FORM S-1/A

General form of registration statement for all companies including face-amount certificate companies [amend]

Filing Date: **1997-12-18**
SEC Accession No. 0000950135-97-005100

FILER

PENWEST PHARMACEUTICALS CO

CIK:**1047188**| IRS No.: **911513032** | State of Incorp.:**WA** | Fiscal Year End: **1231**
Type: **S-1/A** | Act: **33** | File No.: **333-38389** | Film No.: **97740431**
SIC: **2834** Pharmaceutical preparations

Mailing Address
2981 ROUTE 22
2981 ROUTE 22
PATTERSON NY 12563-9970

Business Address
2981 ROUTE 22
PATTERSON NY 12563-9970
9148783414

AS FILED WITH THE SECURITIES AND EXCHANGE COMMISSION ON DECEMBER 18, 1997

REGISTRATION NO. 333-38389

SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

AMENDMENT NO. 4

TO
FORM S-1
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

PENWEST PHARMACEUTICALS CO.
(EXACT NAME OF REGISTRANT AS SPECIFIED IN ITS CHARTER)

<TABLE>
<S> <C> <C>

WASHINGTON	2834	91-1513032
(STATE OR OTHER JURISDICTION OF INCORPORATION OR ORGANIZATION)	(PRIMARY STANDARD INDUSTRIAL CLASSIFICATION CODE NUMBER)	(I.R.S. EMPLOYER IDENTIFICATION NUMBER)

</TABLE>

2981 ROUTE 22
PATTERSON, NY 12563-9970
(914) 878-3414

(ADDRESS, INCLUDING ZIP CODE, AND TELEPHONE NUMBER,
INCLUDING AREA CODE, OF REGISTRANT'S PRINCIPAL EXECUTIVE OFFICES)

TOD R. HAMACHEK
CHAIRMAN AND CHIEF EXECUTIVE OFFICER
PENWEST PHARMACEUTICALS CO.
2981 ROUTE 22
PATTERSON, NY 12563-9970
(914) 878-3414

(NAME, ADDRESS, INCLUDING ZIP CODE, AND TELEPHONE NUMBER,
INCLUDING AREA CODE, OF AGENT FOR SERVICE)

COPIES TO:

<TABLE>
<S> <C> <C>

STEVEN D. SINGER, ESQ.	EDMUND O. BELSHEIM, JR., ESQ.	LESLIE E. DAVIS, ESQ.
HALE AND DORR LLP	PENWEST PHARMACEUTICALS CO.	TESTA, HURWITZ & THIBEAULT, LLP
60 STATE STREET	2981 ROUTE 22	HIGH STREET TOWER
BOSTON, MA 02109	PATTERSON, NY 12563-9970	125 HIGH STREET
(617) 526-6000	(914) 878-3414	BOSTON, MA 02110
		(617) 248-7000

</TABLE>

APPROXIMATE DATE OF COMMENCEMENT OF PROPOSED SALE TO THE PUBLIC: As soon as practicable after this registration statement becomes effective.

If any of the securities being registered on this form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box. [ ]

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act of 1933, please check the following box and list the Securities Act registration number of the earlier effective registration statement for the same offering. [ ]

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act of 1933, check the following box and list the Securities Act registration number of the earlier effective registration statement for the same offering. [ ]

If delivery of the prospectus is expected to be made pursuant to Rule 434 under the Securities Act of 1933, check the following box. [ ]

THE REGISTRANT HEREBY AMENDS THIS REGISTRATION STATEMENT ON SUCH DATE OR DATES AS MAY BE NECESSARY TO DELAY ITS EFFECTIVE DATE UNTIL THE REGISTRANT SHALL FILE A FURTHER AMENDMENT WHICH SPECIFICALLY STATES THAT THIS REGISTRATION STATEMENT SHALL THEREAFTER BECOME EFFECTIVE IN ACCORDANCE WITH SECTION 8(a) OF THE SECURITIES ACT OF 1933 OR UNTIL THE REGISTRATION STATEMENT SHALL BECOME EFFECTIVE ON SUCH DATE AS THE COMMISSION, ACTING PURSUANT TO SAID SECTION 8(a), MAY DETERMINE.

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PART II

INFORMATION NOT REQUIRED IN PROSPECTUS

ITEM 16. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES.

(A) Exhibits:

<TABLE>
<CAPTION>

EXHIBIT NO.		DESCRIPTION
<S>	<C>	<C>
1.1*	--	Form of Underwriting Agreement.
3.1*	--	Amended and Restated Articles of Incorporation.
3.2*	--	Amended and Restated Bylaws of the Company.
4.1*	--	Specimen certificate representing the Common Stock.
5.1*	--	Opinion of Edmund O. Belsheim, Jr.
+10.1*	--	Product Development and Supply Agreement dated August 17, 1994 by and between the Registrant and Mylan Pharmaceuticals Inc. ("Mylan").
+10.2*	--	Product Development and Supply Agreement dated August 3, 1995 by and between the Registrant and Mylan.
+10.3*	--	Product Development and Supply Agreement dated March 22, 1996 by and between the Registrant and Mylan.
+10.4*	--	Sales and Distribution Agreement dated January 3, 1997 by and between the

		Registrant and Mylan.
+10.5*	--	Product Development and Supply Agreement dated May 31, 1996 by and between the Registrant and Kremers Urban Development Company.
+10.6	--	Product Development and Supply Agreement dated August 30, 1996 by and between the Registrant and Kremers Urban Development Company.
+10.7*	--	Product Development, License and Supply Agreement dated February 28, 1997 by and between the Registrant and Sanofi Winthrop International S.A., as amended.
+10.8*	--	Agreement dated May 26, 1995 by and between the Registrant and Leiras OY.
+10.9*	--	Agreement dated July 27, 1992 by and between the Registrant and Leiras OY.
+10.10*	--	Strategic Alliance Agreement dated as of September 17, 1997 by and between the Registrant and Endo Pharmaceuticals Inc.
10.11*	--	1997 Equity Incentive Plan.
10.12*	--	1997 Employee Stock Purchase Plan.
10.13*	--	Form of Separation Agreement to be entered into between the Registrant and Penford Corporation ("Penford").
10.14*	--	Form of Excipient Supply Agreement to be entered into between the Registrant and Penford.
10.15*	--	Form of Services Agreement to be entered into between the Registrant and Penford.
10.16*	--	Form of Tax Allocation Agreement to be entered into between the Registrant and Penford.
10.17*	--	Form of Employee Benefits Agreement to be entered into between the Registrant and Penford.
10.18*	--	Recognition and Incentive Agreement dated as of May 14, 1990 between the Registrant and Anand Baichwal, as amended.
21.1*	--	Subsidiaries.
23.1*	--	Consent of Ernst & Young LLP.
23.2*	--	Consent of Edmund O. Belsheim, Jr. (included in Exhibit 5.1).
24.1*	--	Power of Attorney.
27.1*	--	Financial Data Schedule.

</TABLE>

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* Previously filed.

+ Confidential treatment requested as to certain portions, which portions are omitted and filed separately with the Commissioner.

(B) Financial Statements Schedules:

Schedule II -- Valuation and Qualifying Accounts

All other schedules for which provision is made in the applicable accounting regulations of the Securities and Exchange Commission are not required under the related instructions or are inapplicable, and therefore have been omitted.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the Registrant has duly caused this Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized, in Patterson, New York, on December 17, 1997.

PENWEST PHARMACEUTICALS CO.

By: /s/ JOHN V. TALLEY, JR.

John V. Talley, Jr.
President and Chief Operating Officer

POWER OF ATTORNEY AND SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, this registration statement has been signed by the following persons in the capacities and on the dates indicated.

<TABLE>
<CAPTION>

SIGNATURE	TITLE(S)	DATE
<C>	<S>	<C>
*	Chairman, Chief Executive Officer and Director (Principal Executive Officer)	December 17, 1997
Tod R. Hamachek		
*	Vice President, Finance and Chief Financial Officer (Principal Financial and Accounting Officer)	December 17, 1997
Jennifer L. Good		
*	Director	December 17, 1997
Paul E. Freiman		
*	Director	December 17, 1997
Jere E. Goyan, Ph.D.		
*	Director	December 17, 1997
Rolf H. Henel		
*	Director	December 17, 1997
Robert J. Hennessey		
*	Director	December 17, 1997
N. Stewart Rogers		
/s/ JOHN V. TALLEY, JR.	Director	December 17, 1997
John V. Talley, Jr.		
*	Director	December 17, 1997
W. Leigh Thompson, Ph.D., M.D.		

</TABLE>

*By: /s/ JOHN V. TALLEY, JR.

John V. Talley, Jr.
Attorney-in-fact

EXHIBITS

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<CAPTION>

EXHIBIT NO.	DESCRIPTION	SEQUENTIALLY NUMBERED PAGE

<S> <C> <C> <C>

21.1*	--	Subsidiaries.
23.1*	--	Consent of Ernst & Young LLP.
23.2*	--	Consent of Edmund O. Belsheim, Jr. (included in Exhibit 5.1).
24.1*	--	Power of Attorney.
27.1*	--	Financial Data Schedule.

</TABLE>

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* Previously filed.

+ Confidential treatment requested as to certain portions, which portions are omitted and filed separately with the Commissioner.

Exhibit 10.6

CONFIDENTIAL MATERIAL OMITTED AND FILED SEPARATELY WITH
THE SECURITIES AND EXCHANGE COMMISSION.
ASTERISKS DENOTE SUCH OMISSIONS.

PRODUCT DEVELOPMENT AND SUPPLY AGREEMENT

THIS AGREEMENT is entered into as of the 30th day of August, 1996 (the "Effective Date"), by and between TIMERx Technologies, a division of Penwest, Ltd., a Washington corporation, with principal place of business at 2981 Route 22, Patterson, New York 12563 ("TIMERx Technologies"), and SCHWARZ PHARMA INC., a Delaware corporation, with principal place of business at 5600 County Line Road, Mequon, Wisconsin 53092 ("Schwarz Pharma").

A. TIMERx Technologies has developed a controlled-release agent covered by one or more patents, patent applications, know-how and other proprietary technology, which agent TIMERx Technologies markets under the name and mark "TIMERx(R)" ("TIMERx").

