18-05375-E

Sectilis



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

July 24, 2018

Dear Mr. Livornese:

I request pursuant to the Freedom of Information Act (FOIA) 5 U.S.C. § 552. As Amended by Public Law No. 104-231,110 Stat. 3048, copies of the following agreements, based on the **File No. 000-21643 -- CF# 31343,** and as **FOIA Request 10-08715-FOIA.**

Exhibit 10.83 to Form 10-Q filed on 11/06/2000 by CV Therapeutics Inc.

Exhibit Title: Collaboration And License Agreement

CIK: 921506

Sectilis will pay up to $61 for research, copies and review fees for all of the abovementioned agreements. Please forward all releasable material for copying. My daytime telephone number is 202-558-2356. Please call me or e-mail at research@sectilis.com to discuss the total cost or estimated cost of this research/copies should the amount exceed the price indicated in this request.

Sincerely,

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

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

Office of FOIA Services

August 16, 2018

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

RE: Freedom of Information Act (FOIA), 5 U.S.C. § 552
Request No. **18-05375-E**

Dear Ms. Vasconcellos:

This letter is in response to your request, dated and received in this office on July 24, 2018, for access to Exhibit 10.83 to Form 10-Q filed on November 6, 2000 by CV Therapeutics Inc.

In connection with a previous request, access was granted to the subject exhibit. Therefore, we have determined to release the same exhibit (copy enclosed) to you. No fees have been assessed in this instance.

If you have any questions, please contact me at reidk@sec.gov or (202) 551-3504. You may also contact me at foiapa@sec.gov or (202) 551-7900. You also have the right to seek assistance from Lizzette Katilius as a FOIA Public Liaison or contact the Office of Government Information Services (OGIS) for dispute resolution services. OGIS can be reached at 1-877-684-6448 or Archives.gov or via e-mail at ogis@nara.gov.

Sincerely,

*Kay Reid*

Kay Reid
FOIA Lead Research Specialist

Enclosures

10.83

**FUJISAWA HEALTHCARE INC.**

**CV THERAPEUTICS, INC.**

# COLLABORATION AND LICENSE AGREEMENT

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# COLLABORATION AND LICENSE AGREEMENT

**THIS COLLABORATION AND LICENSE AGREEMENT** (this "**Agreement**") is entered into and made effective as of July 10, 2000 (the "Effective Date") by and between **CV THERAPEUTICS, INC.**, a Delaware corporation ("**CVT**"), and **FUJISAWA HEALTHCARE, INC.**, a Delaware corporation ("**FHI**"). CVT and FHI may be referred to herein each individually as a "**Party**" or jointly as the "**Parties**."

## RECITALS

**WHEREAS,** CVT has developed and owns or controls certain proprietary technology relating to the discovery, development, manufacture, use and/or sale of compounds that may selectively stimulate the activity of the adenosine $A_{2A}$ receptor; and

**WHEREAS**, CVT and FHI desire to establish a collaboration to identify and develop such compounds for use in the field of pharmacological stress testing, and FHI desires to acquire an exclusive license to such compounds with the goal of developing, manufacturing and commercializing pharmaceutical products based on such compounds upon the terms and conditions contained in this Agreement.

**NOW, THEREFORE,** the Parties hereby agree as follows:

## 1. DEFINITIONS

**1.1 ["Adenocard®"]** means the patented and trademarked form of **[adenosine]** indicated for the use of **[conversion to sinus rhythm of paroxysmal supraventricular tachycardia]**, including that associated with **[accessory by-pass tracts (Wolff Parkinson-White Syndrome)]**, given on a **[rapid bolus by the peripheral intravenous route adenosine injection]** and supplied in a sterile solution in normal saline.

**1.2 ["Adenoscan®"]** means the patented and trademarked form of **[adenosine]** indicated as an adjunct to **[thallium 201 myocardial perfusion scintigraphy]** in patients unable to **[exercise]** adequately, given as a continuous peripheral intravenous infusion over a period of **[six minutes]** and supplied as a non-pyrogenic solution in normal saline.

**1.3 "Affiliate"** means any company or entity controlled by, controlling or under common control with a Party. As used in this Section 1.3, "control" means (a) that an entity or company owns, directly or indirectly, fifty percent (50%) or more of the voting stock of another entity, or (b) that an entity, person or group has the actual ability to control and direct the management of the entity, whether by contract or otherwise.

**1.4 "Collaborative Clinical Data"** shall have the meaning ascribed in Section 3.7(a).

**1.5 "Collaboration"** means the collaboration to develop Licensed Compounds that stimulate the activity of the adenosine $A_{2A}$ receptor pursuant to the terms and conditions of this Agreement.

1.6 **"Confidential Information"** shall have the meaning ascribed in Section 10.1.

1.7 **"Controlled"** means, with respect to any material, Information or intellectual property right, possession of the ability by a Party to grant access, a license, or a sublicense to such material, Information or intellectual property right as provided for herein without payment to a Third Party.

1.8 **"CVT Manufacturing Activities"** shall have the meaning ascribed in Section 3.4(a).

1.9 **"CVT Trademarks"** means the Trademarks "CVT" and "CV THERAPEUTICS" and any other Trademarks used to specifically identify CVT, other than Product Trademarks.

1.10 **"Designated Patents"** means the Patents designated on Schedule 1.10.

1.11 **"Development Costs"** means the directly allocable out-of-pocket costs of development (but not capital investment costs), plus FTE Charges, incurred by CVT or FHI in accordance with Section 3.4(a) in conducting their respective work under this Agreement and the Development Program in accordance with the Development Plan, including, without limitation, costs associated with preparation and filing of submissions for Regulatory Approvals for Licensed Compounds and/or Licensed Products. Development Costs do not include any costs associated with marketing, sales, promotion or distribution of Licensed Compounds and/or Licensed Products. With respect to the manufacture and supply of Licensed Compounds and/or Licensed Products, Development Costs shall only include the directly allocable out-of–pocket costs (but not capital investment costs), plus FTE Charges, incurred by CVT in conducting CVT Manufacturing Activities under Section 3.4(a), and the directly allocable out-of-pocket costs (but not capital investment costs), plus FTE Charges, incurred by FHI in conducting FHI Manufacturing Activities under Section 3.4(a), and in any event shall not include the costs to manufacture registration batches run at greater than ten percent (10%) of commercial scale or the costs of producing any Licensed Compounds and/or Licensed Products which could be sold commercially. In no event shall such directly allocable out-of-pocket costs include any costs which are otherwise included in FTE Charges.

1.12 **"Development Field"** means the field in which CVT (and/or FHI under the terms of this Agreement) shall conduct the Development Program, relating to: (a) inducement of pharmacological stress and/or (b) vasodilation of the coronary vasculature, to the extent that either such stress or vasodilation is induced strictly for purposes of diagnosing cardiovascular disease.

1.13 **"Development Plan"** means the detailed plan pursuant to which CVT shall conduct the Development Program, as further described in Section 3.3.

1.14 **"Development Program"** means the program of research and development, including without limitation work to obtain all necessary Regulatory Approvals to market, promote, distribute, manufacture and sell Licensed Compounds and/or Licensed Products in the Development Field in the United States, which is to be conducted by CVT with respect to the pre-clinical and clinical development of the Licensed Compounds and Licensed Products, and by FHI to the extent provided in Sections 3.4(a) and 14.2(e) below, all in accordance with the

Development Plan and as overseen by the Management Committee and otherwise in accordance with the terms and conditions of this Agreement. The Development Program conducted by CVT (and/or FHI under the terms of this Agreement) will be considered completed upon transfer of the NDA to FHI according to the terms and conditions of this Agreement.

**1.15 "FDA"** means the United States Food and Drug Administration (or any successor agency thereto).

**1.16 "FHI Clinical Data"** shall have the meaning ascribed in Section 3.7(a).

**1.17 "FHI Development Technology"** means any and all: (a) Collaborative Clinical Data in the FHI Field; (b) FHI Clinical Data in the Development Field; (c) Improvements developed solely by FHI in the Development Field; and (d) FHI's joint interest in any and all Improvements developed jointly by FHI and CVT in the FHI Field.

**1.18 "FHI Field"** means any and all applications, uses and indications.

**1.19 "FHI Manufacturing Activities"** shall have the meaning ascribed in Section 3.4(a).

**1.20 "FHI Trademarks"** means the Trademarks "FHI", "Fujisawa Healthcare, Inc." and "Fujisawa" and any other Trademarks used to specifically identify FHI.

**1.21 "Full Time Employee"** or **"FTE"** shall mean one or more employees or consultants of CVT or FHI who are directly involved in the research and development of Licensed Compounds and/or Licensed Products under this Agreement and who are necessary to carry out CVT's or FHI's responsibilities under the Development Program, in accordance with Section 3.4(a), with such time and effort to constitute one such employee or consultant working the equivalent of a full year of effort on a full time basis (equal to 40 hours per week), or in the case of less than a full-time dedicated employee or consultant, a full-time employee or consultant on a pro-rata basis.

**1.22 "FTE Charges"** means during the first twelve (12) months after the Effective Date the amount of **[Four Hundred Thousand Dollars ($400,000)]** per year per FTE with respect to FTEs at the director level and above, and **[Two Hundred Thousand Dollars ($200,000)]** per year per FTE with respect to FTEs below the director level. At the end of the first twelve (12) months after the Effective Date, and every twelve (12) months thereafter, the amounts to be adjusted according to the change in the San Francisco Bay Area Consumer Price Index during that twelve (12) month period.

**1.23 "Fujisawa Japan"** means FHI's corporate parent, Fujisawa Pharmaceutical Co., Ltd., located in Osaka, Japan.

**1.24 "GAAP"** means generally accepted accounting principles.

**1.25 "Improvements"** means any and all inventions, enhancements, improvements or modifications to any of the Licensed Compounds and/or any of the Licensed Products created or identified by either Party, or both Parties, under this Agreement.

**1.26** **"IND"** means an investigational new drug application as defined in 21 C.F.R. 312 et seq. for the FDA, or equivalent application to the relevant regulatory authority of a country, to commence clinical testing of a drug in humans, as defined by the FDA or other relevant Regulatory Authority, as the case may be.

**1.27** **"Information"** means any and all information, data, know-how, processes, manufacturing processes, trade secrets, inventions, discoveries (whether or not patentable), inventions (whether or not patentable), developments, results, techniques (including without limitation, manufacturing techniques) and materials.

**1.28** **"Lead Compound"** shall have the meaning ascribed in Section 3.2.

**1.29** **"Licensed Compounds"** means the compounds known as CVT 3146 and **[CVT 3033]**.

**1.30** **"Licensed Know-How"** means any and all Information Controlled by CVT as of the Effective Date or during the Term that is necessary or useful for the development, use, manufacture, registration, formulation, marketing, promotion, distribution and/or sale of Licensed Compounds and/or any Licensed Product in the FHI Field in the Territory, including, without limitation, CVT's interest in any and all unpatented Improvements.

**1.31** **"Licensed Patents"** means: (a) the Designated Patents; and (b) any and all Patents Controlled by CVT (including any Patents solely owned by CVT and any Patents jointly owned by CVT and FHI, under Section 9.1) as of the Effective Date or anytime during the Term that contain at least one claim that covers the use, manufacture, importation, exportation, offer for sale and/or sale in the Territory of Licensed Compounds and/or Licensed Products, intermediates or methods used in manufacturing of Licensed Compounds and/or Licensed Products or methods of use of Licensed Compounds and/or Licensed Products, including, without limitation, CVT's interest in any and all patented or patentable Improvements.

**1.32** **"Licensed Product"** means any product containing or constituting either of the Licensed Compounds in any formulation or dosage. **"Licensed Products"** shall mean more than one (1) Licensed Product.

**1.33** **"Licensed Technology"** means the Licensed Patents and the Licensed Know-How.

**1.34** **"Management Committee"** means the committee established by the Parties to oversee the Collaboration, as further described in Section 2.1.

**1.35** **["Medco"]** means **[Medco Research, Inc.]**, or its successor in interest and/or assignee, including without limitation **[King Pharmaceuticals, Inc.]** and/or any successor in interest and/or assignee to **[King Pharmaceuticals, Inc.]**

**1.36** **"NDA"** means an application for Regulatory Approval by the FDA as defined in 21 CFR 314 et seq., to commence commercial sale of a Licensed Product in the United States.

1.37 **"Net Sales"** means, collectively, the gross invoiced sales price of all Licensed Products sold by FHI (or for the purposes of Section 3.7(e) only, CVT or its Affiliates or sublicensees), or its Affiliates or its Sublicensees to Third Party purchasers after deduction of the following items whether currently in effect or which become effective during the Term as they pertain to the Licensed Products:

**(a)** any and all normal and customary trade and quantity discounts, customary allowances actually granted to purchasers of a Licensed Product for returns and recalled Licensed Product, chargeback and reporting fees paid to wholesalers and other distributors, allowances to end users participating in trial support, capitation, market share or other compliance incentive programs, and other credit adjustments based upon shipping discrepancies, order errors, etc. The allowance may be in the form of a credit, free goods, or cash and offset against the gross invoiced sales at time of issuance;

**(b)** Medicaid rebates given pursuant to agreements with U.S. Department of Health and Human Services and any other rebates given pursuant to government based rebate programs (including without limitation state and local rebate programs). Such rebates will be offset against gross invoiced sales at the time of payment;

**(c)** normal and customary prompt payment discounts which will be offset against gross invoiced sales at the time of sale. Such prompt payment discount will be specifically calculated only on those customer classes in which the prompt payment terms are offered at the discount percentage currently in effect at the time of sale;

**(d)** administrative fees to managed health care organizations (including but not limited to group purchasing organizations, HMOs, PBMs, etc.). Such administrative fees will be offset against gross invoiced sales at the time of sale in the case of a direct sale to such organization and in the case of an indirect sale (i.e., through a wholesaler or distributor), at the time of receipt of such data. The administrative fee will be calculated as the units reported during the period multiplied by the rebate percentage in effect during the period;

**(e)** freight expenses for shipping finished Licensed Product (including insurance) to such purchasers, which will be calculated by multiplying units of the Licensed Product sold by a per unit freight charge calculated based upon total freight and insurance charges divided by total FHI units sold during the previous fiscal year. Such per unit amount will be updated annually; and

**(f)** any excise and value added taxes paid on sales of Licensed Product in finished package form.

No deductions shall be made from Net Sales for items (a), (b), (d), (e) or (f) above, except to the extent of amounts for such items actually granted or paid with respect to a Licensed Product; provided that FHI may reconcile such amounts within a given calendar quarter.

No deductions shall be made from Net Sales for commissions paid to individuals whether they are with independent sales agencies or are regularly employed by FHI (or for the purposes of Section 3.7(e) only, CVT or its Affiliates or sublicensees), and/or its Affiliates or its Sublicensees and are on its or their payroll, or for the cost of collections. Licensed Products

shall be considered "sold" when billed out or invoiced. Sales by FHI (or for the purposes of Section 3.7(e) only, CVT or its Affiliates or sublicensees), or its Affiliates or Sublicensees of a Licensed Product to a Third Party distributor of such Licensed Product in any given country shall be considered a sale to a Third Party purchaser. Sale or transfer to an Affiliate or Sublicensee for re-sale by such Affiliate or Sublicensee shall not be considered a sale for the purpose of this provision, but the resale by such Affiliate or Sublicensee to a Third Party shall be a sale for such purposes.

**1.38 "Patent"** means any and all patents, inventor certificates, patent applications (including provisionals, divisionals, continuations and continuations in part), patents issuing from any applications, reissues, reexaminations, extensions and supplemental protection certificates, and all foreign cognates of the foregoing.

**1.39 "Phase I Clinical Trial"** means any human clinical trial in normal volunteers and/or patients intended to establish that a pharmaceutical product is safe for its intended use, and to support its continued testing in a Phase II Clinical Trial.

**1.40 "Phase II Clinical Trial"** means any human clinical trial in patients intended to establish the safety and biological activity of a pharmaceutical product for its intended use, and designed to support its continued testing in a Phase III Clinical Trial.

**1.41 "Phase III Clinical Trial"** means any human clinical trial in patients intended to establish that a pharmaceutical product is safe and efficacious for its intended use, and designed to support a filing for Regulatory Approval of such pharmaceutical product for marketing and sale for such intended use.

**1.42 "Phase IV Trial"** means any trial which is designed to fulfill any post-approval commitments made to the FDA in the United States or to any other Regulatory Authority in any other country in the Territory for a Licensed Product.

**1.43 "Post Approval Regulatory Issues"** means those issues which are discussed with the FDA or any other Regulatory Authority in the Territory that primarily or exclusively relate to post-approval marketing or clinical or safety monitoring of Licensed Product such as any Phase IV Trial of a Licensed Product or the wording of any package insert and/or labeling for a Licensed Product or any post marketing safety surveillance or spontaneous adverse event reports.

**1.44 "Product Trademarks"** means all Trademarks which pertain to promotion, marketing or sale of Licensed Products but excluding all CVT Trademarks and all FHI Trademarks.

**1.45 "Regulatory Approval"** means any approvals (including pricing and reimbursement approvals), licenses, registrations or authorizations of any Regulatory Authority necessary for the manufacture, distribution, use or sale of Licensed Compounds and/or Licensed Products in the applicable jurisdiction in the Territory.

**1.46 "Regulatory Authority"** means any national, supra-national, regional, state or local regulatory agency, department, bureau, commission, council or other governmental entity,

with jurisdiction over the manufacture, distribution, use or sale of Licensed Compounds or a Licensed Product in the applicable jurisdiction in the Territory.

**1.47 "Sublicensee"** shall have the meaning ascribed in Section 8.1(a).

**1.48 "Term"** shall have the meaning ascribed in Section 12.1.

**1.49 "Territory"** means the United States and its territories and possessions, Canada and Mexico.

**1.50 "Third Party"** means any Party other than CVT or FHI or their respective Affiliates.

**1.51 "Trademarks"** means all trademarks, service marks, trade names and logos, whether registered or not, and all applications therefor, and all goodwill associated therewith.

**1.52 "Valid Claim"** means a claim of an issued and unexpired Patent that (a) has not been revoked, declared unenforceable or unpatentable, or held invalid by a court or other governmental agency of competent jurisdiction that is unappealable or unappealed within the time allowed for appeal, (b) has not been admitted to be or rendered invalid or unenforceable through reissue, disclaimer or otherwise, and (c) has not been finally cancelled, withdrawn, abandoned or rejected by any governmental agency of competent jurisdiction.

## 2. MANAGEMENT DURING DEVELOPMENT OF LICENSED COMPOUNDS

### 2.1 Management Committee.

**(a) Formation.** Within ten (10) days after the Effective Date, CVT and FHI shall establish the Management Committee, which shall oversee, review and coordinate the development of the Licensed Compounds and Licensed Products in the Development Field for Regulatory Approval in the United States under the Development Program, under the terms and conditions of this Agreement.

**(b) Purpose and Principles.** The general purposes of the Management Committee shall be (i) to determine the overall Development Program, (ii) to coordinate the development activities hereunder, and (iii) to approve plans and budgets for the development of a Licensed Product in the Development Field for Regulatory Approval in the United States, as set forth more fully in Article 3, all based on the principles of prompt, diligent and commercially reasonable development of the Licensed Product consistent with good pharmaceutical practices. In addition to its overall development responsibility, the Management Committee in particular shall: (1) establish the strategy for the pre-clinical and clinical development of Licensed Compounds and Licensed Products in the Development Field, and Regulatory Approval of Licensed Products in the Development Field in the United States, together with preparing the applicable Development Plans and Annual Plans and Budgets (as defined in Section 3.3); and (2) perform such other functions as are appropriate to further the purposes of this Agreement as determined by the Parties.

2.2 **Limitation of Powers.** The Management Committee shall not have the right to amend or interpret this Agreement. Issues regarding the interpretation of this Agreement shall be referred to the respective chief executive officers of each Party. The actions of the Management Committee shall not substitute for either Party's ability to exercise any right set forth herein, nor excuse the performance of any obligation set forth herein.

2.3 **Liaisons.** Each Party will designate an individual to serve as the liaison between the Parties to undertake and coordinate any day-to-day communications as may be required between the Parties relating to their respective activities under this Agreement. Each Party may change such liaison from time to time during the Term upon written notice thereof to the other Party.

2.4 **Meetings.**

(a) **General.** The Management Committee shall hold meetings at such times as it elects to do so, but in no event shall such meetings be held less frequently than three (3) times per calendar year. The Management Committee shall meet on an alternating basis at CVT's facilities in Palo Alto, CA and FHI's facilities in Deerfield, IL, or at such other locations as the Parties may otherwise agree. Other representatives of either Party may attend meetings of the Management Committee as non-voting participants. With the consent of the representatives of each Party serving on the Management Committee, Third Parties involved in the Development Program or the manufacture or commercialization of Licensed Compounds and/or Licensed Products may attend meetings of such Committee as non-voting observers. Meetings of the Committee may be held by audio or video teleconference with the consent of each Party, provided that at least two (2) meetings per year as set forth above shall be held in person. Each Party shall be responsible for all of its own out-of-pocket expenses of participating in the Management Committee. Meetings of the Management Committee shall be effective only if a voting representative of each Party is present or participating.

(b) **Membership.** The Management Committee shall initially have three (3)-voting representatives of each Party, each of whom shall be authorized to vote on behalf of his or her respective Party. The Management Committee may change its size from time to time by written agreement of the Parties; provided, however, that at all times it shall be composed of an equal number of voting representatives appointed by each of CVT and FHI. Each Party may replace its Committee voting representatives at any time upon notice to the other Party; provided, however, that each Party's voting representatives shall at all times be persons possessing the appropriate level of skill, experience and familiarity with the Development Program.

