Theralase® - Ferring Clinical Study Agreement

Ferring Agreement Number	BD-4480

Ferring Pharmaceuticals Inc. having a place of business at 100 Interpace Parkway, Parsippany, New Jersey, 07054, United States ("**Ferring**") and **Theralase® Technologies Inc.** having a place of business at 41 Hollinger Road, Toronto, Ontario, Canada, M4B 3G4 ("**Theralase®**") do hereby enter into this Theralase® - Ferring Clinical Study Agreement ("**Agreement**") effective as of the date signed by the last Party ("**Effective Date**").

Ferring and Theralase® are sometimes referred to in this Agreement individually as the "**Party**" or collectively as the "**Parties**".

Overview:

1) Ferring and Theralase® wish to enter into an Agreement to appoint Theralase® the sponsor of record ("**Sponsor**") for a Phase II, single arm, open label clinical study ("**Study**").

2) The Study will be conducted on a patient population diagnosed with Bacillus-Calmette-Guérin ("**BCG**")-Unresponsive Non-Muscle Invasive Bladder Cancer ("**NMIBC**") Carcinoma In-Situ ("**CIS**") (with or without resected papillary disease (Ta, T1)) (collectively, the "**Condition**").

3) The Study procedure, as mutually agreed by the Parties and as amended by the Parties from time-to-time ("**Study Procedure**") will consist of treating patients with Theralase®'s small molecule ("**Ruvidar®**"), light-activated with the TLC-3200 Medical Laser System ("**TLC-3200**"), in combination with Ferring's non-replicating adenovirus vector, which delivers the interferon-alfa 2b gene ("**nadofaragene firadenovec**" or "**Adstiladrin®**"). The Study will be conducted in compliance with the clinical protocol summary ("**Clinical Protocol**"), with an overview of the Clinical Protocol summary set forth in Appendix A.

4) The Study will take place initially in the United States and then subject to written agreement by the Parties in Canada or any other country designated by the Joint Development Committee ("**JDC**").

5) Theralase® will supply Ruvidar® and the TLC-3200 for the Study directly to CSSs (as defined below) at no additional cost. Ferring will supply Adstiladrin® for the Study directly to CSSs at no additional cost, per Appendix B.

6) **Redacted:** Commercially sensitive information.

Ferring and Theralase® desire to enter into this Agreement for the performance of the Study in accordance with the Clinical Protocol, Applicable Law and in accordance with the terms of this Agreement.

In consideration of the foregoing premises and the mutual promises and covenants contained herein, the Parties hereby agree as follows:

Article 1: Definitions

The terms in this Agreement, with initial letters capitalized, whether used in the singular or the plural, shall have the meaning set forth below or, if not listed below, the meaning designated in places throughout this Agreement.

1) **Adverse Event** ("**AE**"), **Serious Adverse Event** ("**SAE**") and **Serious Adverse Drug Reaction** ("**SADR**") shall have the meanings provided to such terms in the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use ("**ICH**") guideline for industry on Clinical Safety Data Management (E2A, Definitions and Standards for Expedited Reporting).

2) **Affiliates** means, with respect to a particular Party, an entity that, directly or indirectly, through one or more intermediaries, controls, is controlled by or is under common control with such Party, only for so long as such control exists. As used in this definition, the term "**controls**" (with correlative meanings for the terms "**controlled by**" or "**under common control with**") means:
   a) that an entity or company owns, directly or indirectly, more than fifty percent (50%) of the voting stock of another entity; or
   b) that an entity, person or group otherwise has the actual ability to control and direct the management of the entity, whether by contract or otherwise.

3) **Agreement** shall have the meaning set forth in the preamble to this Agreement, and includes the Appendices attached hereto and any and all amendments of any of the foregoing; hereafter, duly signed by the Parties with reference to this Agreement and made part hereof.

4) **Alliance Manager** ("**AM**") means the Personnel designated by each of the Parties pursuant to Section 2.2(c). The AMs shall serve as the primary point of contact for preparing agendas, presenting any issues arising under this Agreement or Study, recording meeting minutes, documenting resolution of the open, pending and closed issues, endeavoring to ensure clear and responsive communication and the effective exchange of information between the Parties.