B. Schwarz Pharma is interested in developing for manufacture the active pharmaceutical ingredient verapamil ("Verapamil") and desires to formulate Verapamil into a solid-dosage controlled-release delivery system for oral administration in humans in two dosage strengths to be therapeutically equivalent AB rated to the drug currently sold under the brand name "Covera-HS."

C. The parties, under a separate agreement (the "Diltiazem Agreement"), are engaging in certain activities relating to the development and testing of a product incorporating diltiazem and TIMERx, and designed to be bioequivalent to the product currently being marketed in the United States under the name "Cardizem CD." The parties now desire to engage in a separate program of research, development, and testing activities designed to determine if a drug that is bioequivalent to Covera-HS can be developed using TIMERx. If such activities under this separate program are successful, Schwarz Pharma desires to contract for a supply of TIMERx for use in the manufacture of such a controlled-release form of Verapamil, and TIMERx Technologies is willing to supply the same provided that Schwarz Pharma agrees to obtain all of its requirements of TIMERx from TIMERx Technologies as provided herein.

NOW, THEREFORE, the parties hereby agree as follows:

1. DEFINITIONS.

1.1 "AFFILIATE" of TIMERx Technologies or of Schwarz Pharma shall mean entities that, directly or indirectly, own and control the voting of more than 50% of the voting capital shares of such party ("Parent"), or more than 50% of the voting capital shares (or equivalent control) of which is, directly or indirectly, owned, and the voting of which is controlled, by such party or its Parent, as of the Effective Date. For purposes of this definition and this Agreement no Affiliate shall remain such unless it continues to meet the foregoing criteria. Current Affiliates of TIMERx Technologies and Schwarz Pharma are listed as such in Exhibit .

1.2 "APPROVAL DATE" shall mean the date on which a Designated Product in either dosage strength is first approved by the U.S. Food and Drug Administration (herein "FDA") (the "U.S. Approval Date") or other equivalent regulatory authority in the Territory for commercial sale in oral solid-dosage form for administration in humans, pursuant to an Abbreviated New Drug Application (or the equivalent in such other regulatory authority) ("ANDA").

1.3 "CERTIFICATION PERIOD" with respect to the United States shall mean the period beginning at the end of the Development Period and ending on the earlier of:

1.3.1 the U.S. Approval Date;

1.3.2 the termination of this Agreement as provided herein. With respect to Canada and/or Mexico, the Certification Period, if any, will mean the period described as such for that nation in Section 3.3.

1.4 "COMPETING GENERIC VERSION" shall mean a drug that meets all of the following criteria:

1.4.1 it is Therapeutically Equivalent to the applicable Designated Product being studied, manufactured, or marketed, as the case may be;

1.4.2 it has been fully approved for commercial sale in oral solid-dosage form for administration in humans by the FDA (for all purposes of this Agreement, "solid- dosage form" shall include tablets, capsules, hydrogels, or any combination thereof);

1.4.3 it is actively on the market and immediately available for retail sale throughout the United States other than under the brand "Covera" or "Covera-HS"; and

3

1.4.4 it is not marketed by Schwarz Pharma, any of its Affiliates, or under a license or sublicense from Schwarz Pharma or its Affiliates or sublicensees in any tier.

1.5 "CONFIDENTIAL TECHNOLOGY" shall mean all technology that is, at the relevant time hereunder, protected or required to be protected by both parties hereto as confidential information pursuant to Section 7 hereof.

1.6 "DESIGNATED PRODUCT" shall mean a Therapeutically Equivalent solid- dosage form of a controlled-release pharmaceutical for oral administration in humans that combines Verapamil with TIMERx and other excipients. The parties contemplate that the Designated Product will be developed and marketed in the following dosage strengths: 180mg and 240mg.

1.7 "DEVELOPMENT PERIOD" shall mean the period from the Effective Date through the earlier of the termination of this Agreement as provided herein or the successful completion, through demonstration of bioequivalence to FDA standards, of the Pivotal Biostudies.

1.8 "DISSOLUTION PROFILE STUDIES" shall mean the studies contemplated in Section 2.2.

1.9 "FORMULATED TIMERx" shall mean TIMERx and certain additives in a formulation to be developed hereunder specifically for use in the Designated Product.

1.10 "LICENSE TERM" shall mean the cumulative period covered by the Development Period, the Certification Period, and the Marketing Period.

1.11 "MARKETING PERIOD" with respect to a nation shall mean the period beginning on the Approval Date for such nation and ending on the earlier of:

1.11.1 the twentieth anniversary of the Effective Date; or

1.11.2 the termination of the License Term and/or this Agreement as provided herein.

1.12 "MILESTONE FEE SCHEDULE" shall mean the schedule set forth in Exhibit .

1.13 "NET SALES" shall mean that portion of the net sales (or

equivalent current value, where Designated Product is used without being sold, other than as to reasonable quantities of samples of Designated Products marketed as branded drugs, if any) recognized by Schwarz Pharma or its Affiliate, or a sublicensee of either (excluding sales by Schwarz Pharma to its Affiliate or sublicensee, or by Schwarz Pharma's Affiliate to Schwarz Pharma or its sublicensee, for resale to a third party), calculated in accordance with United States Generally Accepted Accounting Principles

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ASTERISKS DENOTE SUCH OMISSIONS.

("GAAP") consistently applied, which pertains to the Designated Product. The calculation of Net Sales shall include amounts specifically identifiable to the Designated Product and amounts allocated to the Designated Product in accordance with GAAP, it being understood that amounts which are not specifically identifiable to the Designated Product by virtue of their being identifiable to a group of products or services that includes the Designated Product shall be allocated to the Designated Product in a consistent and equitable manner which will not unduly or disproportionately reduce Net Sales of the Designated Product. Net Sales shall be considered "made" as of the date of the applicable invoice. Amounts to be included in the calculation of Net Sales shall be those representing:

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1.14 "PILOT BIOSTUDIES" shall mean the biostudies to be conducted by Schwarz Pharma as more fully described in Section 2.3 and Exhibit 1.14.

1.15 "PIVOTAL BIOSTUDIES" shall mean the biostudies contemplated in Section 2.4, it being understood that such Pivotal Biostudies are those that will be designed and conducted in a manner to support the submission to the FDA of an ANDA for the Designated Products (whether or not such ANDA is ultimately approved).

1.16 "PROJECT CONTACT(S)" shall mean the persons appointed by each party to serve as contact persons between the parties during the Development Period and the Certification Period. The initial Project Contact for TIMERx Technologies for business matters is Dr. Paul K. Wotton, and the initial Project Contact for TIMERx Technologies for technical and scientific matters is Dr. Anand Baichwal. The initial Project Contact for Schwarz Pharma for business matters is Dr. Klaus Veitinger, and the initial Project Contact for Schwarz Pharma for technical and scientific matters is Dr. Tammy Antonucci. Each party shall promptly notify the other party of any substitution of other personnel as its Project Contact(s). Each party may select and supervise its other project staff as needed.

1.17 "ROYALTIES" shall mean the royalties payable to TIMERx Technologies pursuant to Section 4.3 hereof.

1.18 "SCHWARZ PHARMA IMPROVEMENTS" shall mean any and all improvements, modifications, alterations, or enhancements to any of the inventions covered by the TIMERx Technologies Patents, TIMERx Technologies' Confidential Technology, or the TIMERx Production Technology, that are developed for or are otherwise related to or useful with the Designated Product and that are developed, owned, or controlled by Schwarz Pharma or any of its Affiliates or sublicensees, or in which Schwarz Pharma or any of its Affiliates or sublicensees otherwise has any rights or interests during the term of this Agreement; together with all United States and foreign intellectual property and other rights and interests of Schwarz Pharma and its Affiliates and sublicensees

thereto and therein, including without limitation patents, trade secrets, copyright, periods of market exclusivity, and other related rights or interests.

1.19 "SCHWARZ PHARMA TEST AND REGULATORY DATA" shall mean any and all test data, test designs and protocols, clinical studies and results thereof, government licenses and applications therefor, government certifications and findings, and related materials, information and rights (including without limitation information regarding bioavailability and bioequivalence, and any adverse drug reactions), developed, commissioned or otherwise obtained by Schwarz Pharma or any of its Affiliates or sublicensees during the term of this Agreement for the uses intended by this Agreement relating to TIMERx, Schwarz Pharma Improvements, the Designated Product, TIMERx Technologies Patents, TIMERx Production Technology and/or TIMERx Technologies' Confidential Technology; together with all intellectual property and other rights and interests of Schwarz Pharma and its Affiliates and sublicensees thereto and therein, worldwide.

1.20 "SOLID-DOSAGE UNIT" shall mean any individual tablet, capsule, hydrogel, or any combination thereof, manufactured to be a solid-dosage form of the Designated Product in the following dosage strengths: 180mg and 240mg.

1.21 "SPECIFICATIONS" shall mean such standards and analytical methods established by TIMERx Technologies and Schwarz Pharma by agreement during the Development Period; provided, however, that once such specifications are established in an application for regulatory approval, such specifications shall become the Specifications referred to herein, and shall remain unchanged, unless either changes are required by the regulatory authorities or are mutually agreed to by the parties. It is understood and agreed that the Specifications for Formulated TIMERx for use in Designated Product to be sold outside the United States shall be the same as those for Formulated TIMERx for use in Designated Product to be sold in the United States, because this will be required for the technically satisfactory production, regulatory approval, and exploitation of the Designated Product. Accordingly, in no event will Schwarz Pharma permit the Designated Product to be certified for sale outside the United States on any other basis, unless TIMERx Technologies has consented thereto in writing after detailed consultation with Schwarz Pharma.

1.22 "TERRITORY" shall, subject to Section 3.3, mean Canada, Mexico, the United States, and the territories and possessions thereof.

1.23 "THERAPEUTICALLY EQUIVALENT" shall mean that a drug of a given dosage strength is rated AB bioequivalent to the drug, in the same dosage

strength, currently sold in the United States under the brand name "Covera-HS".

