

FOIA / PA Officer John Livornese U.S. Securities & Exchange Commission FOIA Office 100 F Street NE, Mail Stop 5100 Washington, DC 20549



18-02464-E

February 13, 2018

Dear Mr. Livornese:

I request pursuant to the Freedom of Information Act (FOIA) 5 U.S.C. § 552. As Amended by Public Law No. 104-231,110 Stat. 3048, copies of the following agreements, as **FOIA Request: 12-00543-FOIA.**

Exhibit 10.2 to Form SB-2 filed on 04/18/1997 by Depomed Inc.

Exhibit Title: Letter Agreement

CIK: 1005201

Sectilis will pay up to \$61 for research, copies and review fees for all of the abovementioned agreements. Please forward all releasable material for copying. My daytime telephone number is 202-798-8809. Please call me or e-mail at research@sectilis.com to discuss the total cost or estimated cost of this research/copies should the amount exceed the price indicated in this request.

Sincerely,

Stella Vasconcellos Research Assistant Sectilis LLC 6931 Arlington Rd. # 580 Bethesda, MD 20814



Office of FOIA Services

February 21, 2018

Ms. Stella Vasconcellos Sectilis LLC 6931 Arlington Rd., #580 Bethesda, MD 20814

> RE: Freedom of Information Act (FOIA), 5 U.S.C. § 552 Request No. 18-02464-E

Dear Ms. Vasconcellos:

This letter is in response to your request, dated and received in this office on February 13, 2018, for access to Exhibit 10.2 to Form SB-2 filed by Depomed, Inc. on April 18, 1997.

The search for responsive records has resulted in the retrieval of 13 pages of records that pertain to Exhibit 10.2. They are being provided to you in their entirety with this letter.

No fees have been assessed for the processing of this request. If you have any questions, please contact me at <u>neilsonc@sec.gov</u> or (202) 551-3149. You may also contact me at <u>foiapa@sec.gov</u> or (202) 551-7900. You also have the right to seek assistance from Dave Henshall as a FOIA Public Liaison or contact the Office of Government Information Services (OGIS) for dispute resolution services. OGIS can be reached at 1-877-684-6448 or <u>Archives.gov</u> or via e-mail at <u>ogis@nara.gov</u>.

Sincerely,

Curtis Neilson FOIA Research Specialist

Enclosure

CONFIDENTIAL TREATMENT REQUESTED

July 11, 1996

CONFIDENTIAL TREATMENT REQUESTED

Dr. John W. Shell President and Chief Executive Officer DepoMed, Inc. 1170 B Chess Drive Foster City, CA 94404-1167

Dear Dr. Shell:

This Letter Agreement ("Agreement") sets forth the terms and conditions under which Bristol-Myers Squibb Company ("BMS") and DepoMed, Inc. ("DepoMed") will collaborate in a joint research project (the "Research") to determine optimal conditions for the production of a product (the "Product") consisting of formulations of the chemical compound known as [metformin] ("[Metformin]") incorporated in the DepoMed GR System (the "DP System"). The specific terms and conditions of this Agreement are as follows:

1. THE RESEARCH

- A. DepoMed agrees to use its diligent efforts to implement and complete the Research Plan attached herewith and fully incorporated herein as Appendix A. Specific milestones and targets of the Research Plan are also summarized in Appendix A. Said milestones and targets may be modified, but only by mutual written agreement of BMS and DepoMed (the "Parties") at any time during the term of this Agreement.
- B. BMS agrees to collaborate with and assist DepoMed in the implementation and completion of the Research Plan set forth in Appendix A by providing to DepoMed:
 - 1. Bulk [Metformin] in sufficient quantities to perform the Research Plan;
 - 2. Appropriate analytical and handling procedures for [Metformin]; and
 - 3. Such other technology and expertise possessed by BMS which may be deemed necessary, by subsequent mutual agreement of the Parties, to achieve the objectives of this Agreement.
- C. All [Metformin] shall remain the sole property of BMS. DepoMed agrees not to make any modifications of the BMS Materials provided by BMS hereunder, except as required in the performance of the Research Plan.
- D. The [Metformin] shall be used solely to conduct the Research Plan, and not for any other purpose. The [Metformin] shall not be made available to anyone other than employees of DepoMed working in furtherance of the Research Plan, shall not be transferred to any other persons outside of DepoMed for any purpose, and shall not be transferred to another institution or company without the prior written consent of