5) **Applicable Law** means all applicable laws, rules and regulations (whether federal, state or local) that may be in effect from time to time; including applicable GCP, GLP and GMP guidelines.

6) **Arbitration Matter** means any Disputed matter that relates to or arises out of the validity, interpretation or construction of, or the compliance with or breach of, this Agreement; provided that such Disputed matter has been considered, but not resolved, by the respective Study Executive Managers as set forth in Section 13.3. For clarity, no Publication Dispute, or any matter requiring mutual agreement of both Parties, shall be considered an Arbitration Matter.

7) **Background Intellectual Property** means Intellectual Property, and any improvements or variations thereof, owned or otherwise Controlled by a Party that is in existence on or before the Effective Date or arises otherwise after the Effective Date from activities not conducted pursuant to this Agreement.

8) **Breaching Party** shall have the meaning set forth in Section 12.2(a).

9) **Business Day** means a day other than a Saturday, Sunday, statutory holiday or any day on which commercial banks located in New York, New York or Toronto, Ontario, Canada are authorized or obligated by Applicable Law to close.

10) **Case Report Form** ("**CRF**") means a paper or electronic questionnaire, used in clinical research to collect specific data from Study patients, as defined by the Clinical Protocol. CRFs are essential for ensuring complete and accurate data collection to assess the safety and effectiveness of a medical intervention, with electronic CRFs ("**eCRFs**") being the modern, preferred method for their accuracy and immediate use in digital databases.

11) **Certificate Of Analysis** ("**COA**") means a formal document prepared by a laboratory that confirms a product's quality and composition by detailing the results of quality tests.

12) **Clinical Hold** means that:
   a) the FDA has issued an order or direction to a Party pursuant to 21 CFR § 312.42 to delay a proposed clinical investigation or to suspend an ongoing clinical investigation of a clinical study in the United States; or
   b) a Regulatory Authority other than the FDA, such as Health Canada under Part C, Division 5 of the *Food and Drug Regulations*, has issued an equivalent order to that set forth in (a) in any other country or group of countries.

13) **Clinical Protocol** shall have the meaning set forth in the Overview.

14) **Clinical Research Agreement** ("**CRA**") means an agreement executed between Theralase®, the applicable principal investigator ("**PI**") and the applicable CSS to conduct a Study.

15) **Clinical Research Organization** ("**CRO**") means any Third Party contract research organization used to conduct preclinical or clinical research, laboratory testing, Samples analysis, pathology analysis, biostatistical analysis, or regulatory support or provide electronic data capture ("**EDC**") services for a clinical study; for clarity, CROs exclude CSSs.

16) **Clinical Study Report** ("**CSR**") means a document that details the data and outcomes of a clinical study, providing information on the Study's conduct, patient data and analysis.

17) **Clinical Study Site** ("**CSS**") means a clinical organization that conducts clinical research led by a PI and their associated clinical research team.

18) **Combined Therapy** means a Study Procedure that administers Ruvidar® and Adstiladrin® in concomitant or sequential combination according to the Clinical Protocol.

19) **Commercially Reasonable Efforts** ("**CRE**") means, with respect to a Party, the level of effort and resources normally devoted by such Party to conduct a clinical study for a biopharmaceutical product or compound that is owned by it or to which it has rights to and which is similar to the biopharmaceutical product or compound, as applicable, such Party supplies for the Study hereunder.

20) **Condition** shall have the meaning set forth in the Overview.

21) **Confidential Information** of a Party means any and all information of a Party and/or any of its Affiliates ("**Disclosing Party**") which has or will come into the possession or knowledge of the other Party and/or any of its Affiliates ("**Receiving Party**") in connection with or as a result of entering into this Agreement; including information concerning the Disclosing Party's past, present and future customers, suppliers, technology, markets, research and business. For the purposes of this definition, "**Confidential Information**" includes any and all: IP, licensed IP,

product, commercial, research, scientific, customer, or market information, analyses or conclusions drawn or derived therefrom, this Agreement and information developed or disclosed hereunder or any Party's raw materials, processes, formulations, analytical procedures, methodologies, products, samples, specimens, functions, know-how, data, patents, copyrights, trade secrets, processes, techniques, programs, designs, formulae, marketing, advertising, financial, commercial, sales or programming materials, written materials, compositions, drawings, diagrams, hardware, firmware, software, computer programs, studies, work in progress, visual demonstrations, ideas, concepts, and other data, in oral, written, graphic, electronic, or any other form or medium whatsoever.