1.24 "TIMERx TECHNOLOGIES PATENTS" shall mean:

1.24.1 those United States patents and foreign equivalents in the Territory and United States and foreign patent applications in the Territory listed in Exhibit and all divisions, continuations, reissues, or extensions thereof, any periods of marketing exclusivity relating thereto, and any letters patent that issue thereon; and

1.24.2 TIMERx Technologies' rights under United States and foreign patents in the Territory, if any, obtained and in force during the License Term covering any of TIMERx Technologies' improvements, modifications, alterations, or enhancements to any of the inventions covered by the TIMERx Technologies Patents that are developed for or are otherwise related to or useful with the Designated Product.

1.25 "TIMERx PRODUCTION TECHNOLOGY" shall mean TIMERx Technologies' rights under the TIMERx Technologies Patents and any and all other patents, patent applications, and other technology belonging to TIMERx Technologies or which TIMERx Technologies has the right to practice and to sublicense from time to time during the term of this Agreement that directly relate to, are desirable for, or are necessary for the production of, Formulated TIMERx for use in the Designated Product.

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ASTERISKS DENOTE SUCH OMISSIONS.

1.26 "TIMERX TECHNOLOGIES TEST AND REGULATORY DATA" shall mean any and all test data, test designs and protocols, clinical studies and results thereof, government licenses and applications therefor, government certifications and findings, and related materials, information and rights (including without limitation information regarding bioavailability and bioequivalence, and any adverse drug reactions), developed, commissioned or otherwise obtained by TIMERx Technologies or any of its Affiliates during the term of this Agreement relating to TIMERx, TIMERx Technologies Patents, and/or TIMERx Production Technology and that are developed for or are otherwise related to or useful with the Designated Product; together with all intellectual property and other rights and interests of TIMERx Technologies and its Affiliates thereto and therein in the Territory.

1.27 "UNIT PRICE" shall mean the price for Formulated TIMERx as stated in Exhibit hereto, ********** by TIMERx Technologies to reflect changes in the ********** **********.

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2. DEVELOPMENT PERIOD.

2.1 In consideration of TIMERx Technologies' entering into this Agreement, Schwarz Pharma shall pay TIMERx Technologies upon the Effective Date a nonrefundable initial fee of **********.

2.2 During the Development Period, TIMERx Technologies will exert its continuing best efforts to conduct in vitro Dissolution Profile Studies in accordance with its normal practices of a TIMERx formulation designed to be Therapeutically Equivalent to Covera-HS in each of the dosage strengths. TIMERx Technologies will ********** **********. Regardless of the outcome or results of such study, Schwarz Pharma agrees to pay TIMERx Technologies a fee therefor equal to *******, payable in four equal monthly installments of ******* each, the first such installment to be due and payable thirty days after the Effective Date.

2.3 Following successful completion of the Dissolution Profiles Studies, Schwarz Pharma will exert its continuing best efforts to perform the Pilot Biostudies by engaging the laboratory stated in Exhibit to conduct the same in accordance with that Exhibit and with a study design and budget mutually agreed by Schwarz Pharma and TIMERx Technologies. Schwarz Pharma will pay all costs of the initial Pilot Biostudy with respect to one or both dosage strengths, as needed, ********** ********** **********. The initial Pilot Biostudy will be completed within four months of such agreement to proceed. If the initial Pilot Biostudy requires further optimization of the TIMERx formulation, Schwarz Pharma agrees to pay similarly all the costs for an additional biostudy to develop a formulation of TIMERx Therapeutically Equivalent to each desired dosage strength of Covera-HS. **********

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2.4 Within thirty days following the completion of a successful Pilot Biostudy (i.e., a formulation of TIMERx is indicated within the limits of such study to be Therapeutically Equivalent to either of the desired dosage strengths of Covera- HS), Schwarz Pharma shall pay TIMERx Technologies a fee determined as set forth in the Milestone Fee Schedule, **********
****
********** ********. Within twelve months of successful completion of such Pilot Biostudies, Schwarz Pharma exert its continuing best effort to perform and complete at its expense ********** . TIMERx Technologies will cooperate in such

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effort. Upon successful completion of a Pivotal Biostudy through demonstration of AB rated bioequivalence to FDA standards, Schwarz Pharma will pay TIMERx Technologies a fee determined as set forth in the Milestone Fee Schedule,
****
**********.

2.5 Each party's Project Contact(s) will provide written reports to the other party's Project Contact(s) at least quarterly (and more often upon reasonable request of the other party) throughout the Development Period, stating in detail all efforts made and in process, and all significant progress achieved and difficulties encountered in the reporting party's portion of the development effort since the last such report. Each of the Project Contacts will also be available throughout the Development Period to answer any reasonable questions from the other party's Project Contacts, as appropriate.

2.6 Each party will, promptly and throughout the Development Period, provide to the other all necessary information in or coming into its possession or reasonably available to it to support the goals of the Development Period. Notwithstanding anything else to the contrary contained herein, nothing shall require either party to disclose confidential information for which such party has an obligation of confidentiality to a third party. Each party understands and agrees that the other does not warrant or commit that the Designated Product will be successfully developed, and neither party shall have any liability or

responsibility to the other or to third parties for any such failure of the development process hereunder, except wherein such failure occurs as a result of a party's intentional misconduct, negligence, or breach of its duties or obligations under this Agreement.

2.7 Except as provided otherwise in the cost reimbursement provisions of Section 2.3, Schwarz Pharma will supply to TIMERx Technologies, without charge, all Verapamil and Covera-HS (in both dosage strengths) reasonably required to support the ********** ********** for such effort, and each party shall otherwise bear its own expenses for all activities during the Development Period.

2.8 As the term is used in this Section 2 and in Section3 , the exertion of a party's best efforts will mean that (i) such party will exert on a continuing basis such reasonable efforts as would be normal for sponsors or applicants for regulatory approval of drugs under ANDAs generally, and (ii) this project will receive a priority at least as high as any of such party's other generic drug development efforts (if such a priority would lead to the exertion of greater efforts than those described in clause (i).

2.9 Either party may terminate this Agreement before completion of the Development Period by delivery of 30 days' written notice to the other, if, due to

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unfavorable or inconclusive results to that time, no further development efforts are likely to lead to the successful development of the Designated Product. In addition, Schwarz Pharma may terminate this Agreement prior to the completion of the Development Period by delivery of 30 days' written notice to TIMERx Technologies if at any time it determines (and reasonably demonstrates to TIMERx Technologies) that, due to changed circumstances following the date this Agreement is signed, the potential commercial viability of the Designated Product will not justify the devotion of the best efforts of Schwarz Pharma called for during the remainder of the Development Period or during the Certification Period. No such termination under this section will lessen any duty of Schwarz Pharma to make any of the payments called for hereunder, which have accrued prior to the effective date of such termination.

3. CERTIFICATION PERIOD.

3.1 During the Certification Period with respect to the United States, Schwarz Pharma will exert its continuing best efforts, at its expense, to prepare and file an ANDA or ANDAs for the Designated Products with the FDA and to prosecute the same successfully to the granting of an FDA license to market the Designated Product in both of the dosage strengths. TIMERx Technologies will, promptly and throughout the Certification Period, provide to Schwarz Pharma all necessary information in or coming into TIMERx Technologies' possession or reasonably available to it for such purpose. Also, during the Certification Period, **********.

3.2 Schwarz Pharma shall exert its continuing best efforts to conduct or arrange for, at Schwarz Pharma's expense, all further testing and studies during the Certification Period, including as to efficacy, bioavailability, bioequivalence, and safety and toxicology, in connection with the development, licensing, manufacture and marketing of the Designated Product, and for compliance with all requirements imposed by the government of the United States with respect to the Designated Products, and, if there is a Certification Period for Canada and/or Mexico pursuant to Section 3.3, also as imposed by the government of such nation(s). TIMERx Technologies will, promptly and throughout the Certification Period, provide to Schwarz Pharma all necessary information in or coming into TIMERx Technologies' possession or reasonably available to it for such purpose.

3.3 If, at any time or times during the License Period, TIMERx Technologies reasonably demonstrates to Schwarz Pharma that

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(i) Covera-HS or an AB bioequivalent to it has been approved for marketing in Canada or Mexico, or such approval has been applied for and is reasonably likely to be granted; and

(ii) TIMERx Technologies or a third party is interested in good faith in undertaking to market the Designated Product in such nation pursuant to the equivalent of an ANDA in such nation,

then TIMERx Technologies shall afford Schwarz Pharma a period of 60 days in which to agree that a Certification Period with respect to such nation, and governed by this Section 3, shall commence hereunder, during which Schwarz Pharma will exert its continuing best efforts, at its expense, to prepare and file such ANDA-equivalent applications for the Designated Products with the regulatory authorities in such nation, and to prosecute the same successfully to the granting of marketing approvals from such authorities for the Designated Product in both of the dosage strengths. It is understood that Schwarz Pharma may meet such obligations with respect to such nation through the efforts of its sublicensee, which may be TIMERx or the third party (if any) identified by TIMERx Technologies and referenced in clause (ii) above, to whom Schwarz Pharma may sublicense its rights as set forth in this Agreement. (If TIMERx Technologies is the sublicensee, the same terms and conditions of this Agreement shall apply to the sublicense.) If Schwarz Pharma fails to agree in writing within such period to prepare, file and prosecute an ANDA equivalent, either directly or through sublicensing as described herein, such nation and its territories and possessions shall thereupon be removed from the Territory.

3.4 Schwarz Pharma's Project Contacts will provide written reports to TIMERx Technologies' Project Contacts, as appropriate, at least quarterly (and more often upon reasonable request of the other party) throughout the Certification Period, stating in detail all efforts made and in process, and all significant progress achieved and difficulties encountered in the certification effort since the last such report. Schwarz Pharma's Project Contacts will also be available throughout the Certification Period to answer any reasonable questions from TIMERx Technologies' Project Contacts, as appropriate.

3.5 During the Certification Period, Schwarz Pharma shall provide at its ********** reasonably required to support the testing and certification effort, and **********.

3.6 If TIMERx Technologies personnel travel outside the Patterson, New York area during the Certification Period at the request of Schwarz Pharma, Schwarz Pharma shall bear all of the reasonable travel, lodging and meal expenses for such

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personnel. Otherwise, each party shall bear its own expenses for all activities during the Certification Period.

3.7 In consideration of TIMERx Technologies' entering into this Agreement, Schwarz Pharma agrees to pay TIMERx Technologies the following non-refundable fees:

3.7.1 a milestone fee payable within **********; and

3.7.2 a milestone fee payable within **********.