(c) **Chairpersons.** The Management Committee shall be chaired by a representative of CVT. The chairperson shall be responsible for calling meetings, preparing and circulating an agenda in advance of each meeting, and preparing and issuing minutes of each meeting within thirty (30) days thereafter. Any such agenda and minutes shall be approved by the other Party in advance of any issuance. From time to time, the Management Committee may establish subcommittees or subordinate committees (which may or may not include members of the Management Committee itself) to oversee particular projects or activities, and such subcommittees or subordinate committees shall be constituted and shall operate as the Management Committee agrees.

2.5 **Decision-Making.** The Management Committee shall attempt to operate by consensus, with each Party's voting representatives to present a unified position on each issue. The Management Committee shall attempt in good faith to resolve any disagreement among the voting representatives of the Management Committee in light of the principles set forth in this Article 2. Should the Management Committee be unable to reach consensus on an issue, however, CVT shall have the right to cast the tie-breaking vote (subject to the terms of Sections 3.4(a), 6.2 and 14.2 below).

2.6 **Collaboration Guidelines.**

(a) **General.** In all matters related to the Collaboration, the Parties shall strive to balance as best they can the legitimate interests and concerns of the Parties and to realize the economic potential of Licensed Compounds and Licensed Products.

(b) **Independence.** Subject to the terms of this Agreement, the activities and resources of each Party shall be managed by such Party, acting independently and in its individual capacity. The relationship between CVT and FHI is that of independent contractors and neither Party shall have the power to bind or obligate the other Party in any manner, other than as is expressly set forth in this Agreement.

2.7 **Termination**. Notwithstanding anything to the contrary contained herein, the Management Committee shall disband and terminate upon the transfer of the NDA for the first Licensed Product from CVT to FHI in accordance with Section 7.1(a) below; provided, however, that FHI will provide semi-annual reports to CVT in accordance with Section 4.3.

2.8 **Time Included in Development Costs.** Time spent by CVT representatives attending and preparing for meetings of the Management Committee shall be included in the Development Costs and charged to FHI pursuant to Section 3.4(b). Time spent by FHI representatives attending and preparing for meetings of the Management Committee shall also be included in the Development Costs and shall be charged to CVT pursuant to Section 3.4(c).

## 3. DEVELOPMENT PROGRAM

3.1 **General.** The Management Committee shall coordinate and facilitate development of Licensed Compounds and Licensed Products in order to obtain Regulatory Approvals and commercialize Licensed Products in the U.S. as expeditiously as is commercially reasonable. The Management Committee shall prepare and approve the Development Program, the Development Plan and the Annual Plans and Budgets as described in Section 3.3 and direct the clinical development and regulatory program for Licensed Compounds and Licensed Products. Subject to Sections 3.4(a) and 14.2(e) below, and except as set forth in such plans and budgets approved by the Management Committee, or as otherwise agreed to by the Management Committee (under Section 3.4(a) or otherwise), the Development Program will be implemented by CVT.

3.2 **Lead Compound.** The Parties acknowledge and agree that CVT 3146 is the lead development candidate (**"Lead Compound"**). CVT may replace the Lead Compound with **[CVT 3033]** at any time during the Term by providing FHI with forty five (45) days written notice thereof, which notice shall include the reason(s) for making any such replacement. Upon

FHI's receipt of such notice, FHI shall have forty five (45) days in which to notify CVT that: (a) CVT should proceed with the development of **[CVT 3033]** as the Lead Compound under the terms and conditions of this Agreement; or (b) FHI will terminate this Agreement under Section 12.2 below; provided, however, that if FHI has not provided any written notice by the end of such forty five (45)-day period, FHI automatically shall be deemed to have elected clause (a). If such notice from FHI to CVT indicates that FHI desires for CVT to proceed with the development of **[CVT 3033]** as the Lead Compound, the Management Committee will then promptly and expeditiously prepare a Development Program and Annual Plan and Budget for **[CVT 3033].** FHI shall not be responsible for any Development Costs other than for pre-clinical studies after the Effective Date in connection with **[CVT 3033],** until the date that FHI notifies CVT that it accepts (or, as set forth above, is deemed to have accepted) development of **[CVT 3033]** as the new Lead Compound. The Parties acknowledge and agree that while CVT 3146 is the Lead Compound, CVT shall have no responsibility to conduct in parallel development activities with respect to **[CVT 3033]** other than pre-clinical studies after the Effective Date, unless the parties otherwise mutually agree. Once CVT has replaced CVT 3146 with **[CVT 3033]** as the Lead Compound, FHI shall be free to develop CVT 3146 in the FHI Field at FHI's sole cost and expense.

### 3.3 Development Plan; Annual Plans and Budgets.

**(a) Development for Regulatory Approval in the United States.** The development of the Licensed Compounds and Licensed Products in the Development Field for Regulatory Approval in the United States shall be governed by a comprehensive development plan (**"Development Plan"**) and a detailed and specific plan and budget for all development proposed for the Licensed Compounds and Licensed Products for each calendar year and by each clinical phase of development during the Development Program (**"Annual Plan and Budget"**). The Development Plan will be the planned development program for Licensed Compounds and Licensed Products designed to generate the pre-clinical, clinical and regulatory information required for filing NDAs in the U.S. Each Annual Plan and Budget shall be consistent with the Development Plan as then in effect. An initial Development Plan and Annual Plan and Budget for activities through Phase I Trial(s) for the first Licensed Compound is set forth as Schedule 3.3 to this Agreement and has been approved by both Parties. Promptly after the Effective Date, the Management Committee shall complete and approve a detailed Development Plan and an Annual Plan and Budget covering the remainder of calendar year 2000 and calendar year 2001. The Development Plan and Annual Plan and Budget shall include commercially reasonable timelines in order to achieve the prompt and diligent development of Licensed Compounds and Licensed Products. Periodically thereafter, the Management Committee shall assign responsibilities for updating the Development Plan and preparing the Annual Plan and Budgets on such schedule and with such process as the Management Committee shall determine. The Management Committee shall review and approve the Annual Plan and Budget on a timely basis.

**(b) Development in the Territory Outside the U.S.** The Parties acknowledge and agree that the development of Licensed Compounds and Licensed Products in the Territory outside of the U.S. shall be determined by FHI in its sole discretion, subject to the remainder of this Section 3.3(b). If FHI determines that it would like to develop Licensed Compounds and/or Licensed Products outside the U.S. prior to the transfer of the NDA from CVT in accordance with 7.1(a) below, then FHI will coordinate such development with CVT and

such development will be managed by the Management Committee under the terms and conditions of this Agreement; provided, however, that FHI shall not conduct any clinical studies of Licensed Compounds or Licensed Products prior to the transfer of the NDA to FHI under Section 7.1(a) below without obtaining CVT's prior written consent. FHI will be responsible at its sole expense for filing, obtaining and maintaining any and all Regulatory Approvals for Licensed Compounds and Licensed Products in the Territory outside the U.S. FHI shall be responsible for any Development Costs for development of Licensed Compounds and Licensed Products in the Territory outside of the U.S.

**(c) Development Outside the Development Field in the Territory.** The Parties acknowledge and agree that the development of Licensed Compounds and Licensed Products outside of the Development Field in the Territory shall be determined by FHI in its sole discretion. FHI shall be responsible for any Development Costs for development of Licensed Compounds and Licensed Products outside of the Development Field.

### 3.4 Conduct of the Development Program including Manufacturing Activities.

**(a)** CVT shall manage all pre-clinical and clinical development of Licensed Compounds and Licensed Products in the Development Field in the U.S. and all "CVT Manufacturing Activities" (as defined below) under the oversight of the Management Committee as provided in Section 2.1 and in accordance with the Development Program, Development Plan, Annual Plan and Budget and the terms of this Agreement. FHI shall manage all "FHI Manufacturing Activities" (as defined below) under the oversight of the Management Committee as provided in Section 2.1 and in accordance with the Development Program, Development Plan, Annual Plan and Budget and the terms of this Agreement. Specifically, with respect to each Party's respective Manufacturing Activities under this Agreement, the Parties will coordinate and cooperate with each other as reasonably requested. Notwithstanding anything to the contrary contained in this Agreement, and subject to the budget provisions of Section 3.4(c), FHI Manufacturing Activities shall be within the sole control and discretion of FHI; provided, however, that FHI will provide status reports at the meetings of the Management Committee and cooperate with the Management Committee. CVT will coordinate with FHI from and after the Effective Date with respect to CVT Manufacturing Activities. Consistent with the other terms of this Section 3.4(a), the Management Committee shall determine the timeline(s) for each Party's respective Manufacturing Activities that will reasonably allow each Party to meet its respective obligations under this Agreement, including, without limitation, the timing of transition from CVT Manufacturing Activities to FHI Manufacturing Activities and the timing of commencement of FHI Manufacturing Activities hereunder. As used herein, "**CVT Manufacturing Activities**" shall mean CVT's activities in identifying, selecting, qualifying and entering into definitive agreement(s) with Third Party(ies) to manufacture clinical supplies of Licensed Compounds and Licensed Products and to supply raw materials and components for clinical supplies of Licensed Compounds and Licensed Products. As used herein, "**FHI Manufacturing Activities**" shall mean FHI's activities, in accordance with the timeline(s) and transition plan to be determined by the Management Committee as provided above, to: (i) identify, select, qualify and enter into a definitive agreement(s) with Third Party(ies) to contract manufacture commercial supplies of Licensed Compounds and Licensed Products and to supply raw materials and components for commercial supplies of Licensed Compounds and Licensed Products; and (ii) to conduct process development and scale up work to develop a commercial

process for the manufacture and supply of Licensed Compounds and Licensed Products, including, without limitation, related analytical and stability work. In addition to FHI Manufacturing Activities, FHI shall undertake such other development activities as may be determined by the Management Committee and set forth in the Development Plan, and shall be entitled to elect to assume development as (but only as) provided in Section 14.2(e).

**(b)** FHI shall reimburse CVT for seventy-five percent (75%) of CVT's Development Costs incurred after the Effective Date with respect to CVT's activities under Section 3.4(a) above, including CVT Manufacturing Activities, provided that CVT's Development Costs are in accordance with the applicable Annual Plan and Budget. CVT shall invoice FHI for such CVT Development Costs on a quarterly basis, within thirty (30) days after the end of each calendar quarter, and such invoices shall be accompanied by the appropriate documentation, including a comprehensive summary of FTE time, costs and listing of expenditures, and such completed and acceptable reports as may be required under the Development Plan and otherwise meeting the requirements of the applicable Annual Plan and Budget. FHI shall pay all such invoices within forty-five (45) days after the end of each such calendar quarter.

**(c)** CVT shall reimburse FHI for twenty-five percent (25%) of FHI's Development Costs incurred after the Effective Date with respect to FHI's activities (if any) under Section 3.4(a) above, including FHI Manufacturing Activities, provided that FHI's Development Costs are in accordance with the applicable Annual Plan and Budget; provided however, that if FHI elects to assume development under Section 14.2(e), in such event CVT shall reimburse FHI for twenty five percent (25%) of FHI's Development Costs, up to a maximum of twenty-five percent (25%) of CVT's Development Costs for the last Annual Plan and Budget approved in good faith under which CVT was conducting the development activities under this Agreement. FHI shall invoice CVT for such FHI Development Costs on a quarterly basis, within thirty (30) days after the end of each calendar quarter, and such invoices shall be accompanied by the appropriate documentation, including a comprehensive summary of FTE time, costs and listing of expenditures, and such completed and acceptable reports as may be required under the Development Plan and otherwise meeting the requirements of the applicable Annual Plan and Budget. CVT shall pay all such invoices within forty-five (45) days after the end of each such calendar quarter. At FHI's option, but only with the prior written agreement of CVT, any monies owed by CVT under this Section 3.4(c) may be deducted from amounts FHI owes to CVT under Section 3.4(b). In no event will CVT be responsible for payment of any Development Costs incurred by FHI after the transfer of the NDA to FHI pursuant to Section 7.1(a) below.

### 3.5 Diligence.

**(a)** Each Party shall use commercially reasonable, diligent efforts consistent with industry standards to carry out their respective responsibilities under this Agreement to develop and market Licensed Products in the Development Field in the United States. In the event one Party in good faith believes that the other Party is in material breach of its obligations under this Section 3.5(a) not caused by the first Party, the first Party shall promptly notify the other Party of such breach in writing. In the event of any such notice hereunder, the other Party shall have sixty (60) days thereafter to cure such material breach. In the event the other Party

fails to timely cure its material breach within such sixty (60) day period, then either Party may submit the issue for binding arbitration under Section 14.2 below.

**(b)** The Parties will use commercially reasonable diligent efforts to cooperate with each other in carrying out the Development Plan and the applicable Annual Plan and Budget under this Agreement.

From and after the date of transfer of the NDA for the first Licensed Product from CVT to FHI under Section 7.1(a) below, FHI shall have the authority in its sole discretion to make any and all decisions relative to all clinical matters and any Phase IV Trial, Post Approval Regulatory Issues or other post approval research studies relating to Licensed Compounds and/or Licensed Products, and with respect to all such matters CVT shall have no responsibility to make any payments that might otherwise be required under Section 3.4(c) or to perform any activities under Section 3.4(a).

**3.6 Disclosure of Information.** CVT shall provide FHI with Information relating to the Licensed Compounds and/or Licensed Products, as follows:

**(a)** Promptly following the Effective Date (but in no event more than thirty (30) days thereafter), CVT shall provide FHI access (and upon request for specified items, provide copies to FHI), of any and all Information that is in CVT's possession and/or Control relating specifically to the Licensed Compounds.

**(b)** Thereafter, through the Management Committee CVT shall disclose to FHI any material Information in CVT's possession and/or Control specifically relating to the Licensed Compounds and/or Licensed Products and shall provide FHI access to any and all such Information, whether material or not, as is reasonably requested by FHI at reasonable times and upon reasonable advance written notice.

Nothing herein shall require CVT to breach any confidentiality obligations owed to Third Parties. CVT shall notify FHI of any such confidentiality obligations and, if requested by FHI, shall use good faith efforts to attempt to obtain a waiver of them for the benefit of FHI.

**3.7 Collaborative Clinical Data and FHI Clinical Data.**

**(a)** Any and all pre-clinical and clinical data developed for, related to and/or relative to the Licensed Compounds and/or any Licensed Products and generated by CVT pursuant to this Agreement is referred to herein as the **"Collaborative Clinical Data"**. The Collaborative Clinical Data shall not include any "**FHI Clinical Data**", which means any and all pre-clinical and clinical data (if any) developed for, related to and/or relative to the Licensed Compounds and/or any Licensed Products and generated solely by FHI pursuant to this Agreement. All Collaborative Clinical Data and all FHI Clinical Data will be owned solely by FHI, subject to the license rights for the benefit of CVT under Section 8.2 below and the remaining provisions of this Section 3.7.

**(b)** CVT shall have the right to disclose the Collaborative Clinical Data in the FHI Field and/or the FHI Clinical Data in the Development Field to potential partners for any use outside the Territory, and to qualified potential financial investors in CVT, under confidentiality

obligations binding the recipients of such information under terms that are consistent with Article 10, provided that such partner and/or financial investor could not be reasonably anticipated to compete with FHI in the Development Field in the Territory. In addition, CVT shall have the right to disclose the Collaborative Clinical Data in the FHI Field and/or the FHI Clinical Data in the Development Field to Regulatory Authorities outside the Territory.

**(c)** Either Party shall be entitled to use the Collaborative Clinical Data in the FHI Field and/or the FHI Clinical Data in the Development Field in scientific publications consistent with standard industry practice, subject however to the terms of Section 6.2 hereof.

**(d)** CVT shall have the exclusive (except as to FHI) license (with the right to sublicense) to use the Collaborative Clinical Data in the FHI Field and/or the FHI Clinical Data in the Development Field outside of the Territory under the license granted to CVT under Section 8.2 below, in consideration for which CVT shall make payment to FHI of the following percentages of any and all monies, upfront fees, licensing fees, royalties, milestones and premium on any equity investment and/or discount on any research and development support and/or loans (but excluding the fair market value of any research and development support, loans or other amounts received in connection with the purchase of equity and the like) received by CVT from a Third Party sublicensee of CVT under CVT's license rights with respect to such Collaborative Clinical Data in the FHI Field and FHI Clinical Data in the Development Field (collectively the **"Total Consideration"**), but only if such Third Party sublicensee includes such Collaborative Clinical Data in the FHI Field and/or the FHI Clinical Data in the Development Field in a filing submitted to a Regulatory Authority outside of the Territory (collectively, the **"Third Party-Filed Clinical Data"**):

**(i)** **[Seven and one half percent (7 1/2%)]** of the Total Consideration if the Third Party-Filed Clinical Data includes non-public safety data with respect to a Licensed Compound and/or Licensed Product, but not any non-public efficacy data from any Phase II Clinical Trial of a Licensed Compound and/or Licensed Product or any Phase III Clinical Trial of a Licensed Compound and/or Licensed Product; or

**(ii)** **[Eleven and one quarter percent (11.25%)]** of the Total Consideration if the Third Party-Filed Clinical Data includes any non-public efficacy data from any Phase II Clinical Trial of a Licensed Compound and/or Licensed Product, but not any non-public efficacy data from any Phase III Clinical Trial of a Licensed Compound and/or Licensed Product; or

**(iii)** **[Fifteen percent (15%)]** of the Total Consideration if the Third Party-Filed Clinical Data includes any non-public efficacy data from any Phase III Clinical Trial of a Licensed Compound and/or Licensed Product.

**(e)** In the event CVT (rather than a Third Party as provided in Section 3.7(d) above) includes such Collaborative Clinical Data in the FHI Field and/or FHI Clinical Data in the Development Field in a filing submitted by CVT to a Regulatory Authority outside of the Territory (collectively **"CVT-Filed Clinical Data"**), then in consideration for CVT's license rights to use such CVT-Filed Clinical Data, CVT shall make payment to FHI of the following percentages of Net Sales of Licensed Products:

(i) **[One and one half percent (1.5%)]** of the Net Sales of Licensed Products by CVT or its Affiliates or sublicensees if the CVT-Filed Clinical Data includes non-public safety data with respect to a Licensed Compound and/or Licensed Product, but not any non-public efficacy data from any Phase II Clinical Trial of a Licensed Compound and/or Licensed Product or any Phase III Clinical Trial of a Licensed Compound and/or Licensed Product; or

(ii) **[Two and one quarter percent (2.25%)]** of the Net Sales of Licensed Products by CVT or its Affiliates or sublicensees if the CVT-Filed Clinical Data includes any non-public efficacy data from any Phase II Clinical Trial of a Licensed Compound and/or Licensed Product, but not any non-public efficacy data from any Phase III Clinical Trial of a Licensed Compound and/or Licensed Product; or

(iii) **[Three percent (3%)]** of the Net Sales of Licensed Products by CVT or its Affiliates or sublicensees if the CVT-Filed Clinical Data includes any non-public efficacy data from any Phase III Clinical Trial of a Licensed Compound and/or Licensed Product.

As used in Sections 3.7(d) and (e), "non-public" data comprising the Collaborative Clinical Data in the FHI Field or the FHI Clinical Data in the Development Field shall include any Information published or otherwise disclosed by CVT in violation of its confidentiality obligations under Article 10. CVT shall promptly notify FHI in the event CVT and/or any Third Party uses any such Collaborative Clinical Data and/or FHI Clinical Data as provided in Sections 3.7(d) and (e) above.

## 4. COMMERCIALIZATION

**4.1 General**. Except as otherwise provided in Section 4.4 below, FHI: (a) shall have the exclusive right in its sole discretion to commercialize the Licensed Compounds and Licensed Products in the FHI Field in the Territory; (b) shall be solely responsible for manufacturing, marketing, promotion, sales and distribution of the Licensed Compounds and each Licensed Product in the FHI Field in the Territory; and (c) shall have the sole responsibility and decision-making authority over all aspects of the manufacturing, marketing, promotion, sale and distribution of Licensed Compounds and Licensed Products in the FHI Field in the Territory.

**4.2 Diligence.** FHI shall, directly or through its Affiliates or Sublicensees, use commercially reasonable, diligent efforts consistent with industry standards to carry out its responsibilities under this Agreement to manufacture (or cause to be manufactured), market, promote and sell Licensed Products in the Development Field in the United States. Without limiting the generality of the foregoing, FHI shall commence commercial sales of each Licensed Product in the United States for a particular indication within **[six (6) months]** after receiving Regulatory Approval of the NDA (or NDA supplement) to market and sell such Licensed Product in the United States for such indication, except in the case where commercial supplies of the Licensed Product are unavailable for reasons reasonably outside FHI's control, in which case the **[six (6) month]** time period may be extended on written notice from FHI to CVT (including an explanation of the reasons for such delay) for up to an additional **[six (6) months].** Notwithstanding the foregoing, however the Parties agree that FHI's diligence obligations under

this Section 4.2 with respect to indications outside of the Development Field and in the Territory outside the United States shall not apply unless FHI has determined, in its sole discretion, to proceed under Section 3.3(b) and/or Section 3.3(c), as the case may be.

