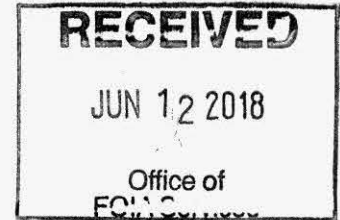


FOIA / PA Officer John Livornese  
U.S. Securities & Exchange Commission  
FOIA Office  
100 F Street NE, Mail Stop 5100  
Washington, DC 20549

18-04766-E



June 12, 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:

Exhibit 10.6 to Form S-1/A filed on 10/02/2003 by Aderis Pharmaceuticals Inc

Exhibit Title: Exclusive License Agreement

CIK: 1164722

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](mailto: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



UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
STATION PLACE  
100 F STREET, NE  
WASHINGTON, DC 20549-2465

Office of FOIA Services

July 09, 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. 18-04766-E

Dear Ms. Vasconcellos:

This letter is in response to your request, dated and received in this office on June 12, 2018, for information regarding Exhibit 10.6 to Form S-1/A filed on October 2, 2003 filed by Aderis Pharmaceuticals, Inc.

The search for responsive records has resulted in the retrieval of thirty eight pages of records that may be responsive to your request. They are being provided to you with this letter.

If you have any questions, please contact me at moodyd@sec.gov or (202) 551-8355. You may also contact me at [foiapa@sec.gov](mailto:foiapa@sec.gov) or (202) 551-7900. You also have the right to seek assistance from Aaron Taylor 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 [Archives.gov](http://Archives.gov) or via e-mail at [ogis@nara.gov](mailto:ogis@nara.gov).

Sincerely,

A handwritten signature in black ink that reads "Denise R. Moody".

Denise R. Moody  
FOIA Research Specialist

Enclosures

**EXCLUSIVE LICENSE AGREEMENT**

**between**

**DISCOVERY THERAPEUTICS, INC.**

**and**

**SCHWARZ PHARMA AG**

## AGREEMENT

Effective as of July 16, 1998 (the "Effective Date"), **Discovery Therapeutics, Inc.**, a Delaware corporation having a principal place of business at 2028 Dabney Road, Suite E-17, Richmond, VA 23230-3311, U.S.A. ("DTI") and **Schwarz Pharma AG**, a corporation having a principal place of business at Alfred-Nobel-Straße 10, 40789 Monheim, Germany ("Schwarz"), agree as follows:

### Witnesseth

**Whereas**, DTI owns certain patents, patent applications and know-how relating to DTI's proprietary dopamine receptor agonist N-0923 and various other compounds;

**Whereas**, DTI has, over the past ten years, successfully advanced N-0923 through substantial preclinical and clinical development including a Phase IIb clinical trial (TDS-0923-004);

**Whereas**, Schwarz desires an exclusive license under such patents, patent applications, and know-how to make, use and sell Licensed Products in all countries of the world except Japan for the therapeutic treatment of disease in humans;

**Whereas**, DTI and Schwarz have executed a Letter Agreement dated May 6, 1998 to confirm the mutual understanding, with lump sum payment to DTI by Schwarz in the amount of Two Hundred Fifty Thousand Dollars (\$250,000) creditable against the License fee, that the parties will negotiate in good faith to finalize a License Agreement pertaining to worldwide rights (except in Japan) to Licensed Products. 38

**Now, therefore**, in consideration of the above premises and covenants contained herein, the parties agree as follows:

### 1. DEFINITIONS

**1.1 "Additional Products"** means Licensed Products other than the Initial Product.

**1.2 "Additional Product Development Plan"** means the plan for development of Additional Products described in Section 3.4(b).

**1.3 "Affiliate"** means any entity that directly or indirectly Owns, is Owned by or is under common Ownership with, a party to this Agreement. "Own" or "Ownership" means direct or indirect possession of at least fifty percent (50%) of the outstanding voting securities of a corporation or a comparable equity interest in any other type of entity, or means substantial control of a corporation.

**1.4 "Compounds"** means:

(a) (-)-5,6,7,8-tetrahydro-6-[propyl-[2-(2-thienyl)ethyl]amino]-1-naphthalenol hydrochloride (also known as N-0923); 39



(b) (-)-5,6,7,8-tetrahydro-6-[propyl-[2-(t-butoxy)ethyl]amino]-1,2-naphthalenediol diacetate (also known as WRC-0495);

(c) (-)-6,7,8,9-tetrahydro-N-[2-(t-butoxy)ethyl]amino]-N-propylnaphtho[1,2-d]-1,3-dioxol-7-amine hydrochloride (also known as WRC-0502); and

(d) (-)-6,7,8,9-tetrahydro-N-[2-(isopropoxy)ethyl]amino]-N-propylnaphtho[1,2-d]-1,3-dioxol-7-amine hydrochloride (also known as WRC-0319).

**1.5 “Development Plan”** means the Initial Product Development Plan, as revised from time to time, pursuant to Section 3.5(a), and the Additional Product Development Plan, collectively.

**1.6 “DTI Know-How”** means all information, trade secrets, data, inventions and know-how that is (i) owned by or licensed to DTI (with the right to sublicense) during the term of this Agreement and (ii) necessary or useful to the manufacture, use or sale of Licensed Products.

**1.7 “DTI Patent(s)”** means all patent applications (including divisionals, continuations and continuations in part) and issued patents (including inventors’ certificates, reissues, reexaminations, extensions or other governmental actions which extend any of the subject matter of a patent, and any substitutions, confirmations, registrations or additions of or to any of the foregoing) owned by or licensed to DTI (with the right to sublicense) during the term of this Agreement which claim inventions necessary or useful to the manufacture, use or sale of Licensed Products, including any patent applications and patents to which DTI acquires rights after the Effective Date, and including without limitation any patents and patent applications that are jointly owned by DTI, including but not limited to any future patents related to the transdermal formulation of Compounds invented and owned jointly by DTI and LTS, and excluding any patent applications pending before or patents issued by the patent authorities in Japan. The DTI Patents (ex Japan) in existence as of the Effective Date are set forth on Exhibit A.

**1.8 “FDA”** means the United States Food and Drug Administration or its equivalent outside the United States.

**1.9 “Field”** means therapeutic treatment of disease in humans.

**1.10 “Initial Product”** means the first Licensed Product sold by Schwarz, its Affiliate or its sublicensee in the Territory.

**1.11 “Initial Product Development Plan”** means the plan for development of the Initial Product described in Section 3.4(a).

**1.12 “Licensed Product(s)”** means any form or dosage of a Compound, delivered by any mode of administration, including *inter alia*, a transdermal patch formulation produced by LTS.

**1.13** “**LTS**” means Lohmann Therapie-Systeme headquartered in Andernach, Germany.

**1.14** “**Major Countries**” means the United States, the United Kingdom, France, Germany and Italy.

**1.15** “**Net Sales**” means gross amounts invoiced by Schwarz and/or its Affiliate or sublicensee(s) for sales of Licensed Product(s) produced hereunder (excluding without limitation Licensed Product(s) used in clinical trials) to a third party, less the sum of the following items:

- (a) Sales, excise taxes and custom duties paid or allowed by the selling party;
- (b) Refunds, allowances or credit for returns or recalled Licensed Product;
- (c) Normal and customary trade, quantity and cash discounts and allowances actually allowed;
- (d) Transportation, freight and insurance allowances; and
- (e) Rebates actually granted to wholesalers, administrative fees in lieu of rebates paid to managed care and similar institutions, chargebacks and retroactive price adjustments.

No deductions shall be made for commissions paid to individuals whether they be with independent sales agencies or regularly employed by Schwarz, and/or its sublicensee(s) and on its or their payroll or for cost of collections. Licensed Products shall be considered “sold” when billed out or invoiced. Sale or transfer to an Affiliate or Sublicensee for re-sale by such Affiliate or Sublicensee shall not be considered a sale for the purpose of this provision, but the resale by such Affiliate or Sublicensee to a third party shall be a sale for such purposes.

**1.16** “**Regulatory Approval**” means all approvals by the regulatory agency in the relevant country of the Territory necessary to market and sell a Licensed Product, including all pricing approvals.

**1.17** “**Schwarz Technology**” means, to the extent necessary or useful to make, use or sell a Licensed Product, all patents and patent applications and information, trade secrets, data, inventions and know-how, owned by or licensed to Schwarz (with the right to sublicense) during the term of this Agreement.

**1.18** “**Territory**” means all countries of the world other than Japan.

## **2. LICENSE GRANT**

**2.1 License to Schwarz.** DTI hereby grants and Schwarz hereby accepts an exclusive license, with the right to sublicense, under the DTI Patent(s) and DTI Know-How to develop, make, have made, import use, market, offer for sale and sell Licensed Product(s) in the Field in the Territory. If requested by Schwarz, DTI shall furnish to Schwarz or to such representative(s) or patent attorney(s) as Schwarz may designate all papers and documents

necessary to permit Schwarz to register the exclusive license under the DTI Patents with the patent office in such countries of the Territory as may be required by regulation or otherwise. Schwarz shall bear all expenses of registering such license.

## **2.2 Sublicenses**

(a) Subject to Section 5.1(b), Schwarz shall have the right to grant sublicenses to any party with respect to any rights conferred upon Schwarz under this Agreement, provided, however, that (i) any such sublicense shall be subject in all respects to the restrictions, exceptions, royalty and other payment obligations, reports, and other provisions contained in this Agreement, and (ii) Schwarz shall notify DTI of the identity of such sublicensee promptly on execution of the sublicense.

(b) Schwarz agrees to forward to DTI a copy of any and all sublicense agreements promptly upon execution by the parties.