3.8 Either party may terminate this Agreement before completion of the Certification Period by delivery of 30 days' written notice to the other if, due to unfavorable action by the FDA, the ANDA is not likely (regardless of any further steps or submissions that could be made) to be approved by the FDA. In addition, Schwarz Pharma may terminate this Agreement prior to the completion of the Certification Period by delivery of 30 days' written notice to TIMERx Technologies if at any time it determines (and reasonably demonstrates to TIMERx Technologies) that, due to changed circumstances following the date this Agreement is signed, the potential commercial viability of the Designated Product will not justify the devotion of the best efforts of Schwarz Pharma called for during the remainder of the Certification Period or during the Marketing Period. No such termination under this section will lessen any duty of Schwarz Pharma to make any of the payments called for hereunder, which have accrued prior to the effective date of such termination.

4. MARKETING PERIOD.

4.1 Subject to the granting of all necessary governmental approvals or concurrences to sell the Designated Products, Schwarz Pharma hereby agrees, during the Marketing Period, to use its continuing best efforts to market, promote and sell the Designated Products throughout the United States following the U.S. Approval Date, and in Canada and/or Mexico, following the Approval Date, if any, for that nation(s). As the term is used in this Section 4, the exertion of Schwarz Pharma's best efforts will mean that Schwarz Pharma will devote to such marketing, promotion and sales of the Designated Products resources and priorities at least as substantial and high as any like-kind resources and priorities devoted by Schwarz Pharma or any of its Affiliates to the marketing, promotion or sale of any other generic drug of substantially the same potential in the same nation of the Territory, measured in terms of sales and profitability potentials.

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4.2 In consideration of TIMERx Technologies' entering into this Agreement, Schwarz Pharma agrees to pay TIMERx Technologies a non-refundable milestone fee payable ********** in the amount determined as set forth in the Milestone Fee Schedule.

4.3 Schwarz Pharma hereby agrees to pay to TIMERx Technologies Royalties equal to the percentages of all Net Sales during the License Term, as determined under Exhibit ; provided,**********.

4.4 All Royalties and other amounts payable pursuant to this Agreement shall be due quarterly ********** of each calendar quarter for Net Sales in such calendar quarter. Each such payment shall be accompanied by a statement of Net Sales for the quarter and the calculation of Royalties payable hereunder. All Royalties and all other amounts payable under this Agreement will bear interest at the rate of 1 1/2% per month or the maximum legal rate, whichever is less, from the date due through the date of payment. Schwarz Pharma shall keep and shall cause its Affiliates and its and their sublicensees to keep complete, true and accurate records for the purpose of showing the derivation of all Royalties payable to TIMERx Technologies under this Agreement. TIMERx Technologies or its representatives shall have the right to inspect, copy, and audit such records at any time during reasonable business hours upon notice to Schwarz Pharma or any of its Affiliates or sublicensees, respectively. Information gathered during such an audit shall be held in confidence by TIMERx Technologies and its Affiliates, except to the extent any of the exceptions stated in Sections through apply thereto. Any such audit shall be at the expense of TIMERx Technologies, unless the audit reveals that, with respect to the period under audit, less than 95% of the Royalties due to TIMERx Technologies hereunder have been paid, in which event Schwarz Pharma shall pay or reimburse TIMERx Technologies for the reasonable expenses of such audit, in addition to TIMERx Technologies' other remedies for such underpayment.

4.5 All monies due hereunder shall be paid in United States Dollars to TIMERx Technologies in Patterson, New York, USA. The rate of exchange to be used shall be the average commercial rate of exchange for the 30 days preceding the date of payment for the conversion of local currency to United States Dollars as published by The Wall Street Journal (or if it ceases to be

published, a comparable publication to be agreed upon by the parties) or, for those countries for which such average exchange rate is not published by The Wall Street Journal, the exchange rate fixed on the fifth day prior to the date of payment as promulgated by the appropriate United States governmental agency as mutually agreed upon by the parties.

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5. SUPPLY OF FORMULATED TIMERx.

5.1 It is understood and agreed that supply of Formulated TIMERx by TIMERx Technologies (or otherwise as provided in Section 5.13) in accordance with the Specifications is desired by both parties for the technically satisfactory production, regulatory approval, and exploitation of the Designated Product. Accordingly, except as provided in Section 5.13, and subject to the other provisions hereof, TIMERx Technologies will supply Schwarz Pharma and its Affiliates and sublicensees with sufficient quantities of Formulated TIMERx produced in accordance with the Specifications in compliance with GMP and all applicable laws and regulations, to meet their reasonable requirements for development, testing and manufacturing of the Designated Product during the Certification Period and the Marketing Period, and Schwarz Pharma shall purchase all of its and its Affiliates' and sublicensees' requirements for TIMERx from TIMERx Technologies during such period.

5.2 The price for all Formulated TIMERx sold hereunder shall equal ********** (subject to ****** adjustment by TIMERx Technologies to reflect changes in the Pharmaceutical Producers' Index, or an equivalent index, its Affiliates and its and their sublicensees. Schwarz Pharma shall keep and shall cause its Affiliates and its and their sublicensees to keep complete, true and accurate records of the number of such Solid-Dosage Units produced. TIMERx Technologies or its representatives shall have the right to inspect, copy, and audit such records, and otherwise to enter upon the premises of Schwarz Pharma or its Affiliates or such sublicensees, at any time during reasonable business hours upon notice, for purposes of verifying the number of Solid-Dosage Units

produced. Information gathered during such an audit shall be held in confidence by TIMERx Technologies and its Affiliates, except to the extent any of the exceptions stated in Sections through apply thereto. Any such audit shall be at the expense of TIMERx Technologies, unless the audit reveals that, with respect to the period under audit, less than 95% of the aggregate price due to TIMERx Technologies hereunder was paid, in which event Schwarz Pharma shall pay or reimburse TIMERx Technologies for the reasonable expenses of such audit, in addition to TIMERx Technologies' other remedies for such underpayment.

5.3 All sales of Formulated TIMERx shall be ********** and Schwarz Pharma shall bear all transportation, insurance, taxes, duties, and other costs and risks of loss, spoilage and damage associated with the shipping and delivery of Formulated TIMERx to Schwarz Pharma or its Affiliates or sublicensees.

5.4 TIMERx Technologies shall perform routine quality control tests with respect to all Formulated TIMERx as required by the FDA, or otherwise as TIMERx Technologies deems necessary in accordance with its applicable policies. TIMERx Technologies will also bear the expenses and fees for filing the Drug Master File for TIMERx with the FDA. No other or special tests by TIMERx Technologies with respect to the raw materials or Formulated TIMERx will be required, unless and to the extent that Schwarz Pharma establishes that the same are required in order to obtain or maintain a governmental license to market the Designated Product in the Territory. In any event, the cost of providing any such other or special tests shall be separately reimbursed to TIMERx Technologies by Schwarz Pharma. TIMERx Technologies shall promptly, upon completion of each lot or batch of Formulated TIMERx, deliver a copy of the record of such test performed on said lot or batch. Schwarz Pharma will perform quality control tests on Formulated TIMERx immediately on receipt at its plant and advise TIMERx Technologies within thirty (30) days of any deviations from Specifications.

5.5 If Schwarz Pharma considers any such shipment not to conform to the applicable Specifications, Schwarz Pharma shall notify TIMERx Technologies immediately and provide TIMERx Technologies with the relevant analysis. TIMERx TECHNOLOGIES' SOLE OBLIGATION AND SCHWARZ PHARMA'S EXCLUSIVE REMEDY FOR ANY SUCH NONCONFORMITY SHALL BE AS FOLLOWS:

i) TIMERx Technologies shall at its own expense accept return of any shipment not accepted, or else reimburse Schwarz Pharma for the cost of disposal or destruction; and

iii) TIMERx Technologies shall use its best efforts to replace the non-conforming shipment with conforming Formulated TIMERx.

5.6 While TIMERx Technologies is supplying Formulated TIMERx hereunder to Schwarz Pharma, TIMERx Technologies shall, after receipt of reasonable prior notice, give duly accredited representatives of Schwarz Pharma access at all reasonable times during regular business hours to TIMERx Technologies' or its Affiliate's plant in which the Formulated TIMERx is being produced, to ensure production practices created Formulated TIMERx conforming to Specifications.

5.7 TIMERx Technologies will exert its best efforts to supply test quantities of Formulated TIMERx during the Certification Period within 90 days following receipt of Schwarz Pharma's firm written order therefor.

5.8 As the term is used in this Section 5, the exertion of TIMERx Technologies' best efforts will mean that it will devote to the production and supply of Formulated TIMERx called for hereunder efforts that would be reasonable and

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normal for such supply arrangements, and if, greater, that it will devote thereto resources and priorities at least as substantial and high as any like-kind resources and priorities devoted by TIMERx Technologies to the production or supply of TIMERx for any other drug or project, and also (if additional) that TIMERx Technologies will attempt at all times to maintain an inventory of approximately six months' production of Formulated TIMERx for Schwarz Pharma and its Affiliates and sublicensees, in light of their recent ordering history and reasonable projections.

5.9 Schwarz Pharma shall deliver to TIMERx Technologies a firm written order stating its (and/or its Affiliates' and sublicensees') requirements for Formulated TIMERx to be used for production of the Designated Product for commercial use or sale no less than ********** ********** **********.

5.10 At least ****** before Schwarz Pharma and/or its Affiliates or sublicensees begin production of the Designated Product for commercial use or sale (and in any event not later than concurrently with the submission of the

first order for use in the production of Designated Product intended for commercial sale -- herein called the "Initial Order"), Schwarz Pharma shall deliver to TIMERx Technologies a written, non-binding estimate of all requirements of Formulated TIMERx therefor during the following **********. Schwarz Pharma will deliver to TIMERx Technologies updates to such estimates on or before the first day of each January, April, July and October thereafter, which updates may revise estimates previously submitted, and will add estimates for additional months so that each such estimate covers the ********** period following the end of the firm-order period (that is, the ********** after the month in which such estimates are made).