**4.3 Reviews with CVT.** Subject to Section 4.4(b) below, following NDA approval for the first Licensed Product, FHI shall provide CVT on a semi-annual basis during the Term (every February 1 and August 1) with reports describing all of FHI's material marketing and clinical and regulatory efforts with respect to Licensed Products during the immediately preceding six (6) month period and forecasts and plans for such efforts for the immediately following twelve (12) month period. Such reports will be provided by FHI to CVT commencing within ninety (90) days after the first such NDA approval, with the next such report to be provided on the February 1 or August 1 deadline next following the initial report (provided that if this would result in the second report being provided within less than six (6) months, FHI may deliver the second report at the next applicable deadline). The Parties shall meet once annually to review all such reports.

**4.4 Loss of Exclusive Rights.**

**(a)** CVT shall have the right to convert the exclusive licenses granted to FHI pursuant to Section 8.1 below to co-exclusive licenses to FHI (with co-exclusive licenses to CVT as provided in Section 8.2 below), with such conversion to take effect automatically upon thirty (30) days' prior written notice from CVT to FHI if either of the following events occurs at any time during the Term of this Agreement:

**(i)** FHI's net royalty obligation to Third Parties on its sales of **[Adenoscan®]** in the U.S. is less than **[twenty percent (20%)],** provided that this subsection (i) shall not apply if FHI's underlying license agreement(s) with all Third Parties with respect to **[Adenoscan®]** have been terminated, or if **[Adenoscan®]** or its manufacture, use or sale in the U.S. have expired, terminated or lapsed or is no longer covered by a Valid Claim within any Patent in the U.S.; or

**(ii)** FHI files an NDA for, commercially launches or acquires rights, in any case to any approved product for use in the Development Field in the Territory, other than a Licensed Product or any other product (if any) licensed by FHI from CVT.

FHI shall notify CVT in writing promptly of the occurrence of any event covered under this Section 4.4(a).

**(b)** In the event that FHI's licenses under Section 8.1 below become co-exclusive with CVT as provided in Section 4.4(a) above, from and after the effective date of the conversion of such license rights: (i) FHI's royalty obligations to CVT under Section 5.5 below shall be reduced by **[fifty percent (50%)];** (ii) FHI's royalty obligations under Section 5.6 shall terminate; (iii) FHI's obligations under Sections 4.3 and 8.6 shall terminate; and (iv) CVT shall no longer have any obligations to FHI under Sections 3.7(d), 3.7(e) or 8.5 of this Agreement. In addition, FHI shall provide CVT, at CVT's reasonable request, such reasonable cooperation (including any information included in FHI Development Technology) with respect to the

Licensed Compounds and/or Licensed Products or their development, manufacture or use in FHI's possession or Control as may be necessary for CVT to market and sell Licensed Products.

**4.5 Recognition of CVT.** CVT shall receive recognition on all package labels of all Licensed Products in the Territory where legally permissible. If the space required for such recognition would result in additional production costs, FHI shall promptly notify CVT in writing of such costs, and shall only be required to include such recognition based on CVT's written agreement to reimburse FHI for such additional costs. CVT shall receive recognition in all promotional materials for all Licensed Products where legally permissible. The Parties acknowledge and agree that in the event CVT exercises its option under Section 4.4 to convert the exclusive licenses granted to FHI hereunder to co-exclusive licenses, then, at FHI's option, CVT shall no longer receive recognition on all package labels and/or promotional materials.

## 5. COMPENSATION

**5.1 License Fee.** On the Effective Date, FHI shall pay to CVT a non-creditable, non-refundable license fee of Two Million Dollars ($2,000,000.00).

**5.2 Equity.** The Parties have entered into that certain stock purchase agreement of even date herewith, a copy of which is attached as Schedule 5.2, pursuant to which FHI shall make an investment of Four Million Dollars ($4,000,000) in return for shares of CVT common stock as further described in such agreement. Such equity investment as described in accordance with the terms of such agreement shall be paid to CVT on the Effective Date.

**5.3 IND Payment.** On the Effective Date hereof, FHI shall pay to CVT a fee of Four Million Dollars ($4,000,000) in consideration for successfully filing the IND (the "**IND Payment**"). Notwithstanding anything to the contrary contained herein, if the IND (or any other application outside the U.S in one of the Permitted Countries, as hereinafter defined, to permit human clinical testing) for the Lead Compound is not successfully filed prior to the Effective Date or within **[twelve (12) months]** after the Effective Date, then CVT shall within two (2) business days thereafter refund to FHI by wire transfer the IND Payment. CVT will use its commercially reasonable diligent efforts consistent with industry standards to successfully file the IND (or such other application). "**Permitted Countries**" shall mean **[the United Kingdom or the Netherlands]**. If subsequently the IND or such other application is successfully filed by CVT under this Agreement, then FHI shall within two (2) business days thereafter either (a) repay CVT by wire transfer the full amount of the IND Payment or (b) terminate this Agreement under Section 12.2 (including the notice provision therein), in which event FHI shall be entitled to keep the IND Payment previously refunded by CVT. Under this Section 5.3, a "successfully filed" IND or such other application shall mean that (i) if an IND was filed with the FDA, a period of thirty (30) days has passed from CVT's receipt of a notice from the FDA that the FDA has received such IND, and during such thirty (30) day period the FDA has not put a clinical hold on such IND (or did so but CVT has subsequently received a notice from the FDA confirming that the clinical hold has been removed), or (ii) if an application was filed outside the U.S. in one of the Permitted Countries to permit human clinical testing, such application has been accepted by the appropriate Regulatory Authority, or CVT is otherwise able to commence human clinical testing thereunder as provided under applicable laws and regulations. If within thirty (30) days after the expiration of such twelve (12) month period, FHI in good faith believes

that CVT is in material breach of its obligations to file the IND or such other application under this Section 5.3, either Party may initiate arbitration pursuant to Section 14.2 below.

**5.4 Milestones.** FHI shall make the following non-creditable, non-refundable payments to CVT within five (5) business days after receipt by FHI of written notice from CVT of the occurrence of each of the corresponding events:

| Event | Payment |
|---|---|
| Initiation of the first Phase II Clinical Trial for the first Licensed Product under an IND filed in the U.S. | **[$2 Million]** |
| Initiation of the first Phase III Clinical Trial for the first Licensed Product under an IND filed in the U.S. | **[$3 Million]** |
| First submission of an NDA for the first Licensed Product in the U.S. | **[$7 Million]** |
| First receipt of approval of an NDA for the first Licensed Product in the U.S. | **[$12 Million]** |

If under the Development Program CVT is able to file an NDA for the first Licensed Product without having had to conduct a Phase II Clinical Trial, or is able to file such NDA without having had to conduct a Phase III Clinical Trial, then FHI shall pay CVT the milestone payment applicable to such missed event at the time of receipt of approval of the NDA, in addition to the milestone payment payable at the time of such NDA approval. FHI shall make each of the foregoing milestone payments no more than once, regardless of the number of times a particular milestone is achieved. "Initiation" as used in this Section 5.4 shall mean the enrollment of the first patient in the study.

**5.5 Royalties.**

**(a)** Subject to Section 4.4(b) above:

**(i)** FHI shall owe and pay to CVT a royalty of **[twenty percent (20%)]** of Net Sales of all Licensed Products by FHI and its Affiliates and Sublicensees in the Territory, subject to clause (ii) below.

**(ii)** On a country-by-country and Licensed Product-by-Licensed Product basis, FHI's royalty obligation under clause (i) above shall be reduced to **[ten percent (10%)]** of Net Sales of a Licensed Product by FHI and its Affiliates and Sublicensees in any country in the Territory in which such Licensed Product or the manufacture, sale, promotion, distribution or use thereof would not be covered by a Valid Claim within the Licensed Patents.

**(b)** FHI's royalty obligations to CVT under Section 5.5(a)(i) above shall expire, on a country-by-country and Licensed Product-by-Licensed Product basis, on the later of (i) the expiration of the last-to-expire of the Valid Claims within the Licensed Patents that would (but for the licenses granted to FHI under this Agreement) be infringed by the manufacture, sale, promotion, distribution or use of a Licensed Product in such country, or (ii) the tenth (10th) anniversary of the date of the first commercial sale of such Licensed Product in such country by FHI, its Affiliates or its Sublicensees hereunder. FHI's royalty obligations to CVT under Section 5.5(a)(ii) above shall expire, on a country-by-country and Licensed Product-by-Licensed Product basis, on the tenth ($10^{th}$) anniversary date of the first commercial sale of such Licensed Product in such country by FHI, its Affiliates or its Sublicensees. Following any such expiration, the licenses granted to FHI by CVT pursuant to Section 8.1 below shall terminate with respect to such Licensed Product in such country, and CVT automatically shall be deemed to have granted to FHI a non-exclusive, fully paid-up, royalty-free, perpetual license under the Licensed Technology to develop, use, make, have made, import, export, offer for sale and sell such Licensed Product in such country.

**5.6 Additional Royalties.**

**(a)** Subject to Section 4.4(b) above, commencing at the start of the first full calendar quarter which is at least forty-five (45) days after the date on which the FDA approves the NDA for the first Licensed Product, and terminating **[thirty-six (36) months]** thereafter, FHI shall owe and pay to CVT a royalty on Net Sales of **[FHI's Adenoscan® product]** in the Territory as follows: (i) for that portion of Net Sales of **[Adenoscan®]** by FHI or its Affiliates or sublicensees up to **[Fifty Million Dollars ($50,000,000.00)]** in each one (1)-year period (as defined below), FHI shall owe and pay CVT **[no royalty]**; (ii) for that portion of Net Sales of **[Adenoscan®]** by FHI or its Affiliates or sublicensees over **[Fifty Million Dollars ($50,000,000.00)]** in each one (1)-year period and up to **[One Hundred Million Dollars ($100,000,000.00)]** in each one (1)-year period, FHI shall owe and pay CVT a royalty equal to **[two percent (2%)]** of such Net Sales of **[Adenoscan®]** by FHI or its Affiliates or sublicensees; and (iii) for that portion of such Net Sales of **[Adenoscan®]** by FHI or its Affiliates or sublicensees in excess of **[One Hundred Million Dollars ($100,000,000.00)]** in each one (1)-year period, FHI shall owe and pay CVT a royalty equal to**[five percent (5%)]** of Net Sales of **[Adenoscan®]** by FHI or its Affiliates or sublicensees. For purposes of this provision, the one (1)-year periods for measurement of Net Sales of **[Adenoscan®]** shall consist of periods of four (4) calendar quarters, commencing as set forth above.

**(b)** Subject to Section 4.4(b) above, after the expiration of such **[thirty-six (36) month]** period under clause (a), FHI shall pay CVT royalty equal to **[five percent (5%)]** of Net Sales of **[Adenoscan®]** by FHI or its Affiliates or sublicensees for that portion of Net Sales in excess of **[Fifty Million Dollars ($50,000,000.00)]** per one (1)-year period (as measured as provided above).

**(c)** Subject to Section 4.4(b) above, FHI's obligations to pay royalties to CVT under this Section 5.6 shall expire in the same fashion and at the same time as FHI's obligations to CVT under Section 5.5(a) hereof, as more fully described in Section 5.5(b) hereof; provided, however, that if FHI's underlying license agreement(s) with all Third Parties with respect to **[Adenoscan®]** have been terminated, or if **[Adenoscan®]** or its manufacture, use or sale in the

U.S. have expired, terminated or lapsed or is no longer covered by a Valid Claim within any Patent in the U.S., then FHI's obligations to pay royalties to CVT under this Section 5.6 shall terminate upon the effective date set forth in Sections 4.4(a) and (b) for conversion of license rights.

**5.7 Payment of Royalties and Other Amounts.**

**(a)** Within thirty (30) days of the end of each calendar quarter following the first commercial sale of a Licensed Product in the Territory hereunder: (i) FHI shall provide CVT with a written report of Net Sales of all Licensed Products and of **[Adenoscan®]** in the Territory during such quarter, accompanied by full payment of all royalties accrued and owing to CVT under Sections 5.5 and 5.6 (if applicable) during such quarter; and (ii) CVT shall provide FHI with a written report of Net Sales of Licensed Products by CVT and its Affiliates and sublicensees under Section 3.7(e), accompanied by full payment of all royalties accrued and owing to FHI under Section 3.7(e). Within sixty (60) days following the end of each calendar year following the first commercial sale of a Licensed Product hereunder, FHI or CVT, as the case may be shall provide the other Party with a written report of Net Sales of all Licensed Products and FHI shall provide CVT with a written report of Net Sales of **[Adenoscan®]** during such year. Each such report shall set forth on a Licensed Product-by-Licensed Product and country-by-country basis, aggregate Net Sales of such Licensed Product and of **[Adenoscan®],** the number of units of such Licensed Product and of **[Adenoscan®]** sold, gross sales for such Licensed Product and of **[Adenoscan®],** and the deductions taken from such gross sales in calculating any Net Sales.

**(b)** All amounts due to each Party from the other Party under this Agreement shall be made by wire transfer of immediately available United States funds into an account designated in writing by an officer of CVT or FHI, as the case may be.

**5.8 Third Party Royalties.**

**(a)** During the Term:

**(i)** if FHI is ordered by a court of competent jurisdiction in a final unappealable judgment to license Valid Claims under one (1) or more Patents owned or Controlled by a Third Party, or otherwise to pay any monies to a Third Party (including, without limitation, **[Medco]**) in order to make, have made, export, import, use, offer for sale and/or sell any Licensed Product in the FHI Field in the Territory; or

**(ii)** if FHI deems it necessary or desirable to enter into an agreement for a license under one or more issued Patents owned or Controlled by a Third Party (including, without limitation, **[Medco]**), to develop, make, have made, export, import, manufacture, use, offer for sale and/or sell a Licensed Product in the FHI Field in the Territory, and CVT agrees in writing that such license agreement is necessary or desirable, or Independent Patent Counsel as provided in Section 5.8(b) determines that such license agreement is necessary or desirable;

then, for purposes of this Section 5.8 the Parties shall share any and all monies, upfront fees, licensing fees, royalties and milestones, required to be paid by FHI to any such Third Party (collectively the "**Total Amount Payable to Third Parties**"), as follows:

**(1)** If the Total Amount Payable to Third Parties includes any lump sum payments, then FHI shall be entitled to offset **[forty percent (40%)]** of such lump sum payments actually made by FHI, against up to **[fifty percent (50%)]** of the milestones payable to CVT under this Agreement pursuant to Section 5.4 above, or in the event all milestones have been paid by FHI to CVT hereunder, then within thirty (30) days of CVT's receipt of written notice from FHI that FHI has made such lump sum payment to such Third Party, CVT shall promptly reimburse FHI for the balance of the **[forty percent (40%)]** of such lump sum payment not otherwise offset against milestone payments as provided herein.

**(2)** With respect to any payments comprising the Total Amount Payable to Third Parties other than lump sum payments covered by the foregoing clause (1), FHI shall be entitled to offset **[forty percent (40%)]** of such payments actually made by FHI (the **"Offset Amount"**), against up to **[fifty percent (50%)]** of the royalties payable to CVT under Sections 5.5 and 5.6 of this Agreement. If the Offset Amount to which FHI is entitled under the preceding sentence exceeds **[fifty percent (50%)]** of the royalties due to CVT during any calendar quarter, then FHI shall be entitled to carry forward such excess amount not yet offset hereunder (the **"Unused Offset Amount"**) to subsequent calendar quarter(s) during the Term of this Agreement, and to offset such Unused Offset Amount and future Offset Amounts (if any) against up to **[fifty percent (50%)]** of the royalties subsequently due to CVT hereunder, until the full Offset Amounts are repaid to FHI by the offsetting mechanism under this provision. If, upon the expiration or termination of this Agreement, there remains any Unused Offset Amount (and any unused offset under clause (1) above), FHI shall be entitled to deduct any such remaining Unused Offset Amount (and any unused offset under clause (1) above) from the final royalty payment owed to CVT under this Agreement, and if such final royalty payment is less than the amount of such remaining Unused Offset Amount, CVT shall pay FHI an amount equal to the difference within thirty (30) days after receipt of an invoice from FHI.

**(b)** In the event FHI determines that it is necessary or desirable to enter into an agreement for a license under Section 5.8(a)(ii) above and CVT does not agree in writing with FHI, then either Party may submit resolution of the matter to an independent outside patent counsel in accordance with the following procedure (such counsel shall be referred to as "**Independent Patent Counsel**"). If the Parties cannot agree whether such license is necessary or desirable, either Party may send the other Party written notice requesting that an Independent Patent Counsel render an opinion as to whether such agreement is necessary or desirable. Each Party shall select its own outside patent counsel and both such outside patent counsel shall select the Independent Patent Counsel, within thirty (30) days from the date of the first notice above. Both Parties and their respective outside patent counsel will cooperate with Independent Patent Counsel, so that Independent Patent Counsel can render an opinion as expeditiously as possible. Independent Patent Counsel is to act as a neutral participant and shall have no past, present or anticipated future affiliation with either Party. If Independent Patent Counsel determines that such license arrangement is necessary or desirable, then CVT shall share in the Total Amount Payable to Third Parties as provided for in this Section 5.8. If Independent Patent Counsel determines that such license arrangement is not necessary or desirable, then CVT shall not be obligated to so share in such Total Amount Payable to Third Parties, and FHI shall not be entitled to such offset against royalties due to CVT. The decision of Independent Patent Counsel shall be final and binding on the Parties, and the cost and expenses of Independent Patent

Counsel shall be shared between the Parties. Each Party shall bear its own costs and expenses with respect to it own respective outside patent counsel.

**5.9 Withholding of Taxes.** Any tax required to be withheld by a Party on account of royalties payable to the other Party under this Agreement shall be deducted from the amount of royalties otherwise due. The withholding Party shall secure and send to the other Party written proof of any such taxes withheld by the withholding Party or its Sublicensees (or sublicensees, in the case of CVT) for the benefit of the other Party. The withholding Party shall reasonably assist the other Party in claiming exemption from such deductions or withholdings under any double taxation or similar agreement or treaty from time to time in force.

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

**5.11 Non-Monetary Consideration.** In the event FHI (or for the purposes of Section 3.7(e) only, CVT or its Affiliates or sublicensees), or its Affiliates or Sublicensees receives any non-monetary consideration in connection with the sale of Licensed Products, the Net Sales of such Licensed Product shall be calculated based on the fair market value of such other consideration. In such case, such Party shall disclose the terms of such arrangement to the other Party and the Parties shall endeavor in good faith to agree on such fair market value as promptly as possible. Similarly, in the event the Total Consideration received by CVT under Section 3.7 or to be paid by FHI under Section 5.8, is made up of any non-monetary consideration, such non-monetary consideration shall be calculated based on the fair market value of such other consideration.

**5.12 Foreign Exchange.** Subject to Section 5.10, for the purpose of computing the Net Sales of Licensed Products sold in a currency other than United States Dollars, such currency shall be converted into United States Dollars using the rate of exchange set forth in the *Wall Street Journal* for the close of business the last day of the calendar quarter in which such sales occurred.

**5.13 Late Payments.** Any amount not paid when due under this Agreement shall bear interest at the lesser of (a) one and one half percent (1 ½%) per month, compounded monthly or (b) the highest rate permitted by applicable law.

## 6. RECORDS AND PUBLICATIONS

**6.1 Records.** Each Party shall keep or cause to be kept such records as are required to determine, in a manner consistent with generally accepted accounting principles in the United States, any sums or credits due under this Agreement, including, but not limited to, development costs, royalties, etc. At the request (and expense) of either Party, the other Party and its Sublicensees (or sublicensees, in the case of CVT) shall permit an independent certified public accountant appointed by such Party who shall be subject to the confidentiality restrictions set forth in Article 10 and reasonably acceptable to the other Party, at reasonable times not more than once a year and upon reasonable notice, to examine only those records as may be necessary

to determine, with respect to any calendar year ending not more than three (3) years prior to such Party's request, the correctness or completeness of any payment made under this Agreement. Results of any such examination shall be (a) limited to information relating to the Licensed Compounds and Licensed Products, (b) made available to both Parties and (c) deemed Confidential Information subject to Article 10. The Party requesting the audit shall bear the full cost of the performance of any such audit, unless such audit discloses a variance of more than five percent (5%) from the amount of the original report, royalty or payment calculation. In such case, the Party being audited shall bear the full cost of the performance of such audit, as well as promptly paying any shortfall reported and any interest due thereon. Any overpayments shall be promptly repaid, and any interest due thereon.

**6.2 Publications.** Prior to the filing of the first NDA for the Licensed Product neither Party shall publish or present the results of studies carried out under this Agreement without the opportunity for prior review by the other Party. Subject to Section 10.3, each Party agrees to provide the other Party the opportunity to review any proposed abstracts, manuscripts or presentations (including verbal presentations) which relate to the Licensed Compounds and/or any Licensed Product at least five (5) business days prior to their intended submission for publication or presentation and agrees, upon request of the other Party, not to submit any such abstract, manuscript or presentation for publication or publication until the other Party is given a reasonable period of time to file for patent application(s) for any material in such publication or presentation which it believes to be patentable. The Parties agree to review and consider delay of publication and filing of patent applications as appropriate. In the event of a disagreement over publication, the Management Committee will review such requests and recommend subsequent action but in such event CVT shall not have a tie-breaking vote. Neither Party shall have the right to publish or present Confidential Information of the other Party which is subject to Section 10.1 without the prior consent of the other Party. Nothing contained in this Section 6.2 shall prohibit the inclusion of information necessary for a patent application, except for Confidential Information of the non-filing Party, provided the non-filing Party is given a reasonable opportunity to review the information to be included prior to submission of such patent application. Notwithstanding anything to the contrary contained in this Agreement, only FHI in its sole discretion shall have the right to publish or present the results of any Phase IV Trials conducted at its expense or any other studies conducted at its expense following the filing of the first NDA for the Licensed Product.