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BMS, except to authorize subcontractors as provided in Article I.H hereinbelow. The [Metformin] shall not be used by DepoMed for research, testing or treatment involving human subjects or for making any decisions relating to human diagnosis or care.

- E. Nothing herein shall create or imply any license in intellectual property rights related to [Metformin] owned or controlled by BMS to DepoMed, except for the non-exclusive license to use the [Metformin] for the research purposes expressly set forth herein.
- F. Upon conclusion of the Research Plan, or upon request by BMS, DepoMed shall discontinue use of the [Metformin] and will arrange for the return to BMS of all unused [Metformin].
- G. DepoMed will take appropriate steps to inform all Research Plan personnel of their obligations under this Agreement and to obtain their agreement to abide by the terms and conditions of this Agreement in the same manner as DepoMed.
- H. DepoMed shall have no right to subcontract portions of the Research Plan to be performed by it without the prior written consent of BMS, except for the gastric retention study described in Appendix A, Section II.B2; provided, however, that (a) any such subcontracts shall not involve the transfer of confidential information of BMS to the subcontracted third party; (b) the subcontracted third party shall enter into a written confidentiality agreement with DepoMed adequate to preserve the confidentiality of [Metformin] formulations developed pursuant to the Research Plan and DepoMed Project Proprietary Information, and the rights granted to BMS under this Agreement; and (c) promptly after entering into such subcontract, DepoMed shall give written notice thereof to BMS.

II. <u>TERM</u>

- A. This Agreement is effective as of April 15, 1996, and shall continue in effect for a period of eight and one-half months, until December 31, 1996, or until DepoMed notifies BMS in writing that the milestones and targets set forth in Appendix A have been realized, if earlier.
- B. The term of this Agreement may be extended at the same rate of compensation as is then in effect (pro rated) for up to six (6) months at BMS' election, if the aforementioned milestones and targets are not realized at the end of the Agreement term. This election shall be made by written notice to DepoMed at least fifteen (15) days prior to December 31, 1996, specifying the desired term of the extension. The term of this Agreement may also be extended by an amendment in writing executed by both Parties.

III <u>COSTS/PAYMENTS</u>

- A. DepoMed agrees to perform and complete the Research Plan for a total fee of one hundred ninety-seven thousand, seven hundred seventy-eight dollars (\$197,778.00) in accordance with this Paragraph 3.
- B. BMS therefore agrees to make the following payments to DepoMed as full and complete consideration for the performance and completion of the Research Plan by DepoMed:
 - 1. A payment of seventy thousand dollars (\$70,000.00) which shall be paid to DepoMed by BMS within thirty (30) days of the complete execution of this Agreement by the Parties.
 - 2. A second payment of seventy thousand dollars (\$70,000.00) which shall be paid to DepoMed by BMS upon completion by DepoMed of the work described in Appendix A, Section II.
 - 3. A final payment of fifty-seven thousand, seven hundred seventy-eight dollars (\$57,778.00), payable upon release by BMS of formulation for a clinical pharmacokinetic study.
- C. BMS and DepoMed understand that developments, unforeseen circumstances beyond the reasonable control of DepoMed or changes in the scope of the Research or DepoMed's responsibilities for the Research may increase the funding requirements for the Research. BMS will consider requests for additional funding should such a need arise. The decision to supply such additional funding shall be in the sole discretion of BMS.