5.11 The Initial Order will be firm and will not be cancelled or deferred by Schwarz Pharma. No other order for Formulated TIMERx hereunder may be cancelled or deferred by Schwarz Pharma except by written notice delivered to TIMERx Technologies at least 90 days prior to the scheduled delivery date. No orders may be cancelled or deferred (even with such 90-day notice) without TIMERx Technologies' approval if such cancellation or deferral would reduce Schwarz Pharma's purchases for the applicable ****** to less than ********** of the quantities ordered under Section 5.9 for that ******* . TIMERx Technologies will exert its best efforts to supply Schwarz Pharma with all amounts of Formulated TIMERx requested by Schwarz Pharma, but TIMERx Technologies shall have no obligation to supply Schwarz Pharma with quantities of Formulated TIMERx during any ****** in excess of ******* of the quantity estimated in Schwarz Pharma's estimate for that ****** which estimate was given to TIMERx Technologies ******* prior to the end of such ****** pursuant to Section .

5.12 In case TIMERx Technologies cannot supply Schwarz Pharma the requested quantities of the Formulated TIMERx, the shipments may be made by an

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alternate supplier designated by TIMERx Technologies with Schwarz Pharma's consent, which consent shall not be unreasonably withheld. ********** ********** ********** and notify Schwarz Pharma thereof within 90 days from the filing of the first ANDA. If Schwarz Pharma has any objections to such alternate supplier(s), it shall so notify TIMERx Technologies within fifteen days following TIMERx Technologies' notice of such qualification, or else Schwarz Pharma will be deemed to have consented to such qualification

and the designation of such supplier(s). Such shipment by the alternate supplier shall be made under the same agreed terms and conditions as those set forth herein, except that an additional 90 days shall be added to the order lead time stated in any then-outstanding order for Formulated TIMERx hereunder to reflect the transition time required to shift to such alternate supplier. Notwithstanding anything to the contrary set forth herein, TIMERx Technologies will be responsible for enforcing all relevant terms and conditions set forth herein against such alternate supplier and remain liable to Schwarz Pharma for any breach of such terms and conditions by such supplier.

5.13 If for any reason TIMERx Technologies or an alternate supplier, as described in Section , fails to supply Schwarz Pharma with its and its Affiliates' and sublicensees' requirements of Formulated TIMERx during the Certification Period or the Marketing Period, TIMERx Technologies shall, AS SCHWARZ PHARMA'S SOLE AND EXCLUSIVE REMEDY FOR ANY FAILURE TO SUPPLY FORMULATED TIMERx, grant Schwarz Pharma a nonexclusive license to manufacture Formulated TIMERx under the TIMERx Production Technology and make knowledgeable personnel reasonably available, at TIMERx Technologies' expense, to consult with Schwarz Pharma, all to the extent necessary to enable Schwarz Pharma to produce Formulated TIMERx that would otherwise have been supplied by TIMERx Technologies hereunder for Schwarz Pharma and its Affiliates and sublicensees in connection with the production of the Designated Product pursuant to this Agreement.

5.13.1 **********

5.13.2 Schwarz Pharma shall maintain TIMERx Production Technology delivered to Schwarz Pharma pursuant to this Section, whether orally or in writing, in strictest confidence and shall use such information and technology only for the purpose of producing Formulated TIMERx for its own use and the use of its Affiliates and sublicensees in connection with this Agreement.

5.13.3 Schwarz Pharma acknowledges that, in doing the foregoing, TIMERx Technologies will not be providing a "turnkey" operation. Rather, TIMERx Technologies will only be required to make reasonably available to Schwarz Pharma the best standard of knowledge and information then available to TIMERx Technologies and directly used in its or its Affiliate's manufacture of Formulated

TIMERx. TIMERx Technologies will not be required to prepare, provide or obtain any information not then in its possession, nor to adapt any of the knowledge or information provided to the particular plant or manufacturing location of Schwarz Pharma, including without limitation any local legal, licensing, or

environmental considerations.

5.13..4 Neither TIMERx Technologies nor its Affiliates or licensees will be responsible for any failure of Schwarz Pharma or its personnel to understand or properly to implement such knowledge and information or for any materials made by any party other than TIMERx Technologies or such respective Affiliate or licensee using such knowledge and information.

5.13.5 If TIMERx Technologies' non-delivery of Formulated TIMERx resulted in whole or in part from a temporary inability to produce and deliver the same, TIMERx Technologies may, at its option and on at least 90 days' prior written notice to Schwarz Pharma, terminate the license to produce Formulated TIMERx hereunder once TIMERx Technologies has demonstrated to the reasonable satisfaction of Schwarz Pharma that it is again able and willing to reliably supply Formulated TIMERx hereunder. If and to the extent that Schwarz Pharma has, prior to the receipt of such notice from TIMERx Technologies, committed itself to produce, or to purchase from a permitted sublicensee, any Formulated TIMERx deliverable during the nine months following such notice from TIMERx Technologies, Schwarz Pharma may continue to produce or to purchase from such sublicensee such Formulated TIMERx during such period, but not thereafter.

5.14 Each party shall promptly notify the other of any fact, circumstance, condition or knowledge dealing with TIMERx, Formulated TIMERx, or the Designated Product of which the Party becomes aware that bears upon the safety or efficacy of TIMERx, Formulated TIMERx, or the Designated Product. Each party shall immediately notify the other of any inspection or audit relating to TIMERx, Formulated TIMERx, or the Designated Product by any governmental regulatory authority in the Territory. If a representative of the governmental authority takes samples in connection with such audit or inspection, the parties shall immediately provide each other, as appropriate, samples from the same batch. The party in receipt of such notice will provide the other party within 72 hours, with copies of all relevant documents, including FDA Forms 482 and 483 (as applicable), warning letters and other correspondence and notifications as such other party may reasonably request. TIMERx Technologies and Schwarz Pharma agree to cooperate with each other during any inspection, investigation or other inquiry by the FDA or other governmental entity, including providing information and/or documentation, as requested by the FDA, or other governmental entity. To the extent permissible, TIMERx Technologies and Schwarz Pharma also agree to discuss any responses to observations or notifications received and to give the other party an opportunity to comment on any proposed response before it is made. In the event of disagreement

concerning the content or form of such response, Schwarz Pharma shall be

responsible for deciding the appropriate form and content of any response with respect to any of its cited activities and TIMERx Technologies shall be responsible for deciding the appropriate form and content of any response with respect to any of its cited activities. Each party shall inform the other of all comments and conclusions received from the governmental authority.

6. OWNERSHIP AND LICENSES.

6.1 Except as otherwise explicitly licensed or transferred as provided herein, each party will, as between it and the other party hereto, retain ownership of any and all inventions, copyrights, trade secrets, patent rights and other technology and rights to the extent conceived or developed by its personnel or contractors (other than the other party hereto). Neither party makes any grant of rights by implication. TIMERx Technologies will retain ownership in (but Schwarz Pharma shall have the right to use within the scope of its licenses) all Dissolution Profile Studies and Pilot Biostudies and Schwarz Pharma will retain ownership of its Pivotal Biostudies and its ANDA. Except as otherwise provided herein, each party shall be responsible, as it shall determine, for the filing and prosecution of any and all patent applications with respect, in whole or in part, to its own intellectual property and for the maintenance of any available patent protection with respect thereto; provided however, that neither party commits that any such patent protection will be available or continuous hereunder.

6.2 TIMERx Technologies hereby grants to Schwarz Pharma an exclusive license under the TIMERx Technologies Patents and TIMERx Technologies' Confidential Technology disclosed to Schwarz Pharma hereunder to make, have made, use and sell the Designated Product in the Territory during the License Term. Such license does not extend to the making of TIMERx or Formulated TIMERx, but does cover the incorporation of the same into the Designated Product. Schwarz Pharma shall have the right to grant sublicenses of its rights hereunder to any Affiliate(s) of Schwarz Pharma, but shall otherwise have no right to grant sublicenses hereunder without the prior written consent of TIMERx Technologies, which consent shall not be unreasonably withheld. TIMERx Technologies will, throughout the License Term, promptly notify Schwarz Pharma of all TIMERx Technologies Patents referred to in Subsection and provide Schwarz Pharma with access to all of the same, solely for use within the scope of the license stated in this section.

6.3 Schwarz Pharma acknowledges that TIMERx Technologies, for itself and for others, applies, and will seek to apply, TIMERx to products (which may include, without limitation, the Designated Product and other controlled-release products containing Verapamil) for manufacture and sale outside the Territory, or to products within the Territory (but in that case, during the License Term, only for products

other than the Designated Product or another controlled-release product containing Verapamil). No provision hereof, and no exclusivity hereunder, shall prevent TIMERx Technologies from so applying TIMERx or Formulated TIMERx, so long as the end product is not the Designated Product (or another controlled-release product containing Verapamil) for manufacture or sale in the Territory, it being understood that the Diltiazem Agreement will continue to govern on this point as to the products covered by it.

6.4 Schwarz Pharma hereby grants to TIMERx Technologies a nonexclusive, paid-up, worldwide license, with right to sublicense, under any and all patents, patent applications, trade secrets, copyrights, and other intellectual property rights of any sort owned or controlled by Schwarz Pharma or its Affiliates, to make, have made, use and sell Formulated TIMERx during the License Term for supply to Schwarz Pharma or its Affiliates or sublicensees, if and to the extent such license is necessary for TIMERx Technologies to do so as agreed hereunder.

6.5 Subject to and conditional upon the failure or continuing unwillingness of TIMERx Technologies to meet Schwarz Pharma's and its Affiliates' and sublicensees' requirements as provided in Section , TIMERx Technologies grants to Schwarz Pharma a nonexclusive license under the TIMERx Production Technology to make and have made Formulated TIMERx in the Territory solely for use in the Designated Product for sale in the Territory during the License Term, subject to Section . Schwarz Pharma shall have no right to grant sublicenses of its rights hereunder (whether to Affiliate(s) or otherwise) without the prior written consent of TIMERx Technologies, which consent shall not be unreasonably withheld.