22) **Control** or **Controlled** means, with respect to particular information or IP, that the applicable Party owns or has a license or right to and has the ability to grant a right, license or sublicense to without violating the terms of any agreement or other arrangement with any Third Party; provided that no Party or Affiliate shall be deemed to Control any Patent Rights or information of a Third Party invented or otherwise arising following the Effective Date if access by the other Party requires or triggers a payment obligation, unless the other Party agrees to bear such payment obligation.

23) **Cover**, **Covered** or **Covering** means, with respect to a given product (or component thereof) or process and a Patent Right, that a claim of such Patent Right would, absent a license thereunder or ownership thereof, be infringed by the making, having made, use, sale, offer for sale or importation of such product, component, process or product-by-process, and, for purposes of determining such infringement, considering claims of pending patent applications as if they have already been issued.

24) **Cure Period** shall have the meaning set forth in Section 12.2(a).

25) **Data Protection Terms** shall have the meaning defined in Appendix D.

26) **Designated Supply Contact** shall have the meaning set forth in Section 4.5.

27) **Data Safety Monitoring Board** ("**DSMB**") means an independent group of experts who oversee the safety and effectiveness Study Data during a clinical study. The DSMB reviews cumulative data to advise on whether the applicable study should continue, be modified or be stopped early due to safety concerns or if the research question has already been answered.

28) **Development Safety Update Report** ("**DSUR**") means a common standard for periodic reporting on drugs under development (including marketed drugs that are under further study).

29) **Dispute** shall have the meaning set forth in Section 13.3(b).

30) **Effective Date** shall have the meaning set forth in the preamble to this Agreement.

31) **Eligible Costs** shall have the meaning set forth in Section 7.2.

32) **Filing Party** shall have the meaning set forth in Section 6.3.

33) **Food and Drug Administration** ("**FDA**") means the United States Food and Drug Administration or any successor agency having the same or similar authority.

34) **Global Safety Database** means the database containing AEs, SAEs, SADRs and pregnancy reports for the Study. The Global Safety Database shall be the authoritative data source for regulatory reporting and responding to regulatory queries with respect to the Study.

35) **Good Clinical Practices** ("**GCP**") means international ethical and scientific quality standards for designing, conducting and reporting clinical studies involving human subjects. Key principles include obtaining informed consent, having scientifically sound protocols and maintaining quality systems and records.

36) **Good Laboratory Practices** ("**GLP**") means a quality system for ensuring the reliability and integrity of non-clinical safety studies through proper organization, standardized procedures and meticulous documentation. Key components include maintaining suitable facilities and calibrated equipment, following detailed Standard Operating Procedures ("**SOPs**"), having clear study protocols and accurate record-keeping, ensuring Personnel are properly trained and performing quality assurance checks.

37) **Good Manufacturing Practices** ("**GMP**") means a set of regulations that ensure products are consistently produced, manufactured and controlled to quality standards. Key components include well-designed facilities, qualified and trained Personnel, detailed procedures, clean and well-maintained equipment, thorough record-keeping and a robust quality control system.

38) **Indemnify** shall have the meaning set forth in Section 11.1.

39) **Indemnifying Party** shall have the meaning set forth in Section 11.1.

40) **Indemnitees** shall have the meaning set forth in Section 11.1.

41) **Individual Case Safety Report** ("**ICSR**") means a standardized document that captures information about an AE, SAE or SADR related to a medical product, such as a drug or vaccine, experienced by a single patient.

42) **Informed Consent Form** ("**ICF**") is a document signed by a patient that signifies that they are participating in a clinical study of their own free will, allowing them to be legally enrolled and participate in the Study.

43) **Infringe** and **Infringement** means any actual, alleged or threatened (in writing) infringement or misappropriation by a Third Party of any Patent Rights.