IV. PROGRESS REPORTS/JOINT MEETINGS

A. Commencing with the first day of the first month following the effective date of this Agreement, and for each subsequent month for the duration of the term of this Agreement, DepoMed shall submit to BMS monthly progress reports containing summaries of all Research Plan tasks completed or still in progress at the date of such progress report. The Parties agree that information contained in the aforementioned progress reports shall be general rather than detailed in nature. All of such information contained in such progress reports shall be and shall remain non-enabling proprietary information ("Non-Enabling Project Proprietary Information"). It is the express intent of the Parties that all Non-Enabling Project Proprietary Information provided to BMS by DepoMed shall be in such reasonable detail as shall permit BMS to assess DepoMed's progress versus the Research Plan and milestones and targets but shall not contain such information or detail as might reasonably be expected to enable BMS to reproduce or utilize in any way (other than the assessment as aforesaid) DepoMed's Enabling Project Proprietary Information (as defined in Paragraph V,

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Mr. John W. Shell DepoMed, Inc. July 11, 1996 Page 4

hereinbelow). Progress reports submitted to BMS by DepoMed may also contain and address any conclusions, problems or issues, which, in the opinion of DepoMed are significant matters requiring the attention of BMS and, if appropriate, recommendations for necessary action by BMS.

B. At least twice during the term of this Agreement and at more frequent intervals if deemed necessary by mutual agreement, representatives of BMS and DepoMed shall meet at mutually acceptable times and places to discuss and evaluate the status and progress of the Research which is the subject of this Agreement.

V. PROPRIETARY/CONFIDENTIAL INFORMATION

- A. DepoMed and BMS agree that, with the exception of Non-Enabling Project Proprietary Information (as defined in Paragraph IV.A, hereinabove), any and all data, information, materials and technology produced, developed or generated by DepoMed as a result of the Research which specifically relates to the DepoMed technology for the formulation of [Metformin] shall be enabling proprietary information of DepoMed ("DepoMed Enabling Project Proprietary Information"). DepoMed agrees to fully disclose to BMS any and all DepoMed Enabling Project Proprietary Information referred to in Appendix A, and upon written request from BMS, any and all additional DepoMed Enabling Project Proprietary Information to BMS.
- B. BMS and DepoMed agree that all DepoMed Project Proprietary Information (i.e. Non-Enabling Project Proprietary Information and Enabling Project Proprietary Information) transferred to BMS shall be governed by the provision of the [Metformin] Confidentiality Agreement dated February 8, 1996, among the Bristol-Myers Squibb Pharmaceutical Research Institute, DepoMed, Inc., and [Lipha S.A.] (hereinafter, the "Prior Agreement"). DepoMed understands and agrees that all DepoMed Project Proprietary Information transferred to BMS may be transferred by BMS to [Lipha S.A.] pursuant to the provisions of the Prior Agreement.
- C. The transfer of all confidential information of the Parties other than DepoMed Project Proprietary Information shall be governed by the provisions of the Prior Agreement.
- D. Notwithstanding anything to the contrary contained in this Agreement or the Prior Agreement, DepoMed shall have no right to disclose any DepoMed Project Proprietary Information to any third party, or use such DepoMed Project Proprietary Information for any purpose other than for the purpose of collaborating with BMS.

VI. OPTION

A. DepoMed hereby grants to BMS an option (on terms provided or to be negotiated in accordance with Paragraph VI.B) for two (2) years following completion of the

> clinical pharmacokinetic study referred to in Article III.B.3 hereinabove, but in no event later than three (3) years from the date of this Agreement, to obtain an exclusive, worldwide license under the DepoMed Project Proprietary Information and DepoMed Intellectual Property (i.e., any patents, patent applications, know-how, trade secrets, licenses or any other intellectual property rights of whatever nature, owned or controlled by DepoMed, including without limitation DepoMed Patent Rights as defined below) to make, have made, use, import, offer for sale and sell the Product incorporating formulations of [Metformin]. Such license shall include the right of BMS to sublicense any license granted to BMS under DepoMed Project Proprietary Information and DepoMed Intellectual Property. Such license shall also include the right of BMS to utilize any improvements to DepoMed Project Proprietary Information and DepoMed Intellectual Property developed by DepoMed during the two (2) years following the completion of work under the Research Plan.