6.6 Schwarz Pharma hereby grants to TIMERx Technologies a nonexclusive, paid-up, worldwide license, with right to sublicense, under any and all Schwarz Pharma Improvements to make, have made, use and sell any products or services using or based upon TIMERx or related technology. ****** ********** ******* Agreement pursuant to Section 2.9, 3.8 , or 10.2, this license to TIMERx Technologies ********** ********** of the Designated Product or any services involving the Designated Product. Schwarz Pharma will, throughout the License Term, promptly notify TIMERx Technologies of all Schwarz Pharma Improvements and provide TIMERx Technologies with access to all of the same, solely for use within the scope of the license stated in this section.

6.7 Schwarz Pharma hereby grants TIMERx Technologies a nonexclusive

license, with right to sublicense, under all rights of Schwarz Pharma and its Affiliates and sublicensees in and to the Schwarz Pharma Test and Regulatory Data to use the same for purposes of complying with governmental requirements of any country, other than with respect to the Designated Product or another controlled-release

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product containing Verapamil for manufacturing, marketing or use in the Territory, it being understood that the Diltiazem Agreement will continue to govern on this point as to the products covered by it. Schwarz Pharma hereby consents to TIMERx Technologies' and its sublicensees' cross-referencing, in any ANDA or NDA filings made by them within the scope of such license, any ANDA or NDA filing made or FDA master file created by Schwarz Pharma or its Affiliates relating to or containing any of the Schwarz Pharma Test and Regulatory Data. Except as provided in Section ********** ********** ***** under such license,********** the only portions of the Schwarz Pharma Test and Regulatory Data so used or referenced could have been properly accessed and used by third parties not operating under such a license. It is also understood that ********** ********** will not prevent the use of the Schwarz Pharma Test and Regulatory Data as licensed hereunder, as such consideration may be later determined either by agreement of the parties or pursuant to Section . The license under this section shall survive any termination or expiration of the term of this Agreement, except a termination under Section due to an uncured breach by TIMERx Technologies. Schwarz Pharma will, throughout the License Term and solely for use within the scope of the license stated in this section, provide to TIMERx Technologies on request access to all of the Schwarz Pharma Test and Regulatory Data in or coming into Schwarz Pharma's possession or otherwise reasonably available to it.

6.8 TIMERx Technologies hereby grants Schwarz Pharma a nonexclusive, paid-up license, with right to sublicense, under all rights of TIMERx Technologies and its Affiliates in and to the TIMERx Technologies Test and Regulatory Data to use the same for purposes of complying with governmental requirements, but solely with respect to the Designated Product for marketing or use in the Territory. TIMERx Technologies hereby consents to Schwarz Pharma's and its sublicensees' cross- referencing, in any ANDA filings made by them within the scope of such license, any NDA filing made or FDA master file created by TIMERx Technologies or its Affiliates relating to or containing any of the

TIMERx Technologies Test and Regulatory Data. The license and rights under this section shall survive any termination or expiration of the term of this Agreement, except a termination under Section due to an uncured breach by Schwarz Pharma. TIMERx Technologies will, throughout the License Term and solely for use within the scope of the license stated in this section, provide to Schwarz Pharma on request access to all of the TIMERx Technologies Test and Regulatory Data in or coming into TIMERx Technologies' possession or otherwise reasonably available to it.

6.9 Each party agrees to mark and to have marked by its sublicensees every product manufactured, used or sold by it or its sublicensees in accordance with the

laws of the United States or other applicable nation relating to the marking of patented articles with notices of patent.

7. CONFIDENTIALITY AND NON-SOLICITATION.

7.1 In the course of performance under this Agreement, or during the discussions leading thereto, a party may disclose, or may have disclosed, to the other confidential information belonging to such party in writing, orally or by demonstration or sample, which information is marked or stated in writing at or within 30 days after its disclosure to be "confidential" or "trade secret" information. All such confidential information of a party shall be maintained in confidence by the other and will not be used by the other party for any purpose except as authorized hereunder. Each party shall exercise, and shall cause its Affiliates, sublicensees, and consultants to exercise, a reasonable degree of care and at least the same degree of care as it uses to protect its own confidential information of similar nature to preserve the confidentiality of such information of the other party. Each party shall safeguard such information against disclosure to third parties, including without limitation employees and persons working or consulting for such party that do not have an established, current need to know such information for purposes authorized under this Agreement. This obligation of confidentiality does not apply to information and material that:

7.7.1 were properly in the possession of the receiving party, without any restriction on use or disclosure, prior to receipt from the other party;

7.1.2 are at the time of disclosure hereunder in the public domain by public use, publication, or general knowledge;

7.1.3 become general or public knowledge through no fault of the receiving party or its Affiliates following disclosure hereunder;

7.1.4 are properly obtained by the receiving party from a third party not under a confidentiality obligation to the disclosing party hereto;

7.1.5 are independently developed by or on behalf of the receiving party without the assistance of the confidential information of the other party;

7.1.6 consist merely of an idea or conception for the combination of one or more active drug ingredients with a controlled-release agent such as TIMERx; or

7.1.7 are required to be disclosed by order of any court or governmental authority.

7.2 Neither party shall make any public announcement or other publication regarding this Agreement (whether as to the existence or terms hereof) or the development work or project hereunder or the results thereof without the prior, written consent of the other party, which consent shall not be unreasonably withheld; provided that the foregoing shall not prohibit any disclosure which, in the opinion of counsel to the disclosing party, is required by any applicable law or by any competent governmental authority. In no event shall either party make any disclosure of any such results before a patent application has been filed with respect thereto, except upon the prior written approval of the other party.

7.3 Each of TIMERx Technologies and Schwarz Pharma agrees that during the License Period, neither of them will directly or indirectly solicit or encourage any employee or consultant of the other to leave or terminate such employment or consultancy for any reason, including without limitation, becoming employed or otherwise engaged in any capacity by such party (or any person or entity associated with such party, whether or not an Affiliate), nor will it assist others in doing so.

8. INFRINGEMENT.

8.1 TIMERx Technologies shall promptly inform Schwarz Pharma of any suspected infringement of any of the TIMERx Technologies Patents or the infringement or misappropriation of the TIMERx Production Technology by a third

party, to the extent such infringement involves the manufacture, use or sale of the Designated Product in the Territory ("Covered Infringement"). Schwarz Pharma shall promptly inform TIMERx Technologies of any suspected infringement of any of the TIMERx Technologies Patents or infringement or misappropriation of the TIMERx Production Technology of which Schwarz Pharma is aware, whether or not the same involves a Covered Infringement.

8.2 If the suspected infringement or misappropriation does not involve a Covered Infringement, TIMERx Technologies may take, or refrain from taking, any action it chooses, with or without notice to Schwarz Pharma, and Schwarz Pharma shall have no right to take any action with respect to such suspected infringement or misappropriation, nor to any recoveries with respect thereto. TIMERx Technologies will exert reasonable efforts to keep Schwarz Pharma informed of actions TIMERx Technologies may take as described in the preceding sentence to the extent the same bear on rights protected within the Territory. If the suspected infringement or misappropriation involves a Covered Infringement, TIMERx Technologies shall, within 120 days of the first notice referred to in Section , inform Schwarz Pharma whether or not TIMERx Technologies intends to institute suit against such third party with respect to a Covered Infringement. Schwarz Pharma will not take any steps toward instituting suit against any third party involving a Covered Infringement until

TIMERx Technologies has informed Schwarz Pharma of its intention pursuant to the previous sentence.

8.3 If TIMERx Technologies notifies Schwarz Pharma that it intends to institute suit against a third party with respect to a Covered Infringement, and Schwarz Pharma does not agree to join in such suit as provided in Section , TIMERx Technologies may bring such suit on its own and shall in such event bear all costs of, and shall exercise all control over, such suit. TIMERx Technologies may, at its expense, bring such action in the name of Schwarz Pharma and/or cause Schwarz Pharma to be joined in the suit as a plaintiff. Recoveries, if any, whether by judgment, award, decree or settlement, shall belong solely to TIMERx Technologies.

8.4 If TIMERx Technologies notifies Schwarz Pharma that it desires to institute suit against such third party with respect to a Covered Infringement, and Schwarz Pharma notifies TIMERx Technologies within 30 days after receipt of such notice that Schwarz Pharma desires to institute suit jointly, the suit shall be brought jointly in the names of both parties and all costs thereof shall be borne equally. Recoveries, if any, whether by judgment, award, decree or settlement, shall, after the reimbursement of each of TIMERx

Technologies and Schwarz Pharma for its share of the joint costs in such action, be shared between TIMERx Technologies and Schwarz Pharma as the interests of the parties were affected by the infringement.

8.5 If TIMERx Technologies notifies Schwarz Pharma that it does not intend to institute suit against such third party with respect to a Covered Infringement, Schwarz Pharma may institute suit on its own. Schwarz Pharma shall bear all costs of, and shall exercise all control over, such suit. Recoveries, if any, whether by judgment, award, decree or settlement, shall belong solely to Schwarz Pharma; provided however that, after reimbursement of Schwarz Pharma for its costs in such action, any portion of such net recoveries which constitutes the equivalent of, or damages or payments in lieu of, a royalty measured by the defendant's Net Sales, shall be shared between TIMERx Technologies and Schwarz Pharma in accordance with Section as if they were Schwarz Pharma's Net Sales (counting the infringing party's product as a Competing Generic Version).

8.6 Should either TIMERx Technologies or Schwarz Pharma commence a suit under the provisions of this Section and thereafter elect to abandon the same, it shall give timely notice to the other party, who may, if it so desires, be joined as a plaintiff in the suit (or continue as such if it is already one) and continue prosecution of such suit, provided, however, that the sharing of expenses and any recovery of such suit shall be as agreed upon between TIMERx Technologies and Schwarz Pharma.

9. REPRESENTATIONS, WARRANTIES AND INDEMNITIES.

9.1 Each party represents and warrants to the other that, to its current knowledge, without undertaking any special investigation, it has the full right and authority to enter into this Agreement and to grant the licenses granted herein.

9.2 TIMERx Technologies represents and warrants that any Formulated TIMERx supplied by it to Schwarz Pharma hereunder for use in the Designated Product, at the point of delivery:

9.2.1 will conform to the Specifications in effect as of the order date therefor; and

9.2.2 to TIMERx Technologies' current knowledge, without undertaking any special investigation, will not infringe upon an article patent of any third party. Without limiting the generality of this clause, TIMERx specifically

warrants that it will be able to formulate the Designated Product such that it will not be infringing of that certain United States Patent No. 5,419,917, issued May 30, 1995 and assigned to Andrx Pharmaceuticals, Inc. (the "Andrx Patent").

