Current Agreements

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Sixth amendment to development and licensing agreement for oral parathyroid hormone

GSK
Unigene Laboratories

Apr 09 2008

Sixth amendment to development and licensing agreement for oral parathyroid hormone

Companies:	GSK Unigene Laboratories
Announcement date:	Apr 09 2008
Related contracts:	Development and licensing agreement for oral parathyroid hormone First amendment to development and licensing agreement for oral parathyroid hormone Second amendment to development and licensing agreement for oral parathyroid hormone Third 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 Amended and restated development and licensing agreement for oral parathyroid hormone

- Details
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- Termsheet
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- Contract

Details

Announcement date:	Apr 09 2008
Start date:	Apr 09 2008
Industry sectors:	Bigpharma Pharmaceutical
Therapy areas:	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. 6 TO

LICENSE AGREEMENT

DATED AS OF APRIL 13, 2002

BY AND BETWEEN

UNIGENE LABORATORIES, INC.

AND

SMITHKLINE BEECHAM CORPORATION

This Amendment No. 6 (“Amendment No. 6”) dated as of April 9, 2008 (the “Amendment Date”) to the License Agreement dated as of April 13, 2002, as amended on January 27, 2007, January 16, 2003, October 14, 2003, May 27, 2004 and September 23, 2004 (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.

WHEREAS, GSK and Unigene entered into the Agreement to provide for the license grant by Unigene to GSK of certain Licensed Technology to discover, develop, make, have made, market, sell and import certain Licensed Products throughout the world under the Unigene Patent Rights (as defined in the Agreement) and Unigene Know-How; 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 but not defined 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. (a) Unigene shall conduct a research program *** for the Licensed Product *** (the “Research Program”). The Research Program shall ***. Except as otherwise provided herein, the scope, protocols and outcomes of the Research Program shall be solely determined by Unigene, after consultation with GSK, and it is anticipated that the Research Program will be completed within *** from the date hereof (the “Completion Date”). The Research Program shall be *** by Unigene. Unigene shall have the right, in its sole discretion, to terminate the Research Program at any time for any reason. *** Unigene shall provide to GSK all study data, reports and other information generated during the course of the Research Program through the date of termination reasonably necessary *** to determine in its sole discretion *** whether to ***. Such *** period *** to not more than *** upon written notice from *** to *** prior to *** then the Parties will negotiate in good faith ***. If *** then the Parties shall keep it confidential and shall not *** disclose it to any third party during the Term of the Agreement. ***.

(b) In the event that GSK either (i) *** or (ii) *** then Unigene shall have the right to *** the Research Results shall be deemed Unigene Know-How and Unigene Confidential Information as provided in Paragraph 5(b) hereof.

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2. GSK agrees and consents to the use by Unigene of the Licensed Technology for the limited and sole purpose of conducting the Research Program. GSK further agrees to *** providing to Unigene such clinical study results, development batch records, tablets and such other data, documents, materials and samples related to the Research Program as Unigene may reasonably request, ***. *** GSK shall either (i) provide to Unigene the information or materials requested, or (ii) provide a written response setting forth its reasons for failing to deliver any of the requested information or materials.

3. Unigene hereby agrees and acknowledges that *** under the Agreement ***, due or payable for any activities *** conducted pursuant to the Research Program.

4. Immediately upon the completion of the Research Program, *** Unigene shall provide to GSK a written notice of such completion accompanied by sufficient information (including without limitation such final reports) with respect to the results, findings and data generated by the Research Program to enable GSK to ***. Unigene shall also provide GSK with such additional information with respect to the results, findings

and data generated by the Research Program as may be reasonably requested by GSK. ***, GSK shall *** for a purchase price of *** (the “Research Purchase Price”). *** Unigene shall not offer any Third Party rights to the Research Results.

5. (a) In the event that *** GSK shall so notify Unigene *** and all Research Results *** shall automatically be deemed *** Confidenital Information and shall be subject to the rights granted to Unigene in Article 2 and Section 6.2 of the Agreement. The physical transfer of the Research Results by Unigene and the payment of the Research Purchase Price by GSK shall be made ***.

(b) In the event *** if GSK notifies Unigene in writing *** such Research Results *** shall automatically be deemed *** Confidential Information. In such event, Unigene shall have the right to *** and the provisions of *** shall apply as if *** pursuant to Section ***. For the avoidance of doubt, the foregoing *** provision shall be an addition to, and not a replacement of, the *** rights afforded to the Parties in *** of the Agreement.

(c) In the event that *** or *** then within the *** period following the date *** shall have the right to submit to *** written notice that *** becoming effective on the date that is *** days after the date of such *** notice. *** treated as if it *** pursuant to Section *** of the Agreement. For the avoidance of doubt, the foregoing *** provision shall be an addition to, and not a replacement of, the *** rights afforded to the Parties in *** of the Agreement.

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6. Notwithstanding Sections 4 and 5 of this Amendment No. 6, if Unigene provides GSK with any *** data arising from the Research Program prior to the completion of the Research Program, GSK shall have the option, *** to *** acquire all of the then-existing and future Research Results, if any, in exchange for *** prior to completion of the Research Program. GSK may ***. ***, it may elect to require Unigene to continue the Research Program at GSK’s cost and expense. For the avoidance of doubt, if Unigene provides data, reports and other information to GSK upon early termination of the Research Program pursuant to Section 1 above, and GSK ***, then the payment to Unigene *** shall cover transfer to GSK of all Research Results, including any data, reports or other information provided under Section 1 ***.

7. Unigene may in its discretion *** conduct ***. If Unigene conducts such *** GSK may elect to acquire the results thereof, ***. If GSK elects to so acquire such results, ***.

8. Except as specifically provided herein, all other terms and conditions of the Agreement shall remain in full force and effect, and this Amendment No. 6 to the Agreement shall not be construed to amend or waive any provisions of the Agreement except as specifically set forth above.

9. This Amendment No. 6 to the Agreement, and the rights and obligations of the Parties hereunder, shall be construed in accordance with, and governed by the laws of the Commonwealth of Pennsylvania (without regard to its conflict of laws principles).

10. This Amendment No. 6 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.

11. This Amendment No. 6 shall inure to the benefit of and be binding upon GSK and Unigene and their respective successors, heirs and assigns.

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/ Carol G. Ashe

Name: Ronald S. Levy Name: Carol G. Ashe

Title: Executive Vice President Title: Vice President & Secretary