**2.3 License Grant to DTI in Countries Excluded From the Territory.** Subject to the conditions and limitation set forth herein, Schwarz hereby grants to DTI an exclusive (even as to Schwarz), paid-up license, under the Schwarz Technology, to develop, make, have made, import, use, offer for sale or sell Licensed Products in any country that becomes excluded from the Territory during the term of this Agreement, except as specified section 4.2(b). Schwarz shall also, to the extent it has the right to do so, sublicense to DTI any third party licenses to which Schwarz has rights, to the extent that such rights are necessary or useful to make, use and sell the Licensed Products, and DTI shall thereafter assume the cost of maintaining such licenses.

**2.4 Disclosure of Know-How.** Promptly following the Effective Date, DTI shall disclose to Schwarz all DTI Know-How. In addition, DTI shall make available to Schwarz, upon reasonable notice and during normal business hours, the reasonable assistance of DTI's employees who are knowledgeable about the DTI Know-How in order to facilitate Schwarz' efforts to develop and commercialize Licensed Products. DTI shall provide such assistance for a period of 1 year from the Effective Date, and Schwarz may, at its election, extend its right yearly to receive such DTI assistance until the last regulatory filing necessary to obtain marketing approval is made. Schwarz shall reimburse DTI for such assistance at the rate equivalent to 1 FTE (\$240,000) annually, payable in quarterly installments, but may terminate its right to receive DTI's assistance at any time. DTI will, at its own expense, transfer to Schwarz all active INDs (and equivalent regulatory submissions in other countries) for all Licensed Compounds, together with all regulatory files and related documentation associated with such submissions. DTI will make such transfer no later than 3 months after the Effective Date, *provided however*, that if transfer is delayed due to actions, lack of action, or policies of FDA, then the period for transfer shall be extended by the length of the relevant delay.

**2.5 Covenant Not to Launch Competitive Product.** In consideration for the rights granted and sums paid pursuant to this Agreement, neither party shall, during the term of this Agreement, conduct, fund, license or participate in, directly or indirectly through one or more third parties, the development, distribution or commercialization in any country, of any transdermal patch containing a dopamine receptor agonist as an active ingredient for use in the Field other than the Licensed Products.

43



### 3. PRODUCT DEVELOPMENT

**3.1 General.** Schwarz shall be responsible for the development of, and obtaining Regulatory Approval for, the Licensed Products in the Territory. Subject to the Development Plan described in Sections 3.4 and 3.5, Schwarz shall have the final decision-making authority with respect to all aspects of the development of the Licensed Products.

**3.2 Engagement of Third Parties.** In the course of performing its development obligations under this Agreement, Schwarz may engage third parties to perform certain development activities, provided that (i) DTI is informed of the use and identity of third parties for the relevant activity, and (ii) Schwarz obtains contractual undertakings from such third parties (including in particular with respect to quality assurance, compliance with law, and confidentiality) which are customary in the pharmaceutical industry for the relevant activity.

**3.3 Development Committee.** Promptly after the Effective Date, the parties shall form a Development Committee which shall consist of two (2) representatives of each party with expertise in such disciplines as clinical, regulatory affairs, manufacturing or marketing, *provided that* Schwarz shall, in addition, appoint an additional representative who shall serve as the chairperson of the Development Committee. All decisions of the Development Committee shall be made by a majority vote of the five (5) representatives on the Development Committee. The Development Committee shall meet regularly (but in no event less than semi-annually) at such times and at such locations as shall be mutually agreed by the parties. The Development Committee shall coordinate development activities in accordance with the Development Plan including, but not limited to, the choice of contract research organization (CRO), consultants, third party contract manufacturers and assignment of development activities including the design and execution of studies to expand labeling claims, develop new formulations and other product changes and communication with FDA and other third parties. At least 10 business days prior to each regularly scheduled meeting of the Development Committee, Schwarz shall provide a written report to the Development Committee concerning its progress with respect to the Development Plan and shall also provide minutes of each meeting of the Development Committee, which shall include: (a) progress and results since the previous meeting; (b) critical issues or problems encountered or anticipated; and (c) a statement of goals for the scheduled activities.

#### **3.4 Development Plan.**

**(a) Initial Product.** Within 6 months of the Effective Date of this Agreement, the Development Committee will provide DTI with an Initial Product Development Plan setting forth Schwarz's anticipated development program for the Initial Product in the Territory, including target dates for key clinical and regulatory events in the Major Countries. Such plan shall specify the dates by which Schwarz shall enroll the first patient in a pivotal Phase III study and file for regulatory approval in the first Major Country (these two dates are hereafter referred to as the Critical Target Dates). Such plan shall be finalized by the Development Committee and approved by DTI not later than 7 months after the Effective Date. Exhibit F contains a reasonable preliminary plan which has been reviewed by both parties.

**(b) Additional Products.** In the event Schwarz elects to develop and commercialize any Additional Products, it shall notify DTI. The Development Committee shall provide DTI with an Additional Product Development Plan setting forth the anticipated development program for such Additional Products in the Territory, including target dates for key clinical and regulatory events in the Major Countries. Such Additional Product Development Plan shall be finalized by the Development Committee and approved by DTI not later than 6 months after the date of Schwarz's notice to DTI.

### **3.5 Diligence.**

**(a) Development Efforts.** Schwarz shall use commercially reasonable efforts to carry out development of the Initial Product in accordance with the Development Plan, and the Additional Products, if any, in accordance with the Additional Product Development Plan. If Schwarz determines that it will be unable to accomplish any of the key clinical events identified in the relevant Development Plan within 6 months of the date specified in such Development Plan, it shall promptly notify the Development Committee, and it shall develop a revised Development Plan for the relevant Licensed Product. This revised plan shall set new Critical Target Dates. As per Section 3.1, Schwarz shall have the final decision making authority with respect to all aspects of any revised Development Plan, except that DTI must agree to any change in the Critical Target Dates, such agreement not to be unreasonably withheld. In the event DTI does not agree to the Critical Target Dates set forth in the revised plan, then the most recently approved Critical Target Dates shall apply and Schwarz may, at its election, proceed under Section 3.5(c).

**(b) Extended Delay.** With respect to the most recently approved Critical Target Dates, if Schwarz does not initiate Phase III trials within 12 months of the date specified in the Development Plan or file for Regulatory Approval of the Licensed Product in any Major Country within 18 months of the date specified for such filing in the Development Plan then this shall be considered a dispute and shall be resolved according to the process set forth in Section 3.5(c). In the event that Schwarz is held to the Critical Target Dates, *and* does not agree to meet these dates, then DTI may terminate Schwarz's rights under this Agreement with respect to Licensed Products in the Major Country in question, in which case such Major Country shall be deleted from the Territory. In such event, Schwarz shall promptly transfer to DTI all INDs or their non-U.S. equivalent (as applicable) and other relevant regulatory filings as it may hold with respect to Licensed Products in such country, and any information as Schwarz may possess which is useful to gain Regulatory Approval for and to commercialize the Licensed Products in such country. Such transfer shall be without cost to DTI, provided however, that DTI shall pay any governmental filing or transfer fees that may be required. Schwarz shall also, to the extent it has the right to do so, sublicense to DTI any third party licenses to which Schwarz has rights, to the extent that such rights are necessary or useful to make, use and sell the Licensed Products, and DTI shall thereafter assume the cost of maintaining such licenses. As used in this Section, initiation of Phase III trials shall mean enrollment of the first patient.

**(c) Disputes Regarding Critical Target Dates.** If the parties are unable to reach agreement as to the Critical Target Dates in any Development Plan, then either party may submit the issue for binding arbitration before an expert or expert panel in the field of clinical drug development (rather than before a judge or an attorney) under this Section 3.5(c). Such

expert may be mutually agreed by the parties, but if no such expert is agreed upon within ten (10) days after the written notice from one party to the other, then each party shall promptly select one expert, and those two experts shall select a third expert, which shall comprise the panel. The panel shall meet with the parties within fifteen (15) days of selection to examine the Development Plan and shall hear the views and proposals of each party. Within ten (10) days thereafter, it shall render its binding decision by majority vote, as to whether the Development Plan is reasonable under all of the circumstances. The parties shall share equally in the cost of the expert or expert panel, including any fees and expenses payable to the experts. If the expert or expert panel determines that the Development Plan is not reasonable, then Schwarz will be held to the Critical Target Dates set forth in the most recently approved Development Plan, subject to any modifications agreed to by DTI.

**3.6 Drug Approval Applications.** Schwarz shall be responsible for preparing and filing for Regulatory Approval of the Licensed Products in the Territory. Schwarz will file the drug approval applications in its own name and shall be responsible for prosecuting them. After filing for Regulatory Approval, Schwarz shall use commercially reasonable efforts to obtain such approval in each country of the Territory where it has decided to seek Regulatory Approval. Schwarz shall keep DTI reasonably informed as to the progress of such drug approval applications and of any issues raised by the relevant regulatory agencies together with Schwarz' proposed response. Schwarz shall report to DTI concerning its progress in obtaining Regulatory Approval on a periodic basis, but not less than every [6] months. In the event any regulatory agency threatens or initiates any action to remove a Licensed Product from the market in any country of the Territory, Schwarz shall immediately notify DTI of such communication. DTI shall use commercially reasonable efforts to cooperate with Schwarz in Schwarz's performance of its obligations under this Section 3.6 including preparation for and participation with Schwarz when meeting with regulatory authorities.

**3.7 Replacement of Compounds.** If during its development of the Initial Product Schwarz determines that the Compound which is the active ingredient in the Initial Product (the "Original Compound") is not suitable for further development into a therapeutic product for use in humans, for safety, efficacy, or other reasons, Schwarz may then substitute a different Compound in place of the Original Compound. In such event, the parties shall discuss appropriate changes to the Development Plan to accommodate the changes in the regulatory schedule necessitated by such substitution. If the parties are unable to agree on such changes, either party may proceed in accordance with Section 3.5(c).