- B. The terms and conditions of any license acquired by BMS from DepoMed under the option provided for in Paragraph VI.A., above, shall be as agreed by BMS and DepoMed in good faith negotiations regarding the terms and conditions of a definitive license agreement consistent with this Article VI.B which shall commence upon DepoMed's receipt of BMS' written notice of its intention to exercise its option and acquire said license. Any license agreement entered into by BMS and DepoMed shall be in a form reasonably acceptable to DepoMed and BMS, and shall be consistent with industry standards and permit BMS to fully exploit the licensed rights in a manner consistent with this Agreement. Any license agreement entered into between BMS and DepoMed shall provide for the following:
 - 1. BMS shall be required to pay to DepoMed the following royalty amounts:
 - a. [Three percent (3%)] of net sales of Licensed Product sold by BMS, its affiliates or sublicensees for the first [one hundred million dollars (\$100,000,000.00)] of net sales of Licensed Product per calendar year within the United States, and [five percent (5%)] of net sales of Licensed Product sold by BMS, its affiliates or sublicensees for net sales of Licensed Product greater than [one hundred million dollars (\$100,000,000.00)] per calendar year within the United States; and
 - b. [Three percent (3%)] of net sales of Licensed Product sold by BMS, its affiliates or sublicensees for the first [seventy-five million dollars (\$75,000,000.00)] of net sales of Licensed Product per calendar year outside of the United States, and [two percent (2%)] of net sales of Licensed Product sold by BMS, its affiliates or sublicensees for net sales of Licensed Product greater than [seventy-five million dollars (\$75,000,000.00)] per calendar year outside of the United States.

"Licensed Product" shall mean a Product, the manufacture, use or sale of which is covered within a country by a claim of an issued and unexpired patent included within the DepoMed Intellectual Property licensed to BMS by DepoMed which has not been *

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> held permanently revoked, unenforceable or invalid by a decision of a court or other government agency of competent jurisdiction, unappealable or unappealed within the time allowed for appeal and which has not been abandoned, or admitted to be invalid or unenforceable through reissue, disclaimer or otherwise. The obligation to pay royalties will expire on a country-by-country basis upon the expiration, invalidity or abandonment of all patents included within the DepoMed Intellectual Property covering any such Licensed Product within such a country, and not withstanding the number of patents included within the DepoMed Intellectual Property licensed to BMS by DepoMed, only a single royalty will be due with respect thereto.

- 2. BMS shall be required to pay to DepoMed the following milestone payments upon the first occurrence of each event set forth below:
 - a. [Five hundred thousand dollars (\$500,000.00)] upon complete execution by DepoMed and BMS of the license agreement;
 - b. [One million dollars (\$1,000,000.00)] upon filing by BMS with the United States Food and Drug Administration or the successor thereto of the first New Drug Application for a Licensed Product; and
 - c. [Two million dollars (\$2,000,000.00)] upon receipt by BMS of the required marketing approval from the United States Food and Drug Administration or the successor thereto of the first New Drug Application for a Licensed Product.
- 3. Except for such royalties and milestone payments as provided in this Agreement, no other payments, royalties, or other consideration will be payable with respect to any license granted to BMS by DepoMed. Such royalty and milestone payments shall be reduced by the amount of any fees, royalties or other consideration (not to exceed [fifty percent (50%)] of such royalties and milestone payments payable to DepoMed) payable by BMS to any third parties having dominant rights to DepoMed Project Proprietary Information or to DepoMed Intellectual Property.
- 4. BMS shall have the right to terminate any license agreement upon sixty (60) days prior written notice to DepoMed. Termination of any such license agreement shall not relieve BMS of the obligation to make payments of royalties or milestone payments accruing prior to the effective date of such termination.
- C. Notwithstanding anything to the contrary contained in this Agreement, in the event that BMS does not elect to exercise its option as aforesaid, or in the event the parties are unable to reach agreement on license terms, DepoMed shall have no right, whether by itself or with or by any affiliate or third party, to make, have made, use, import, offer for sale, sell, develop or otherwise commercialize any formulations of [Metformin] developed pursuant to this Agreement, any DepoMed Project Proprietary

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Mr. John W. Shell DepoMed, Inc. July 11, 1996 Page 7

Information related solely to [Metformin], or any Inventions related solely to [Metformin].