44) **Intellectual Property** ("**IP**") means Inventions (whether patentable or not), Patent Rights, discoveries, written material, drugs, drug formulations, compounds, information, know-how, trade secrets, copyright, designs, hardware, firmware, software, ideas, formulae, algorithms, concepts, proprietary data, techniques, instructions, processes, expert opinions, information, materials, program listings, flow charts, logic diagrams, manuals, specifications, instructions, or any copies of the foregoing in any medium, or the expression thereof.

45) **Intellectual Property Rights** ("**IP Rights**") means any rights in IP which a Party owns, or is seeking to own, or otherwise Controls; including any regular or provisional patent applications filed in the U.S., Canada or any other jurisdiction, divisions, continuations, patents issuing thereon or renewals or reissues and any and all patents and patent applications in other countries corresponding thereto in respect of IP.

46) **Invention** means any IP conceived and reduced to practice in the conduct of the Agreement that may form the subject matter of a Patent Right after the Effective Date.

47) **Investigational New Drug Application** ("**IND**") means:
   a) an Investigational New Drug Application as defined in the United States Food, Drug, and Cosmetic Act, as amended, and regulations promulgated thereunder, or any successor application or procedure required to initiate clinical testing of a drug in humans in the United States;
   b) a counterpart of such Investigational New Drug Application that is required in any other country before beginning clinical testing of a drug in humans in such country, including, for clarity, a Clinical Trial Application ("**CTA**") in Canada or the European Union; and
   c) all supplements and amendments to any of the foregoing.

48) **Investigator's Brochure** ("**IB**") means a document that provides a comprehensive summary of clinical and nonclinical data on an investigational product (drug or device) for use in human clinical studies. Its purpose is to inform PIs about the product's properties, risks and expected side effects so they can conduct a study safely and effectively.

49) **Investigational Review Board** ("**IRB**") means an Institutional Review Board, Review Ethics Board, Ethics Committee or similar body in a given country.

50) **Joint Development Committee** ("**JDC**") means the committee established by the Parties pursuant to Section 2.2.

51) **Joint Intellectual Property** shall have the meaning set forth in Section 6.3.

52) **Joint Patent Rights** shall have the meaning set forth in Section 6.3.

53) **Licensee** shall have the meaning set forth in Section 13.10(b).

54) **Losses** shall have the meaning set forth in Section 11.1.

55) **Manufacture** means manufacturing, processing, formulating, packaging, labeling, holding (including storage) and quality control testing of a Study Drug suitable for use in the Study, under Applicable Law.

56) **Material Safety Issue** means a Party's good faith belief that there is an unacceptable safety risk for humans based upon:
   a) pre-clinical safety data; including, data from animal toxicology studies; or
   b) the observation of new or unknown SAEs or SADRs in humans after the administration of Ruvidar® or Adstiladrin® or the combination or timing of administration thereof.

57) **New Drug Application** ("**NDA**") means:
   a) any new drug application or biologics license application filed with the FDA or any successor application or procedure required to introduce a drug or biologic into commerce in the United States;
   b) a counterpart of such a new drug application or biologics license application that is required in any other country before beginning the commercialization of a drug or a biologic in humans in such country; and
   c) all supplements and amendments to any of the foregoing.

58) **Non-Breaching Party** shall have the meaning set forth in Section 12.2(a).

59) **Officials** shall have the meaning set forth in Section 10.9.

60) **Operational Matters** shall have the meaning set forth in Section 5.1.

61) **Party** or **Parties** shall have the meaning set forth in the preamble to this Agreement.

62) **Patent Rights** means:
   a) United States or foreign patents;
   b) United States or foreign patent applications; including, all provisional applications, substitutions, continuations, continuations-in-part, divisions, renewals and all patents granted thereon;
   c) United States or foreign patents-of-addition, reissues, reexaminations (including *ex parte* reexaminations, *inter partes* reviews, *inter partes* reexaminations, post grant reviews and supplemental examinations) and extensions or restorations by existing or future extension or restoration mechanisms; including, supplementary protection certificates, patent term extensions or the equivalents thereof; and
   d) any other form of government-issued right substantially similar to any of the foregoing.