**3.8 Exchange of Information Between the Parties.** Subject to the obligations of confidentiality set forth in this Agreement and promptly following the Effective Date, DTI shall provide to Schwarz all material documents in DTI's possession as of the Effective Date describing preclinical, clinical, chemical, pharmacological, toxicological, assay, control, and manufacturing data and other information which is useful for development, registration and commercialization of Licensed Products in the Territory, obtained by DTI in its study of Licensed Products. Following the Effective Date, each party shall own all data generated by such party and agrees to provide the other with all material information available to such party concerning the Licensed Products, subject to any contractual restrictions on disclosure.

**3.9 Exchange of Information Among Licensees.** Subject to the obligations of confidentiality set forth in this Agreement and its agreement with its other licensees, DTI will use its best efforts to facilitate full and open exchange of information among its licensees, including but not limited to post-market surveillance information. Prior to disclosing any data generated by Schwarz to other licensees of DTI, DTI shall discuss the conditions of disclosure with Schwarz in good faith and shall obtain Schwarz approval for such disclosure, such approval not to be unreasonably withheld. Exhibit B lists all third parties with which DTI has developed agreements with respect to the Compounds.

**3.10 Exchange of Adverse Event Information.** Without delay, each party agrees to provide the other party and any other licensees or sublicensees with any serious adverse event information of which it becomes aware, including but not limited to post-market surveillance information, which may be required to be provided to regulatory authorities in any jurisdiction. Such information shall be provided as soon as possible, and all non-serious adverse event information shall be exchanged between the parties at least quarterly. DTI shall disclose to Schwarz the names of all DTI's licensees in order to allow the exchange of information provided for in this Section 3.10 between Schwarz and DTI's licensees.

#### **4. COMMERCIALIZATION**

**4.1 General.** Schwarz shall be responsible for commercializing the Licensed Products in the Territory. Decisions regarding matters such as advertising and promotion shall be the sole responsibility of Schwarz, provided however that Schwarz's commercialization activities shall be consistent with Schwarz' activities in commercializing pharmaceutical other products of similar market potential, profit potential or strategic value, based on conditions then prevailing.

##### **4.2 Failure to Launch.**

(a) If Schwarz or its sublicensee does not launch a Licensed Product in a Major Country in the Territory within 12 months of obtaining Regulatory Approval for such Licensed Product in such Major Country, or sooner notifies DTI that it will not launch in such Major Country, Schwarz's rights under this Agreement shall terminate upon the earlier of such notice or the 1 year anniversary of the grant of Regulatory Approval, and DTI shall be free to commercialize Licensed Products in such Major Country without any further obligation to Schwarz. In such event, Schwarz shall promptly transfer to DTI all INDs, applications for Regulatory Approval and Regulatory Approvals, or their non-U.S. equivalents (as applicable) as it may hold with respect to Licensed Products in such Major Country, and any information as Schwarz may possess which is useful to gain Regulatory Approval for and to commercialize the Licensed Products in such Major Country. Such transfer shall be without cost to DTI, provided however that DTI shall pay any governmental filing or transfer fees that may be required.

(b) If Schwarz elects not to launch a Licensed Product in a country in the Territory other than a Major Country because Schwarz has concluded in good faith that Licensed Products distributed in such country will be imported into other countries of the Territory where Schwarz has retained exclusive rights, then Schwarz will not be obligated to launch such Licensed Product in such country and DTI shall not launch Licensed Product in such country.



**4.3 Pricing and Product Distribution.** Schwarz shall set prices for Licensed Products in the Territory and shall obtain all pricing approvals as may be required. Schwarz shall also be responsible for distribution of the Licensed Products in the Territory.

**4.4 Advertising and Promotion.** Schwarz will prepare or have prepared all advertising and education materials for the Licensed Product in the Territory.

**4.5 Trademarks.** Schwarz shall be responsible for developing and registering trademarks for the Licensed Products, and shall own all such trademarks. To facilitate worldwide brand recognition, Schwarz shall, to the extent practicable in Schwarz' sole discretion, market and sell the Licensed Products under a single trademark throughout the Territory. Schwarz agrees to consult with DTI's licensees set forth on Exhibit B to endeavor to coordinate its trademark selection with the trademarks selected by such other licensees.

## **5. PAYMENTS AND ROYALTIES**

### **5.1 Fees.**

**(a) License Fee.** Schwarz shall pay to DTI a noncreditable license issue fee of Five Million Dollars (\$5,000,000) upon execution of this Agreement. Such payment shall be nonrefundable, and the \$250,000 lump sum payment made by Schwarz to DTI pursuant to the Letter Agreement between the parties dated May 6, 1998 shall be deducted from this License Fee.

**(b) Sublicense Fees.** DTI has engaged in discussions, prior to the Effective Date, with entities listed on Exhibit C. In the event Schwarz grants a sublicense to any of the entities (or their Affiliates) set forth on Exhibit C, Schwarz shall pay to DTI 35% of all non-royalty consideration (excluding sums received for the purchase of equity or to fund research and development activities) Schwarz receives as a result of such sublicense.

**5.2 Milestones.** Schwarz shall pay to DTI the following amounts within thirty (30) days of the first achievement, by any Licensed Product, of the respective milestone event set forth below and shall not pay again for subsequent Licensed Products:

<b>Milestone Event</b>	<b>Payment</b>
Commencement of Phase III clinical trial (enrollment of first patient)	\$4,000,000
First issuance of joint DTI-LTS patent in any Major Country of the Territory	\$1,500,000
NDA Approval	\$5,000,000

Milestone Event	Payment
Regulatory Approval in the first three non-US Major Countries	\$1,000,000 each

46

Milestone payments shall be noncreditable and shall be nonrefundable.

**5.3 Earned Royalties.** In addition, Schwarz shall pay DTI a running royalty on annual Net Sales of all Licensed Products according to the following marginal rates:

(a) For annual Net Sales of Licensed Products up to \$75 million, nine percent (9%) of such Net Sales; and

47

(b) For the portion of annual Net Sales of Licensed Products in excess of \$75 million and not exceeding \$200 million, eleven percent (11%) of such Net Sales; and

47

(c) For the portion of annual Net Sales of Licensed Products in excess of \$200 million, fifteen percent (15%) of such Net Sales.

47

(d) As of the effective date of this Agreement, the parties anticipate Schwarz will consummate a supply agreement with LTS. In such case the parties may decide that Schwarz shall pay to LTS some or all of royalties pursuant to Section 6.2 and reduce its royalty payments to DTI accordingly.

#### 5.4 Minimum Royalties

(a) Notwithstanding the provisions of Section 5.3, Schwarz shall pay DTI minimum annual royalties after launch of the Initial Product in any country of the Territory in an amount equal to seventy percent (70%) of Forecast Net Sales (defined below) multiplied by the applicable royalty rate pursuant to Section 5.3. For example, if the Forecast Net Sales are \$200 million, then the minimum royalties would be calculated as follows:

48

\$200,000,000 x .7 = \$140,000,000 (Net Sales amount on which minimum royalties will be calculated)

48

\$75,000,000 x .09 = \$6,750,000

\$65,000,000 x .11 = \$7,150,000

Total Minimum Royalties Due: \$13,900,000

48

All earned royalties paid by Schwarz pursuant to Section 5.3 shall be fully creditable against minimum royalties.

(b) As used in this Section 5.4, Forecast Net Sales shall be Schwarz's projected Net Sales for the Licensed Products in the Territory during the relevant calendar year ("Commercialization Year"), with the first Commercialization Year being the calendar year of launch of the Initial Product in the first country of the Territory. Schwarz shall deliver to DTI,



not later than forty-five (45) days prior to launch of the Initial Product in such country , and thereafter on or before November 15 of each calendar year its projected Net Sales of Licensed Products in the Territory for the relevant Commercialization Year. Notwithstanding the foregoing, after the first Commercialization Year which includes a full calendar year, Schwarz's minimum royalty obligation shall be calculated on Forecast Net Sales in an amount not less than seventy percent (70%) of Schwarz actual Net Sales in the previous Commercialization Year.

49

(c) Schwarz's minimum royalty obligation shall expire as to a particular country in the event any of the following occur:

(i) The expiration, lapse or invalidation of the last remaining DTI patents in such country which contains a valid and unexpired claim covering the sale of the Initial Product and a third party launches a generic form of the Initial Product delivered by a transdermal patch;

(ii) A third party launches a new product approved for marketing and sale in any country of the Territory for the treatment of Parkinson's Disease, which achieves a 10% share of the total annual worldwide sales of products approved for marketing and sale for the treatment of Parkinson's Disease as reported in the publication Data Monitor or an equivalent publication.

(iii) Schwarz has paid minimum royalties to DTI for ten (10) years.

(d) At any time during the term of the Agreement, the parties agree to renegotiate, in good faith, the conditions of this Section 5.4 in the event of changes including, but not limited to, competition, pricing, reimbursement, and distribution in the therapeutic treatment of Parkinson's Disease and or the Parkinson Disease market.