D. The decision as to whether to proceed with the preclinical and clinical development and marketing of any Product containing formulations of [Metformin] developed pursuant to this Agreement shall be in the sole discretion of BMS. Nothing contained in this Agreement shall be interpreted as requiring BMS to develop or market any such formulations of [Metformin].

VII. PATENTS

- A. All rights, title and interest to inventions, discoveries or improvements first conceived or made as a result of the performance of the Research Plan ("Inventions")
 - (i) shall belong solely to DepoMed, if made solely by DepoMed or its employees,
 - (ii) shall be jointly owned by DepoMed and BMS, if made jointly by DepoMed or one or more employees of DepoMed and by one or more employees of BMS ("Joint Inventions"), and
 - (iii) shall belong solely to BMS, if made solely by BMS.

Determinations of inventorship shall be made in accordance with U.S. law. DepoMed's interest in any Inventions and patent rights pertaining thereto described under (i) and (ii) above is referred to hereinafter as "DepoMed Patent Rights." BMS's interest in any Inventions and patent rights pertaining thereto described under (ii) and (iii) above shall not be subject to the terms and conditions of this Agreement.

- B. DepoMed represents and warrants to BMS that any Inventions that may be made by its employees in the performance of the Research Plan are owned by and shall be assigned to DepoMed, wholly and completely.
- C. DepoMed will promptly notify BMS in writing of any Inventions that relate solely to **[Metformin]**, including without limitation formulations of **[Metformin]**, conceived and/or made by DepoMed as a result of the performance of the Research Plan. Such notice shall describe the substance of any such Invention in writing in sufficient detail so as to enable BMS to determine if a patentable Invention has been made.
- D. BMS shall have the sole right to have prepared, filed and prosecuted the necessary papers for obtaining patent protection for any Inventions that relate solely to [Metformin], including without limitation formulations of [Metformin], in any and all countries of the world which BMS, in its sole judgment, determines are of sufficient interest to merit such filing. BMS shall bear all costs incurred in connection with the preparation, filing, prosecution, issuance and maintenance of any such U.S.

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Mr. John W. Shell DepoMed, Inc. July 11, 1996 Page 8

> and foreign patent applications. DepoMed agrees that it will cooperate and do whatever is necessary to assist BMS in obtaining and maintaining such patent rights at the request and expense of BMS. In the event that BMS, in its sole discretion, decides it is not appropriate to file a patent application which constitutes a DepoMed Patent Right that relates solely to [Metformin], including without limitation formulations of [Metformin], DepoMed shall have no right to file any patent applications thereon.

E. Except as provided in Article VII.D hereinabove, DepoMed shall have the sole right to have prepared, filed and prosecuted the necessary papers for obtaining patent protection for any Inventions that relate to the DP System in any and all countries of the world which DepoMed, in its sole judgment, determines are of sufficient interest to merit such filing. DepoMed shall bear all costs incurred in connection with the preparation, filing, prosecution, issuance and maintenance of any such U.S. and foreign patent applications.

VIII. PUBLICITY

- A. Neither BMS or DepoMed shall disclose any material terms of this Agreement or any of the information contained in the Appendix to this Agreement to any third party other than their professional advisors and third parties whose rights are or may be affected thereby without the prior written permission of the other Party, except where such disclosure is required by law. [For purposes of this Agreement, Lipha S.A. shall be considered a third party whose rights are or may be affected thereby.] Such permission shall not be unreasonably withheld or delayed, and shall be deemed given unless the party from whom permission is requested responds to a request with consent or specific reasons for objection within fourteen (14) days after the request is received.
- B. Neither BMS nor DepoMed shall use the name of the other Party in any advertising or promotional context in any medium, provided, that upon execution of this Agreement by both Parties, a mutually agreeable press release may be jointly published by the Parties.