OTHERWISE, TIMERx TECHNOLOGIES PROVIDES "AS-IS," AND MAKES NO REPRESENTATIONS OR WARRANTIES AS TO, ANY TIMERx OR FORMULATED TIMERx SUPPLIED BY IT TO SCHWARZ PHARMA FOR TESTING, DEVELOPMENT, OR ANY OTHER PURPOSES EXCEPT EXPLICITLY FOR USE IN THE DESIGNATED PRODUCT FOR COMMERCIAL USE OR SALE.

9.3 Each party represents and warrants to the other that it has obtained, and will at all times during the term of this Agreement hold and comply with, all licenses, permits and authorizations necessary to perform this Agreement and to test, manufacture, market, export, and import the Designated Product or Formulated TIMERx, as now or hereafter required under any applicable statutes, laws, ordinances, rules and regulations of the United States and any applicable foreign, state, and local governments and governmental entities.

9.4 THE FOREGOING WARRANTIES ARE IN LIEU OF, AND THE PARTIES EACH DISCLAIM, ALL OTHER WARRANTIES, EXPRESS, IMPLIED OR ARISING BY LAW, INCLUDING WITHOUT LIMITATION ANY IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, AND NON-INFRINGEMENT. NOTHING IN THIS AGREEMENT SHALL BE CONSTRUED AS A REPRESENTATION OR WARRANTY (i) BY TIMERx TECHNOLOGIES AS TO THE PATENTABILITY, VALIDITY, OR SCOPE OF ANY TIMERX TECHNOLOGIES PATENTS, TIMERx TECHNOLOGIES' CONFIDENTIAL TECHNOLOGY, TIMERx PRODUCTION TECHNOLOGY, OR TIMERx TECHNOLOGIES TEST AND REGULATORY DATA, NOR AS TO THE UTILITY, EFFICACY, NONTOXICITY, SAFETY OR APPROPRIATENESS OF TIMERx OR THE DESIGNATED PRODUCT; OR (ii) BY SCHWARZ PHARMA AS

CONFIDENTIAL MATERIAL OMITTED AND FILED SEPARATELY WITH
THE SECURITIES AND EXCHANGE COMMISSION.
ASTERISKS DENOTE SUCH OMISSIONS.

TO THE PATENTABILITY, VALIDITY, OR SCOPE OF ANY SCHWARZ PHARMA IMPROVEMENTS OR SCHWARZ PHARMA TEST AND REGULATORY DATA, NOR AS TO THE UTILITY, EFFICACY, NONTOXICITY, SAFETY OR APPROPRIATENESS OF ANY PRODUCTS MADE THEREFROM.

9.5 TIMERx Technologies shall indemnify, defend and hold harmless Schwarz Pharma and its Affiliates and sublicensees from any claim, action or damages arising out of any alleged infringement by reason of the manufacture, use or sale by Schwarz Pharma of the Designated Product to the extent such infringement would apply as well to the manufacture, sale or distribution of

TIMERx alone or otherwise to the extent the same is covered by Section . If Schwarz Pharma or its Affiliate or sublicensee, by reason of its manufacture, sale or distribution of Designated Product, is accused of infringing the patent of a third party, and such claim of infringement, as framed by the claimant, would apply as well to the manufacture, sale or distribution of TIMERx alone or otherwise to the extent the same is covered by Section , Schwarz Pharma shall immediately so notify TIMERx Technologies and provide TIMERx Technologies all available information, and the parties shall consult reasonably as to the proper course of action. If TIMERx Technologies and Schwarz Pharma jointly determine that such claim is likely to prevail, or if an arbitrator hereunder or a court of competent jurisdiction so determines, Schwarz Pharma shall be entitled to offset against any Royalties payable to TIMERx Technologies hereunder any third party royalties for which Schwarz Pharma or its Affiliate or sublicensee becomes liable.

9.6 TIMERx Technologies shall indemnify, defend and hold Schwarz Pharma and its Affiliates and sublicensees harmless from any and all third-party claims to the extent arising from, in connection with, based upon, by reason of, or relating in any way to:

9.6.1 the formulation, development, supply, production, manufacture, sale, delivery, distribution or use of TIMERx in the Designated Product;

9.6.2 TIMERx Technologies' ********** ********** and the Specifications therefor hereunder, including without limitation any infringement claims based on the Andrx Patent;

9.6.3 any failure of the Formulated TIMERx manufactured by TIMERx Technologies or its alternate supplier (but not by Schwarz Pharma under Section), as delivered to Schwarz Pharma hereunder for use in the Designated Product, to conform to the Specifications; or

9.6.4 any failure of TIMERx Technologies to comply with its obligation under Section to notify Schwarz Pharma of any information coming into TIMERx Technologies' possession and **********.

and not arising from any other aspect of the Designated Product or its formulation, development, supply, production, manufacture, sale, delivery, distribution or use, nor from any act or omission of Schwarz Pharma with respect to the Formulated TIMERx following its delivery to Schwarz Pharma hereunder.

9.7 Schwarz Pharma shall indemnify, defend and hold TIMERx

Technologies harmless from any and all third-party claims to the extent arising from, in connection with, based upon, by reason of, or relating in any way to, the formulation, development, supply, production, manufacture, sale, delivery, distribution or use of the Designated Product by Schwarz Pharma, its Affiliates or sublicensees, except for any matters which are covered by TIMERx Technologies' indemnities under Sections and .

9.8 Notwithstanding anything to the contrary set forth elsewhere herein, neither Schwarz Pharma nor TIMERx Technologies shall be obligated to indemnify the other party for claims or liabilities to the extent arising from such other party's, or its Affiliates', sublicensees' or assigns', negligence, intentional misconduct, or breach of its duties, obligations, warranties or representations set forth herein.

9.9 Whenever indemnification is provided for a party under this Agreement, such right of indemnification shall extend also to the indemnified party's Affiliates, officers, directors, shareholders, successors, assigns, agents, employees, and insurers to the extent the same become subject to such claim in such capacity. The party seeking indemnification shall provide the indemnifying party with written notice of any claim or action within ten (10) days of its receipt thereof, and shall afford the indemnifying party the right to control the defense and settlement of such claim or action. The party seeking indemnification shall provide reasonable assistance to the indemnifying party in the defense of such claim or action. If the defendants in any such action include both Schwarz Pharma and TIMERx Technologies and either party concludes that there may be legal defenses available to it which are different from, additional to, or inconsistent with, those available to the other, that party shall have the right to select separate counsel to participate in the defense of such action on its behalf, and such party shall thereafter bear the cost and expense of such separate defense. Should the indemnifying party determine not to defend such claim or action, the other party shall have the right to maintain the defense of such claim or action and the indemnifying party agrees to provide reasonable assistance to it in the defense of such claim or action. Neither party shall settle any such claim or action in a way that prejudices or adversely impacts the other party to this Agreement without the prior approval of such other party (which approval shall not be unreasonably withheld).

9.10 NOTWITHSTANDING ANYTHING TO THE CONTRARY CONTAINED IN THIS AGREEMENT (OTHER THAN SECTION WITH RESPECT TO BREACHES OF CONFIDENTIALITY AND NONSOLICITATION

AND SECTION WITH RESPECT TO INDEMNITIES FOR PATENT INFRINGEMENT AND SECTIONS AND

WITH RESPECT TO INDEMNITIES FOR HARM TO PERSONS OR TANGIBLE PROPERTY), NEITHER PARTY SHALL UNDER ANY CIRCUMSTANCES BE LIABLE FOR ANY THIRD PARTY CLAIMS OR FOR ANY INCIDENTAL, CONSEQUENTIAL, INDIRECT OR SPECIAL DAMAGES, INCLUDING ANY LOST PROFITS OR SAVINGS, ARISING FROM ANY BREACH OF WARRANTY OR THE PERFORMANCE OR BREACH OF ANY OTHER PROVISION OF THIS AGREEMENT OR THE USE OR INABILITY TO USE TIMERx, THE DESIGNATED PRODUCT, TIMERx TECHNOLOGIES PATENTS, TIMERx TECHNOLOGIES' CONFIDENTIAL TECHNOLOGY, TIMERx PRODUCTION TECHNOLOGY, TIMERx TECHNOLOGIES TEST AND REGULATORY DATA, SCHWARZ PHARMA IMPROVEMENTS, OR SCHWARZ PHARMA TEST AND REGULATORY DATA, OR ANY CLAIMS ARISING IN TORT, PERSONAL INJURY, OR PRODUCT LIABILITY, EVEN IF SUCH PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.

10. TERM AND TERMINATION.

10.1 The term of this Agreement shall begin on the date set forth above and shall, unless earlier terminated as provided herein, continue until the end of the License Term.

10.2 Schwarz Pharma may at its option terminate this Agreement following the U.S. Approval Date, upon at least 120 days' written notice to TIMERx Technologies.

10.3 In the event that either party materially breaches any of the terms, conditions or agreements contained in this Agreement to be kept, observed or performed by it, then the other party may terminate this Agreement, at its option and without prejudice to any of its other legal or equitable rights or remedies, by giving the party who committed the breach (i) in the case of breach of obligations other than the payment of money, 60 days' notice in writing, unless the notified party within such 60-day period shall have cured the breach, and (ii) in the case of breach of an obligation for the payment of money, 20 days' notice in writing, unless the notified party within such 20-day period shall have cured the breach, including any required payment of interest on previously unpaid amounts as set forth herein.

10.4 This Agreement will automatically terminate if Schwarz Pharma files for protection under federal or state bankruptcy laws, becomes insolvent, makes an assignment for the benefit of creditors, appoints or suffers appointment of a receiver

or trustee over its property, files a petition under any bankruptcy or

insolvency act or has such petition filed against it.

10.5 Any sublicenses granted by Schwarz Pharma under this Agreement shall provide for assignment to TIMERx Technologies of Schwarz Pharma's interest therein upon termination of this Agreement, subject to TIMERx Technologies' approval, which shall not be unreasonably withheld, but which, if properly withheld, shall result in the termination of such sublicense.

