



Current Agreements

Dealdoc

Fifth amendment to development and licensing agreement for oral parathyroid hormone

GSK

Unigene Laboratories

Jan 24 2007

Fifth amendment to development and licensing agreement for oral parathyroid hormone

Companies:	GSK
	Unigene Laboratories
Announcement date:	Jan 24 2007
	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
Related contracts:	Third amendment to development and licensing agreement for oral parathyroid hormone
	Fourth 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

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- [Contract](#)

Details

Announcement date:	Jan 24 2007
Start date:	Jan 24 2007
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. 5 TO

LICENSE AGREEMENT

DATED AS OF APRIL 13, 2002

BY AND BETWEEN

UNIGENE LABORATORIES, INC.

AND

SMITHKLINE BEECHAM CORPORATION

This Amendment No. 5 ("Amendment No. 5") dated as of January 24, 2007 (the "Amendment Date") to the License Agreement dated as of April 13, 2002, as amended on 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 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. Article I of the Agreement is hereby amended by adding a new Section 1.0 which shall read as follows:

"1.0. "**** PTH" means all formulations of PTH *** including, but not limited to fusion proteins, muteins and chemical modifications of any or all of the aforementioned

PTH ***." For the avoidance of doubt, "**** PTH shall not include any other formulations of PTH *** or any other formulations of PTH.

2. The Agreement shall be deemed to be modified to include the following provisions:

(A) GSK hereby consents and agrees that Unigene may enter into one or more agreement(s) with *** (or its Affiliates) providing for the development, manufacturing, marketing or sale of *** PTH into a drug product in the Field in finished pharmaceutical form in an oral formulation containing or incorporating *** PTH, alone or in combination with a peptide or a small molecule that is not proprietary to GSK (or its Affiliates), and which such oral formulation of *** PTH product incorporates Unigene Know-How or is covered by Unigene Patent Rights (a "**** PTH Product"). The foregoing agreement(s) shall be referred to herein as the ("**** Agreement").

(B) Subject to the terms and conditions of the Agreement, GSK hereby grants back to Unigene, but only to the extent necessary to effectuate the *** Agreement, an exclusive license (even as to GSK) under the Licensed Technology that relates solely to the manufacturing of *** PTH API for use solely in a *** PTH Product for Unigene to make and sell to *** (and for *** as Unigene's licensee to subsequently sell, have sold, make, have made and import) *** PTH API for use solely in a *** PTH Product in the Territory in the Field. For the avoidance of doubt, the foregoing license back to Unigene shall only apply to Licensed Technology that is solely related to the manufacturing of *** PTH API for use solely in a *** PTH Product and not any other aspects of Licensed Technology such as (but not limited to) Licensed Technology as to the oral delivery method or amidation technology relating to *** PTH API or a *** PTH Product, and GSK retains all other rights to the Licensed Technology granted to

GSK under the Agreement. For the further avoidance of doubt, the foregoing references to an "oral formulation" shall not include an inhaled or spray form.

(C) In no event shall any Joint Inventions, Joint Patent Rights or Dependent GSK Improvements, GSK Confidential Information, GSK Patent Rights, GSK Know-How or any data, results, protocols, regulatory filings or approvals related to (or arising from) the Agreement (or the activities undertaken thereunder) shall in any way whatsoever be used in connection with the *** Agreement or the development, manufacturing, marketing or sale of *** PTH or a *** PTH Product pursuant thereto. Unigene and GSK hereby represent and warrant that as of the Amendment Date, no Dependent GSK Improvements exist.

(D) For the avoidance of doubt, the *** Agreement or the development, manufacturing, marketing or sale of *** PTH or a *** PTH Product pursuant thereto shall in no way trigger any payments, responsibilities or obligations under the Agreement by or on behalf of GSK (or its Affiliates) to Unigene (or its Affiliates) (including the payment of any milestones or royalties thereunder by GSK (or its Affiliates) to Unigene (or its Affiliates)).

3. As partial consideration for entering into this Amendment No. 5, effective as of the Amendment Date and notwithstanding the provisions of Section 7.3 of the Agreement:

Unigene hereby consents and agrees that GSK (and its Affiliates) shall be entitled to evaluate and conduct due diligence activities (including entering into appropriate confidentiality, evaluation or material transfer agreements related thereto) related to *** for PTH compounds or PTH-containing products.

4. As partial consideration for entering into this Amendment No. 5, Unigene shall remit to GSK:

(a) *** percent (***) of all payments or consideration (including, but not limited to, any and all upfront, licensing and milestone payments) received by Unigene pursuant to, or in connection with, the *** Agreement, provided, however, that such payments shall not include: (x) proceeds from the sale and issuance of equity securities by Unigene to *** in a transaction where the *** for such securities (i.e., there shall not be mark-up on such equity securities representing additional consideration as part of the *** Agreement), and further provided the *** Agreement is not to be structured in a way that results in *** purchasing such equity securities as consideration remitted to Unigene for entering into the *** Agreement), and (y) any payments received by Unigene directly resulting from its provision to *** of research, development or manufacturing services and peptide supply in the form of technical and GMP grade of *** PTH, but only to the extent that such payments are substantially consistent with Unigene's past practice (i.e., such payments may include a mark-up on such services or supply that is consistent with Unigene's past practice); and

(b) *** percent (***) of earned royalties on the first U.S. *** Dollars (U.S. \$***) of net sales of *** PTH or a *** PTH Product arising out of (or related to) the *** Agreement, and *** percent (***) of earned royalties on all net sales of such *** PTH or a *** PTH Product in excess thereof.

5. Unigene shall pay GSK the amounts due under Section 4 hereof, in United States Dollars, within *** (***) days of receipt by Unigene under the *** Agreement. Each payment shall be accompanied by a report detailing the amount payable and the basis for such payment. GSK is hereby granted the right to inspect and audit the records of Unigene on the same terms and conditions as provided in Section 3.14 of the Agreement. Unigene's obligation to make payments pursuant to Section 4 hereof shall terminate upon the termination of the Agreement, provided, however, (a) GSK shall be entitled to retain any sums it has received from Unigene hereunder, and (b) GSK shall continue to be entitled to receive the appropriate percentage (as set forth in Paragraph 4 hereof) of all payments or royalties earned or received by Unigene prior to such termination date.

6. Except as specifically provided herein, all other terms and conditions of the Agreement shall remain in full force and effect, and this Amendment No. 5 to the Agreement shall not be

construed to amend or waive any provisions of the Agreement except as specifically set forth above.

7. This Amendment No. 5 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).

8. This Amendment No. 5 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.

9. This Amendment No. 5 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/ Donald F. Parman

Name: Ronald S. Levy Name: Donald F. Parman

Title: Executive Vice President Title: Vice President & Secretary