**5.5 Royalties Term.** If this Agreement is not terminated in accordance with other provisions hereof, Schwarz's obligation to pay royalties hereunder shall continue on a country-by-country and product-by-product basis until the expiration, lapse or invalidation by a decision of a court or tribunal of competent jurisdiction from which no appeal is or can be taken of the last remaining DTI Patent (including any extension thereof) in such country which contains a valid and unexpired claim covering the sale of the relevant Licensed Product in such country or the fifteenth (15th) anniversary of the date of the first commercial sale of Licensed Product(s) in the relevant country of the Territory, whichever is longer (the "Royalty Term"). For purposes of Section 5.4 and this Section 5.5 "valid and unexpired claim" shall mean a composition of matter or method of use claim or equivalent thereof, of an issued and unexpired DTI Patent (or corresponding patent application, provided that the original application containing such claim has not been pending for more than five (5) years) in a country covering Licensed Product, which (i) has not been revoked or held unenforceable or invalid by a decision of a court or other governmental agency of competent jurisdiction, unappealable or unappealed within the time allowed for appeal; or (ii) has not been abandoned, disclaimed, denied or admitted to be invalid or unenforceable through reissue of disclaimer or otherwise.

**5.6 Third-Party Royalties and Competing Products.** DTI shall be responsible for payment of royalties due to the third parties listed on Exhibit B under DTI's existing agreements

with such third parties. In the event that Schwarz is obligated to pay a royalty to a third party because the use and sale of the Licensed Product(s) in a country of the Territory infringes one or more patents held by such third party claiming subject matter that is also claimed in the DTI Patents, then Schwarz may reduce the royalties owed to DTI under Section 5.3 for the relevant country by fifty percent (50%) of the amount of all license fees paid to the third party, and any royalties paid to the third party in the same calendar year, *provided however*, that the royalties otherwise due to DTI in any particular calendar year shall not be reduced by more than fifty percent (50%). In the event that, and only for so long as, sale of a Competing Product occurs, then the royalties payable pursuant to section 5.3 shall on a country by country basis, be reduced by fifty percent (50%) and the sublicense fees payable pursuant to section 5.1(b) shall be reduced to fifteen percent (15%). A Competing Product shall mean any therapeutic product for Parkinson's disease or its symptoms or related conditions which contains a Licensed Product. (50)

**5.7 Withholding Taxes.** Any tax paid or required to be withheld by Schwarz on account of royalties payable to DTI under this Agreement shall be deducted from the amount of royalties otherwise due. Schwarz shall secure and send to DTI written proof of any such taxes withheld and paid by Schwarz or its sublicensees for the benefit of DTI. Schwarz shall reasonably assist DTI in claiming exemption from such deductions or withholdings under any double taxation or similar agreement or treaty from time to time in force.

**5.8 Blocked Currency.** In each country where the local currency is blocked and cannot be removed from the country, at the election of Schwarz, royalties accrued in that country shall be paid to DTI in the country in local currency by deposit in a local bank designated by DTI.

**5.9 Royalty Payments and Reports.** Beginning with the first commercial sale of a Licensed Product, royalties shall accrue on a calendar quarter basis, and Schwarz shall pay DTI all such amounts within 30 days following the end of the relevant quarter. Each royalty payment shall be accompanied by a report summarizing the number, description, and aggregate sales of Licensed Products made and the royalty payable thereon according to Section 5.3, including a description of any offsets or credits deducted from such sales, on a product-by-product and country-by-country basis during the relevant three-month period. For any given royalty period, Schwarz shall pay to DTI the royalty at the rate specified in Section 5.3 applicable to the then current year-to-date Net Sales level. Each statement provided at the end of the fourth quarter of each year shall contain a reconciliation of actual royalty payments made during that year and the amount actually owed for such year, and the resulting amount shall be paid to DTI at the time of such fourth quarter statement, in accordance with the terms of this Section 5.9.

**5.10 Currency; Exchange Rate.** All amounts paid under this Agreement shall be paid in U.S. dollars to DTI by wire transfer to a financial institution to be designated by DTI. The royalty on sales by Schwarz or sublicensee(s) of Licensed Products sold in a currency other than United States Dollars, such currency shall be converted into United States Dollars using the selling rate of exchange for the currency of the country from which the royalties are payable as published by the Wall Street Journal, New York, N.Y., U.S.A., for the last business day of the quarterly period for which the royalties are due.



**5.11 Accounting.** Schwarz agrees to keep and maintain such records, using generally accepted accounting principles (GAAP), as it normally generates in the ordinary course of its business for a period of three (3) years showing the manufacture, sale, use, and other disposition of products sold or otherwise disposed of under the license herein granted. Such records shall be kept in sufficient detail to enable the royalties payable hereunder by Schwarz to be determined. Schwarz further agrees to permit its books and records to be examined by an independent certified public accountant selected by DTI, at ordinary business hours with reasonable prior notice to Schwarz and consent by Schwarz, (not to be unreasonably withheld or delayed), and not more than once per year, to the extent necessary to verify reports provided for in Section 5.9. No copies of any Schwarz records shall be copied or retained by such examiner. Such examination is to be made under appropriate confidentiality restrictions, at the expense of DTI, except in the event that the results of the audit reveal an underreporting of royalties due DTI of five percent (5%) or more in any year, then the audit costs shall be paid by Schwarz.

## **6. MANUFACTURING**

**6.1 General.** Schwarz will be responsible for identifying a suitable manufacturer, developing commercial manufacturing processes and supplying clinical and commercial quantities of Licensed Products in the Territory.

**6.2 Transdermal Patch Product.** Schwarz will use commercially reasonable efforts to negotiate and finalize an agreement with LTS for fill and finish manufacturing of Transdermal Patch Products prior to the commencement of any clinical trials with respect to the Licensed Product. DTI will provide reasonable assistance to Schwarz in concluding such negotiations with LTS. Schwarz will bear any royalty due LTS pursuant to Section 3.03 of the LTS Feasibility Agreement dated January 22, 1996, which might become due to LTS as a result of sales of Licensed Products by Schwarz, its Affiliates or its Sublicensees. Any such royalties paid shall be fully creditable against royalties to be paid by Schwarz pursuant to Sections 5.3 and 5.4 of this Agreement.

**6.3 Quality Assurance.** Schwarz shall have day to day responsibility for commercial manufacturing and formulation issues related to product safety and regulatory compliance. All Licensed Products used in clinical and commercial supplies will be manufactured, tested, and released according to current cGMP's. Schwarz will be responsible for maintaining its facilities and procedures, including those of third parties, in compliance with cGMP's. Schwarz will promptly notify DTI of the results of any governmental regulatory inspections or other governmental regulatory action concerning the facilities or other manufacturing or formulation issues, and will promptly provide to DTI copies of all Form 483's (or their non-U.S. equivalents) and compliance related documentation, including all actions taken by Schwarz in response thereto or as a result thereof. Any expenses incurred in improving compliance with regulatory requirements or responding to Form 483's (or their non-U.S. equivalents) or other compliance related documentation will be the full responsibility of Schwarz. Schwarz shall indemnify and hold DTI harmless against any claims or liabilities incurred by DTI as a result of Schwarz' breach of its obligations under this Section 6.3.

**6.4 Technology Transfer in Event of Termination.** Upon termination by Schwarz of this Agreement (other than a termination for DTI's breach), Schwarz shall continue to provide

for such manufacture of such Licensed Products to the extent provided prior to notice of such termination, from the time notice of such termination is provided until such time as DTI is able to secure an equivalent alternative commercial manufacturing source (provided, however, that "equivalent" shall not be deemed to require an equivalent cost or price), in the event that DTI using its best efforts is unable to secure such an alternative source during the notice period. In no event shall Schwarz be required to continue such supply for a period of more than one year from the time notice of such termination is provided. To this end, as of the effective date of such termination, Schwarz shall use its reasonable commercial efforts to assign all third party manufacturing contracts to DTI, and the cost charged to DTI for any manufacturing activities by Schwarz shall be the same as Schwarz's fully burdened cost during the time that the Agreement was in effect. Further, upon DTI's request, Schwarz shall provide such technical assistance and Know-how licenses on a royalty free basis as may reasonably be requested to transfer such technology as needed by DTI to commence or provide for commercial manufacture of Licensed Products. Such technical assistance shall be provided at Schwarz's cost, which cost shall be reimbursed by DTI. Schwarz shall also, to the extent it has the right to do so, sublicense to DTI any third party licenses to which Schwarz has rights, to the extent that such rights are necessary or useful to make, use and sell the Licensed Products, and DTI shall thereafter assume the cost of maintaining such licenses, provided, however, that if such Licensed Product is not the Initial Product and utilizes delivery technology other than a DTI Patent, then such license shall be upon commercially reasonable terms, including a reasonable royalty to Schwarz. If the parties cannot agree upon terms for such license, then either party may submit the issue for resolution pursuant to Section 13 of this Agreement.

**6.5 Patent Marking.** Schwarz shall mark all Licensed Products in accordance with applicable patent marking requirements for the territory in which the Products will be sold.

## **7. REPRESENTATIONS AND WARRANTIES**

### **7.1 Warranties.**

(a) Each party hereby warrants to the other that:

(i) this Agreement is a legal and valid obligation binding upon such party and enforceable in accordance with its terms. The execution, delivery and performance of this Agreement by such party does not conflict with any agreement, instrument or understanding, oral or written, to which it is a party or by which it is bound, nor violate any law or regulation of any court, governmental body or administrative or other agency having jurisdiction over it. Each party expressly represents and warrants that it has full power and authority to execute and deliver this agreement and to perform the obligations contemplated hereby.

(ii) such party owns, in whole or in part, or controls all patents and know-how that are the subject of the licenses granted to the other party in this Agreement.

(iii) such party has not, and during the term of the Agreement will not, grant any right to a third party relating to its respective patents and know-how in the Field that would conflict with the rights granted to the other party under this Agreement.

(b) DTI represents and warrants, as of the Effective Date, that it has not received any notices of infringement with respect to the Compounds, and to the best of its knowledge the manufacture, use or sale of products containing a Compound as set forth herein does not infringe any third party rights which have not been licensed to DTI and by DTI to Schwarz pursuant to this Agreement.

