POZEN who are not POZEN’s GPT representatives may attend GPT meetings as observers; provided, that such persons shall comply with all policies and reasonable restrictions imposed by AstraZeneca and provided to POZEN in writing."

1.5 Amendment to Section 2.2.1(c). Section 2.2.1(c) of the Agreement is hereby amended and restated to read in its entirety as follows:

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"(c) Meetings. The GPT will hold meetings when called by the GPT Chair. Meetings may be held in person or by means of telecommunication (telephone, video, or web conference). Face-to-face GPT meetings that require POZEN attendance will be convened on an as-needed basis as mutually agreed by AstraZeneca and POZEN, but in any event, at least twice per annum. The location of these meetings, will be based on business requirements and determined by mutual agreement between AstraZeneca and POZEN. Following any GPT meeting, the GPT Chair will be responsible for preparing and issuing minutes of such meeting within fifteen (15) Business Days thereafter. When POZEN has participated in the meeting, such minutes will not be finalized until a representative of the GPT designated by each Party has reviewed and confirmed the accuracy of such minutes in writing. If a disagreement regarding the accuracy of such minutes cannot be resolved, the minutes will reflect such disagreement."

1.6 Amendment to Section 3.3.3. In Section 3.3.3 of the Agreement, the phrase "(including upon finalization of the scope of the *** and *** studies)" is hereby deleted and replaced with the following:

"(including upon the finalization of the design of the ***, ***, ***, and *** Studies, and any agreed Additional New Studies referenced in Section 1.15 of this Amendment)"

1.7 Amendment to Section 8.2. Section 8.2 of the Agreement is hereby amended and restated to read in its entirety with the following:

“8.2 Development Milestone Payments. Subject to the terms and conditions of this Agreement, including without limitation the last paragraph of this Section 8.2 (Development Milestone Payments), AstraZeneca will pay to POZEN the following one-time, non-creditable, non-refundable payments with respect to the first achievement of the corresponding events with a POZEN Product.

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Milestone Event Milestone Payment

1. Execution of this Amendment. $10,000,000

2. Achievement of *** ***, and achievement of ***. $20,000,000

3. Notification by the FDA that it has accepted the first U.S. NDA submission for a POZEN Product in accordance with Section 4.1.1 (Regulatory Responsibilities Inside the U.S.). $***

4. Receipt of the first NDA Approval for a POZEN Product in the U.S. $***

5. *** of the first *** to *** a *** in a *** that includes *** and/or *** (if available) at an *** of the POZEN Product *** than the *** of (a) the *** for a *** in such ***, or (b) ***. $***

"POZEN shall notify AstraZeneca in writing upon the achievement of Milestones Events 3 and 4 above, and shall provide AstraZeneca with reasonable evidence that such Milestone Events have been achieved. The payments due with respect to achievement of each Milestone Event shall be due and payable within *** (***) days after (i) AstraZeneca receives notification from POZEN of the achievement of Milestone Events #3 and 4, and (ii) the occurrence of the Milestone Event #5. The Parties agree that Milestone Event #2 above has been achieved as of the Amendment Effective Date, and that development Milestone Event #1 previously set forth in Section 8.2 the Agreement will be deemed to have been achieved through the performance and achievement of Milestone Event #2 above. Milestone Events #1 and 2 shall be payable within *** (***) Business Days after the execution of this Amendment. The date on which any such milestone payment is due and payable in accordance with the preceding sentence is hereinafter referred to as the “Milestone Due Date.”

*** Portion for which confidential treatment requested.

"Each milestone payment identified in this Section 8.2 (Development Milestone Payments) shall be payable one time only, irrespective of the number of POZEN Products that achieve the applicable Milestone Event. Notwithstanding the foregoing, if a Milestone Event for which a payment would be due under this Section 8.2 (Development Milestone Payments) is achieved, but AstraZeneca provides notice to POZEN that it is exercising its right to terminate this Agreement pursuant to Section 12.3 (Termination for Material Breach), 12.4 (Termination for Cause) or 12.5 (Termination at Will) prior to the applicable Milestone Due Date for such Milestone Event, then such milestone payment will not be payable; provided, that AstraZeneca complies with its obligations under Section 12.6.3(b) (Effect of Termination for Cause or Material Breach) or 12.6.4

(Effect of Termination at Will) if applicable."