## 7. REGULATORY MATTERS

### 7.1 Regulatory Matters Before Transfer of NDA from CVT to FHI.

The Parties agree that before the NDA is transferred from CVT to FHI in accordance with Section 7.1(a) below, the following shall apply:

**(a)** CVT shall prepare and submit the IND for the Lead Compound in accordance with Section 3.2 hereof. CVT shall prepare and submit in its name the NDA for the first Licensed Product; provided, however, that the CMC section of the NDA ("**CMC Section**") shall be prepared by FHI, in coordination and cooperation with CVT. The Parties will coordinate and cooperate with respect to the various activities needed to complete and file the NDA. Within ten (10) days after FDA approval of such NDA, CVT shall transfer such NDA to FHI. Until

such time as such NDA is transferred to FHI, CVT shall own and hold all Regulatory Approvals under the Development Program and shall be responsible for the filing and maintenance of all such Regulatory Approvals, with all costs and expenses associated therewith to be included in Development Costs under this Agreement.

**(b)** Except for FHI Manufacturing Activities (as provided in Section 3.4(a)), Post Approval Regulatory Issues (as provided in Section 7.1(c)) and the preparation of the CMC Section (as provided in Section 7.1(a)), CVT will have all other regulatory responsibility under the Development Program in collaboration and cooperation with FHI and under the oversight of the Management Committee. Such regulatory responsibility of CVT shall include, without limitation, the following: (i) preparation and modification of all protocols, investigator brochures and other clinical trial documentation; (ii) drug shipments; (iii) meetings with FDA or any other Regulatory Authority, including, without limitation, meeting preparation, meeting coordination, preparation of minutes and reaching agreement with the FDA or any other Regulatory Authority on applicable regulatory matters; (iv) preparation and coordination of any FDA or other Regulatory Authority advisory committee presentation for the first Licensed Product (which FHI shall be entitled to attend); (v) the processing, tracking and reporting of all IND adverse event reports; and (vi) the maintenance of one (1) or more databases of the Collaborative Clinical Data accumulated from all clinical trials of Licensed Compounds and Licensed Products conducted by CVT under this Agreement.

**(c)** With respect to any Post Approval Regulatory Issues, FHI shall be responsible for and control any and all decisions with respect thereto, including without limitation meetings, meeting minutes and reaching agreement with FDA or any other Regulatory Authority. FHI will coordinate Post Approval Regulatory Issues with CVT, but FHI shall have the final decision making authority with respect to any Post Approval Regulatory Issues.

**(d)** Prior to the transfer of the NDA to FHI under Section 7.1(a), FHI shall be entitled to attend the advisory committee presentation (if any) for the first Licensed Product and any preparatory practice sessions held with respect to such advisory committee presentation (if any), as noted in Section 7.1(b)(iv) above, and also to attend the end-of-Phase II Trials meeting and pre-NDA meeting with the FDA relating to such Licensed Product. CVT shall make all reasonable efforts to provide FHI copies of any materials relating to any Post Approval Regulatory Issue prior to their presentation or disclosure to the FDA or any other Regulatory Authority in the Territory, so that FHI may have an opportunity to review and provide comments, and CVT shall make reasonable efforts to allow FHI to be involved in the preparation for any meetings or telephone calls with the FDA or any other Regulatory Authority in the Territory relating to any Post Approval Regulatory Issue. Notwithstanding the foregoing, in the event any such meetings and/or telephone calls with the FDA and/or any other Regulatory Authority in the Territory relate to and/or concern Post Approval Regulatory Issues, the Parties agree that: (i) CVT shall not meet with the FDA without FHI; and (ii) with respect to any such telephone calls, CVT will use reasonable efforts to have FHI participate in such calls and to the extent FHI is unable to so participate, CVT agrees that it will make no commitments to FDA and/or any such Regulatory Authority regarding any Post Approval Regulatory Issues without FHI's prior consent.

**7.2 Regulatory Matters After Transfer of NDA from CVT to FHI.**

The Parties agree that after the transfer of the NDA from CVT to FHI in accordance with Section 7.1(a) above, the following shall apply:

**(a)** FHI shall have the authority in its sole discretion to make any and all decisions relative to all clinical, manufacturing and regulatory matters from and after the date of transfer of the NDA for the first Licensed Product to FHI under Section 7.1(a) above, including without limitation Post Approval Regulatory Issues. Once such NDA is transferred to FHI, FHI shall own and hold all such Regulatory Approvals, and any other Regulatory Approvals for Licensed Products in the Territory, and shall be responsible for the maintenance thereof at its own cost and expense.

**(b)** FHI shall have the sole authority and responsibility to report any and all adverse events related to the use of Licensed Products in the Territory from and after the date of the NDA for the first Licensed Product is transferred to FHI under Section 7.1(a) above.

**7.3 Adverse Events.** For so long as CVT is conducting any clinical trials of Licensed Compounds or Licensed Products under this Agreement, CVT shall own and maintain (or cause to be maintained) one (1) or more databases of adverse event information for such trials. If FHI conducts any clinical trials of Licensed Compounds or Licensed Products under this Agreement, FHI shall own and maintain (or cause to be owned and maintained) one (1) or more databases of adverse drug event information for such trials, and after the transfer of the NDA to FHI under Section 7.1(a) above, FHI shall own and maintain (or cause to be maintained) one (1) or more databases of product complaints and adverse drug event information for all Licensed Products sold by FHI or its Affiliates or Sublicensees in the Territory. Each Party shall provide the other with access to such database as requested to meet the requesting Party's regulatory obligations. The Parties shall establish in writing and maintain a procedure for the mutual exchange of adverse event reports and safety information associated with Licensed Compounds or Licensed Products, to permit each Party to satisfy its respective regulatory requirements.

**7.4 Licensed Product Recalls, Withdrawals and Safety Notifications.**

**(a) Licensed Product Sold by FHI.** Subject to Section 7.4(b), with respect to any Licensed Product sold by FHI or its Affiliates or Sublicensees under this Agreement, FHI in its sole discretion as the controlling Party shall determine if such Licensed Product should be recalled, withdrawn or the subject of a safety notification.

**(b) Licensed Product Sold by CVT.** In the event the licenses to FHI become co-exclusive with CVT under Section 4.4, or if this Agreement is terminated under Section 12.3 with respect to a particular indication for a Licensed Product, with respect to any Licensed Product (if any) for any indication sold by CVT or its Affiliates or sublicensees in such circumstances under this Agreement, CVT in its sole discretion as the controlling Party shall determine if such Licensed Product should be recalled, withdrawn or the subject of a safety notification if such Licensed Product (or a Licensed Product for such indication) is not being sold under an NDA held by FHI; provided, however, that if such Licensed Product (or a Licensed Product for such indication) is being sold under an NDA held by FHI, FHI as the NDA

holder shall determine in good faith as the controlling Party if such Licensed Product should be recalled, withdrawn or the subject of a safety notification, after first consulting with CVT, and if such Licensed Product (or a Licensed Product for such indication) is being sold under an NDA held jointly by FHI and CVT, the Parties shall consult and agree on how to proceed before taking any such action hereunder.

**(c) Direction and Cooperation.** Any such action shall occur under the direction of the controlling Party(ies) (as provided in Sections 7.4(a) and (b) above), who shall notify the other Party promptly following its determination to take such action, and the other Party shall cooperate as reasonably requested.

**(d) Expenses.** The out-of-pocket expenses incurred by either Party in connection with any notification, shipping, disposal and return of the Licensed Product that is the subject of a recall, withdrawal or safety notification shall be paid by the controlling Party(ies) (as provided in Sections 7.4(a) and (b) above), except for any expenses or other Losses (as defined in Section 13.1) that are the responsibility of an indemnifying Party as provided in Article 13.

## 8. LICENSES

### 8.1 Licenses To FHI.

**(a)** Subject to the terms of this Agreement, CVT hereby grants to FHI an exclusive, royalty-bearing license under the Licensed Technology to develop, make, have made, use, offer for sale, sell, import and export Licensed Compounds and Licensed Products for the FHI Field in the Territory. FHI may grant sublicenses under such license rights without CVT's prior approval to Affiliates of FHI and to Third Parties, provided that CVT's prior written consent to a sublicense (not to be unreasonably withheld or delayed) shall be required if such sublicensee shall have responsibility for marketing and sales of Licensed Compounds and Licensed Products (in any case, a **"Sublicensee"**). Notwithstanding the foregoing however, FHI may grant sublicenses under such license rights without CVT's prior approval if the Sublicensee is in the Territory outside of the U.S. and/or will not be the primary entity marketing and selling the Licensed Compound and/or Licensed Product in the Territory. Any Sublicensee shall agree to be bound by the terms and conditions of this Agreement. FHI shall provide written notification to CVT of any Sublicensee for which CVT's prior consent is not required hereunder, within thirty (30) days of granting the sublicense. Notwithstanding the foregoing exclusive grant of rights to FHI, FHI agrees that CVT retains the right to use and practice the Licensed Technology to develop Licensed Compounds and Licensed Products as agreed upon under the Development Program and under this Agreement.

**(b)** FHI hereby covenants that it will use and practice the Licensed Technology in accordance with the terms and conditions of this Agreement and in substantial compliance with all applicable laws and regulations.

**8.2 Licenses To CVT.** FHI and CVT hereby agree on the following license rights to CVT to use the FHI Development Technology (as defined in Section 1.17), including, without limitation, the Collaborative Clinical Data in the FHI Field and the FHI Clinical Data in the Development Field:

**(a)** As provided in Section 3.7 above, FHI hereby grants to CVT an exclusive (except as to FHI) license (with the right to sublicense) to use the Collaborative Clinical Data in the FHI Field and the FHI Clinical Data in the Development Field outside of the Territory to develop, make, have made, use, market, sell, export and import any pharmaceutical products (including any Licensed Products), in consideration for CVT's payment to FHI of the royalty provided in Section 3.7 above, and an exclusive (except as to FHI) royalty-free license (with the right to sublicense) to use and practice all other FHI Development Technology (other than Collaborative Clinical Data and FHI Clinical Data) outside of the Territory to develop, make, have made, use, market, sell, export and import any pharmaceutical products (including any Licensed Products).

**(b)** In the event CVT exercises its right to convert the licenses granted to FHI hereunder from exclusive to co-exclusive under Section 4.4 above, FHI automatically shall be deemed to grant to CVT a co-exclusive (with FHI) license (with right to sublicense) to use any and all FHI Development Technology to use, market, sell, export and import any Licensed Product inside the Territory.

**(c)** In connection with termination of the Agreement (if any), FHI automatically shall grant CVT an exclusive (except as to FHI) license (with right to sublicense) to use any and all FHI Development Technology as provided in Section 12.6(b) below.

**8.3 Non-Compete.** CVT hereby covenants that for the Term, and for **[two (2) years]** following expiration thereof pursuant to Section 12.1, CVT shall not, and shall not grant a license to a Third Party to, in whole or in part, develop, manufacture, sell, distribute or commercialize products in the Territory in the Development Field; provided however, that in the event that FHI's licenses under Section 8.1 become co-exclusive with CVT as provided in Section 4.4 above, or upon termination of this Agreement pursuant to Section 12.2, 12.3, 12.4 or 12.5 below, upon such license conversion or termination, as the case may be, CVT shall have no further obligations to FHI under this Section 8.3. Notwithstanding the foregoing, however, in the event that under Section 12.3 below, there is only a partial termination of this Agreement and the indication for which this Agreement is still in effect is in the Development Field in the United States, CVT's obligations under this Section 8.3 shall remain in full force and effect. Nothing in this Section 8.3 shall be construed or implied in any manner to limit or narrow the scope of FHI's exclusive licenses described in Section 8.1.

**8.4 Reservation of Rights.** CVT reserves all rights to use the Licensed Technology, except as otherwise expressly granted to FHI pursuant to this Agreement, including, without limitation, the right of CVT (with or without Third Parties or Affiliates) to freely use, assign, transfer, grant licenses thereunder and otherwise dispose of the Licensed Technology for any purpose(s) that do(es) not conflict with and is(are) consistent with the terms and conditions of this Agreement. Nothing in this Agreement shall be construed or implied in any manner to grant FHI any license rights with respect to any technology of CVT other than as expressly set forth in this Agreement.

**8.5 Right of First Negotiation for FHI.**

**(a)** Subject to the terms and conditions of this Section 8.5, CVT hereby grants to FHI a right of first negotiation to obtain a license under the Licensed Technology to develop, use, make, have made, import, export, offer for sale and sell Licensed Products in the rest of the world outside of the Territory (an "Ex-North American License").

**(b)** CVT shall notify FHI in writing if it intends to grant a license under the Licensed Technology to a Third Party to develop, use, make, have made, import, export, offer for sale or sell Licensed Products for some or all of the world outside of the Territory. CVT will not grant a Third Party such a license prior to the completion of the initial Phase I Clinical Trial for a Licensed Product hereunder. FHI shall then have a period of forty-five (45) days from its receipt of such notice (the "**FHI Notification Period**") to notify CVT in writing if FHI is interested in obtaining an Ex-North American License. If, by the end of FHI Notification Period, CVT receives written notice from FHI that it desires to obtain such a license, which notice shall include FHI's proposed terms for such license, then CVT and FHI, for a period of ninety (90) days or such longer period of time as mutually agreed to in writing by the Parties (the **"FHI Negotiation Period"**), shall negotiate in good faith the terms upon which the Parties would be willing to enter into an agreement for such license, and if such terms are agreed upon, then the Parties shall enter into a definitive written agreement pursuant to which CVT shall grant to FHI an Ex-North American License. Neither Party shall be obligated to enter into any agreement under this Section 8.5 except on terms acceptable to such Party in its sole discretion.

**(c)** If the Parties fail to execute a definitive written agreement for an Ex-North American License by the end of the FHI Negotiation Period, or if CVT does not receive written notice from FHI that it is interested in obtaining an Ex-North American License by the end of the FHI Notification Period, then FHI's right of first negotiation shall terminate and CVT shall have no further obligations to FHI under this Section 8.5.

**(d)** Notwithstanding Section 8.5(c) above, in the event that the Parties have conducted negotiations pursuant to Section 8.5(b), but have not executed a definitive written agreement for an Ex-North American License by the end of the FHI Negotiation Period, then CVT agrees that it shall not enter into an agreement to grant a license under the Licensed Technology with a Third Party, the territory for which includes Japan, on economic terms (which economic terms shall include without limitation marketing and selling capabilities and other expertise of such Third Party) that taken as a whole are less favorable to CVT than those last proposed in writing by FHI, unless CVT first offers FHI the opportunity to accept such terms. CVT shall notify FHI in writing of such terms, and unless within thirty (30) days of FHI's receipt of such notice, CVT receives written notice from FHI that FHI accepts such terms, then CVT shall have no further obligations to FHI under this Section 8.5.

**8.6 Right of First Negotiation for CVT.**

**(a)** Subject to the terms and conditions of any underlying license agreements for **[Adenocard® and Adenoscan®]** that FHI may have with **[Medco]** and/or any other Third Party and subject to the terms and conditions of this Section 8.6, FHI hereby grants to CVT a right of first negotiation to obtain a license of FHI's rights and interests in the Licensed

Compounds, **[Adenoscan®]** in the **[pharmacologic stress]** market and **[Adenocard®]** **[("Adenosine Franchise")]**.

**(b)** FHI shall notify CVT in writing if it intends to grant a license of its rights and interests in the **[Adenosine Franchise]** to a Third Party. CVT shall then have a period of forty-five (45) days from its receipt of such notice (the "**CVT Notification Period**") to notify FHI in writing if CVT is interested in obtaining a license to the **[Adenosine Franchise]**. If by the end of CVT Notification Period FHI receives written notice from CVT that it desires to obtain such a license, which notice shall include CVT's proposed terms for such license, then CVT and FHI, for a period of ninety (90) days or such longer period of time as mutually agreed to in writing by the Parties (the **"CVT Negotiation Period"**), shall negotiate in good faith the terms upon which the Parties would be willing to enter into an agreement for such license, and if such terms are agreed upon, then the Parties shall enter into a definitive written agreement pursuant to which FHI shall grant to CVT such a license. Neither Party shall be obligated to enter into any agreement under this Section 8.6 except on terms acceptable to such Party in its sole discretion.

**(c)** If the Parties fail to execute a definitive written agreement for such license by the end of the CVT Negotiation Period, or if FHI does not receive written notice from CVT that it is interested in obtaining such a license by the end of the CVT Notification Period, then CVT's right of first negotiation shall terminate and FHI shall have no further obligations to CVT under this Section 8.6.

**(d)** Notwithstanding anything to the contrary contained in this Agreement, in no event shall FHI have any obligation under this Section 8.6 if FHI desires to license, sell and/or grant any other rights in whole or in part to its parent or any Affiliate.

**(e)** Notwithstanding Section 8.6(c) above, in the event that the Parties have conducted negotiations pursuant to Section 8.6(b), but have not executed a definitive written agreement for a license to the **[Adenosine Franchise]** by the end of the CVT Negotiation Period, then FHI agrees that it shall not enter into an agreement to grant a license to a Third Party on economic terms (which economic terms shall include without limitation marketing and selling capabilities and other expertise of such Third Party) that taken as a whole are less favorable to FHI than those last proposed in writing by CVT, unless FHI first offers CVT the opportunity to accept such terms. FHI shall notify CVT in writing of such terms, and unless within thirty (30) days of CVT's receipt of such notice, FHI receives written notice from CVT that CVT accepts such terms, then FHI shall have no further obligations to CVT under this Section 8.6.

**8.7 Trademarks.**

**(a) CVT Trademarks.** CVT hereby grants to FHI the non-exclusive, royalty free license to use its relevant CVT Trademarks solely in connection with the commercialization of Licensed Products hereunder during the Term of this Agreement, and subject to the terms and conditions of this Agreement including the remainder of this Section 8.7.

**(b) Use of CVT Trademarks.**

**(i)** FHI agrees to conform to reasonable quality control standards of CVT with respect to the goods sold and services provided in connection with the CVT Trademarks. FHI recognizes and agrees that no ownership rights are vested or created by the limited rights of use granted to FHI in connection with this limited use of the CVT Trademarks, and that all use thereof inures to the benefit of CVT. Further, except when used strictly in accordance with such quality control standards provided by CVT, FHI shall submit to CVT any materials bearing the CVT Trademarks for review and approval prior to the use thereof and shall make no use of the CVT Trademarks without CVT's prior written consent. CVT agrees that it will cooperate with FHI in order to allow FHI to meet its obligations to CVT under Section 4.5.

**(ii)** FHI shall execute any documents required in CVT's reasonable opinion to be entered as a "registered user" or recorded licensee of the CVT Trademarks, or to be removed as registered user or licensee thereof.

**(c) FHI Trademarks**. CVT shall have no right to use FHI Trademarks.

**(d) Product Trademarks**. FHI shall own all Product Trademarks.

## 9. INTELLECTUAL PROPERTY

### 9.1 Ownership.

**(a)** Notwithstanding anything to the contrary in this Agreement, but subject to Section 3.7(a), CVT shall remain the sole owner of the Licensed Technology (except for any joint inventions or other joint Improvements of CVT and FHI under this Agreement as provided under Sections 9.1(c) or (d) below), and of all intellectual property that it owned as of the Effective Date, and FHI shall be the sole owner of all of any FHI Clinical Data (if any), the Collaborative Clinical Data and the FHI Development Technology and any intellectual property that it owned as of the Effective Date.

**(b)** CVT shall own all right, title and interest to the CVT Trademarks. FHI shall own all right, title and interest to the Product Trademarks and the FHI Trademarks.

**(c)** Any and all inventions discovered solely by CVT under this Agreement shall be solely owned by CVT. Any and all inventions discovered solely by FHI under this Agreement shall be solely owned by FHI. Any and all inventions made under this Agreement jointly by employees or agents of (or others obligated to assign inventions to) CVT and FHI respectively shall be jointly owned by CVT and FHI, and the Parties shall jointly own any Patents on any jointly owned inventions hereunder. All determinations of inventive contribution and inventorship shall be determined under United States laws of inventorship.

**(d)** Any and all Improvements that are not inventions (covered by Section 9.1(c) above) and that are discovered solely by CVT under this Agreement shall be solely owned by CVT. Any and all such Improvements discovered solely by FHI under this Agreement shall be solely owned by FHI. Any and all such Improvements made under this Agreement jointly by

employees or agents of (or others obligated to assign any such Improvements to) CVT and FHI respectively shall be jointly owned by CVT and FHI.