(c) DTI represents and warrants that to the best of its knowledge DTI has disclosed to Schwarz all the information in DTI's possession or control concerning side effects, injury, toxicity or sensitivity reaction and incidents associated with the use of Licensed Products obtained from any clinical and non-clinical studies.

**7.2 Negation of Representations.** Nothing in this Agreement is or shall be construed as:

(a) A warranty or representation by DTI as to the validity or scope of any DTI Patent(s);

(b) A warranty or representation that anything made, used, sold, or otherwise disposed of under any license granted in this Agreement is or will be free from infringement of patents, copyrights, and other rights of third parties;

(c) An obligation to bring or prosecute actions or suits against third parties for infringement, except to the extent and in the circumstances described in Section 9.1; or

(d) Granting by implication, estoppel, or otherwise any licenses or rights under patents or other rights of DTI or other persons other than DTI Patent(s), regardless of whether such patents or other rights are dominant or subordinate to any DTI Patent(s).

**7.3 Warranty Disclaimer.** Except expressly set forth in this Agreement, DTI MAKES NO REPRESENTATIONS AND EXTENDS NO WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED. THERE ARE NO EXPRESS OR IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, OR THAT THE USE OF THE LICENSED PRODUCT(S) WILL NOT INFRINGE ANY PATENT, COPYRIGHT, TRADEMARK, OR OTHER RIGHTS OR ANY OTHER EXPRESS OR IMPLIED WARRANTIES.

## **8. INDEMNITY AND INSURANCE**

**8.1 Indemnification of DTI by Schwarz.** Schwarz agrees to indemnify, hold harmless and defend DTI and its officers, employees and agents against any and all third party claims for death, illness, personal injury, property damage or improper business practices arising out of the use, sale, handling or other disposition of Licensed Product(s) by Schwarz or sublicensee(s), or their customers, except to the extent such claims result from the negligent or intentional misconduct of DTI and its officers, employees and agents.

**8.2 Indemnification of Schwarz by DTI.** DTI agrees to indemnify, hold harmless and defend Schwarz and its officers, employees and agents against any and all third party claims for death, illness, personal injury, property damage and improper business practices arising out



of the negligent or intentional misconduct of DTI and its officers, employees and agents with respect to the use, sale or other disposition of Licensed Products in the Territory, except to the extent such claims result from the negligent or intentional misconduct of Schwarz and its officers, employees and agents.

**8.3 Insurance.** In addition to the foregoing, Schwarz shall obtain appropriate insurance in accordance with standard commercial practices to cover the indemnity granted in Section 8.1 and such insurance policy shall name DTI as an additional insured. Such insurance shall be written to cover claims incurred, discovered, manifested, or made in connection with clinical development and sale of the Licensed Product(s) in the Territory. Schwarz agrees to provide evidence of such coverage if requested by DTI.

## **9. INFRINGEMENT BY OTHERS; PROTECTION OF PATENTS**

**9.1 Infringement of DTI Patents.** Each party shall promptly inform the other of any suspected infringement of any DTI Patent(s) by a third party. DTI and Schwarz each shall have the right to institute an action for infringement of the DTI Patent(s) against such third party in accordance with the following:

(a) If DTI and Schwarz agree to institute suit jointly, the suit shall be brought in both their names, the out-of-pocket costs, including but not limited to litigation costs, thereof shall be borne equally and any recovery or settlement shall be shared equally. Schwarz and DTI shall work together to manage such litigation with Schwarz having the primary responsibility for controlling such suits. DTI may, if it so desires, also be represented by separate counsel of its own selection, the fees for which counsel shall be paid by DTI;

(b) In the absence of agreement to institute a suit jointly, Schwarz shall have the first right, but not the obligation, to institute suit and, at its option, let DTI join as a party plaintiff. Schwarz shall bear the entire cost of such litigation and shall be entitled to retain the entire amount of any recovery or settlement. Schwarz shall indemnify DTI against any order for costs that may be made against DTI in such proceedings, including photocopying costs and witness travel fees, but expressly excluding attorneys' fees.

(c) In the absence of agreement to institute a suit jointly as provided in (a) above, and if Schwarz notifies DTI that it has decided not to institute a suit as provided in (b) above, DTI may institute suit, and, at its option, let Schwarz join as a party plaintiff. DTI shall bear the entire cost of such litigation including attorneys' fees and shall be entitled to retain the entire amount of any recovery or settlement.

(d) Should either DTI or Schwarz commence a suit under the provisions of Section 9.1 and thereafter elect to abandon the same, it shall give timely notice to the other party who may, if it so desires, continue prosecution of such suit, provided, however, that the sharing of expenses and any recovery in such suit shall be agreed upon between DTI and Schwarz in advance of such continuation.

(e) In the event that DTI jointly owns any patent valid in the Territory with a third party manufacturer, DTI shall use its best efforts to arrange for such manufacturer to

cooperate in any infringement actions in accordance with the terms of this Section 9.1 and agrees not to prevent any suit contemplated by Schwarz.

## **9.2 Prosecution and Maintenance of DTI Patents.**

(a) DTI shall be primarily responsible for prosecuting and maintaining the DTI Patent(s) in the Territory. DTI shall work with Schwarz to develop a reasonable patent strategy appropriate for the technology at issue, and shall permit Schwarz to review and comment on any documents filed with the relevant patent authorities in the Territory with respect to the DTI Patent(s). DTI shall notify Schwarz if it intends to abandon any such patent or otherwise forego any patent rights in the Territory at least sixty (60) days prior to any relevant deadline. Schwarz shall have the right, at its own expense and under Schwarz's name, to file and assume prosecution and maintenance of any patent or patent application abandoned by DTI. Thereafter, Schwarz shall not be required to pay royalties with respect to such patent or patent application.

(b) All reasonable costs incurred for prosecuting and maintaining the DTI Patents in the Territory shall be borne by Schwarz, including costs of registering this license as provided in Section 2.1, *provided however*, that Schwarz shall only be responsible for DTI's share of the costs of prosecuting and maintaining PCT Appl. No. US94/08845. Schwarz shall provide reasonable support and assistance with such patent prosecution and maintenance.

## **10. CONFIDENTIALITY**

**10.1 Information.** Each party shall keep all information received from the other party (the "Information") confidential and shall not disclose nor use the Information without the other party's written consent except to the extent contemplated by this Agreement. This restriction shall not, however, prevent disclosure of the Information if and to the extent that disclosure is required by law, provided that the disclosing party informs the other party without delay of any such requirement, in order to allow such other party to object to such disclosure and to seek an appropriate protective order or similar protection prior to disclosure.

**10.2 Exceptions.** The above obligations shall not apply or shall cease to apply to Information which:

(a) is now, or hereafter becomes, through no act or failure to act on the part of the receiving party, generally known or available;

(b) is known by the receiving party at the time of receiving such information, as evidenced by its written records;

(c) is hereafter furnished to the receiving party by a third party, as a matter of right and without restriction on disclosure;

(d) is independently developed by the receiving party without any breach of this Section 10; or

(e) is the subject of a written permission to disclose provided by the disclosing party.

**10.3 Permitted Disclosures.** Information may be disclosed for the purpose of filing, prosecuting and maintaining patents and patent applications, and for obtaining regulatory approvals, manufacture and sale of Licensed Products, and to employees, agents, consultants, sublicensees or suppliers of the recipient party or its affiliates, but only to the extent required to accomplish the purposes of this Agreement and only if such individuals are required by law, contract or otherwise not to use or disclose such information except as permitted by this Agreement. Each party will use at least the same standard of care as it uses to protect proprietary or confidential information of its own to ensure that such employees, agents, consultants, sublicensees or suppliers do not disclose or make any unauthorized use of the Information.

**10.4 Disclosure of Agreement.** Except as required by law, neither DTI nor Schwarz shall release to any third party or publish in any way any non-public information with respect to the terms of this Agreement or concerning their cooperation without the prior written consent of the other, which consent will not be unreasonably withheld or delayed; provided; however that either party may disclose the terms of this Agreement to the extent required to comply with applicable laws, including without limitation the rules and regulations promulgated by the Securities and Exchange Commission. Notwithstanding any other provision of this Agreement, each party may disclose the terms of this Agreement to lenders, investment bankers, financial advisors and other financial institutions of its choice solely for purposes of financing the business operations of such party, or to potential investors in or acquirers of such party either (i) upon the written consent of the other party or (ii) if the disclosing party obtains a signed confidentiality agreement with such intended recipient with respect to such information, upon terms substantially similar to those contained in this Section. Notwithstanding the foregoing, the parties will issue a joint press release in the form attached hereto as Exhibit D which shall be specified within 60 days of the Effective Date.

## **11. TERM AND TERMINATION**

**11.1 Term.** This Agreement shall commence on the Effective Date and expire at the end of the Royalty Term under Section 5.5. Upon the expiration (but not the earlier termination) of the Royalty Term, the licenses granted hereunder to Schwarz shall convert to an exclusive, as to the territory, fully paid and royalty-free licenses.

**11.2 Termination by Schwarz.** Schwarz may terminate this Agreement by giving DTI notice in writing as follows:

(a) Upon twelve (12) months prior written notice to DTI, provided that such notice may not be given prior to the first anniversary of the date of this Agreement; or;

(b) Upon thirty (30) days prior written notice to DTI if Schwarz in the exercise of its reasonable judgment, determines that there are issues concerning the safety, efficacy, or supply of the Licensed Product which materially adversely affect its medical or competitive commercial viability, including, without limitation, a clinical hold or other adverse regulatory action.