1.8 Amendment to Section 8.3. Section 8.3 of the Agreement is hereby amended and restated and replaced in its entirety with the following:

"8.3 Sales Milestone Payments. Subject to the terms and conditions of this Agreement, AstraZeneca will pay to POZEN the following one-time, non-creditable, non-refundable payments within thirty (30) days following the achievement of the corresponding events described in the table below.

Milestone Event Milestone Payment

1.End of first calendar year during which aggregate annual Net Sales of Products were at least $*** $***

2.End of first calendar year during which aggregate annual Net Sales of Products were at least $*** $***

3.End of first calendar year during which aggregate annual Net Sales of Products were at least $*** $***

4.End of first calendar year during which aggregate annual Net Sales of Products were at least $*** $***

"Each milestone payment identified in this Section 8.3 (Sales Milestone Payments) shall be payable one time only, and not for each time that the "annual Net Sales" of Products exceeds a specified amount."

1.9 Amendment to Section 8.4.1. Section 8.4.1 of the Agreement is hereby amended and restated and replaced in its entirety with the following:

"8.4.1 Royalty Rate. Subject to the terms and conditions of this Agreement, AstraZeneca will pay to POZEN royalties based on the aggregate annual Net Sales of Products sold by AstraZeneca, its Affiliates or Sublicensees, at the rates set forth below:

"(a) ***% of the portion of aggregate Net Sales of Products sold in the United States during a calendar year.

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"(b) For Net Sales of Products sold outside the United States:

"(i) For Net Sales ***:

"1. ***% of the portion of aggregate Net Sales of Products during a calendar year that is equal to or less than $***;

"2. ***% of the portion of aggregate Net Sales of Products during a calendar year that is greater than $*** but equal to or less than $***; and

"3. ***% of the portion of aggregate Net Sales of Products during a calendar year that is greater than $***."

"(ii) For Net Sales ***:

"1. ***% of the portion of aggregate Net Sales of Products during a calendar year that is equal to or less than $***; and

"2. ***% of the portion of aggregate Net Sales of Products during a calendar year that is greater than $***.

"(c) Notwithstanding the foregoing provisions of this Section 8.4.1 (Royalty Rate), if a *** is sold in one or more countries where ***, the total royalties owed for Products shall be determined ***, according to the following calculations:

"(i) *** percent (***%) of the total Net Sales of the *** sold in any country shall be added to the total Net Sales of the *** (the resulting amount being the "Segregated Net Sales"), and the applicable royalty rates set forth in Section 8.41(a) and (b) shall be applied to the Segregated Product Net Sales (the resulting amount being the "Segregated Royalty Amount");

"(ii) the applicable royalty rates set forth in Section 8.4.1(a) and (b) shall be applied to the remaining *** percent (***%) of the total Net Sales of the *** (the resulting amount being the "Remaining Royalty Amount"); and

"(iii) the amount owed by AstraZeneca shall be equal to the Segregated Royalty Amount plus the Remaining Royalty Amount.

*** Portion for which confidential treatment requested.

“(iv) If *** are also sold in a country where there are at least *** being sold, then the calculations above shall be applied similarly to each such ***, such that *** percent (***%) of the Net Sales of each *** shall be added to the Segregated Royalty Amount, and the remaining *** percent (***%) of each *** shall be combined only with the remaining *** percent (***%) of Net Sales of the other *** (i.e., ***) that are being sold in other countries. The example set forth in Schedule 8.4.1 illustrates the application of this 8.4.1(c).”

