Current Agreements

Dealdoc

Third amendment to development and licensing agreement for oral parathyroid hormone

SmithKline Beecham
Unigene Laboratories

Sep 23 2004

Third amendment to development and licensing agreement for oral parathyroid hormone

Companies:	SmithKline Beecham Unigene Laboratories
Announcement date:	Sep 23 2004
Related contracts:	Development and licensing agreement for oral parathyroid hormone (terminated) First amendment to development and licensing agreement for oral parathyroid hormone Second amendment to development and licensing agreement for oral parathyroid hormone Fourth amendment to development and licensing agreement for oral parathyroid hormone Fifth amendment to development and licensing agreement for oral parathyroid hormone Sixth amendment to development and licensing agreement for oral parathyroid hormone Amended and restated development and licensing agreement for oral parathyroid hormone

- Details
- Financials
- Termsheet
- Press Release
- Filing Data
- Contract

Details

Announcement date:	Sep 23 2004
Start date:	Sep 23 2004
Industry sectors:	Bigpharma Pharmaceutical
Therapy areas:	Metabolic Musculoskeletal » Osteoporosis
Technology types:	Biological compounds Drug delivery Peptides
Deal components:	Development Licensing
Stages of development:	Phase II
Geographic focus:	Worldwide

Financials

Termsheet

Not available.

Press Release

Not available.

Filing Data

Not available.

Contract

AMENDMENT NO.3 TO

LICENSE AGREEMENT

DATED AS OF APRIL 13, 2002

BY AND BETWEEN

UNIGENE LABORATORIES, INC.

AND

SMITHKLINE BEECHAM CORPORATION

This Amendment No. 3 (“Amendment No. 3”) dated as of 23 Sept., 2004 (“Amendment Date”), to the License Agreement, entered into as of the 13th of April, 2002, and amended on January 16, 2003 and October 14, 2003 (referred to hereinafter as the “Agreement”), by and between Unigene Laboratories, Inc. (“Unigene”), a Delaware corporation, and SmithKline Beecham Corporation, a GlaxoSmithKline company (“GSK”), a Pennsylvania corporation.

RECITALS:

WHEREAS, GSK and Unigene entered into the Agreement to provide for the license grant by Unigene to GSK of certain Licensed Technology (as defined in the Agreement) to discover, develop, make, have made, market, sell and import certain Licensed Products (as defined in the Agreement) throughout the world under the Unigene Patent Rights (as defined in the Agreement) and Unigene Know-How (as defined in the Agreement); and

WHEREAS, GSK and Unigene have also entered into a Phase I Clinical Manufacture and Supply Agreement dated November 20, 2002 (the “Phase I Agreement”); and

WHEREAS, pursuant to Section 11.10 of the Agreement, the Parties to the Agreement may, by written instruments specifically referring to and executed in the same manner as the Agreement, amend the Agreement; and

WHEREAS, the Parties hereto desire to amend the Agreement as provided herein, and any capitalized terms used herein shall have the meaning set forth in the Agreement;

NOW THEREFORE, for and in consideration of the premises and the mutual promises and benefits contained herein, GSK and Unigene hereby agree as follows:

1. Exhibit C to the Phase I Agreement (Cost of Goods) is hereby amended to add the 2004 and 2005 Cost of Goods set forth in Appendix A to this Amendment No. 3.

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2. Exhibit A to the Phase I Agreement (Current Manufacturing Process) is hereby amended by replacing the existing Process Flow Diagram-PTH with the Process Flow Diagram-PTH set forth in Appendix B to this Amendment No. 3.

3. Appendix B to the Agreement (the WorkPlan) is hereby amended to add the activities regarding API set forth in Appendix C to this Amendment No. 3 at the FTE costs set forth in Appendix C to this Amendment No. 3.

4. Article 1 of the Phase I Agreement is hereby amended to add the following new section:

1.25. Commercially Reasonable Efforts means, with respect to a Party, the efforts and resources which would be used (including without limitation the promptness in which such efforts and resources would be applied) by that Party consistent with its normal business practices, which in no event shall be less than the level of efforts and resources standard in the pharmaceutical industry for a company similar in size and scope to such Party, with respect to a product or potential product at a similar stage in its development or product life taking into account efficacy, safety, commercial value, the competitiveness of alternative products of third parties that are in the marketplace or under development, and the patent and other proprietary position of such product.