IX. COVENANT AND WARRANTY

DepoMed hereby covenants that it will use its diligent efforts to conduct and complete the Research Plan set forth in Appendix A in accordance with the milestones and targets set forth therein. DepoMed hereby warrants, as of the date hereof, and covenants that (a) it has all necessary rights and is legally entitled to grant the rights it has agreed to grant to BMS hereunder, and (b) its entry into this Agreement and its performance of its obligations hereunder do not and will not conflict with any other restrictions or obligations of whatsoever nature by which DepoMed is bound.

X. ASSIGNMENT

This Agreement may not be assigned by either party without the prior written consent of the other Party. No obligations or rights under this Agreement may be assigned or delegated by DepoMed without the prior written consent of BMS. This Agreement shall be binding upon and inure to the benefit of and be enforceable by the Parties hereto and their respective heirs, legal and personal representatives, successors and permitted assigns.

XI. NOTICES

All notices permitted or required under this Agreement shall be deemed effective upon receipt by the Party to whom it is addressed, if made in writing and deposited, postage prepaid in a facility for the collection of mail maintained by the United States Post Office or if deposited with Federal Express or any other generally recognized expedited delivery service, or if personally delivered, or if transmitted by fax, addressed as follows:

To Bristol-Myers Squibb Company:

A. Scientific and Technical Matters:

Dr. Peter Timmins Director, International Development Laboratories Bristol-Myers Squibb Pharmaceutical Research Institute Reeds Lane, Moreton, Wirral Merseyside L46 1QW, England FAX: 011-44-151-677-0869

B. All Business and Other Matters:

Ms. Mary Furlong Director, Business Development, U.S. Bristol-Myers Squibb Company P.O. Box 4000 Princeton, New Jersey 08543-4000 FAX: (609) 252-3974

To DepoMed:

A. Scientific and Technical Matters:

Dr. John W. Shell President and Chief Executive Officer DepoMed, Inc. 1170 B Chess Drive Foster City, CA 94404-1167 FAX: (415) 513-0999

B. All Business and Other Matters:

Dr. John W. Shell President and Chief Executive Officer DepoMed, Inc. 1170 B Chess Drive Foster City, CA 94404-1167 FAX: (415) 513-0999

XII. GOVERNING LAW

This Agreement shall be governed by and construed in accordance with the laws of the State of New Jersey. Caption and paragraph headings are for convenience only and shall not form an interpretive part of this Agreement. This Agreement shall not be strictly construed against either Party hereto.

XIII. TERMINATION

- A. This Agreement may be terminated by BMS, with or without cause, upon thirty (30) days written notice to DepoMed.
- B. Upon any material breach by a party to the Agreement, the other party may terminate this Agreement by thirty (30) days written notice to the breaching party, specifying the material breach, default or other defect. The termination becomes effective, at the option of the non-breaching party, at the end of the thirty (30) day period unless the breaching party cures the breach during the thirty (30) day period.
- C. Upon expiration or termination of this Agreement, the provisions of Articles I.F, V, VI, VII, VIII, IX and XII shall continue in full force and effect, as well as any other provision herein which, by its intent or meaning, is intended to survive such expiration or termination.
- D. Any expiration or early termination of this Agreement shall not affect the rights and obligations of the parties accruing under this Agreement prior to the effective date of such expiration or termination, including, but not limited to, any rights and obligations accruing under Articles I.F, V, VI, VII, VIII, IX and XII.

XIV. INDEPENDENT CONTRACTOR

For purposes of this Agreement, and in the performance of all services hereunder, the relationship of BMS to DepoMed is, and shall be deemed to be, one of independent contractors and not as agents or employees of one to the other.