In the event of termination under this Section 11.2(a), Schwarz shall, during the twelve (12) month period between notice and the effective date of the termination, continue to fund development activities in accordance with the Development Plans and shall cooperate with DTI to effect an orderly transition of such development activities from Schwarz to DTI. Under any termination Schwarz shall promptly transfer to DTI at DTI's written request all INDs, applications for Regulatory Approval and Regulatory Approvals, or their non-U.S. equivalents (as applicable) as it may hold with respect to Licensed Products in such country, and any information as Schwarz may possess which is useful to gain Regulatory Approval for and to commercialize the Licensed Products in such country. Such transfer shall be without cost to DTI, provided however that DTI shall pay any governmental filing or transfer fees that may be required.

**11.3 Termination for Material Breach.** If either party commits a material breach of this Agreement and such breach is not cured within sixty (60) days after written notice thereof by the non-breaching party, or if such breach is incapable of cure during the applicable notice period, the breaching party fails to make good faith efforts to cure such breach, the non-breaching party may terminate this Agreement upon expiration of the notice period. (51)

**11.4 Effect of Termination by DTI for Material Breach.** In the event of a termination by DTI under Section 11.3, all licenses to Schwarz under this Agreement shall terminate. In addition:

(a) Schwarz and DTI shall cooperate to ensure that the development and commercialization of Licensed Products in the Territory continues with a minimum of delay resulting from the transfer of rights back to DTI. In particular, Schwarz shall provide to DTI all available preclinical and clinical data and regulatory documents in its possession or control, and shall promptly assign or cause to be assigned to DTI, or its designee, every government approval, clearance, registration or permit relating to the Licensed Products obtained by Schwarz in the Territory. In the event such assignment is not permitted by law, Schwarz will cooperate in the cancellation of such government approval, clearance, registration or permit standing in its name and the reissuance of such government approval, clearance, registration or permit to DTI or its designee. Schwarz shall take all such other actions and execute such other instruments, assignments and documents as may be necessary to effect the transfer of rights hereunder to DTI.

(b) If Schwarz has already commenced manufacturing of the Licensed Product, Schwarz shall continue to provide for manufacture of the Licensed Products to the extent necessary to meet market demand, from the effective date of such termination until such time as DTI is able to secure an equivalent alternative commercial manufacturing source, as requested by DTI, provided, however, that cost to DTI shall not be considered as a constituent factor of such equivalency, and further provided, that Schwarz shall in no event be required to continue to manufacture for more than eighteen (18) months after the notice of such termination or in quantities in excess of those being produced at the time of such termination. The cost charged to DTI for any manufacturing activities by Schwarz shall be the same as Schwarz's fully burdened cost during the time that the Agreement was in effect. As of the effective date of such termination, all third party manufacturing contracts for manufacture of Licensed Products shall be assigned to DTI, to the extent that Schwarz has the right to do so, and DTI will assume payment for third party royalties, if any. In addition, upon DTI's request, Schwarz shall provide (52)



such technical assistance and know-how licenses on a royalty-free basis as may reasonably be requested to transfer such technology as is needed by DTI to commence or provide for commercial manufacture of Licensed Product. If any technology needed by DTI to commence or provide for commercial manufacture of Licensed Product is covered by one or more patents owned or controlled by Schwarz, DTI shall receive a fully paid-up, royalty-free, non-exclusive worldwide license to practice any and all such patents for the purposes contemplated in this Section 11.4, with the right to grant sublicenses.

**11.5 Accrued Obligations.** Except where expressly provided for otherwise in this Agreement, termination of this Agreement shall not relieve the Parties hereto of any liability, including any obligation to make payments hereunder, which accrued hereunder prior to the effective date of such termination, nor preclude any Party from pursuing all rights and remedies it may have hereunder or at law or in equity with respect to any breach of this Agreement nor prejudice any Party's right to obtain performance of any obligation.

**11.6 Effect of Termination by Schwarz for Material Breach.** If Schwarz terminates this Agreement pursuant to Section 11.3, it shall continue to be obligated during the termination notice period to perform all of its obligations under this Agreement; provided that Schwarz shall have no obligation to make any milestone payments pursuant to Section 5.2 with respect to any milestone achieved during the termination notice period.

**11.7 Surviving Obligations.** Surviving any termination are:

- (a) Schwarz's obligation to pay accrued royalties up to the effective date of termination;
- (b) any cause of action or claim of Schwarz or DTI, accrued or to accrue, because of any breach or default by the other party; and
- (c) the provisions of Sections [3.5(c), 3.10, 4.5, 5.6, 5.7, 5.8, 5.9, 5.10, 5.11, 6.4, 11.2, 11.4, 11.5, 11.6, 11.7, 13 and 14.3 and Articles 7, 8, 10 and 13]

**11.8 Bankruptcy.** All rights and licenses granted under or pursuant to this Agreement by DTI to Schwarz are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the Bankruptcy Code, licenses of rights to "intellectual property" as defined under Section 101(52) of the Bankruptcy Code. The parties agree that Schwarz, as a licensee of such rights under this Agreement, shall retain and may fully exercise all of its rights and elections under the Bankruptcy Code. The parties further agree that in the event of the commencement of a bankruptcy proceeding by or against DTI under the Bankruptcy Code, Schwarz shall be entitled to a complete duplicate of, or complete access to, as appropriate, any such intellectual property and all embodiments of such intellectual property, and same, if not already in its possession, shall be promptly delivered to Schwarz (i) upon any such commencement of a bankruptcy proceeding upon written request therefor by Schwarz unless DTI elects to continue to perform all of its obligations under this Agreement, or (ii) if not delivered under (i) above, upon the rejection of this Agreement by or on behalf of DTI upon written request therefor by Schwarz.

## **12. ASSIGNMENT**

This Agreement may not be assigned by either party without the prior written consent of the other party except to an Affiliate or in connection with a merger, consolidation or sale of all or substantially all of the line of business to which this Agreement relates. This Agreement shall be binding upon and inure to the benefit of all successors and permitted assigns of the parties.

## **13. DISPUTE RESOLUTION**

**13.1 Discussion.** In the event of any dispute between the parties regarding their respective rights or obligations under this Agreement, each party agrees to discuss such matter in good faith in an effort to resolve the dispute without resort to formal dispute resolution procedures. At any time, either party may call a meeting between an Executive Board member of Schwarz and the Chief Executive Officer of DTI to attempt to resolve the dispute. Such meeting shall be held not later than thirty (30) days after it is requested in writing by either party in New York, New York. If such dispute cannot be resolved through such procedures within forty-five (45) days of the date either party requests a meeting of the officers designated above, then either party may request an arbitration proceeding as provided in Section 13.2.

**13.2 Alternative Dispute Resolution.** Any dispute controversy or claim arising out of or relating to the validity, construction, enforceability or performance of this Agreement, including disputes relating to an alleged breach or to termination of this Agreement and including any claim of inducement by fraud or otherwise, but excluding (i) any dispute, controversy or claim arising out of or relating to the validity, enforceability, or infringement of any DTI Patent or any Schwarz Patent and (ii) any dispute which is expressly prohibited herein from being resolved by this mechanism, shall be settled by binding Alternative Dispute Resolution ("ADR") by Mediation and Arbitration in the manner described below:

### **13.3 Mediation.**

(a) Any such dispute, controversy or claim which would, but for this provision, be submitted to arbitration shall, before submission to arbitration, first be mediated through non-binding mediation in accordance with the Model Procedures for the Mediation of Business Disputes promulgated by the Center for Public Resources ("CPR") then in effect, except where those rules conflict with these provisions, in which case these provisions control. The mediation shall be conducted in the United States and shall be attended by a senior executive with authority to resolve the dispute from each of the operating companies that are parties.

(b) The mediator shall be an attorney specializing in business litigation who has at least 15 years of experience as a lawyer with a law firm of over 25 lawyers or was a judge of a court of general jurisdiction and who shall be appointed from the list of neutrals maintained by CPR.

(c) The Parties shall promptly confer in an effort to select a mediator by mutual agreement. In the absence of such an agreement, the mediator shall be selected from a list generated by CPR with each party having the right to exercise challenges for cause and two peremptory challenges within 72 hours of receiving the CPR list.

(d) The mediator shall confer with the Parties to design procedures to conclude the mediation within no more than 45 days after initiation. Under no circumstances shall the commencement of arbitration under Section 13.4 be delayed more than 45 days by the mediation process specified herein.

(e) Each party agrees to all applicable statutes of limitation during the mediation process and not to use the period or pendency of the mediation to disadvantage the other party procedurally or otherwise. No statements made to either side during the mediation may be used by the other during any subsequent arbitration.

(f) Each party has the right to pursue provisional relief from any court such as attachment, preliminary injunction, replevin, etc., to avoid irreparable harm, maintain the status quo, or preserve the subject matter of the arbitration, even though mediation has not been commenced or completed.

**13.4 Arbitration.** Except as provided in paragraph (c) below, any dispute, controversy or claim arising out of or relating to the validity, construction, enforceability or performance of this Agreement which is not resolved by mediation, including disputes relating to alleged breach or to termination of this Agreement, other than disputes which are expressly prohibited herein from being resolved by this mechanism, shall be settled by binding Alternative Dispute Resolution (“ADR”) in the manner described below:

(a) If a party intends to begin an ADR to resolve a dispute, such party shall provide written notice (the “ADR Request”) to counsel for the other party informing such other party of such intention and the issues to be resolved. From the date of the ADR Request and until such time as any matter has been finally settled by ADR, the running of the time periods contained in Article 14 as to which party must cure a breach of this Agreement shall be suspended as to the subject matter of the dispute.

(b) Within ten (10) business days after the receipt of the ADR Request, the other party may, by written notice to the counsel for the party initiating ADR, add additional issues to be resolved.