5. Section 2.3 of the Phase I Agreement is hereby amended by replacing the current language with the following language in lieu thereof:

Unigene shall supply GSK at least four (4) batches of API (two (2) batches shall be cGMP grade and two (2) shall be process development batches). Unigene shall use its Commercially Reasonable Efforts to achieve a fermentation batch yield of ***. The Parties agree and acknowledge that one Changeover shall be required before supply of the first batch. Any batches in excess of four (4) shall be supplied pursuant to the terms of this Agreement, including but not limited to, Article 4.6(b).

6. Article 2 of the Phase I Agreement is hereby amended to add the following new section:

2.9. GSK Equipment. In order to support the manufacture of GSK material requirements, GSK will purchase and Unigene will install *** Columns, including spare parts therefore (the "Columns"), in the facility. The Parties agree that the Columns are the property of GSK and will be used solely for the purpose of manufacturing GSK material requirements. Following receipt of written notification from GSK that Unigene will no longer be producing API for GSK for any purpose, GSK will notify Unigene of whether GSK intends to: a) keep the Columns and have them removed from the Unigene facility(ies) or, b) offer the Columns for sale to Unigene. The parties will negotiate in good faith a price for the purchase of the Columns by Unigene, said price not to exceed the depreciated value of the Columns (straight-line depreciation over ten (10) years) minus

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Unigene's actual FTE costs for their assembly and installation/operation qualification. In the event GSK elects to keep the Columns and have them removed from the Unigene facility or, if the parties are unable to agree on a good faith purchase price, GSK will: a) reimburse Unigene for its actual FTE costs incurred for assembly and installation/operation qualification and, (b) reimburse Unigene for its actual FTE costs of disassembling and unpacking the Columns prior to their return and, c) pay for any associated shipping costs incurred to ship the Columns via a GSK-approved carrier.

7. For the avoidance of doubt, the Parties agree and acknowledge that GSK has ordered the Columns identified in Section 6 of this Amendment and the Columns will be shipped directly to Unigene for installation.

8. Section 11.1 of the Phase I Agreement is hereby is amended to replace the words "twenty-four (24) months" with the words "thirty (30) months."

9. This Amendment No. 3 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.

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

UNIGENE LABORATORIES, INC. SMITHKLINE BEECHAM CORPORATION,

a GlaxoSmithKline Company

By: /s/ Ronald S. Levy

By: /s/ John Knighton

Name: Ronald S. Levy Name: John Knighton

Title: Executive Vice President Title: Director, GSK

Appendix A

COST OF GOODS

The Cost of Goods* for API manufactured pursuant to the Agreement for the 2004 and 2005 calendar years is:

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*

Cost of Goods is subject to revisions as set forth in Article 2 of the Agreement.

Appendix B

CURRENT MANUFACTURING PROCESS – PROCESS FLOW DIAGRAM

PROCESS FLOW DIAGRAM - PTH

Process Steps

Step

Molecular

Form of

Product

Batch Records

Fermentation

1 *** (Shake Flask Inoculum),

*** (Fermentation to

Harvesting)

Harvest

2

***

3 rPTH-*** *** (Capture)

***

4 ***

(Purified PTH)

***

5

***

6

***

7 rPTH

***

8

***

9

***

10 *** (Parathyroid Hormone)

Bulk Parathyroid Hormone

Appendix C

WORKPLAN OF UNIGENE ACTIVITIES AND FTE REQUIREMENTS

ESTIMATED

PERIOD DURATION UNIGENE

STAFF MAXIMUM

COST ($)

DEVELOPMENT ACTIVITY PRIOR TO PHASE II

MANUFACTURING CAMPAIGN

Replacement of *** with *** and Optimization of *** reaction

May 04 –July 04 7 weeks * ** * **

Development of *** to replace *** in process steps *** and ***

July 04 – Sep 04 9 weeks * ** * **

SUB TOTAL

16 weeks * **

TECHNOLOGY TRANSFER[1]

Unigene to work with GSK on validation and technology transfer prior to phase III clinical studies.

TBC * ** * ** * **

Unigene to work with GSK on NDA preparation, validation and technology transfer at or beyond phase III clinical studies.

TBC * ** * ** * **

[1] Timing of technology transfer dependent on manufacturing strategy to be determined. The two options are mutually exclusive and NOT additive.