63) **Payment** shall have the meaning set forth in Section 10.9.

64) **Person** means any individual, sole proprietorship, partnership, limited partnership, limited liability partnership, corporation, limited liability company, business trust, joint stock company, trust, unincorporated association, joint venture or other similar entity or organization; including, a government or political subdivision, department or agency of a government.

65) **Personnel** means the employees, directors, officers, or Third Party consultants of a Party.

66) **Personal Data** means any information relating to an identified or identifiable natural person.

67) **POTV** shall have the meaning set forth in Section 9.6(a).

68) **Publication Dispute** shall have the meaning set forth in Section 9.4(b).

69) **Quarter** means a calendar quarter; specifically, a quarter ending: March 31st, June 30th, September 30th or December 31st.

70) **Regulatory Authority** means the FDA or any other governmental authority outside the United States, whether supranational, international, national, federal, provincial and/or local, that is the counterpart to the FDA.

71) **Regulatory Documentation** means, with respect to the Study, submissions to a Regulatory Authority in connection with the regulatory approval of the Study; including, INDs and amendments thereto, NDAs and amendments thereto, drug master file ("**DMF**"), TMF, eTMF, correspondence with Regulatory Authorities, periodic safety update reports, AE, SAE, SADR files, complaint files, inspection reports and manufacturing records, in each case together with all supporting documents (including documents that include clinical data).

72) **Results** shall have the meaning set forth in Section 9.4(b).

73) **Right of Cross-Reference** means, with regard to a Party, allowing the applicable Regulatory Authority in a country to have access to relevant information (by cross-reference, incorporation by reference or otherwise) contained in Regulatory Documentation (and any data contained therein) filed with such Regulatory Authority with respect to a pharmaceutical compound and the right to cross reference the Study only to the extent necessary for the conduct of the Study in such country or as otherwise expressly permitted or required under this Agreement to enable a Party to exercise its rights or perform its obligations hereunder.

74) **Safety Issue** means any information suggesting an emerging safety concern or possible change in the risk-benefit balance for a pharmaceutical drug; including, information on a possible causal relationship between an AE, SAE or SADR and a pharmaceutical drug, the relationship being unknown or incompletely documented previously.

75) **Safety Signal** means information arising from one or multiple sources; including, observations and experiments, which suggests a new potentially causal association, or a new aspect of a known association between an intervention and an event or set of related events, either adverse or beneficial, that is judged to be of sufficient likelihood to justify verificatory action.

76) **Samples** means biological specimens collected from Study patients (including fresh and/or archived tumor samples, urine, serum, peripheral blood mononuclear cells, plasma and/or whole blood for RNA and DNA sample isolation).

77) **Shortage** shall have the meaning set forth in Section 4.1.

78) **Statistical Analysis Plan** ("**SAP**") means a document that outlines the statistical methods the Study will use to analyze data to answer research questions. Key components include the Study's hypotheses, data collection methods, variables, the specific statistical tests to be used, how data will be cleaned and handled, especially for missing data.

79) **Study** shall have the meaning set forth in the Overview.

80) **Study Completion** means: (a) the date when the last patient enrolled in the Study has completed such patient's last study-related assessment for evaluation, excluding survival follow-up; or (b) an alternative date as agreed to by the JDC in writing.

81) **Study Data** shall have the meaning set forth in Section 8.1.

82) **Study Drug** means Ruvidar® for Theralase® (not currently FDA approved) and Adstiladrin® for Ferring (FDA approved).

83) **Study Executive Manager** ("**SEM**") means the senior executive designated from each of the Parties responsible for final decisions concerning the respective party's Study Drugs, Clinical Protocol and Study amendments.

84) **Subsequent Study** means an additional clinical study(ies) between the Parties that utilize Adstiladrin®, Ruvidar®, Rutherrin®, TLC-3200, X-ray activation, or a combination thereof, for this Condition or other conditions.

85) **Sunshine Laws** shall have the meaning set forth in Section 9.5(c).

86) **Supply and Quality Documentation** shall have the meaning set forth in Section 4.3(a).