XV. <u>SEVERABILITY</u>

The provisions of this Agreement are severable. If any item or provision of this Agreement shall to any extent be invalid or unenforceable, the remainder of this Agreement shall not be affected thereby, and each term and provision of this Agreement shall be valid and shall be enforced to the fullest extent permitted by law.

XVI. ENTIRE AGREEMENT

This Agreement and the Prior Agreement constitute the entire agreement between BMS and DepoMed with respect to the subject matter hereof and supersede any and all previous understandings or agreements between the Parties, whether written or verbal. No terms or provisions of this Agreement may be varied or modified by the parties hereto except by a written instrument specifically referring to and executed in the same manner as this Agreement. No provision of this Agreement may be waived by any act, omission or knowledge of a Party or its agents or employees, except by a writing expressly waiving such provision and signed by the waiving Party. The failure of a Party at any time or times to require performance of any provision hereof shall in no manner affect its rights at a later time to enforce the same. No waiver by a Party of any condition, remedy or term in any one or more instance shall be construed as a continuing waiver of such condition, remedy or term or any other condition, remedy or term on any successive occasion. Any inconsistency between the terms of this Agreement and any Appendix shall be resolved in favor of the text of this Agreement.

If this Letter correctly sets forth the terms and conditions of our Agreement, please indicate the acceptance thereof by DepoMed in the space provided below and return an original counterpart of this Agreement to the address first shown above. The other original counterpart should be retained in your files. Thank you.

Sincerely,

BRISTOL-MYERS SQUIBB COMPANY

By: <u>/s/ Robert A. Lipper</u> Title: <u>Vice President, Biopharmaceutics R&D</u>

Accepted and agreed this 15th day of July, 1996

DEPOMED, INC.

By: <u>/s/ John W. Shell</u> Title: <u>President</u>

Appendix A Page 1 of 2

RESEARCH PLAN [METFORMIN] FORMULATION DEVELOPMENT

[I. Upon signing Agreement: By BMS.

BMS to supply Metformin (minimum of 500 gm) and analytical and handling procedures to DepoMed upon signing of this Agreement.

II. By the end of six (6) weeks from receipt by DepoMed of Metformin supply and analytical procedures (the "Materials"): II A. by DepoMed. <u>Concurrently II A. and II B.</u>:

- Al. Adapt analytical procedures.
- A2. Through variation of parameters (different swellable polymers, polymer molecular weights, drug loading levels, hydrophobicity modulators), define range of drug release rates that are possible.
- A3. Adjust parameters so that several different formulations (at least three) can be circumscribed, if possible, with distinctly different drug release rates and release durations. Targeted are ranges of t90% from two hours to nine hours, preferably from two hours to six hours, in simulated gastric fluid at 37°C.
- A4. Assure functionality of stability-indicating HPLC assay for the drug in the defined formulations.
- A5. With BMS concurrence, initiate accelerated stability program on the defined formulations.

By ten (10) weeks from receipt by DepoMed of the Materials: II B. by DepoMed. <u>Concurrent with A. above</u>

- B1. Prepare test materials for a short-term dog study.
- B2. Evaluate the effects of two fed mode-inducing adjuvants on gastric retention, each at two concentrations, using X-radiological procedures on fasting dogs.
- B3. Selection of the best adjuvant and confirmation of the effective concentration.

CONFIDENTIAL TREATMENT REQUESTED

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- Al. Fully characterize the distinctly different formulations.
- A2. Establish specifications.
- A3. In cooperation with BMS, confirmation of human study formulations.
- A4. Provide BMS with full information on composition of formulations, samples of the formulations, tooling for tablet press and other information associated with fabrication of clinical supply materials, product specifications and analytical methods and other laboratory procedures used in checking product performance.
- A5. Contribute to the protocol for gamma scintigraphy and PK studies (to include comparison of retention from meal-induced vs. adjuvant-induced fed mode).
- IV. Following completion of the above: By DepoMed

DepoMed to continue technical cooperation as required to support the clinical studies.

DepoMed to conduct any additional testing of formulations as requested by BMS, at a cost to be agreed upon at that time.]