**9.2 Patent Matters.**

**(a) Licensed Patents.**

**(i)** CVT shall have the first right, but not the obligation to file applications for, prosecute and maintain the Licensed Patents (including, without limitation, any Licensed Patents that consist of Patents jointly owned with FHI under Section 9.1 above). CVT shall use commercially reasonable diligent efforts to prosecute and maintain the Licensed Patents. CVT shall keep FHI regularly informed as to the status and issuance of the applications for the Licensed Patents. CVT must give timely advance notice to FHI of all intended actions and copies of all correspondence that would impact on the existence or scope of the Licensed Patents and CVT (along with its patent counsel) will seriously consider all comments and suggestions made by FHI (or its patent counsel) relating to the prosecution of the Licensed Patents, before any documents, correspondence or other papers are filed with the United States Patent and Trademark Office or other comparable office in the Territory. FHI shall reimburse CVT for **[sixty percent (60%)]** of the costs and expenses incurred by CVT in the filing, prosecution and maintenance of the Licensed Patents in the Territory following the Effective Date; *provided that* FHI shall have no payment obligations under this Section 9.2(a)(i) with respect to any extraordinary costs or expenses related to an interference proceeding (other than an interference brought by or on behalf of **[Medco]**) or legal or administrative action in connection with the Licensed Patents. In the event that FHI notifies CVT that it does not wish to pay its share of the costs and expenses of filing, prosecution or maintenance of a particular Licensed Patent, such Licensed Patent thereafter shall cease to be deemed a "Licensed Patent," and FHI shall have no further obligations under this Section 9.2(a)(i) with respect to such Patent and no further license rights with respect to such Patent under this Agreement.

**(ii)** In the event that FHI notifies CVT in writing that FHI desires that CVT file a patent application in a particular country in the Territory covering a particular invention in the Licensed Know-How, and CVT fails to file such application within one hundred and twenty (120) days of receiving such notice, or such shorter period of time that may be required to preserve such patent rights, then FHI shall thereafter have the right but not the obligation to file and prosecute such application and maintain any Patents issuing therefrom in the Territory, at FHI's expense. Following CVT's receipt of written notice from FHI confirming that FHI intends to so file and prosecute such application, CVT shall assign to FHI all of its right, title and interest in such application and Patents issuing therefrom in the Territory.

**(b)** In the event that a Party that has responsibility for the filing, prosecution and maintenance of a Patent under this Section 9.2 (the **"Responsible Party"**) intends to abandon the prosecution or maintenance of such Patent, it shall notify the other Party no later than one hundred twenty (120) days prior to the date that it intends to abandon the prosecution or maintenance, as applicable, of such Patent, and in any event, no later than sixty (60) days prior to the date that a payment, response or other action is required by the applicable patent agency in order to keep such Patent effective. Such other Party must notify the Responsible Party within such one hundred twenty (120) day period that such other Party wishes to assume the

responsibility for prosecuting (if applicable) and maintaining such Patent, whereupon the Responsible Party shall permit the other Party to take over the prosecution (if applicable) or maintenance of such Patent, and shall cooperate with such other Party in the transfer of such responsibilities. Thereafter, the original Responsible Party shall have no further obligation or rights under this Section 9.2 with respect to such Patent, and the other Party shall have the right, but not the obligation, to prosecute (if applicable) and maintain such Patent at its expense.

**(c)** Without limiting the generality of CVT's obligations to keep FHI informed as to the status of the Licensed Patents described in Section 9.2(a), the Responsible Party (as defined in Section 9.2(b) above) shall keep the other Party regularly informed as to the status and issuance of all Patent applications for which the Responsible Party has the obligation to prosecute under this Section 9.2. The Responsible Party must give timely advance notice to the other Party of all intended actions and copies of all correspondence that would impact on the existence or scope of such Patents with respect to the manufacture, use or sale of the Licensed Compounds and Licensed Products. The Responsible Party (along with its patent counsel) will seriously consider all comments and suggestions made by the other Party relating to the filing and prosecution of such Patent applications before any documents, correspondence, and other communications are filed with the United States Patent and Trademark Office or its foreign equivalent. All Information, including without limitation all documents and materials and the existence thereof, disclosed by the Responsible Party to the other Party pursuant to this Section 9.2(c) shall be deemed Confidential Information and subject to Article 10.

**9.3 Defense and Settlement of Third Party Claims.** FHI shall control the defense of any suits, actions or claims by a Third Party alleging infringement of a Third Party's Patent rights by the manufacture, use, sale, offer for sale, export and/or import by FHI, its Affiliates or Sublicensees of a Licensed Compound and/or Licensed Product. If the basis for such claim of infringement arises from or involves any Licensed Technology, data and/or any Information provided to FHI by CVT or developed by CVT or otherwise generated by either Party in connection with the Collaboration pursuant to this Agreement, the Parties shall share all costs, expenses, fees, charges, monies and/or royalties (collectively **"Costs"**), paid in connection with any such suits, actions or claims or to any Third Party in past or prospective settlement as follows: **[60%]** of all Costs to be paid by FHI and **[40%]** of all Costs to be paid by CVT; provided, however, that such Costs to be shared hereunder shall not include any costs, expenses or other amounts included or includible under the royalty offset provisions of Section 5.8 above. Without limiting the generality of the foregoing, the Parties shall also share in the same fashion **[(60/40)]** any and all Costs (subject to the foregoing proviso) in the event a suit, action or claim brought by **[Medco]** alleges that the practice of any of the Licensed Patents infringes any of **[Medco's]** Patent rights. The Parties will reasonably cooperate with one another with respect to any such Third Party suits, actions or claims.

**9.4 Infringement By Third Parties.** FHI and CVT shall each promptly notify the other in writing if it learns of any actual, alleged or threatened infringement of the Licensed Patents by a Third Party. FHI shall have the first right, but not the obligation, at its own expense, to bring suit (or take other appropriate legal action) against any actual, alleged or threatened infringement of the Licensed Patents by a Third Party, including the defense and settlement thereof (subject to Section 9.5 below), to the extent such infringement relates to a Licensed Compound or a Licensed Product in the Territory. If FHI does not initiate an infringement

action or otherwise abate any such actual, alleged or threatened Third Party infringement of the Licensed Patents within ninety (90) days of the later of (i) receiving notification from CVT under this Section 9.4 of such infringement, (ii) sending notice to CVT under this Section 9.4 of such infringement, or (iii) a written request from CVT to take action with respect to such infringement, or if such infringement is outside the scope of FHI's first right to take action as provided above, then CVT shall have the right, but not the obligation, at its own expense, to bring suit (or take other appropriate legal action) against any such actual, alleged or threatened infringement of the Licensed Patents by a Third Party, including the defense and settlement thereof (subject to Section 9.5 below). In the event either Party brings an infringement action in accordance with this Section 9.4, the other Party shall provide reasonable assistance and authority to file and bring the action, including, if required to bring such action, being joined as a party plaintiff; provided, however, that neither Party shall be required to transfer any right, title or interest in or to any of its property to the other Party or a Third Party to confer standing on a Party hereunder. In addition, if either Party brings an infringement action hereunder, the other Party shall have the right to be represented separately in such action by counsel of its own choice, at its own expense. Any recovery realized as a result of such suit, claim or action or related settlement shall first be applied *pro rata* to reimburse the Parties' costs and expenses in connection with such suit, claim or action, and any remaining amounts shall belong to the Party bringing the suit, action or claim, or fifty percent (50%) to each Party if the suit is brought jointly.

**9.5 Settlements.** Neither Party may enter into any settlement or consent judgment or other voluntary final disposition of a suit under this Article 9 without the prior written consent of the other Party.

**9.6 Cooperation**. Each Party agrees to cooperate with the other and take all reasonable additional actions as may be reasonably required to achieve the intent of this Article 9, including, without limitation, the execution of necessary and appropriate instruments and documents.

## 10. CONFIDENTIALITY

**10.1 Treatment of Confidential Information.** A Party receiving or gaining access to Confidential Information, as defined below, (the "**Receiving Party**") of the other Party (the "**Disclosing Party**") will (i) maintain in confidence such Confidential Information to the same extent the Receiving Party maintains its own proprietary information (but at a minimum each Party shall use commercially reasonable efforts), (ii) not disclose such Confidential Information to any Third Party without prior written consent of the Disclosing Party, except for disclosures made in confidence to any Third Party pursuant to a plan approved in advance by the Management Committee, and (iii) not use such Confidential Information for any purpose except those permitted by this Agreement. As used herein, "Confidential Information" shall mean all Information, and other information and materials, received by the Receiving Party from the Disclosing Party pursuant to this Agreement or designated Confidential Information hereunder. A Party shall have no non-disclosure or non-use obligations under this Article 10 with respect to any portion of any Confidential Information which:

**(a)** is generally known or available to the public through no act or failure to act on the part of the Receiving Party; or

**(b)** was known to the Receiving Party as shown by its written records, without obligation to keep it confidential, prior to when it was received from the Disclosing Party; or

**(c)** is subsequently disclosed to the Receiving Party by a Third Party lawfully in possession thereof without obligation to keep it confidential; or

**(d)** has been independently developed by the Receiving Party without the aid, application or use of Confidential Information or any other breach of this Article 10 as shown by the Receiving Party's written records.

**10.2 Permitted or Required Disclosures.** A Party shall have no non-disclosure obligation under this Article 10 with respect to any portion of Confidential Information which is required by law to be disclosed, but then only to the limited extent of such legally required disclosure; and provided that (a) the Disclosing Party is notified reasonably in advance of such disclosure by the Receiving Party and (b) the Receiving Party cooperates as reasonably requested with the Disclosing Party in attempting to obtain confidential or other protective treatment of such Confidential Information. In addition to the foregoing, either Party may disclose Confidential Information of the other Party under this Agreement to the extent such disclosure is reasonably necessary in filing, prosecuting or maintaining Patents, prosecuting or defending litigation, enforcing rights and/or obligations under this Agreement, conducting pre-clinical or human clinical testing of Licensed Products, or conducting each Party's respective Manufacturing Activities under this Agreement, in each case consistent with the other terms and conditions of this Agreement.

**10.3 Publicity.** The Parties agree that the public announcement of the execution of this Agreement shall be in the form of the press release attached as Schedule 10.3. Any other publication, news release or other public announcement relating to this Agreement or to the performance hereunder, shall first be reviewed and approved by both Parties, which approval shall not be unreasonably withheld or delayed; provided, however, that a Party may reuse a previously approved disclosure without having to re-obtain the other Party's consent. In addition, notwithstanding the foregoing provisions any disclosure which is required by law as advised by the disclosing Party's counsel may be made without the prior consent of the other Party, although the other Party shall be given prompt notice of any such legally required disclosure and to the extent practicable shall provide the other Party an opportunity to comment on the proposed disclosure. In this regard, the Parties recognize that CVT is a publicly-held biotechnology company, that the Licensed Products are among CVT's first potential products and that CVT will need to provide information regarding the status of the Licensed Compounds and Licensed Products to the investment community from time to time. The Parties acknowledge that CVT will be obligated to file a copy of this Agreement with the U.S. Securities and Exchange Commission. CVT will submit a copy of its proposed filing to FHI for review and comment prior to filing.

**10.4 Terms of the Agreement**. The Parties agree that the material terms of this Agreement will be considered Confidential Information of both Parties. Notwithstanding the

foregoing, each Party shall have the right to disclose the material terms of this Agreement in confidence to any bona fide potential investor, or investment banker, provided that such Party shall receive, an adequate binder of confidentiality consistent and substantially similar to the terms contained in this Article 10 and this Agreement.

**10.5 Survival of Confidentiality.** All obligations of confidentiality and non-use imposed upon the Parties under this Agreement shall continue indefinitely until such time as the information that is subject to such obligations no longer comprises Confidential Information under one of the exceptions set forth in Section 10.1.

## 11. REPRESENTATIONS, WARRANTIES AND COVENANTS

**11.1 Mutual Representations and Warranties.** CVT and FHI each represent, warrant and covenant to the other that: (a) it has the authority and right to enter into and perform this Agreement; (b) its execution, delivery and performance of this Agreement will not conflict in any material fashion with the terms of any other agreement to which it is or becomes a party or by which it is or becomes bound; (c) it shall comply in all material respects with all laws, rules, regulations and other governmental requirements applicable to its actions under this Agreement; and (d) no consent of any Third Party is required for either Party to grant the licenses and rights granted to the other Party under this Agreement and/or to perform its obligations hereunder.

**11.2 CVT Representations, Warranties and Covenants.** CVT hereby represents, warrants and covenants to FHI as follows:

**(a)** CVT owns or Controls the Licensed Technology;

**(b)** CVT has not as of the Effective Date, and during the Term of the Agreement will not, grant any right to any Third Party under the Licensed Technology that would conflict with any of the rights granted to FHI under this Agreement;

**(c)** To the best of CVT's knowledge as of the Effective Date, the practice of the Licensed Patents in the Territory would not infringe any intellectual property rights of any Third Party, and there has been no lapse of any claims within the Licensed Patents;

**(d)** To the best of CVT's knowledge as of the Effective Date: (i) CVT has disclosed to FHI all material Information in its possession or Control relating to the Licensed Compounds and the Licensed Products; and (ii) there is no prior art that has not been cited by CVT to the United States Patent and Trademark Office that CVT believes to be material to the patentability of any claims within the Licensed Patents in the Territory;

**(e)** CVT has conducted and shall conduct all pre-clinical studies for the Licensed Compounds and Licensed Products in substantial compliance with then-current good laboratory practices as defined and/or required by Regulatory Authorities, and all applicable, laws, rules, regulations and guidelines governing the conduct of pre-clinical and clinical studies in the Territory. CVT shall conduct all clinical studies for the Licensed Compounds and the Licensed Products in substantial compliance with then-current good clinical practices as they are defined and/or required by Regulatory Authorities, and all applicable laws, rules, regulations and

guidelines governing the conduct of clinical studies in the Territory. To the best of CVT's knowledge as of the Effective Date, neither CVT nor any of the laboratories or other individuals or entities participating in such pre-clinical studies have been or are "debarred" as such term is used in Section 335a of the United States Code. To the best of CVT's knowledge as of the Effective Date, any and all necessary financial disclosures relating to clinical investigators have been obtained in accordance with United States Code of Federal Regulations 21 CFR part 54, from the investigators and/or institutions participating in such clinical studies to the extent required; and

**(f)** As of the Effective Date, CVT has not received any notices or communications that the development, manufacture, use, sale, exportation or importation of the Licensed Compounds and/or Licensed Products would infringe any intellectual property rights of any Third Party in the Territory.

**11.3 FHI Representations, Warranties and Covenants.** FHI hereby represents, warrants and covenants to CVT as follows:

**(a)** FHI has not as of the Effective Date, and during the Term of the Agreement will not, grant any right to any Third Party under any agreement or arrangement that would conflict with any of the rights granted to CVT under this Agreement;

**(b)** With respect to any aspects of the Development Program conducted by FHI or any other activities conducted by FHI to develop Licensed Compounds and Licensed Products and/or manufacturing capacity therefor, FHI shall conduct all such activities in substantial compliance with then-current good practices (including good manufacturing practices) as they are defined and/or required by Regulatory Authorities, and all applicable laws, rules, regulations and guidelines governing such activities in the Territory.

**11.4 Disclaimer of Warranty.** Each Party acknowledges that the other Party cannot assure the safety, usefulness or efficacy of any Licensed Compound or Licensed Product for any use. EXCEPT FOR THE REPRESENTATIONS AND WARRANTIES SET FORTH IN THIS AGREEMENT, NEITHER PARTY MAKES ANY WARRANTY CONCERNING ITS PATENT RIGHTS OR INFORMATION LICENSED UNDER THIS AGREEMENT, INCLUDING WITHOUT LIMITATION THE VALIDITY OR SCOPE OF ITS PATENT RIGHTS OR THAT PRODUCTS WILL BE FREE FROM INFRINGEMENT OF THE PATENT RIGHTS OF THIRD PARTIES. AND NEITHER PARTY MAKES ANY WARRANTY OF ANY TECHNOLOGY'S, COMPOUND'S OR PRODUCT'S MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

## 12. TERM AND TERMINATION

**12.1 Term.** This Agreement shall become effective on the Effective Date and shall remain in effect until expiration of all of FHI's royalty obligations under Section 5.5 (the "**Term**"), unless earlier terminated as provided in Sections 12.2, 12.3 or 12.4 below.

**12.2 Termination by FHI.** FHI may terminate this Agreement at any time upon ninety (90) days prior written notice to CVT, without owing payment of any milestones falling due after the effective date of such termination, but subject to Sections 12.5 and 12.6 below.

**12.3 Termination by CVT.** CVT may terminate this Agreement on thirty (30) days prior written notice to FHI, on a Licensed Product-by-Licensed Product, indication-by-indication and country-by-country basis in the Territory, in the event that FHI or its Affiliates or Sublicensees fail to launch a Licensed Product in any such country within **[six (6) months]** after Regulatory Approval to market such Licensed Product is obtained for a particular indication in such country, except if FHI's right to sell such Licensed Product indication-by-indication in such country has been suspended by the applicable Regulatory Authority of such country for a reason other than FHI's or its Affiliate's, Sublicensee's or distributor's misconduct.

**12.4 Termination For Breach.**

**(a)** If either Party believes that the other Party is in material breach of this Agreement, then the non-breaching Party may deliver notice of such breach to the other Party. In such notice the non-breaching Party shall identify the actions or conduct that such Party would reasonably consider to be an acceptable cure of such material breach. The allegedly breaching Party shall have sixty (60) days from such notice to cure such material breach, or ten (10) business days from such notice if such breach consists of a failure to pay any monies due and payable to the other Party hereunder (in each case, the **"Cure Period"**). If the Party receiving notice of material breach fails to cure such breach within the applicable Cure Period, the Party originally delivering the notice may terminate this Agreement effective immediately on or after the end of the Cure Period by written notice to the other Party.

**(b)** Subject to Article 14, termination of the Agreement under this Section 12.4 shall not prevent a non-breaching Party from seeking any available legal and/or equitable remedies for the damages arising from or in connection with such material breach.

**12.5 Termination Prior to NDA Submission.** Subject to Section 12.6, if FHI terminates this Agreement pursuant to Section 12.2 above, or if CVT terminates this Agreement pursuant to Section 12.4 above for FHI's breach, in either case prior to CVT's submission of the first NDA for a Licensed Product, then: (a) FHI shall reimburse CVT for seventy-five percent (75%) of all budget completion fees incurred by CVT in terminating any studies then being conducted pursuant to the applicable Annual Plan and Budget which CVT (after using its commercial reasonable efforts) was unable to cancel; and (b) CVT shall reimburse FHI for twenty-five percent (25%) of all budget completion fees incurred by FHI in terminating FHI Manufacturing Activities and in terminating those development activities (if any) assigned to FHI by the Management Committee under Section 3.4(a) above, or in the event FHI has assumed development under Section 14.2(e) below, twenty five percent (25%) of all budget completion fees incurred by FHI in such event in accordance with Section 3.4(c), in any case which FHI (after using its commercial reasonable efforts) was unable to cancel. Such fees which either Party may owe the other under this Section 12.5 shall be due and payable within thirty (30) days of a Party's receipt of an invoice detailing such fees. Such reimbursement shall be in addition to any other payments owed to either Party to the other Party under this Agreement.

**12.6 Effect of Termination.** Upon the effective date of any termination of this Agreement at any time before expiration of the Term:

**(a)** All licenses granted by each Party to the other Party pursuant to Article 8 above shall automatically terminate; provided, however, that if CVT terminates this Agreement pursuant to Section 12.3 above, then the foregoing termination of such licenses shall only apply to the particular Licensed Product for the particular indication in the particular country that was the subject of such termination.

**(b)** Subject to Section 12.6(e) below, FHI automatically shall be deemed to have granted to CVT an exclusive (except as to FHI), irrevocable, perpetual, license with the right to sublicense under the Collaborative Clinical Data in the FHI Field, the FHI Clinical Data in the Development Field and under any other FHI Development Technology, to develop, use, make, have made, import, offer for sale and sell Licensed Compounds, Licensed Products and any other pharmaceutical products worldwide; provided, however, that if CVT terminates this Agreement pursuant to Section 12.3, then the foregoing grant of license rights from FHI to CVT shall apply only to the particular Licensed Product for the particular indication in the particular country that was the subject of such termination.

**(c)** Subject to Section 12.6(e) below, FHI automatically shall be deemed to have granted to CVT an irrevocable, non-exclusive, perpetual, sublicenseable right of reference to all Regulatory Approvals (including without limitation NDAs) relating to the Licensed Products, and shall cooperate with CVT (at CVT's expense) to effect such grant in a timely and orderly fashion; provided, however, that if CVT terminates this Agreement pursuant to Section 12.3, then the foregoing grant of license rights from FHI to CVT shall apply only to those Regulatory Approvals relating to the particular Licensed Product for the particular indication, in the particular country that was the subject of such termination.

**(d)** FHI automatically shall be deemed to have granted to CVT exclusive (even as to FHI) irrevocable, perpetual, sublicenseable license to use the Product Trademarks solely in connection with the development and commercialization of Licensed Products, subject to CVT's compliance with reasonable quality control requirements of FHI as customary in a trademark license (to be agreed upon by the Parties at such time); provided, however, that if CVT terminates this Agreement pursuant to Section 12.3 above, then the foregoing license shall apply only to those Product Trademarks that relate to the particular Licensed Product for the particular indication in the particular country that was the subject of such termination. The license granted to CVT under this Section 12.6(d) shall be in consideration of the payment by CVT to FHI of a royalty equal to **[one percent (1 %)]** of the Total Consideration from the sale of any Licensed Products throughout the world (or Licensed Products for the particular indication in the particular country, if applicable) by CVT, its Affiliates and/or its sublicensees, where such royalty shall accrue and be paid on the terms equivalent to those set forth in Sections 5.5 and 5.7 above. If FHI terminates this Agreement under Section 12.4 above, then the royalty in consideration of the license under this Section 12.6(d) shall equal **[three percent (3%)]** of the Total Consideration, and the other royalty terms set forth herein shall apply.