10.6 Following any expiration or termination of the License Term, the license to TIMERx Technologies under Section shall be thereafter extended to include (in addition to its coverage as stated in such section) the use of Schwarz Pharma Test and Regulatory Data for purposes of complying with governmental requirements with respect to the Designated Product for manufacturing, marketing or use in the Territory. While exercises of the rights licensed under Section prior to the extension under this Section will continue to bear a reasonable consideration as provided in Section , exercises of such rights as so extended under this Section for purposes of complying with governmental requirements with respect to the Designated Product or another controlled-release product containing Verapamil for manufacturing, marketing or use in the Territory will be fully paid-up and royalty free.

10.7 Schwarz Pharma's obligations regarding payment of Royalties accrued as of the date of termination, TIMERx Technologies' rights under Sections and (except if this Agreement is terminated due to an uncured breach on the part of TIMERx Technologies), and Schwarz Pharma's rights under Section (except if this Agreement is terminated due to an uncured breach on the part of Schwarz Pharma), and the provisions of Sections , , and , hereof shall survive any expiration or termination of this Agreement.

10.8 All rights and licenses granted under or pursuant to this Agreement by TIMERx Technologies (as the "licensor") to Schwarz Pharma (as the "licensee") or by Schwarz Pharma (as the "licensor") to TIMERx Technologies (as the "licensee") 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 the 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 the licensor under the Bankruptcy Code, the licensee 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 the same, if not already in its possession, shall to the extent required for the exercise of the licenses granted hereunder, be promptly delivered to the licensee (i) upon any such commencement of a bankruptcy proceeding upon written request therefor by the licensee, unless the

licensor 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 the licensee upon written request therefor by the licensee.

11. MISCELLANEOUS.

11.1 This Agreement incorporates the numbered Exhibits referenced herein. This Agreement constitutes the entire agreement and supersedes all prior agreements and understandings, both written and oral, between the parties hereto with respect to the subject matter hereof, it being understood that the Diltiazem Agreement is not superseded by or merged into this Agreement, but, rather, shall continue in effect as to its subject matter and in accordance with its terms.

11.2 This Agreement shall be binding upon and inure to the benefit of the parties hereto and their successors and permitted assigns; provided, however, that except as part of the transfer of all or substantially all assets to a single buyer or pursuant to a merger or other corporate reorganization:

11.2.1 TIMERx Technologies shall not delegate or subcontract any of its obligations during the Development Period, and

11.2.2 Schwarz Pharma shall not assign or delegate its rights or obligations hereunder at any time, without the prior written consent of the other party hereto.

11.3 All notices, requests or other communication provided for or permitted hereunder shall be given in writing and shall be hand delivered or sent by facsimile, reputable courier or by registered or certified mail, postage prepaid, return receipt requested, to the address set forth on the signature page of this Agreement, or to such other address as either party may inform the other of in writing. Notices will be deemed delivered on the earliest of transmission by facsimile, actual receipt or three days after mailing as set forth herein.

11.4 Any terms of this Agreement may be amended, modified or waived only in a writing signed by both parties.

11.5 If any provision of this Agreement shall be held invalid, illegal or unenforceable, such provision shall be enforced to the maximum extent permitted by law and the parties' fundamental intentions hereunder, and the remaining provisions shall not be affected or impaired.

11.6 Nothing herein contained shall constitute this a joint venture agreement or constitute either party as the partner, principal or agent of the

other, this being an

Agreement between independent contracting entities. Neither party shall have the authority to bind the other in any respect whatsoever. Except as provided herein, nothing contained in this Agreement shall be construed as conferring any right on either party to use any name, trade name, trademark or other designation of the other party hereto, unless the express, written permission of such other party has been obtained.

11.7 In the event that either party hereto is prevented from carrying out its obligations under this Agreement by events beyond its reasonable control, including without limitation acts or omissions of the other party, acts of God or government, natural disasters or storms, fire, political strife, labor disputes, failure or delay of transportation, default by suppliers or unavailability of parts, then such party's performance of its obligations hereunder shall be excused during the period of such event and for a reasonable period of recovery thereafter, and the time for performance of such obligations shall be automatically extended for a period of time equal to the duration of such event or events; provided, however, that the other party may, at its election, terminate this Agreement upon 120 days' prior notice to the party affected by such events, unless such events cease to prevent such affected party's performance hereunder during such 120-day period.

11.8 This Agreement shall be governed by, and construed and enforced in accordance with, the laws of the State of New York without regard to its conflict of laws rules.

11.9 Any dispute, other than a question relating to patent validity, between the parties which arises under this Agreement or is otherwise related to this Agreement and which cannot be resolved by good faith negotiation between the parties over a period of at least ninety (90) days shall be resolved by arbitration conducted in the English language in Seattle, Washington, before a panel of three arbitrators under the then current rules and procedures of the American Arbitration Association (the "AAA"), or other rules and procedures as the parties may agree. The prevailing party in any such proceeding shall be entitled to an award of its reasonable attorneys' fees and other costs, including the fees and expenses of the arbitrators and the AAA, provided that the same may be apportioned between the parties by the arbitrators if they determine that each party has prevailed in part. The arbitral award shall be binding and conclusive on both parties and may be enforced in any court of competent jurisdiction. Notwithstanding the foregoing, either party may, on good cause shown, seek a temporary restraining order and/or a preliminary injunction

from a court of competent jurisdiction, to be effective pending the institution of the arbitration process and the deliberation and award of the arbitration panel.

IN WITNESS WHEREOF, the parties hereto have caused their duly authorized officers to execute and acknowledge this Agreement as of the date first written above.

SCHWARZ PHARMA INC.

By [ILLEGIBLE]

Its PRESIDENT

Address:
5600 County Line Road
Mequon, Wisconsin 53092

FAX: (414) 242-1641

Attn:_____

TIMERx TECHNOLOGIES

By [ILLEGIBLE]

Its PRESIDENT

Address:
2981 Route 22
Patterson, N.Y. 12563

FAX: (914) 878-3420

Attn:_____

EXHIBIT 1.1

TIMERx Technologies Affiliates
Schwarz Pharma Affiliates

TIMERx Technologies Affiliates

PENWEST, LTD.

Edward Mendell Co., Inc.

Penford Products Co.

Edward Mendell GmbH

Edward Mendell Finland OY

PENWEST Foreign Sales Corporation

EXHIBIT 1.1, CONTINUED

TIMERx Technologies Affiliates
Schwarz Pharma Affiliates

Schwarz Pharma Affiliates:

Central Pharmaceuticals, Inc.

Schwarz Pharma AG

Schwarz Pharma Deutschland GmbH

Sanol GmbH

ISIS Pharma GmbH

Schwarz Pharma Ltd.

Schwarz Pharma S.p.A.

Laboratories Schwarz Pharma S.A.

Schwarz Pharma Poland Sp.zo.o.

Seloc AG

SIFA Ltd.

SICOR S.A.

HOYER GmBH & Co.

Schwarz/[illegible]

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THE SECURITIES AND EXCHANGE COMMISSION.
ASTERISKS DENOTE SUCH OMISSIONS.

EXHIBIT 1.12

MILESTONE FEE SCHEDULE

The milestone payments will vary ********** ********** for each such milestone. The Trigger Date for a milestone is the date that the conditions to such milestone have been satisfied, as stated in this Agreement; e.g., the Trigger Date for each of the biostudies is the completion of the respective study, the Trigger Date for the Filing is the date of such Filing, the Trigger Date for the Approval is the date of the Approval, and the Trigger Date for the Launch is the date of the Launch. The following table sets forth the applicable milestone payments, in U.S. Dollars:

	**********			
MILESTONE	**********			
---	---	---	---	---
	***	***	***	***
	---	---	---	---
**********				
**********	******	******	******	******
**********	******	******	******	******

**********	******	******	******	******
**********	******	******	******	******
**********	******	******	******	******

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EXHIBIT 1.14

Pilot Biostudies

1. The Clinical Research Organization that we will work with for the Pilot Biostudies ***************************.

2. The Pilot Biostudies will be based on two studies wherein the first study is a **. The second study is a **. These two studies can be done simultaneously and will be done only on the ** described above.

3. We will evaluate the PK data (see #2 above) prior to starting formulation work at Central.

EXHIBIT 1.24

TIMERx Technologies Patents

UNITED STATES:

1) U.S. Patent No. 4,994,276, entitled "Directly Compressible Slow Release Granulation," issued February 19, 1991.

2) U.S. Patent No. 5,128,143, entitled "Sustained Release Excipient and Tablet Formulation," issued July 7, 1992.

3) U.S. Patent No. 5,135,757, entitled "Compressible Sustained Release Dosage Forms," issued August 4, 1992.

4) U.S. Patent No. 5,455,046, entitled "Sustained Release Hetero-Disperse Hydrogel Systems for Insoluble Drugs," issued October 3, 1995.

CANADA:

5) Canadian Patent Application No. 611,700, filed September 18, 1989 (corresponding to items 1), 2) and 3) above).

6) Canadian Patent Application Number 2131647, filed September 8, 1994, corresponding to item 4) above.

MEXICO:

7) Mexican Patent Application Number 94-6885, filed September 8, 1994, corresponding to item 4) above.

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EXHIBIT 1.27

UNIT PRICES

The price for the Formulated TIMERx product to be supplied by TIMERx Technologies to Schwarz Pharma will vary ********** ********** when the product units are ordered. The following table sets forth the applicable prices, per kilogram, in U.S. Dollars, subject to adjustment as stated in the Agreement:

	********** **********			
	**** ----	**** ----	**** ----	**** ----
Price*	****	****	****	****

* In all cases, Price shall be subject to an overall cap (to be determined annually) of ***** per tablet (subject to annual adjustment by TIMERx Technologies to reflect changes in the Pharmaceutical Producers' Index, or an equivalent index) calculated on a unit weighted average of both dosage strengths.

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EXHIBIT 4.3

ROYALTY RATES

The royalty rates ********** during the calendar quarter in which the royalties accrue, and the Net Sales then reached for that year. **********, in percentages of Net Sales:

Portion of Net Sales during Each Year	********** the Applicable Quarter			
	****	****	****	****
First ********	****	****	****	****
******** ********	****	****	****	****
******** ********	****	****	****	****
******** ****	****	****	****	****