1.10 Amendment to Section 8.4.3. Section 8.4.3 of the Agreement is hereby amended and restated and replaced in its entirety with the following:

"8.4.3 Rate Step Down For Competing Product Entrants. With respect to any particular Product and country, if in any Calendar Quarter there is a Market Reduction of such Product (based on prescription market data published by IMS Health, Scott-Levin, or such other industry standard source as the Parties may agree), then the royalty rates which would otherwise apply to Net Sales of such Product in such country during such Calendar Quarter will be reduced to *** percent (***%) of the rates set forth in Section 8.4.1 (Royalty Rate); provided, that in no event will *** (resulting in *** in the ***, and *** and *** for *** of the ***; and *** and *** for *** of the ***). Such reduced royalty rates will continue in effect, on a Product-by-Product and country-by-country basis, until expiration of the applicable Royalty Term. As used in this Section 8.4.3, the term “Market Reduction” of a Product in a Calendar Quarter occurs when (i) *** by *** for such *** by *** in such *** of the *** in such *** of the *** and (ii) the *** the *** in such *** are *** to the *** in which the *** of a *** occurred. The example set forth in Schedule 8.4.3 illustrates the application of this Section 8.4.3."

1.11 Amendment to Section 12.9. Section 12.9 of the Agreement is hereby amended and restated and replaced in its entirety with the following:

"12.9 Post Termination Royalties. Upon any termination of this Agreement pursuant to (i) Section 12.4.1 (Termination for Cause) and *** for the failure of the *** described in the ***, to ***, or (ii) Sections 12.4.1 and *** then, for a period of *** following any such termination, AstraZeneca shall pay POZEN a royalty on Net Sales of Products sold by AstraZeneca, its Affiliates or Sublicensees in an amount equal to *** percent (***%) of the royalty amount calculated according to Section 8.4.1 (Royalty Rate), in accordance with the terms and conditions of Sections 8.4 (Royalties) through 8.7 (Taxes) of this Agreement."

1.12 Amendment to U.S. Development Plan. The U.S. Development Plan of the Agreement is hereby amended and restated to read in its entirety as set forth in Exhibit B attached hereto.

1.13 Amendment to US. Development Plan Timeline. The U.S. Development Plan Timeline of the Agreement is hereby amended and restated to read in its entirety as set forth in Exhibit C attached hereto.

*** Portion for which confidential treatment requested.

1.14 Amendment to Exhibit F (TPP Profile and TPP Studies). Exhibit F of the Agreement is hereby amended and restated to read in its entirety as set forth in Exhibit F attached hereto.

1.15 Amendment to Schedules 8.4.1 and 8.4.3. Schedule 8.4.1 and Schedule 8.4.3of the Agreement is hereby amended and restated to read in its entirety as set forth in Schedule 8.4.1 and Schedule 8.4.3 attached hereto.

1.16 Termination of ***. Promptly after execution of this Amendment, POZEN will terminate *** ***, including ***. POZEN shall terminate these activities in a professional manner and will use reasonable efforts to minimize termination expenses. AstraZeneca will be responsible for the costs associated with the termination of such activities in accordance with Section 3.3.3 (Expenses) of the Agreement. Due to the extraordinary nature of these expenses, AstraZeneca will use commercially reasonable efforts to pay POZEN within *** (***) days, but in any event within *** (***) days, following receipt of invoice for such termination costs. To allow rapid approval of the invoice, copies of vendor documentation of work performed and billing will be included in the invoice.

1.17 New Studies.

(a) As promptly as practicable following the execution of this Amendment, the Parties agree to update the U.S. Development Plan to reflect *** of the ***, in a manner that is consistent with *** in the ***. AstraZeneca will pay POZEN for its costs for *** in accordance with Section 3.3.3 of the Agreement (Expenses); provided, however, that in no event will *** for the *** in the ***. The Parties will ***. The Parties will use Diligent Efforts to *** and to *** in the *** for the *** within the ***.