**(e)** If this Agreement is terminated by either Party pursuant to Section 12.2 or 12.4 above or partially terminated under Section 12.3 above, then the licenses described in Sections 12.6(b) and (c) above shall be in consideration for CVT's payment to FHI of a royalty equal to **[five percent (5%)]** of the Total Consideration from the sale of any Licensed Products throughout the world (or Licensed Products for the particular indication in the particular country,

if applicable) by CVT, its Affiliates and/or its sublicensees, where such royalty shall accrue and be paid on terms equivalent to those set forth in Sections 5.5 and 5.7 above; provided, however, that the foregoing royalty obligation shall continue until such time as the royalties paid by CVT to FHI under this Section 12.6(e) have totaled **[two hundred percent (200%)]** of the total amount of Development Costs incurred by FHI in accordance with the Development Plan, whereupon the licenses granted to CVT under this Section 12.6 shall become fully paid-up and royalty-free (except that only in the case of CVT termination of this Agreement under Section 12.4 for FHI's breach of a payment obligation to CVT, the licenses granted to CVT under this Section 12.6 shall be fully paid up and royalty-free).

**(f)** Following any termination of this Agreement or expiration of the Term, FHI, its Affiliates and Sublicensees shall be entitled to sell all of their finished inventory of Licensed Products in existence on the date of any such termination or expiration, subject to payment to CVT of royalties pursuant to Sections 5.5 and 5.7 above. Notwithstanding the foregoing, however, in no event shall FHI, its Affiliates or Sublicensees be entitled to manufacture any new inventory of Licensed Products (or for a particular indication if there is a partial termination under Section 12.3 above) from and after the effective date of such termination.

**12.7 Bankruptcy Rights.** In the event that this Agreement is terminated or rejected by a Party or its receiver or trustee under applicable bankruptcy laws due to such Party's bankruptcy, then all rights and licenses granted under or pursuant to this Agreement by such Party to the other Party are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the Bankruptcy Code and any similar law or regulation in any other country, licenses of rights to "intellectual property" as defined under Section 101(52) of the Bankruptcy Code. The Parties agree that all intellectual property rights licensed hereunder, including without limitation any patents or patent applications of a Party in any country covered by the license grants under this Agreement, are part of the "intellectual property" as defined under Section 101(52) of the Bankruptcy Code subject to the protections afforded the non-terminating Party under Section 365(n) of the Bankruptcy Code, and any similar law or regulation in any other country.

**12.8 Survival.** The following provisions shall survive any expiration or termination of this Agreement: Sections 3.7, 5.7, 5.8(a)(ii)(1) and (2), 8.3 (to the extent provided therein) and 15.3 and Articles 6, 9, 10, 11, 12, 13 and 14. Termination of this Agreement shall not relieve either Party of any liability which accrued hereunder prior to the effective date of such termination nor preclude either Party from pursuing all rights and remedies it may have hereunder or at law or in equity with respect to any breach of this Agreement nor prejudice either Party's right to obtain performance of any obligation. The remedies provided under this Article 12 are cumulative, and are not exclusive of other remedies available to a Party in law or equity.

## 13. INDEMNIFICATION AND INSURANCE

**13.1 By FHI.** FHI hereby agrees to indemnify, defend and hold harmless CVT and its Affiliates, and their respective officers, directors, agents and employees from and against any and all Third Party suits, claims, actions, demands, liabilities, expenses and/or loss, including reasonable legal expenses and attorneys' fees (collectively, **"Losses"**) resulting from (a) the development (to the extent FHI conducts any of the development of the Licensed Compounds

and/or Licensed Products), use, manufacture, handling, storage, transport, distribution, sale or other disposition of the Licensed Compounds and/or Licensed Products by FHI, its Affiliates, agents or Sublicensees, except to the extent such Losses result from the negligence or wrongdoing of CVT, its Affiliates, sublicensees, agents, representatives, consultants and/or employees (Affiliates, Sublicensees (or in the case of CVT, sublicensees), agents, representatives, consultants or employees of either Party shall be collectively referred to herein as such Party's **"Representatives"**); (b) FHI's breach of any of its obligations, covenants, representations or warranties under this Agreement; and/or (c) the negligence or wrongdoing of FHI and/or any of its Representatives under this Agreement, except to the extent such Losses result from the negligence or wrongdoing of CVT and/or any of its Representatives.

**13.2 By CVT.** CVT hereby agrees to indemnify, defend and hold harmless FHI, its Affiliates, and their respective officers, directors, agents and employees from and against any and all Losses resulting from: (a) CVT's breach of any of its obligations, covenants, representations or warranties under this Agreement; (b) the negligence or wrongdoing of CVT and/or any of its Representatives under this Agreement, except to the extent such Losses result from the negligence or wrongdoing of FHI and/or any of its Representatives; and/or (c) the development, use, handling or other disposition of the Licensed Compounds and/or Licensed Products by CVT and/or any of its Representatives in connection with CVT's conduct of the Development Program, except to the extent such Losses result from the negligence or wrongdoing of FHI and/or any of its Representatives. In the event the licenses granted to FHI are converted to co-exclusive licenses with CVT under Section 4.4 or in the event there is a partial termination of this Agreement under Section 12.3 as to a particular indication for a Licensed Product, CVT hereby agrees to indemnify, defend and hold harmless FHI, its Affiliates, and their respective officers, directors, agents and employees from and against any and all Losses resulting from the development, use, manufacture, handling, storage, transport, distribution, sale or other disposition of the Licensed Compounds and/or Licensed Products by CVT and/or any of its Representatives, except to the extent such Losses result from the negligence or wrongdoing of FHI and/or any of its Representatives.

**13.3 Notice and Procedures**. In all cases where one Party seeks indemnification by the other under this Article 13, the Party seeking indemnification shall promptly notify the indemnifying Party of receipt of any claim or lawsuit covered by such indemnification obligation and shall cooperate fully with the indemnifying Party in connection with the investigation and defense of such claim or lawsuit. The indemnifying Party shall have the right to control the defense, with counsel of its choice, provided that the non-indemnifying Party shall have the right to be represented by advisory counsel at its own expense. The indemnifying Party shall not settle or dispose of the matter in any manner which could negatively and materially affect the rights or liability of the non-indemnifying Party without the non-indemnifying Party's prior written consent, which shall not be unreasonably withheld or delayed.

**13.4 Insurance**. The Parties shall maintain the insurance coverages described on Schedule 13.4.

**13.5 Patent Infringement Matters.** Any suit, claim or action related to infringement of any Third Party Patents (including, without limitation, **[Medco]**) shall be handled in

accordance with the provisions of Section 9.3 and each Party's indemnification obligations under this Article 13 shall not apply with respect to any such suit, claim or action.

## 14. DISPUTE RESOLUTION

**14.1 Disputes.** The Parties recognize that disputes as to certain matters may from time to time arise during the Term which relate to either Party's rights and/or obligations hereunder, or to the interpretation, performance, breach, validity or termination of this Agreement (a "**Dispute**", but excluding any determination as to the validity of any Patents). It is the objective of the Parties to establish procedures to facilitate the resolution of Disputes arising under this Agreement in an expedient manner by mutual cooperation and without resort to litigation. To accomplish this objective, the Parties agree to follow the procedures set forth in this Article 14 if and when a Dispute arises under this Agreement. From the date of referral of any Dispute hereunder to the Management Committee or senior management of the Parties as provided below, and until such time as any matter has been resolved by the Parties or has been finally settled by arbitration hereunder, the running of the cure periods (if any) as to which a Party must cure a breach that is part of the subject matter of the Dispute shall be suspended. Subject to Section 14.2 below, the Parties shall refer any Dispute promptly to the Management Committee for attempted resolution, if it has not been disbanded as provided in Section 2.7 above. If the Management Committee is unable to resolve any dispute within thirty (30) days, or if it has been disbanded as provided in Section 2.7 above, either Party may, by written notice to the other Party, have such Dispute referred to each Party's respective executive officers designated below or their other senior management with settlement authority, for attempted resolution by good faith negotiations within thirty (30) days after such notice hereunder. Said designated officers are as follows:

For FHI: Theron Odlaug

For CVT: Louis G. Lange

In the event the designated executive officers are not able to resolve such Dispute within such thirty (30)-day period, the Parties agree that such Dispute shall be resolved by binding arbitration in accordance with this Section 14.1. If a Party intends to begin arbitration to resolve such Dispute, such Party shall provide written notice (the "**Arbitration Notice**") to the other Party informing such other Party of such intention and the issues to be resolved. Any arbitration hereunder shall be conducted pursuant to the then-current Commercial Arbitration Rules of the American Arbitration Association (**"AAA"**), including the Supplementary Procedures for Large Complex Disputes (the "**AAA Rules**"), except as modified herein. The arbitration shall be conducted by a panel of three (3) arbitrators (the **"Panel"**), to be mutually agreed upon by the Parties and appointed by the AAA within thirty (30) days after the date the Arbitration Notice is filed with the AAA by the Party initiating arbitration hereunder. The individuals comprising the Panel are to act as neutral arbitrators and shall have no past, present or anticipated future affiliation with either Party or their respective counsel. If the Parties are unable to agree upon all or any number of the three (3) mutually acceptable arbitrators within thirty (30) days after the filing of the Arbitration Notice with the AAA, the AAA promptly shall appoint the arbitrator(s) to complete the Panel after the demand for arbitration in accordance with the criteria set forth in this Section 14.1. Also within thirty (30) days after the filing of the Arbitration Notice with the

AAA, the Parties shall mutually agree upon the location of the arbitration; provided, however, that if the Parties cannot mutually agree on a location, then the arbitration shall be conducted in the San Francisco Bay area, California, if the Party initiating the arbitration is FHI or in the Chicago metropolitan area, Illinois, if the Party initiating the arbitration is CVT. The Panel shall apply the substantive law of the State of California, without regard to its conflicts of laws provisions, except that the interpretation of and enforcement of this Section 14.1 shall be governed by the Federal Arbitration Act. The Panel shall issue appropriate protective orders to safeguard each Party's Confidential Information. If a Party can demonstrate to the Panel that the complexity of the issue or other reasons warrant the extension of one or more of the timetables in the AAA rules, the Panel may extend such timetables, but in no event shall the proceeding extend more than one (1) year from the date of filing of the Arbitration Notice with the AAA. The decision of the Panel shall be in writing setting forth the basis therefor. The Panel shall have the authority to award any remedy allowed by law or in equity, including but not limited to compensatory damages and/or prejudgment interest, and to grant final, complete, interim, or interlocutory relief, including specific performance, injunctions and other equitable relief, but not punitive or other damages set forth in Section 14.5 (and the Parties shall be deemed to have waived any right to such excluded damages). Each Party shall bear its own costs, fees and expenses in the arbitration and shall share equally the administrative charges, arbitrators' fees and related expenses of the arbitration, unless the Panel determines that one Party prevailed clearly and substantially over the other Party, in which case the non-prevailing Party shall also pay the fees of the Panel, as well as (if ordered by the Panel) the prevailing Party's reasonable attorneys' fees, expert witness costs and/or other arbitration expenses. The Parties shall abide by the award rendered in the arbitration, and such award may be enforced and executed upon in any court having jurisdiction over the Party against whom enforcement of such award is sought.

**14.2 Disputes Under Sections 3.5(a) or 5.3.** In the event there is a Dispute (as defined in Section 14.1) regarding CVT's exercise of due diligence under Sections 3.5(a) or 5.3, the Parties shall follow the procedures set forth in this Section 14.2. From the date of referral of any Dispute hereunder to senior management of the Parties as provided below, and until such time as any matter has been resolved by the Parties or has been finally settled by arbitration hereunder, the running of the cure periods (is any) as to which a Party must cure a breach that is part of the subject matter of the Dispute shall be suspended, except as expressly provided in Section 14.2(a) below.

**(a)** If CVT fails to cure its material breach under Section 3.5(a) within the sixty (60) day cure period described in such Section ("**CVT Diligence Cure Period**"), the Parties shall immediately refer the Dispute hereunder to each Party's respective executive officers designated below or their other senior management with settlement authority for attempted resolution by good faith negotiations immediately after the end of the CVT Diligence Cure Period:

For FHI: Theron Odlaug

For CVT: Louis G. Lange

In the event the designated executive officers are not able to resolve such Dispute within ten (10) days thereafter, the Parties agree that such Dispute shall be resolved by binding arbitration in accordance with Section 14.2(c).

(**b**) If FHI in its good faith judgment believes that CVT has not been diligent in filing the IND (or other application to permit human clinical testing outside of the United States) pursuant to Section 5.3 above, then during the thirty (30)-day time period set forth in the last sentence of Section 5.3, the Parties shall immediately refer the Dispute hereunder to their respective officers specified in Section 14.2(a) above for attempted resolution. In the event such officers are not able to resolve such Dispute within five (5) days thereafter, the Parties agree that such Dispute shall be resolved by binding arbitration in accordance with Section 14.2(c).

(**c**) If a Party intends to begin arbitration to resolve any Dispute under this Section 14.2, such Party shall provide an Arbitration Notice (as defined in Section 14.1) to the other Party informing such other Party of the intention to begin arbitration and the issues to be resolved. Any arbitration hereunder shall be conducted by the AAA (as defined in Section 14.1) pursuant to the AAA Rules (as defined in Section 14.1), except as modified herein. In the event arbitration is initiated under this Section 14.2, the arbitration shall be conducted by a Panel (as defined in Section 14.1), to be mutually agreed upon by the Parties and appointed by the AAA within ten (10) days after the date the Arbitration Notice is filed with the AAA by the Party initiating arbitration hereunder. The Panel shall be comprised of three (3) experts in the field of clinical trials and/or drug development, and the individuals comprising the Panel are to act as neutral arbitrators and shall have no past, present or anticipated future affiliation with either Party or their respective counsel. If the Parties are unable to agree upon or all or any number of the three mutually acceptable experts comprising the Panel within ten (10) days after the filing of the Arbitration Notice with the AAA, the AAA shall promptly (but in no event more than thirty (30) days thereafter)_ appoint the arbitrator(s) to complete the Panel in accordance with the criteria set forth in this Section 14.2(c). Also within ten (10) days after the filing of the Arbitration Notice with the AAA, the Parties shall mutually agree upon the location of the arbitration; provided, however, that if the Parties cannot mutually agree on a location, then the location criteria set forth in Section 14.1 shall control. The Panel shall apply the substantive law of the State of California, without regard to its conflicts of laws provisions, except that the interpretation of and enforcement of this Section 14.2 shall be governed by the Federal Arbitration Act. The Panel shall issue appropriate protective orders to safeguard each Party's Confidential Information. If a Party can demonstrate to the Panel that the complexity of the issue or other reasons warrant the extension of one or more of the timetables in the AAA rules, the Panel may extend such timetables, but any arbitration proceeding under this Section 14.2 shall be on an expedited basis, as determined by the Panel, and in no event shall the proceeding extend more than one hundred and twenty (120) days from the date of filing of the Arbitration Notice with the AAA. The decision of the Panel shall be in writing setting forth the basis therefor. The Panel shall have the authority to determine whether or not CVT has met its obligations under Section 3.5(a) or Section 5.3, as the case may be, and/or has cured any material breach on its part within the applicable CVT Due Diligence Cure Period, and the remedies set forth in Sections 14.2(d) and (e) below shall be FHI's sole remedy and recourse in the event of CVT's material breach under Section 3.5(a) or Section 5.3. Each Party shall bear its own costs, fees and expenses in the arbitration and shall share equally the administrative charges, arbitrators' fees and related expenses of the arbitration, unless the Panel determines that one

Party prevailed clearly and substantially over the other Party, in which case the non-prevailing Party shall also pay the fees of the Panel, as well as (if ordered by the Panel) the prevailing Party's reasonable attorneys' fees, expert witness costs and/or other arbitration expenses. The Parties shall abide by the determination of the arbitrators, and such determination may be enforced and executed upon in any court having jurisdiction over the Party against whom enforcement of such award is sought.

**(d)** In the event the Panel determines that CVT has met its obligations under Section 3.5(a) or Section 5.3, as the case may be, and/or has cured any material breach on its part within the applicable CVT Diligence Cure Period, CVT shall continue with the Development Program under the terms and conditions of this Agreement. In the event the Panel rules in CVT's favor, FHI shall be precluded from sending CVT another Arbitration Notice regarding CVT's material breach under Section 3.5(a) for a period of at least twelve (12) months from the date of the Panel's decision.

**(e)** In the event the Panel determines that CVT has not met its obligations under Section 3.5(a) or Section 5.3, as the case may be, and/or has not cured any such breach within the applicable CVT Diligence Cure Period, then FHI has the right to elect, on written notice to CVT, either: (i) to terminate this Agreement under Section 12.4 (provided that there will be no additional notice or cure period thereunder); or (ii) to assume control of the Development Program, including without limitation the right to act as chair and cast the tie-breaking vote of the Management Committee under Sections 2.4 and 2.5 above. In the event the Panel rules in FHI's favor, CVT shall still be responsible for its twenty-five percent (25%) share of the Development Costs under Section 3.4(c) above.

**14.3 Governing Law.** Subject to Section 14.1 and 14.2 in the case of arbitration thereunder, resolution of all Disputes arising out of or related to this Agreement or the performance, enforcement, breach or termination of this Agreement and any remedies relating thereto, shall be governed by and construed under the substantive laws of the State of California, as applied to Agreements executed and to be performed entirely in the State of California by residents of the State of California.

**14.4 Injunctive Relief.** Nothing in this Article 14 shall prevent either Party from seeking a temporary restraining order or injunction against the other Party as required to prevent such other Party's misuse of the intellectual property or Confidential Information of the Party seeking such temporary restraining order or injunction.

**14.5 No Consequential Damages.** IN NO EVENT SHALL EITHER PARTY BE LIABLE TO THE OTHER FOR ANY INDIRECT, INCIDENTAL, SPECIAL, CONSEQUENTIAL OR PUNITIVE DAMAGES INCURRED BY EITHER PARTY UNDER THIS AGREEMENT OR OTHERWISE.

## 15. MISCELLANEOUS

**15.1 Entire Agreement; Amendment.** This Agreement sets forth the complete, final and exclusive agreement between the Parties with respect to the subject matter hereof, and all of the covenants, promises, agreements, warranties, representations, conditions and understandings

between the Parties hereto with respect to such subject matter, and supersedes and terminates all prior agreements and understandings between the Parties with respect to such subject matter. There are no covenants, promises, agreements, warranties, representations, conditions or understandings, either oral or written, between the Parties with respect to such subject matter other than as are set forth herein and therein. No subsequent alteration, amendment, change or addition to this Agreement shall be binding upon the Parties unless reduced to writing and signed by an authorized officer of each Party.

**15.2 Force Majeure.** Both Parties shall be excused from the performance of their obligations under this Agreement (including, without limitation, under Sections 3.5(a), 4.2 or 5.3) to the extent that such performance is prevented by force majeure and the non-performing Party promptly provides notice of the prevention to the other Party. Such excuse shall be continued so long as the condition constituting force majeure continues and the non-performing Party takes reasonable efforts to remove the condition. For purposes of this Agreement, "force majeure" shall include conditions beyond the control of the Parties, including without limitation, an act of God, war, civil commotion, labor strike or lock-out, failure of supplier to supply, epidemic, failure or default of public utilities or common carriers, destruction of production facilities or materials by fire, earthquake, storm or like catastrophe;

**15.3 Notices.** Any notice required or permitted to be given under this Agreement shall be in writing, shall specifically refer to this Agreement and shall be deemed to have been sufficiently given for all purposes on the same business day as delivered in person or faxed (with machine confirmation of receipt), five (5) days after mailing by U.S. first class certified or registered mail, postage prepaid, and the next business day after express or courier delivery service. Unless otherwise specified in writing, the mailing addresses of the Parties shall be as described below:

| | |
|---|---|
| For CVT: | CV Therapeutics, Inc.<br>3172 Porter Drive<br>Palo Alto, CA 94304<br>Attention: Chief Executive Officer<br>With a copy to: General Counsel<br>Telephone: (650) 812-0585<br>Telecopy: (650) 858-0390 |
| With a copy to: | Cooley Godward LLP<br>3175 Hanover Street<br>Palo Alto, CA 94306<br>Attention: Robert L. Jones, Esq.<br>Telephone: (650) 843-5000<br>Telecopy: (650) 849-7400 |

For FHI: Fujisawa Healthcare, Inc.
Three Parkway North Center
Deerfield, IL 60015
Attention: General Counsel
With a copy to: the Chief Executive Officer,
the Senior Vice President of Finance, and
the Executive Vice President
Telephone: (847) 317-8870
Telecopy: (847) 317-7288

With a copy to: Richards & O'Neil, LLP
885 Third Avenue
New York, New York 10022-4873
Attention: Michael O. Braun, Esq.
Telephone: 212-207-1210
Telecopy: 212-750-9022

**15.4 Consents Not Unreasonably Withheld or Delayed.** Whenever provision is made in this Agreement for either Party to secure the consent or approval of the other, that consent or approval shall not unreasonably be withheld or delayed, and whenever in this Agreement provisions are made for one Party to object to or disapprove a matter, such objection or disapproval shall not unreasonably be exercised, unless expressly stated that such consent is to be given in such Party's sole discretion.

**15.5 United States Dollars.** References in this Agreement to "Dollars" or "$" shall mean the legal tender of the United States of America.

**15.6 No Strict Construction.** This Agreement has been prepared jointly and shall not be strictly construed against either Party.