(c) Any dispute regarding the validity or enforceability of a patent or trademark applicable to a Product shall be submitted to a court of competent jurisdiction in the country in which such patent or trademark right exists.

**13.5 Procedure.** The ADR shall be conducted pursuant to JAMS/ENDISPUTE Rules A and C, attached hereto as Exhibit E. Notwithstanding those rules, the following provisions shall apply to the ADR hereunder.

(a) **Arbitrator.** The arbitration shall be conducted by a single arbitrators (“the Arbitrator”). The Arbitrator shall be selected from a pool of retired independent federal judges to be presented to the Parties by JAMS/ENDISPUTE. Neither party shall enoagein ex parte contact with the arbitrator.

(b) **Proceedings.** The time periods set forth in the JAMS/ENDISPUTE rules shall be followed, unless a party can demonstrate to the Arbitrator that the complexity of the



issues or other reasons warrant the extension of one or more of the time tables. In such case, the panel may extend such time tables, but in no event shall the time tables being extended so that the ADR proceeding extends more than 18 months from its beginning to the Award. In regard to such time tables, that Parties (i) acknowledge that the issues that may arise in any dispute involving this Agreement may involve a number of complex matters and (ii) confirm their intention that each party will have the opportunity to conduct complete discovery with respect to all material issues involved in a dispute within the framework provided above. The Arbitrator shall not award punitive damages to either party and the Parties shall be deemed to have waived any right to such damages. The Arbitrator shall, in rendering its decision, apply the substantive law of the State of Delaware, without regard to its conflict of laws provisions, except that the interpretation of and enforcement of this Section shall be governed by the Federal Arbitration Act. The Arbitrator shall apply the Federal Rules of Evidence to the hearing. The proceeding shall take place in the United States. The fees of the Arbitrators and JAMS/ENDISPUTE shall be paid by the losing party, which shall be designated by the Arbitrator. If the Arbitrator is unable to designate a losing party, it shall so state and the fees shall be split equally between the Parties.

(c) **Award.** The Arbitrator is empowered to award any remedy allowed by law, including money damages, prejudgment interest and attorneys' fees, and to grant final, complete, interim, or interlocutory relief, including injunctive relief but excluding punitive damages.

(d) **Confidentiality.** The ADR proceeding shall be confidential and the Panel shall issue appropriate protective orders to safeguard each party's Confidential Information. Except as required by law, no party shall make (or instruct the Panel to make) any public announcement with respect to the proceedings or decision of the Panel without prior written consent of each other party. The existence of any dispute submitted to ADR, and the award, shall be kept in confidence by the parties and the Panel, except as required in connection with the enforcement of such award or as otherwise required by applicable law.

## 14. GENERAL

**14.1 Notices.** All notices under this Agreement shall be deemed to have been fully given when done in writing and deposited in the United States mail, registered or certified, or sent by express courier (receipt confirmed) and addressed as follows:

To DTI: 2028 Dabney Road  
Suite E-17  
Richmond, VA 23230-3311  
Attention: Chief Executive Officer

With a copy to: Cooley Godward LLP  
5 Palo Alto Square  
3000 El Camino Real  
Palo Alto, California 94306  
Attn: Alan C. Mendelson, Esq.

To Schwarz: Schwarz Pharma AG  
Alfred Nobel-Strasse 10  
40789 Monheim, Germany  
Attention: President

With two a copies to: Schwarz Pharma USA  
6140 West Executive Drive  
Mequon, Wisconsin 53092  
Attn: Chief Executive Officer  
Attn: General Counsel

Either party may change its address upon written notice to the other party.

**14.2 Entire Agreement.** This Agreement embodies the entire understanding between the parties relating to the subject matter hereof and supersedes all prior understandings and agreements, whether written or oral. None of the terms of this Agreement can be amended or waived except by an instrument in writing executed by authorized representatives of each party.

**14.3 Governing Law.** This Agreement shall be governed by the laws of the State of Delaware, without regard to conflict of laws principles.

**14.4 Severability.** Any of the provisions of this Agreement which are determined to be invalid or unenforceable in any jurisdiction shall be ineffective to the extent of such invalidity or unenforceability in such jurisdiction, without rendering invalid or unenforceable the remaining provisions hereof or affecting the validity or enforceability of any of the terms of this Agreement in any other jurisdiction.

**14.5 Counterparts.** This Agreement may be executed in any number of counterparts, each of which shall be deemed an original, but all of which taken together shall constitute one and the same instrument.

**In Witness Whereof**, the parties hereto have executed this Agreement in duplicate originals by their duly authorized officers or representatives.

**Discovery Therapeutics, Inc.**

Signature: \_\_\_\_\_

Name: Donald A. McAfee

Title: President and CEO

Date: July 17<sup>th</sup>, 1998

**Schwarz Pharma AG**

Signature: \_\_\_\_\_

Name: K. Langer; L. Ekman

Title: Finances & Technical Operations;  
Research & Development; Member of  
Executive Board

Date: July 17, 1998

**Exhibit A**  
**DTI PATENTS**

U.S. Patent No. 4,564,628

U.S. Patent No. 4,885,308

European Patent No. 0168505

Canada Patent No. 1,248,537

Canada Patent No. 1,338,508

S. Korea Patent Appl. No. 700272/1990

U.S. Patent No. 5,382,596

PCT Appl. No. US94/08845

**Exhibit B**

**THIRD PARTY AGREEMENTS**

Licensee

Yoshitomi Pharmaceutical Industries Ltd. Osaka, Japan

53

Other Relationships

Lohmann Therapie-Systeme  
University of Groningen  
Ethyl Corporation

Andernach, Germany  
Groningen, The Netherlands  
Richmond, VA, USA

53

**Exhibit C**

**PROSPECTIVE DTI LICENSEES**

<b>Prospective Licensee</b>	<b>Territory</b>
AMRAD	Australia/Asia
Athena Elan	World Wide
Dexcel	Israel
Dupont/Merck	World Wide
Ferrer Group	Hispanola
Forrest Laboratories	USA
Mylan Laboratories	USA
Neurochem	Canada
Orion Pharmaceuticals	World wide
Prodestfarma	Hispanola
Purdue Frederick/Mundi Pharma	World Wide
Sam Yang Corporation	Korea
Schering Plough	World Wide
Solvay	World Wide
Teva	Israel

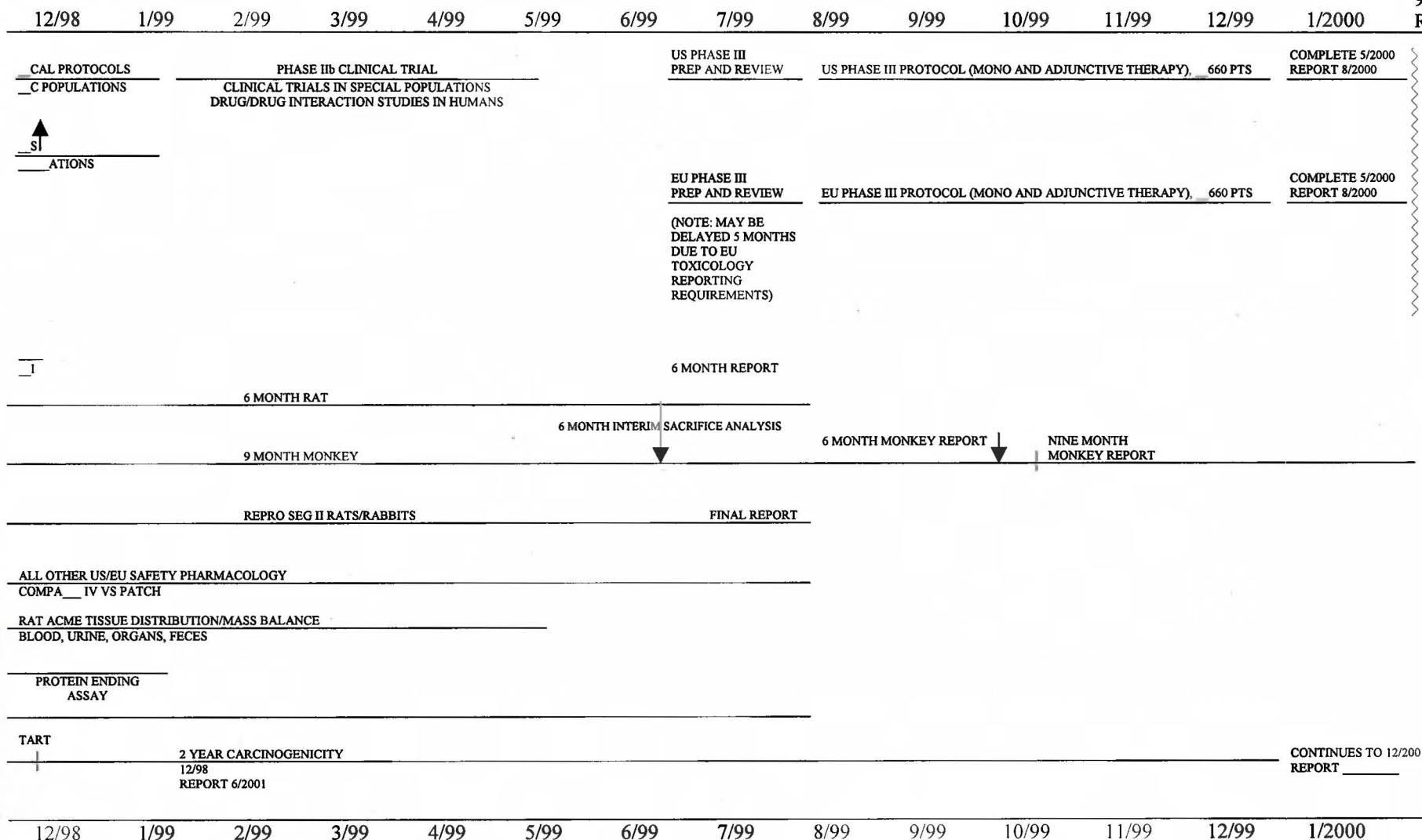
54

**Exhibit D**  
**PRESS RELEASE**



## **EXHIBIT E**

CMC TO \_\_\_\_\_  
 DS SC \_\_\_\_\_ PROCESS  
 VALID \_\_\_\_\_ C/QA  
 3 BAI \_\_\_\_\_ 200KG  
 SCALE  
 9/99 – 9/2000  
 REPORT 12/2000



NOTE:  
 This plan projects first US (FDA) approval in Q4/2002, and first EU approval 12-18 months later.