(b) To the extent that *** in the ***, the GPT will agree upon *** of the *** provided, however, that *** for the *** in the ***, if any, may include, but would not be limited to, *** and a *** of the *** of the ***. If the *** in the *** as an ***. AstraZeneca will conduct *** for the *** taking into account *** to the *** of the ***. Assessments *** for this purpose will include ***. Representatives from POZEN will participate *** to the ***. AstraZeneca will be obligated to *** if the ***. In the event that AstraZeneca’s and POZEN’s representatives on the GPT *** of a *** will be *** of the *** to be *** of the ***. AstraZeneca will conduct ***, but in any event will ***.

(c) *** of the *** but if ***. *** of the ***. Promptly after execution of this Amendment by both Parties, the Parties will *** for the *** and will *** after the *** of the ***. The expenses *** in the ***.

(d) AstraZeneca will ***, at AstraZeneca's expense, *** with the *** of the *** in the *** of the *** in the ***.

*** Portion for which confidential treatment requested.

1.18 Operating Principles. Promptly after the Amendment Effective Date, the GPT will review, discuss and adopt new operating principles consistent with the draft principles attached hereto as Exhibit G that will guide the conduct of the GPT and clinical subteam meetings. To the extent there is any conflict between the attached operating principles and the terms and conditions of the Agreement (as amended by this Amendment), then the Agreement will control.

ARTICLE 2 – REFERENCE TO AND EFFECT ON THE AGREEMENT

2.1 Reference to Agreement. Upon and after the effectiveness of this Amendment, each reference in the Agreement to "this Agreement," "hereunder," "hereof" or words of like import referring to the Agreement shall mean and be a reference to the Agreement as modified and amended hereby.

2.2 Effectiveness of Agreement. The amendments set forth above shall not be effective until execution and delivery of this Amendment by both parties. Except as specifically amended above, the Agreement, as amended, is and shall continue to be in full force and effect and is hereby in all respects ratified and confirmed and shall constitute the legal, valid, binding and enforceable obligations of the parties.

2.3 No Waiver. The execution, delivery and effectiveness of this Amendment shall not operate as a waiver of any right, power or remedy of either Party under the Agreement, nor constitute a waiver of any provision of the Agreement.

ARTICLE 3 - MISCELLANEOUS

3.1 Governing Law; Dispute Resolution. Section 15.4 of the Agreement governs any dispute arising out of or related to this Amendment.

3.2 Notices. All notices or other communications that are required or permitted hereunder will be made according to Section 15.5 of the Agreement.

3.3 Headings. The headings for each Article and Section in this Amendment have been inserted for convenience of reference only and are not intended to limit or expand on the meaning of the language contained in the particular Article or Section.

3.4 Counterparts. This Amendment may be executed in two (2) or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

3.5 No Strict Construction. This Amendment has been submitted to the scrutiny of, and has been negotiated by, both Parties and their counsel, and will be given a fair and reasonable interpretation in accordance with its terms, without consideration or weight being given to any such terms having been drafted by any Party or its counsel. No rule of strict construction will be applied against either Party.

*** Portion for which confidential treatment requested.

IN WITNESS WHEREOF, the Parties have executed this Amendment in duplicate originals by their duly authorized representatives as of the Amendment Effective Date.

POZEN INC.

POZEN INC. ASTRAZENECA AB

By: /s/ John R. Plachetka By: /s/ Olof Ljungstrand

Print Name: John R. Plachetka, Pharm.D. Print Name: Olof Ljungstrand

Title: Chairman, President and Chief Executive Officer Title: Sr. Counsel, Manager Legal Department Molndal

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(Exhibit A to Agreement Unchanged)

*** Portion for which confidential treatment requested.

EXHIBIT B - U.S. DEVELOPMENT PLAN

Study Number Title Endpoints Design/Comment Responsibility to Conduct/Pay

NONCLINICAL:

*** *** *** *** ***

*** *** *** *** ***

PHASE 1

*** *** *** *** ***

*** *** *** *** ***

*** *** *** *** ***

*** *** *** *** ***

*** *** *** *** ***

*** *** *** *** ***

*** *** *** *** ***

*** *** *** *** ***

PHASE 2 ***--

*** *** *** *** ***

*** *** *** *** ***

*** *** *** *** ***

*** Portion for which confidential treatment requested.

Study Number Title Endpoints Design/Comment Responsibility to Conduct/Pay

PHASE 3

*** *** *** *** ***

*** *** . *** *** ***

*** *** *** *** ***

*** *** *** *** ***

*** *** . *** . *** ***

*** *** *** . *** ***

*** *** *** *** ***

*** Portion for which confidential treatment requested.

EXHIBIT C

U.S. DEVELOPMENT PLAN TIMELINE ***

*** Portion for which confidential treatment requested.

EXHIBIT F

TPP STUDIES

*** *** *** *** *** ***

*** *** *** *** *** ***

*** *** *** *** *** ***

*** *** *** *** *** ***

***

*** Portion for which confidential treatment requested.

EXHIBIT G

OPERATING PRINCIPLES

GPT Meetings:

***.

CPT Meetings:

***

Face-to-Face GPT Meetings:

***.

*** Portion for which confidential treatment requested.

SCHEDULE 8.4.1

(i) For Products sold outside the U.S.: In ***, AstraZeneca has Net Sales for *** in country Y in the amounts of $*** for the first Product and $*** for the ***. In *** in all other countries of the Territory (outside the U.S.) the total Net Sales of Products are $*** million, and Net Sales do not occur in any other country for ***. The calculation of the Segregated Royalty Amount would be:

*** *** *** *** *** *** ***

*** *** *** *** *** *** ***

*** *** ***

*** ***

The calculation of the Remaining Royalty Amount would be:

*** *** *** *** ***

*** *** *** *** ***

The total royalty payable for all Net Sales in the Territory (outside of the US) would be $***

(ii) For Products sold in the U.S.: In ***, AstraZeneca has Net Sales for *** in the U.S. in the amounts of $*** for the first Product and $*** for ***. The total royalty payable for all U.S. Net Sales would be $*** (Net Sales for *** would be charged a royalty of ***%).

*** Portion for which confidential treatment requested.

SCHEDULE 8.4.3

(i) For Products sold outside the U.S.: Assume that in the *** the total ex-U.S. Net Sales of Products are $***n. In that example the following royalties would be payable prior to application of any Market Reduction:

*** *** *** *** ***

*** *** *** *** ***

*** *** *** *** ***

*** *** *** *** ***

*** *** *** *** ***

Assume that in country X during the first *** a Competing Product had commenced sales in country X, and in the first *** achieved the criteria to trigger a Market Reduction under Section 8.4.3 (Rate Step Down for Competing Product Entrants). Assume that Net Sales of Products in country X were *** in ***.

***

*** *** *** *** *** ***

*** *** *** *** *** ***

*** *** *** *** *** ***

*** *** *** *** *** ***

*** *** *** ***

The Market Reduction in country X would result in a reduction to royalties payable of an amount equal to $*** ($***). Therefore the total ex-U.S. royalty payable for Product Net Sales would be $***

(ii) For Products sold in the United States:

Assume that in the U.S. during the first *** a Competing Product had commenced sales in the U.S., and in the first *** achieved the criteria to trigger a Market Reduction under Section 8.4.3 (Rate Step Down for Competing Product Entrants). Assume that Net Sales of Products in the U.S. were $*** in ***. The Market Reduction is applied to Net Sales in the U.S. by reducing the royalty rates set forth in Section 8.4.1(a) by ***%. The total royalty payable for all U.S. Net Sales would be $*** (net sales would be charged at a royalty of ***%).

*** Portion for which confidential treatment requested.