**15.7 Assignment.** Neither Party may assign or transfer this Agreement or any rights or obligations hereunder without the prior written consent of the other, except a Party may make such an assignment without the other Party's consent to a successor-in-interest to substantially all of the business assets of such Party to which this Agreement relates, whether in a merger, sale of stock, sale of assets or other transaction. Any permitted successor or assignee of rights and/or obligations hereunder shall, in a writing to the other Party, expressly assume performance of such rights and/or obligations. Any permitted assignment shall be binding on the successors of the assigning Party. Any assignment or attempted assignment by either Party in violation of the terms of this Section 15.7 shall be null and void and of no legal effect.

**15.8 Performance by Affiliates.** The Parties recognize that each Party may perform some or all of its obligations under this Agreement through one or more of its Affiliates; provided, however, that each Party shall remain responsible for and shall guarantee such performance by its Affiliates and shall cause its Affiliates to comply with the provisions of this Agreement in connection with such performance. Each Party hereby expressly waives any requirement that the other Party exhaust any right, power or remedy, or proceed against an

Affiliate, for any obligation or performance hereunder prior to proceeding directly against such Party.

**15.9 Counterparts**. This Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

**15.10 Further Actions.** Each Party agrees to execute, acknowledge and deliver such further instruments, and to do all such other acts, as may be necessary or appropriate in order to carry out the purposes and intent of this Agreement.

**15.11 Severability.** If any one or more of the provisions of this Agreement is held to be invalid or unenforceable by any court of competent jurisdiction from which no appeal can be or is taken, then such provision(s) shall be considered severed from this Agreement and shall not serve to invalidate any remaining provisions hereof. The Parties shall make a good faith effort to replace any invalid or unenforceable provision with a valid and enforceable one such that the objectives contemplated by the Parties when entering this Agreement may be realized.

**15.12 Ambiguities.** Ambiguities, if any, in this Agreement shall not be construed against any Party, irrespective of which Party may be deemed to have authored the ambiguous provision.

**15.13 Headings.** The headings for each Article and Section in this Agreement have been inserted for convenience of reference only and are not intended to limit or expand on the meaning of the language contained in the particular Article or Section.

**15.14 No Waiver.** Any delay in enforcing a Party's rights under this Agreement or any waiver as to a particular default or other matter shall not constitute a waiver of such Party's rights to the future enforcement of its rights under this Agreement, excepting only as to an express written and signed waiver as to a particular matter for a particular period of time.

**IN WITNESS WHEREOF**, the Parties have executed this Agreement in duplicate originals by their proper officers as of the date and year first above written.

| **FUJISAWA HEALTHCARE, INC.** | **CV THERAPEUTICS, INC.** |
|---|---|
| By:_____ | By:_____ |
| | Louis G. Lange, M.D., Ph.D. |
| Title:_____ | Title: Chairman & CEO |
| Date:_____ | Date:_____ |

IN WITNESS WHEREOF, the Parties have executed this Agreement in duplicate originals by their proper officers as of the date and year first above written.

**FUJISAWA HEALTHCARE, INC.**

By: _____
Noboru Maeda

Title: Chairman & CEO

Date: July 10, 2000

**CV THERAPEUTICS, INC.**

By: _____
Louis G. Lange, M.D., Ph.D.

Title: Chairman & CEO

Date: July 10, 2000

TBS

## SCHEDULE 1.10

### DESIGNATED PATENTS

**[The following patent applications entitled:**

**(1) "N-Pyrazole A2A Receptor Agonists";**

**(2) "C-Pyrazole A2A Receptor Agonists"; and**

**(3) "Partial A2A Adenosine Receptor Agonists" (provisional).]**

## SCHEDULE 3.3
## INITIAL PLAN AND BUDGET

[

| Development Phase | | | One | One | | One | One |
|---|---|---|---|---|---|---|---|
| CVT-3146 | Phase I | FY'00 | 3Q' 00 | 4Q' 00 | FY '01 | 1Q '01 | 2Q '01 |
| **Clinical Trials Plan** | **$835** | **$560** | **$255** | **$305** | **$275** | **$75** | **$200** |
| 5111: Phase I | **$400** | $400 | $200 | $200 | $0 | $0 | $0 |
| 5112 : Ph 1:Interaction #1 | **$100** | $0 | $0 | $0 | $100 | $0 | $100 |
| 5113 : Ph 1:Interaction #2 | **$0** | $0 | $0 | $0 | $0 | $0 | $0 |
| 5121: Ph 2: CBF | **$0** | $0 | $0 | $0 | $0 | $0 | $0 |
| 5122: Ph 2:Imaging | **$0** | $0 | $0 | $0 | $0 | $0 | $0 |
| 5123 : Phase II | **$0** | $0 | $0 | $0 | $0 | $0 | $0 |
| 5131-Phase III | **$0** | $0 | $0 | $0 | $0 | $0 | $0 |
| 5132 - Phase III | **$0** | $0 | $0 | $0 | $0 | $0 | $0 |
| Consulting | **$60** | $10 | $5 | $5 | $50 | $25 | $25 |
| Data Analyses/Mgmnt. | **$275** | $150 | $50 | $100 | $125 | $50 | $75 |
| **ADME/TOX/Pharma Dev.** | **$384** | $84 | **$72** | **$12** | $300 | **$75** | **$225** |
| **Non-Clinical Pharmacology** | **$55** | $55 | **$55** | **$0** | $0 | **$0** | **$0** |
| **Materials Plan** | **$350** | $220 | **$0** | **$220** | $130 | **$35** | **$95** |
| **Regulatory (Outside Expenses)** | **$40** | $10 | **$5** | **$5** | $30 | **$15** | **$15** |
| Headcount : FTE Equivalents | | | | | | | |
| Clinical Research MD's | **0.50** | 0.25 | 0.5 | 0.5 | 0.25 | 0.5 | 0.5 |
| Project Manager | **0.50** | 0.25 | 0.5 | 0.5 | 0.25 | 0.5 | 0.5 |
| Clinical Data managmenet | **0.00** | 0 | 0 | 0 | 0 | 0 | 0 |
| Biostatician | **0.00** | 0 | 0 | 0 | 0 | 0 | 0 |
| Clinical Research Associates | **1.00** | 0.5 | 1 | 1 | 0.5 | 1 | 1 |
| Clinical Operations | **0.00** | 0 | 0 | 0 | 0 | 0 | 0 |
| Drug Product/Mfg | **0.25** | 0.125 | 0.25 | 0.25 | 0.125 | 0.25 | 0.25 |
| Analytical Chemistry | **1.00** | 0.5 | 1 | 1 | 0.5 | 1 | 1 |
| Pharmacology | **1.00** | 0.5 | 1 | 1 | 0.5 | 1 | 1 |
| Toxicology | **0.50** | 0.25 | 0.5 | 0.5 | 0.25 | 0.5 | 0.5 |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | ADME | **1.00** | 0.5 | 1 | 1 | 0.5 | 1 | 1 |
| | Bioanalytical Chemistry | **1.00** | 0.5 | 1 | 1 | 0.5 | 1 | 1 |
| | Regulatory Affairs | **0.25** | 0.125 | 0.25 | 0.25 | 0.125 | 0.25 | 0.25 |
| | QA/QC | **0.75** | 0.375 | 0.75 | 0.75 | 0.375 | 0.75 | 0.75 |
| | Executive Management | **0.50** | 0.25 | 0.5 | 0.5 | 0.25 | 0.5 | 0.5 |
| | | | | | | | | |
| FTE | Headcount | **8.25** | 4.125 | 8.25 | 8.25 | 4.125 | 8.25 | 8.25 |
| **FTE** | **Estimated Cost** | **$2,063** | **$1,031** | | | **$1,031** | | |
| | | | | | | | | |
| **Totals** | | **$3,727** | **$1,960** | | | **$1,766** | | |
| Total | | | $3,727 | | | | | |

]

**SCHEDULE 5.2**

**STOCK PURCHASE AGREEMENT**

THIS STOCK PURCHASE AGREEMENT (this "Agreement") is dated and entered into as of July 10, 2000 (the "Effective Date"), by and between CV THERAPEUTICS, INC., a Delaware corporation ("Company"), and FUJISAWA HEALTHCARE, INC., a Delaware corporation ("Purchaser").

WHEREAS, Company and Purchaser are parties to a Collaboration and License Agreement, of even date herewith (as amended, modified or supplemented from time to time, the "License Agreement"), pursuant to which the parties desire to establish a collaboration and Purchaser desires to obtain an exclusive license from Company; and

WHEREAS, as a condition to entering into the License Agreement, Purchaser desires to acquire and Company is willing to issue and sell to Purchaser shares of common stock, $.001 par value, of Company (the "Common Stock"), subject to the terms and conditions specified herein;

NOW, THEREFORE, for good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged by the parties, the parties agree as follows:

ARTICLE I
DEFINITIONS

1.01 Definitions. For purposes of this Agreement, in addition to the terms defined elsewhere herein, the following terms shall have the meanings set forth below:

"Affiliate" shall have the meaning given such term in Rule 12b-2 of the Exchange Act.

"Business Day" shall mean any day other than a Saturday, Sunday or legal holiday on which banks in New York, New York are open for the conduct of their banking business.

"Closing" shall have the meaning specified in Section 2.02 herein.

"Exchange Act" shall mean the Securities Exchange Act of 1934, as amended.

"IPO Documents" shall mean Company's (a) Registration Statement No. 333-12675 declared effective by the SEC on November 19, 1996, and Prospectus dated November 19, 1996, and (b) Registration Statement No. 333-86447 declared effective by the SEC on October 13, 1999, and Prospectus dated October 6, 1999.

"knowledge" of Company shall mean the knowledge of one or more of the executive officers of Company.

"Per Share Fair Market Price" of the Common Stock on any date shall mean (a) if the Common Stock is then traded on a securities exchange or the Nasdaq National Market, the average of the closing prices of the Common Stock on such exchange or market over the thirty (30) Trading Days ending on such date; (b) if the Common Stock is then regularly traded over-the-counter, the average of the sale prices or secondarily the closing bid of the Common Stock over the thirty (30) Trading Days ending on such date; or (c) if there is no active public market for the Common Stock, the fair market value thereof shall be determined as of such date by a nationally recognized investment banking firm chosen in good faith by Company's board of directors.

"Rule 144" shall mean Rule 144 as promulgated by the SEC under the Securities Act, as such Rule may be amended from time to time, or any similar successor rule that may be promulgated by the SEC.

"Securities Act" shall mean the Securities Act of 1933, as amended.

"SEC" shall mean the Securities and Exchange Commission.

"Shares" shall have the meaning specified in Section 2.01 herein.

"Trading Day" shall mean a day on which the principal national securities exchange on which the Common Stock is listed or admitted to trading is open for the transaction of business or, if the Common Stock is not listed or admitted to trading on any national securities exchange, a Business Day.

## ARTICLE II
## PURCHASE AND SALE OF THE SHARES

2.01 Issuance of the Shares. Subject to the terms and conditions of this Agreement, at the Closing (as defined below) Company agrees to issue and sell to Purchaser, and Purchaser agrees to purchase from Company, at an aggregate purchase price of Four Million Dollars ($4,000,000), such number of shares (rounded to the nearest whole share) of Common Stock (the "Shares") equal to $4,000,000 divided by an amount equal to the product of 4/3 multiplied by the Per Share Fair Market Price as of the date which is one Business Day prior to the Effective Date. By way of illustration only, if the Per Share Market Price on such date were $45.00, the number of Shares would equal $4,000,000 divided by $60.00 (the product of $45.00 multiplied by 4/3), or 66,667 Shares.

2.02 Closing; Delivery of the Shares.

(a) The purchase and sale of the Shares shall take place at a closing (the "Closing") to be held at the offices of Cooley Godward LLP, Five Palo Alto Square, 3000 El Camino Real, Palo Alto, CA 94306 at 10:00 A.M. (Pacific Daylight Time) on the Effective Date, or at such other location, time and date as may be mutually agreed upon by the parties. The Closing shall take place contemporaneously with the execution and delivery of this Agreement and the License Agreement by Company and Purchaser.

(b) At the Closing, subject to the terms and conditions contained in this Agreement, Purchaser shall provide a wire transfer of immediately available funds to an account of Company specified to Purchaser, in an amount equal to Four Million Dollars ($4,000,000), in payment of the full purchase price for the Shares.

(c) Within five (5) business days after Closing, Company shall deliver one or more stock certificates evidencing the Shares, registered in the name of Purchaser and dated as of the date of the Closing.

## ARTICLE III
## CONDITIONS TO CLOSING

3.01 Conditions to Purchaser's Obligations. The obligation of Purchaser to purchase and pay for the Shares at the Closing is subject to each of the following additional conditions precedent:

(a) Opinion of Counsel. Purchaser shall have received at the Closing an opinion from Cooley Godward LLP, counsel to Company, regarding this Agreement and the transactions contemplated hereby;

(b) Board Resolutions. Purchaser shall have received at the Closing copies of the resolutions of the Board of Directors of Company authorizing the execution and delivery of this Agreement and the performance by Company of all transactions contemplated hereby, certified by an appropriate officer of Company;

(c) Officer's Certificate. Purchaser shall have received at the Closing, a certificate, executed by the appropriate officer of Company and dated as of the date of the Closing, together with and certifying (A) the names of the officers of Company authorized to sign this Agreement; (B) a copy of the certificate of incorporation of Company, as amended and in effect as of the date of the Closing; (C) a copy of the bylaws of Company, as amended and in effect as of the date of the Closing; and (D) that the representations and warranties contained in Article IV hereof are true and correct as of the date of the Closing; and

(d) License Agreement. Purchaser shall have received at the Closing the License Agreement, duly executed by an authorized officer of Company and dated as of the date of the Closing.

3.02 Conditions to Company's Obligations. The obligation of Company to issue and sell the Shares at the Closing is subject to the following additional conditions precedent:

(a) Board Resolutions. Company shall have received at the Closing copies of the resolutions of the Board of Directors of Purchaser authorizing the execution and delivery of this Agreement and the performance by Purchaser of all transactions contemplated hereby, certified by an appropriate officer of Purchaser;

(b) License Agreement. Company shall have received at the Closing the License Agreement, duly executed by an authorized officer of Purchaser and dated as of the date of the Closing; and

(c) Purchase Price. Purchaser shall have delivered Four Million Dollars ($4,000,000) in immediately available funds to Company's specified account in accordance with Section 2.02(b) herein.

## ARTICLE IV
## REPRESENTATIONS AND WARRANTIES OF COMPANY

Company represents and warrants to Purchaser as follows:

4.01 Corporate Status. Company is a corporation duly incorporated, validly existing and in good standing under the laws of the State of Delaware, and has all requisite corporate power and authority to own and use its properties and assets and to transact the business in which it is currently engaged.

4.02 Corporate Power and Authority. The execution and delivery by Company of this Agreement, the performance of the terms and obligations herein, and the issuance, sale and delivery of the Shares are each within Company's corporate powers, and each has been duly authorized by all necessary corporate action on the part of Company. This Agreement, when executed and delivered hereunder, will constitute the valid and legally binding obligation of Company enforceable against Company in accordance with its terms, subject to (a) applicable bankruptcy, insolvency, reorganization, moratorium or similar laws affecting creditors' rights generally, and (b) the effect of general principles of equity, regardless of whether considered in a proceeding in equity or at law.

4.03 Government Approvals. No authorization, consent, approval or other action by, and no notice to or filing with, any governmental authority or regulatory body is required for the due execution, delivery and performance by Company of this Agreement or the issuance and sale of the Shares to Purchaser except for the filing by Company with the SEC or any state securities authorities of any notices or filings required in connection with the exemptions from the registration or qualification requirements of the Securities Act and/or applicable state securities law.

4.04 Capitalization. As of May 31, 2000, the authorized capital stock of Company consists of: (a) 30,000,000 shares of Common Stock, $.001 par value, of which 18,528,069 shares are issued and outstanding and of which 142,519 shares are treasury shares, and (b) 5,000,000 shares of Preferred Stock, $.001 par value, of which 300,000 are designated Series A Junior Participating Preferred, none of which are issued and outstanding. As of May 31, 2000, an aggregate of 2,331,143 shares of Company's Common Stock were reserved for future issuance pursuant to stock options granted by Company and outstanding on May 31, 2000 and an additional 1,087,179 shares of Company's Common Stock were reserved and available for the grant of future stock options under all of Company's stock option or equity incentive plans. The Shares, when issued against payment of the aggregate purchase price set forth in Section 2.01, will be duly authorized, validly issued, fully paid, non-assessable and free and clear of all liens and encumbrances. As of the date hereof, except for the options described hereinabove or except as described in the IPO Documents, the SEC Documents or the Schedule of Exceptions attached hereto, there are no options, warrants, convertible securities or other rights to purchase shares of capital stock or other securities of Company which are authorized, issued or outstanding, nor is Company obligated in any other manner to issue shares of its capital stock or other securities, and Company has no obligation to purchase, redeem or otherwise acquire any shares of its capital stock or any interest therein or to pay any dividend or make any other distribution in respect thereof, except as contemplated by this Agreement. Except as described in the IPO Documents, the SEC Documents or the Schedule of Exceptions attached hereto, (a) no person is entitled to any preemptive right, catch-up right, right of first refusal or similar right with respect to the issuance of any capital stock of Company, (b) there are no restrictions on the transfer of shares of capital stock of Company other than those imposed by relevant federal and state securities laws and (c) there exists no agreement between Company's stockholders and to which Company is a party with respect to the voting or transfer of Company's capital stock or with respect to any other aspect of Company's affairs.

4.05 No Violation. Neither the execution or delivery by Company of this Agreement, nor the performance of the terms and obligations herein, will (a) violate Company's charter or bylaws, (b) constitute a breach or default under any agreement or instrument to which Company is a party or by which Company is bound, which breach or default would have a material adverse effect on Company, its assets or properties, or (c) violate any applicable law, rule or regulation, which violation would have a material adverse effect on Company, or (d) violate any order, writ, injunction, decree or judgment of any court or governmental authority applicable to or binding upon Company, which violation would have a material adverse effect on Company.

4.06 Financial Statements.

(a) All financial statements contained in the SEC Documents (as defined in Section 4.08) filed by Company with the SEC, have been prepared in accordance with generally accepted accounting principles ("GAAP") consistently applied throughout the periods indicated except as may be expressly stated in the notes thereto and, as to the unaudited financial statements, subject to normal recurring year-end audit adjustments and the absence of notes

thereto. Each balance sheet fairly presents the financial condition of Company and its subsidiaries as at the date of such balance sheet, and each statement of operations, of stockholders' equity and of cash flows, fairly presents the results of operations, the stockholders' equity and the cash flows of Company and its subsidiaries for the periods then ended, all in accordance with GAAP.

(b) Since the date of Company's most recent filing of financial statements with the SEC, there has been no material adverse change in the business, property, assets, operations or financial condition of Company and its subsidiaries.

4.07 Litigation. There is no pending, or to Company's knowledge overtly threatened, action, suit, proceeding, arbitration, or investigation before any court, governmental agency, instrumentality or arbitrator, which, if determined adversely to Company, could reasonably be expected to materially adversely affect the business, property, assets, operations or financial condition of Company and its subsidiaries or which purports to affect the legality, validity or enforceability of this Agreement.

4.08 SEC Filings. Company has filed with the SEC on a timely basis, or received a valid extension of such time of filing, all forms, reports and documents required to be filed by it under the Exchange Act since November 19, 1996 (such documents collectively referred to as the "SEC Documents"). As of their respective dates, the SEC Documents complied in all material respects with the requirements of the Securities Act and the Exchange Act and the rules and regulations of the SEC promulgated thereunder, and none of the SEC Documents, when filed, contained any untrue statement of a material fact or omitted to state a material fact required to be stated therein or necessary to make the statements therein, in light of the circumstances under which they were made, not misleading.

4.9 Compliance with Statutes, etc. Each of Company and its subsidiaries is in compliance with all applicable laws, rules, regulations and orders of, and all applicable restrictions imposed by, all governmental bodies, in respect of the conduct of its business and the ownership of its property except, where such failure to be in compliance would not have a material adverse effect on Company.

4.10 Securities Laws. Assuming the accuracy of the representations and warranties of Purchaser contained in Article V hereof, the issuance of the Shares is exempt from the provisions of the Securities Act. All notices, filings, registrations, or qualifications under state securities or "blue-sky" laws which are required in connection with the offer, issue and delivery of the Shares pursuant to this Agreement, if any, have been or will be completed by Company on a timely basis.

4.11 Tax Returns and Payments. Each of Company and its subsidiaries has filed all federal, state, local, foreign and other tax returns required to be filed by it and has paid all taxes and other assessments which have become due pursuant to such tax returns and all other taxes and assessments which have become due, except for those contested in good faith and for which adequate reserves have been established. Each of Company and its subsidiaries has made adequate provisions on its books of account for all taxes, assessments and governmental charges

with respect to its business, properties and operations for all prior fiscal years and for the current fiscal year to the date hereof. No governmental authority has asserted a lien or other claim against Company or any of its subsidiaries with respect to unpaid taxes which has not been discharged or resolved, which would have a material adverse effect on Company.

4.12 Insurance. Company and each of its subsidiaries maintains insurance on all of its properties with financially sound and reputable insurance companies against such risks and in such amounts as are customarily maintained by companies of comparable size engaged in a similar business.