EXHIBIT F

55

**AMENDMENT NO. 1  
TO THE AGREEMENT  
BETWEEN  
DISCOVERY THERAPEUTICS, INC.  
AND  
SCHWARZ PHARMA AG**

**THIS AMENDMENT NO. 1** is entered into as of the 22 day of December, 1999, ("Amendment Effective Date") by and among **DISCOVERY THERAPEUTICS, INC.**, a Delaware corporation having a principal place of business at 2028 Dabney Road, Suite E-17, Richmond, VA 23230-3311 ("DTI") and **SCHWARZ PHARMA AG**, a corporation formed under the laws of Germany and having a principal place of business at Alfred-Nobel-Strasse 10, 40789 Monheim, Germany ("Schwarz").

**RECITALS**

**WHEREAS**, DTI and Schwarz entered into an Agreement dated as of July 16, 1996, for the late-stage development and commercialization of DTI's proprietary dopamine receptor agonist N-0923 and various other compounds in all countries of the world except Japan (the "Agreement");

**WHEREAS**, DTI and Schwarz desire to amend the Agreement to expand the territory in which Schwarz has rights to include Japan; and

**WHEREAS**, not later than 30 days after the execution of this Amendment, Schwarz will purchase \$5 million worth of Series C Preferred Stock of DTI pursuant to the Stock Purchase Agreement described herein.

**NOW, THEREFORE**, in consideration of the foregoing and the covenants and promises contained in this Amendment, DTI and Schwarz hereby amend the Agreement as follows:

1. Section 1.18 shall be deleted in its entirety and the following shall be inserted in its place:

**1.18 "Territory"** means all countries of the world.

2. Section 5.2 shall be deleted in its entirety and the following shall be inserted in its place:

**5.2 Milestones.** Schwarz shall pay to DTI the following amounts within thirty (30) days of the first achievement, by any Licensed Product, of the respective milestone event set forth below and shall not pay again for subsequent Licensed Products:

<b>Milestone Event</b>
Commencement of Phase III clinical trial (enrollment of first patient)

**Payment**

\$4,000,000

56

Milestone Event	Payment
First issuance of joint DTI-LTS patent in any Major Country of the Territory	\$1,500,000
Submission to regulatory authority of Regulatory Approval in Japan	\$500,000
NDA Approval	\$5,000,000
Regulatory Approval in the first three non-US Major Countries ex Japan	\$1,000,000 each
Regulatory Approval in Japan	\$1,000,000

56

Milestone payments shall be noncreditable and shall be nonrefundable.

3. Section 5.3 shall be deleted in its entirety and the following shall be inserted in its place:

**5.3 Earned Royalties.** In addition, Schwarz shall pay DTI a running royalty on annual Net Sales of all Licensed Products according to the following marginal rates:

(a) For annual Net Sales of Licensed Products up to \$95 million, nine percent (9%) of such Net Sales; and

(b) For the portion of annual Net Sales of Licensed Products in excess of \$95 million and not exceeding \$200 million, eleven percent (11%) of such Net Sales; and

(c) For the portion of annual Net Sales of Licensed Products in excess of \$200 million, fifteen percent (15%) of such Net Sales.

(d) As of the Effective Date of this Agreement, the parties anticipate Schwarz will consummate a supply agreement with LTS. In such case the parties may decide that Schwarz shall pay to LTS some or all of royalties pursuant to Section 6.2 and reduce its royalty payments to DTI accordingly.

4. The following new Section 5.12 shall be added to Article 5 of the Agreement:

**5.12 Equity Investment in DTI.** Not later than thirty (30) days after the Amendment Effective Date, the parties shall enter into a Stock Purchase Agreement pursuant to which Schwarz shall purchase \$5 million worth of Series C Preferred Stock of DTI which shall represent ten percent 10% of DTI's capital stock on a fully diluted basis.

5. Except as otherwise amended herein, the Agreement shall remain in full force and effect.

57  
57  
57

6. This Amendment may be executed in any number of counterparts, each of which shall be deemed an original, and all of which taken together shall constitute one and the same instrument.
7. This Amendment shall be effective as of the date first written above.

**IN WITNESS WHEREOF**, the parties hereto have duly executed this Amendment.

**DISCOVERY THERAPEUTICS, INC.**

**SCHWARZ PHARMA AG**

By: /s/ Donald A. McAfee

By: /s/ Lars Ekman; P. Schwarz-Schutte

Title: Chairman and CEO

Title: Member of Board; Chairman of Board



**AMENDMENT NO. 2 DATED OCTOBER 21, 2002 TO THE EXCLUSIVE  
LICENSE AGREEMENT BETWEEN ADERIS PHARMACEUTICALS, INC.  
(FORMERLY DISCOVERY THERAPEUTICS, INC.)  
AND SCHWARZ PHARMA AG  
Effective as of July 17, 1998**

WHEREAS, Aderis Pharmaceuticals, Inc. ("Aderis") and Schwarz Pharma AG ("Schwarz") have previously entered into an Exclusive License Agreement, dated July 17, 1998 relating to the development, manufacturing and commercialization of a pharmaceutical compound known as Rotigotine ("Agreement"), and

WHEREAS, Aderis and Schwarz have previously entered into an amendment to the Agreement, which amendment is dated December 22, 1999 ("First Amendment");

WHEREAS, Aderis and Schwarz now desire to modify certain terms of the Agreement in order to facilitate the sublicensing of certain rights under the Agreement for the Japanese market, to the mutual financial benefit of both Aderis and Schwarz; and to that end have entered into this Agreement amendment ("Second Amendment");

NOW, THEREFORE, in consideration of the premises and the mutual promises and covenants set forth below, Aderis and Schwarz mutually agree as follows:

1. The provisions of this Second Amendment are hereby made a part of the Agreement and any conflict between the provisions of this Second Amendment and the Agreement shall be resolved in favor of this Second Amendment. All capitalized terms used in this Second Amendment, and not defined herein, shall have the same meanings as given to them in the Agreement.

2. The following modifications are hereby made to the Agreement:

(a) A sentence is added to Section 5.3(c) of the Agreement to read as follows: "However, for any year in which worldwide Net Sales of Licensed Products exceed \$200 million ("Sales Threshold"), the royalty rate applicable for Net Sales in Japan for that portion of the year after the Sales Threshold has been attained, shall be thirteen percent (13%)."

(b) A sentence is added to Section 2.3 of the Agreement to read as follows : "The Parties agree to specifically exclude from the license granted to Aderis pursuant to this Section 2.3, Japan and any country as to which Schwarz has granted to a sub-licensee for Japan rights of first negotiation, first refusal or option to acquire from Schwarz a sub-license for such country, until such time as such sub-licensee's rights regarding such countries have terminated or expired".

(c) A new Section 11.9 is added to the Agreement to read as follows in its entirety: "Aderis agrees and acknowledges that, should this Agreement terminate through no fault of a particular Schwarz sub-licensee, that sub-licensee, providing that it is not in default under its sublicense from Schwarz, shall have the right to continue to commercialize any

sublicensed Licensed Product as set forth in such sublicense and in this Agreement, as a direct licensee of Aderis.”

(d) “2. (d) Section 5.5 shall be amended to read as follows: “whichever is longer (the “Royalty Term”). **However, it is understood between the Parties that the royalties due on Net Sales in Japan shall be reduced by three (3) percentage points from that date onwards when Schwarz or its sublicensee in Japan can no longer market the Licensed Product(s) on an exclusive basis due to the loss of (i) a valid and unexpired claim of a DTI Patent or a LTS patent and/ or (ii) exclusivity in fact based on applicable local laws, rules and/or regulations in Japan; such royalties to be further reduced by an additional two(2) percentage points from that date where in addition a third party launches a pharmaceutical product containing a Compound in patch formulation in Japan and such third party captures a 30% share of the Net Sales in Japan or a 50% share in sales units in Japan in accordance with the sales report of Intercontinental Marketing Service (IMS) in the previous fiscal year of Schwarz or its sublicensee. (quarterly IMS sales figures). For purposes....”**

59

3. Except as modified by this Second Amendment and the First Amendment, all provisions of the Agreement shall remain in full force and effect.

4. This Second Amendment may be executed in any number of counterparts, each of which shall be deemed an original, and all of which taken together shall constitute one and the same instrument.

5. This Second Amendment shall be effective as of the date first written above.

IN WITNESS WHEREOF, the parties have hereto have executed this Agreement in duplicate originals by their duly authorized officers or representatives.

**Aderis Pharmaceuticals, Inc.**

Signature: \_\_\_\_\_

Name: \_\_\_\_\_

Title: \_\_\_\_\_

Date: \_\_\_\_\_

**Schwarz Pharma AG**

Signature: \_\_\_\_\_

Name: Prof. Dr. Iris Löw-Friedrich

Detlef Thielgen

Title: Member of the Executive Board

Member of the Executive Board

Date: October 21, 2002