4.13 No Infringement. To its knowledge, Company owns or possesses rights to use all patents, patent applications, trademarks, service marks, trade names, copyrights, trade secrets, licenses and rights with respect to the foregoing which are required to conduct its business without any known infringement of the rights of others. No event has occurred which, to the knowledge of Company, permits, or after notice or lapse of time or both would permit, the revocation or termination of any such rights, and, to the knowledge of Company, neither Company nor any of its subsidiaries is liable to any person or entity for infringement under applicable law with respect to such rights. As of the Effective Date, Company is not pursuing any action against any third party for the infringement of Company's patents, patent applications, trademarks, service marks, trade names, copyrights, trade secrets, or licenses relating to its business.

## ARTICLE V
## REPRESENTATIONS AND WARRANTIES OF PURCHASER

Purchaser represents and warrants to Company as follows:

5.01 Corporate Status. Purchaser is a corporation duly incorporated, validly existing and in good standing under the laws of the State of Delaware, and has all requisite corporate power and authority to own and use its properties and assets and to transact the business in which it is currently engaged.

5.02 Corporate Power and Authority. The execution and delivery by Purchaser of this Agreement, the performance of the terms and obligations therein, and the purchase of the Shares are each within Purchaser's corporate powers, and each has been duly authorized by all necessary corporate action on the part of Purchaser. This Agreement, when executed and delivered hereunder, will constitute valid and legally binding obligations of Purchaser enforceable against Purchaser in accordance with their terms, subject to (a) applicable bankruptcy, insolvency, reorganization, moratorium or similar laws affecting creditors' rights generally, and (b) the effect of general principles of equity, regardless of whether considered in a proceeding in equity or at law.

5.03 Investment. Purchaser is acquiring the Shares for Purchaser's own account, not as a nominee or agent for investment, and not with a view to, or for resale in connection with, any distribution or public offering thereof within the meaning of the Securities Act.

5.04 Shares Not Registered. Purchaser understands that the Shares are not registered under the Securities Act on the ground that the sale provided for in this Agreement and the issuance of Shares hereunder is exempt from registration under the Securities Act pursuant to Section 4(2) thereof, and that Company's reliance on such exemption is predicated on Purchaser's representations set forth herein.

5.05 Accredited Investor. Purchaser represents that it is an "accredited investor" within the meaning of Rule 501 of Regulation D adopted pursuant to the Securities Act.

5.06 Restricted Shares. Purchaser understands that the Shares may not be sold, transferred, or otherwise disposed of without registration under the Securities Act or an exemption therefrom, and that in the absence of an effective registration statement covering the Shares or an available exemption from registration under the Securities Act, the Shares must be held indefinitely. Purchaser is aware that the Shares may not be sold pursuant to Rule 144 promulgated under the Securities Act unless all of the conditions of that Rule are met.

5.07 Legend. To the extent applicable, each certificate or other document evidencing the Shares, whether upon initial issuance or transfer thereof, shall be endorsed with the legends substantially in the form set forth below:

> "THE SHARES REPRESENTED HEREBY HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED, AND MAY NOT BE SOLD, TRANSFERRED, PLEDGED, OR HYPOTHECATED UNLESS AND UNTIL REGISTERED UNDER SUCH ACT, OR UNLESS COMPANY HAS RECEIVED AN OPINION OF COUNSEL OR OTHER EVIDENCE, SATISFACTORY TO COMPANY AND ITS COUNSEL, THAT SUCH REGISTRATION IS NOT REQUIRED."
>
> "THE SHARES REPRESENTED BY THIS CERTIFICATE ARE SUBJECT TO CERTAIN RESTRICTIONS ON TRANSFER SET FORTH IN AN AGREEMENT BETWEEN THE COMPANY AND THE HOLDER HEREOF DATED AS OF JULY 10, 2000, A COPY OF WHICH IS ON FILE AT THE COMPANY'S PRINCIPAL OFFICES AND IS AVAILABLE UPON REQUEST."

5.08 Investment Information.

(a) Purchaser has been furnished with all the information necessary to make an informed investment decision. Purchaser has been given access to such information relating to Company as Purchaser has requested.

(b) By reason of Purchaser's business or financial experience, Purchaser has the capacity to make the decision referred to in subsection (a) above.

## ARTICLE VI
## COVENANTS OF COMPANY

6.01 Rule 144 Reporting. With a view to making available the benefits of certain rules and regulations of the SEC that may permit the sale of the Shares to the public without registration, Company agrees to use its best efforts to:

(a) make and keep public information regarding Company available (as those terms are understood and defined in Rule 144 under the Securities Act) at all times;

(b) file with the SEC in a timely manner all reports and other documents required of Company under the Securities Act and the Exchange Act at any time; and

(c) so long as Purchaser owns any Shares or securities convertible into, exchangeable for or exercisable for Common Stock, furnish to Purchaser forthwith upon written request as to Company's compliance with the reporting requirements of Rule 144 and of the Securities Act and the Exchange Act, a copy of the most recent annual or quarterly report of Company.

## ARTICLE VII
## COVENANTS OF PURCHASER

7.01 Restrictions on Purchase of Common Stock. Until the first anniversary of the expiration or termination of the License Agreement, Purchaser shall not purchase, and shall ensure that none of its Affiliates purchases, any Common Stock other than the purchase or acquisition of Shares contemplated by this Agreement.

## ARTICLE VIII
## MISCELLANEOUS

8.01 Amendments, Etc. No amendment or waiver of any provision of this Agreement, nor consent to any departure by Company therefrom, shall in any event be effective unless the same shall be in writing and signed by Purchaser, and then such waiver or consent shall be effective only in the specific instance and for the specific purpose for which given.

8.02 Notices. All notices and other communications provided for hereunder shall be in writing, shall specifically refer to this Agreement, shall be addressed to the receiving party's address set forth below or to such other address as a party may designate by notice hereunder, and shall be deemed to have been sufficiently given for all purposes if (a) mailed by first class certified or registered mail, postage prepaid, (b) sent by express delivery service, (c) personally delivered, or (d) made by telecopy or facsimile transmission (with machine confirmation of delivery).

If to Company:

CV Therapeutics, Inc.
3172 Porter Drive
Palo Alto, CA 94304
Attn: General Counsel
Telephone: 650-475-9611
Facsimile: 650-858-0388

with a copy to:

Cooley Godward LLP
Five Palo Alto Square
3000 El Camino Real
Palo Alto, CA 94306
Attn: Robert L. Jones
Telephone: 650-843-5034
Facsimile: 650-857-0663

If to Purchaser:

Fujisawa Healthcare, Inc.
Three Parkway North Center
Deerfield, IL 60015
Attn: General Counsel
Telephone: 847-317-8870
Facsimile: 847-317-7288

with a copy to:

Richards & O'Neil, LLP
885 Third Avenue
New York, NY 10022-4873
Attn: Michael Braun
Facsimile: 212-750-9022

8.03 No Waiver; Remedies. No failure on the part of Purchaser to exercise, and no delay in exercising, any right hereunder shall operate as a waiver thereof; nor shall any single or partial exercise of any such right preclude any other or further exercise thereof or the exercise of any other right. The remedies herein provided are cumulative and not exclusive of any remedies provided by law.

8.04 Attorneys' Fees. In the event that any dispute among the parties to this Agreement should result in litigation, the prevailing party in such dispute shall be entitled to recover from the losing party all fees, costs and expenses enforcing any right of such prevailing party under or with respect to this Agreement, including without limitation, such reasonable fees and expenses of attorneys and accountants, which shall include, without limitation, all fees, costs and expense of appeals.

8.05 Binding Effect; Assignment. This Agreement shall be binding upon and inure to the benefit of Company and Purchaser and their respective successors and assigns, provided that neither Company nor Purchaser may assign or transfer any or all of its rights or obligations under

this Agreement without the prior written consent of the other party. Notwithstanding any assignment by Purchaser, the provisions of Sections 7.01 shall continue to be binding upon Purchaser in accordance with the terms of this Agreement.

8.06 Governing Law; Consent to Jurisdiction. This Agreement shall be governed by, and construed in accordance with, the laws of the State of Delaware, without reference to the conflicts or choice of law principles thereof. Company and Purchaser hereby irrevocably consent to the exclusive personal jurisdiction of any state or federal courts located in Delaware, in any action, claim or other proceeding arising out of any dispute in connection with this Agreement, any rights or obligations hereunder, or the performance of such rights and obligations. Purchaser and Company agree to waive their respective rights to a jury trial with respect to any action, claim, or other proceeding arising out of any dispute in connection with this Agreement, any rights or obligations hereunder, or the performance of such rights and obligations.

8.07 Severability. To the extent any provision of this Agreement is prohibited by or invalid under applicable law, such provision shall be ineffective to the extent of such prohibition or invalidity, without invalidating the remainder of such provision or the remaining provisions of this Agreement.

8.08 Entire Agreement. This Agreement embodies the entire agreement and understanding between the parties hereto with respect to the provisions hereof and supersedes all prior oral or written agreements and understandings relating to the provisions hereof. No statement, representation, warranty, covenant or agreement of any kind not expressly set forth in this Agreement shall affect, or be used to interpret, change or restrict, the express terms and provisions of this Agreement.

8.09 Further Action. Each party shall, without further consideration, take such further action and execute and deliver such further documents as may be reasonably requested by the other party in order to carry out the provisions and purposes of this Agreement.

8.10 Counterparts. This Agreement may be executed in one or more counterparts, each of which shall be deemed to be an original, but all of which, when taken together, shall constitute one and the same instrument.

8.11 Survival. The representations, warranties, covenants and agreements made herein by Company and Purchaser shall survive the Closing.

[THE REMAINDER OF THE PAGE INTENTIONALLY LEFT BLANK;
SIGNATURES ARE ON FOLLOWING PAGE]

IN WITNESS WHEREOF, Company and Purchaser have caused this Stock Purchase Agreement to be executed in their names by their duly authorized officers or representatives effective as of the date first above written.

CV THERAPEUTICS, INC.

By: _____
Name: Louis G. Lange, M.D., Ph.D.
Title: Chairman & CEO

FUJISAWA HEALTHCARE, INC.

By: _____
Name:
Title:

IN WITNESS WHEREOF, Company and Purchaser have caused this Stock Purchase Agreement to be executed in their names by their duly authorized officers or representatives effective as of the date first above written.

CV THERAPEUTICS, INC.

By: _____
Name: Louis G. Lange, M.D., Ph.D.
Title: Chairman & CEO

FUJISAWA HEALTHCARE, INC.

By: _____
Name: Noboru Maeda
Title: Chairman & CEO

## SCHEDULE OF EXCEPTIONS

This Schedule of Exceptions is made and given with respect to Article IV of the attached Stock Purchase Agreement (the "Agreement"), by and between CV Therapeutics, Inc., a Delaware corporation (the "Company"), and Fujisawa Healthcare, Inc., a Delaware corporation (the "Purchaser").

The section numbers in this Schedule of Exceptions correspond to the section numbers in the Agreement, however, any information disclosed herein under any section number shall be deemed to be disclosed and incorporated into any other section number under the Agreement where such disclosures would be appropriate. Unless the context otherwise requires, all capitalized terms shall have the same meaning as defined in the Agreement.

Section 4.04

As of May 31, 2000, an aggregate of 249,203 shares of Common Stock of the Company were reserved for future issuance pursuant to outstanding warrants granted by the Company.

On February 2, 1999, the Company adopted a Preferred Share Purchase Rights Plan pursuant to which shareholders have certain rights to purchase shares of Series A Junior Participating Preferred.

$196,250,000 of 4¾% Convertible Subordinated Notes due March 7, 2007 and Shares of Common Stock Issuable Upon Conversion of the Notes.

**SCHEDULE 10.3**

**FORM OF PRESS RELEASE**

**PRESS RELEASE**

**FOR IMMEDIATE RELEASE**


Contacts: CV Therapeutics
Dan Spiegelman
SVP & Chief Financial Officer
(650) 812-9509

Christopher Chai
Treasurer & Director,
Investor Relations
(650) 812-9560

Fujisawa Healthcare
Maribeth Landwehr
Corporate Communications
(847) 317-8988

Fleishman-Hillard
Carol Harrison
(212) 453-2442


# CV THERAPEUTICS AND FUJISAWA HEALTHCARE ANNOUNCE COLLABORATION ON CVT-3146 FOR CARDIAC IMAGING

CVT partners with market leader in pharmacologic cardiac imaging

PALO ALTO, CA and DEERFIELD, IL (July 11, 2000) – CV Therapeutics, Inc. (Nasdaq: CVTX) and Fujisawa Healthcare, Inc. (FHI) announced today a collaboration to develop and market second generation pharmacologic cardiac stress agents. Under this agreement FHI receives exclusive North American rights to CVT-3146, a short acting selective $A_{2A}$ adenosine receptor agonist, and a backup compound. CVT and FHI will collaborate on the development of CVT-3146. Leveraging the strengths of both organizations, CVT will be responsible for managing the CVT-3146 clinical development program. FHI will be responsible for selling and marketing CVT-3146 in North America. In the U.S. FHI currently markets Adenoscan® (adenosine), the market leading pharmacologic cardiac stress-imaging agent.

CVT will receive $10.0 million from FHI, which consists of a cash payment, the prepayment of a development milestone, and the purchase of CVT common stock at a premium.

CVT may receive up to an additional $24.0 million in cash based upon development and regulatory milestones. FHI will reimburse CVT for 75% of the development costs, and if approved by the FDA, CVT will receive a royalty based on product sales of CVT-3146 and may receive a royalty on other products.

"We are pleased to collaborate with the market leader in cardiac perfusion imaging," said Louis G. Lange, M.D., Ph.D., Chairman and Chief Executive Officer of CV Therapeutics. "The structure of this collaboration reflects our leadership in adenosine technology and cardiovascular drug discovery. In addition, this collaboration will allow us to focus our financial resources on our two late stage clinical programs: ranolazine and CVT-510."

"Our partnership with CV Therapeutics and the development of CVT-3146 represents Fujisawa's continued commitment to the cardiovascular therapeutic area," said Noboru Maeda, Chairman and Chief Executive Officer at Fujisawa Healthcare, Inc. "CVT-3146 allows us to expand our current portfolio of cardiovascular products available to clinicians."

**About cardiac perfusion imaging studies**

Cardiac perfusion imaging studies are used for the detection and characterization of coronary artery disease by identifying areas of insufficient blood flow in the heart. During these tests, blood flow is measured when the patient's heart is at rest and when it is working. Relatively low blood flow when the heart is working is indicative of which areas of the heart may be diseased.

To stimulate the work of the heart sufficiently to perform the test many patients exercise on a treadmill. However, more than a third of the patients who take the test are unable to exercise adequately because of medical conditions such as peripheral vascular disease and arthritis. For these patients, a pharmacologic agent that temporarily increases the coronary blood flow is required to simulate the heart at work. In 1997, approximately 5.2 million cardiac perfusion imaging studies were performed in the US, of which 1.8 million were conducted using a pharmacologic agent.

Stimulation of the $A_{2A}$ adenosine receptor in the heart induces vasodilation and thus increases coronary blood flow. In animal studies, CVT-3146 has been shown to increase coronary blood flow without adversely affecting peripheral blood pressure.

Statements in this press release concerning the development and potential application of CVT-3146 and other compounds are forward-looking statements that involve risks and uncertainties, including, but not limited to, uncertainties related to CVT's early stage of development and clinical trials. Actual results could differ materially. Factors that could cause or contribute to such differences are more fully discussed in CVT's Annual Report on Form 10-K for the year ended December 31, 1999.

CV Therapeutics, Inc., headquartered in Palo Alto, CA, is a biopharmaceutical company focused on applying molecular cardiology to the discovery, development and commercialization of novel, small molecule drugs for the treatment of cardiovascular diseases. CVT is currently conducting clinical trials for two of its products. Ranolazine, the first in a new class of compounds known as partial fatty acid oxidation (pFOX) inhibitors for the potential treatment of

angina, is in Phase III clinical trials. CVT-510, an $A_1$ adenosine receptor agonist, for the potential treatment of atrial arrhythmias, is in Phase II clinical trials. For more information, please visit CV Therapeutics' web site at www.cvt.com.

Fujisawa Healthcare, Inc., headquartered in Deerfield, IL, develops, manufactures, and markets proprietary pharmaceutical products in the United States and abroad. Fujisawa Healthcare, Inc. is a subsidiary of Fujisawa Pharmaceutical Co., Ltd., based in Osaka, Japan. Fujisawa Pharmaceutical Co., Ltd., founded in 1894, is a leading pharmaceutical manufacturer and has international operations in North America, Europe, and Asia. Additional information on Fujisawa Healthcare, Inc. and its products can be found on the Company's web site at www.fujisawa.com.

-end-

## SCHEDULE 13.4

## INSURANCE

### FHI'S INSURANCE OBLIGATIONS

A. FHI shall, at its sole cost and expense, obtain and keep in force during the Term and for a period of not less than **[ten (10)]** years after termination, cancellation or expiration of this Agreement the following insurance: (i) general liability insurance, including blanket contractual liability coverage, with bodily injury, death and property damage limits of **[U.S. $10,000,000 per occurrence and U.S $10,000,000 in the aggregate]**; (ii) clinical studies and product liability insurance with bodily injury, death and property damage limits of not less than **[U.S. $10,000,000 per occurrence and U.S. $10,000,000 in the aggregate]** (provided, however that with respect to such clinical studies liability insurance, FHI shall only be required to maintain such insurance for **[ten (10)]** years after completion of the last clinical study on the Licensed Compounds and Licensed Products conducted by FHI under this Agreement); and, (iii) workers' compensation insurance with limits to satisfy statutory requirements and employer's liability insurance with limits of **[U.S. $1,000,000 per occurrence].** FHI shall furnish to CVT upon within thirty (30) days after the Effective Date, and on annual renewals thereof, certificate(s) of insurance evidencing the insurance coverage required by this Agreement and providing for at least thirty (30) days' prior written notice to CVT of any cancellation, termination, material change or reduction of such coverage.

B. FHI shall use its commercially reasonable efforts to cause Third Parties engaged by FHI to perform services in connection with the Development Program and/or the commercial manufacturing and/or sale of the Licensed Compounds and/or Licensed Products to maintain such types of insurance coverages and for such period of time as are customary for such Third Party given the nature of the services to be provided.

### CVT'S INSURANCE OBLIGATIONS

A. CVT shall, at its sole cost and expense, obtain and keep in force until such time as the NDA is transferred to FHI as provided for in Section 7.1(a) of this Agreement and for a period of not less than **[ten (10)]** years thereafter the following insurance: (i) general liability insurance, including blanket contractual liability coverage, with bodily injury, death and property damage limits of **[U.S. $1,000,000 per occurrence and U.S. $2,000,000 in the aggregate];** (ii) overlying umbrella liability coverage with limits of **[U.S. $7,000,000 per occurrence and U.S. $7,000,000 in the aggregate]**; (iii) clinical studies and product liability insurance with bodily injury, death and property damage limits of not less than **[U.S. $10,000,000 per occurrence and U.S. $10,000,000 in the aggregate]** (provided, however that with respect to such clinical studies liability insurance, CVT shall only be required to maintain such insurance for **[ten (10)]** years after completion of the last clinical study on the Licensed Compounds and Licensed Products conducted by CVT under this Agreement); and, (iv) workers' compensation

insurance with limits to satisfy statutory requirements and employer's liability insurance with limits of U.S. **[$1,000,000 per occurrence].** CVT shall furnish to FHI upon within thirty (30) days after the Effective Date, and on annual renewals thereof, certificate(s) of insurance evidencing the insurance coverage required by this Agreement and providing for at least thirty (30) days' prior written notice to FHI of any cancellation, termination, material change or reduction of such insurance coverage.

B. In the event the licenses granted to FHI are converted to co-exclusive licenses with CVT under Section 4.4 or in the event there is a partial termination of this Agreement under Section 12.3 as to a particular indication for a Licensed Product, CVT shall, at its sole cost and expense, obtain and keep in force as of effective date such licenses become co-exclusive or of such partial termination (such effective date shall be referred to herein as **"CVT Insurance Effective Date"**) and until the termination, cancellation or expiration of this Agreement and for a period of not less than **[ten (10)]** years thereafter the following insurance: (i) general liability insurance, including blanket contractual liability coverage, with bodily injury, death and property damage limits of **[U.S. $1,000,000 per occurrence and U.S. $2,000,000 in the aggregate]**; (ii) overlying umbrella liability coverage with limits of **[U.S. $7,000,000 per occurrence and U.S. $7,000,000 in the aggregate]**; (iii) clinical studies and product liability insurance with bodily injury, death and property damage limits of not less than **[U.S. $10,000,000 per occurrence and U.S. $10,000,000 in the aggregate]** (provided, however that with respect to such clinical studies liability insurance, CVT shall only be required to maintain such insurance for **[ten (10)]** years after completion of the last clinical study on the Licensed Compounds and Licensed Products conducted by CVT under this Agreement); and, (iv) workers' compensation insurance with limits to satisfy statutory requirements and employer's liability insurance with limits of U.S. **[$1,000,000 per occurrence].** CVT shall furnish to FHI upon within thirty (30) days after the CVT Insurance Effective Date, and on annual renewals thereof, certificate(s) of insurance evidencing the insurance coverage required by this Agreement and providing for at least thirty (30) days' prior written notice to FHI of any cancellation, termination, material change or reduction of such insurance coverage.

C. CVT shall use its commercially reasonable efforts to cause Third Parties engaged by CVT to perform services in connection with the Development Program and/or if applicable, the commercial manufacturing and/or sale of the Licensed Compounds and/or Licensed Products to maintain such types of insurance coverages and for such period of time as are customary for such Third Party given the nature of the services to be provided.