87) **Technology** means drugs and drug formulations, information, inventions, discoveries, trade secrets, knowledge, methods, processes, practices, formulae, instructions, skills, techniques, procedures, experiences, ideas, technological advances, designs, drawings, assembly procedures, hardware, firmware, software, computer programs, specifications, data and Results not generally known to the public (including: biological, chemical, pharmacological, toxicological, pharmaceutical, physical and analytical, pre-clinical, clinical, safety, efficacy, manufacturing and quality control data and know-how; including, study designs and protocols), in all cases, whether or not patentable, in written, electronic or any other form now known or hereafter developed and materials, including Regulatory Documentation.

88) **Term** shall have the meaning set forth in Section 12.1.

89) **Territory** is defined in Appendix C.

90) **Third Party** means any Person or entity other than the Parties and their respective Affiliates.

91) **Third Party Claim** shall have the meaning set forth in Section 11.1.

92) **Third Party License Payments** means any payments (e.g.: upfront payments, milestones, royalties) due to any Third Party under license agreements or other written agreements granting rights to IP owned or otherwise Controlled by such Third Party to the extent that such rights are necessary for:
   a) the making, using or importing of a Party's Study Drug for the conduct of the Study; or
   b) the conduct of the Study.

93) **TLC-3200** shall have the meaning set forth in the Overview.

94) **Trial Master File** ("**TMF**") means a centralized collection of essential documents that supports that a clinical study was conducted in accordance with regulatory requirements, such as GCP. These documents are maintained by the Sponsor, PI and CSS, covering the Study's entire lifecycle from initiation to completion and used for demonstrating compliance and data integrity during regulatory inspections and audits. The TMF can be paper based, entirely electronic ("**eTMF**") or a combination of both.

Article 2: Study Scope, Management and Reporting

2.1 Scope. Pursuant to and in accordance with the Study Procedure:

a) Theralase®, as Sponsor in the Territory, will conduct the Study in accordance with the Clinical Protocol, GCP guidelines and the terms of this Agreement.

b) Theralase® and Ferring through the JDC shall discuss and agree upon any proposed amendments to the Clinical Protocol or Study prior to Theralase®'s submission to any regulatory organizations or respective IRBs for review.

c) Theralase® shall be the sole holder of all legal interests in the Study IND application.

d) Ferring will provide Adstiladrin® in sufficient quantities (up to 4 quarterly instillations per year for the duration of treatment, of Adstiladrin supply for each patient enrolled into the Study, as specified in the Clinical Protocol) to complete the Study at no additional charge and instructions for the safe and effective administration of it (i.e.: the current package insert), along with any updates that are available.

e) Theralase® will provide Ruvidar® in sufficient quantities to complete the Study at no additional charge and instructions for the safe and effective administration of it, along with any updates that are available.

f) Ferring will supply the current version of the Adstiladrin® IB for use by PIs in the conduct of the Study and any IB amendments, as available. The PIs will maintain confidentiality of the IB in accordance with their CRA and as set forth in Article 5.1.

g) Theralase® will supply the current version of the Ruvidar® IB for use by PIs in the conduct of the Study and any IB amendments, as available. The PIs will maintain confidentiality of the IB in accordance with their CRA and as set forth in Article 5.1.

h) If required, Ferring shall provide a Right of Cross-Reference to its existing Regulatory Documentation for Adstiladrin® for the Territory where the Study will be conducted solely as necessary to allow the Study to be conducted under the Study IND; provided, however, that Theralase® may not grant any Third Party any Right of Cross-Reference (or other license rights thereto) with respect to any portion of the Study IND pertaining to Adstiladrin® for use as monotherapy or for use in combination with any molecules, agents, antibodies or compounds other than Ruvidar®; and provided, further, that such Right of Cross-Reference shall terminate upon the expiration or termination of this Agreement and shall not be used for purposes of conducting any other clinical studies, except that, in the case of termination for a Material Safety Issue pursuant to Section 12.4, such Right of Cross-Reference shall remain in effect solely:
    i) to the extent necessary to permit Theralase® to comply with any outstanding obligations required by a Regulatory Authority and/or Applicable Law; or
    ii) as necessary to permit Theralase® to continue to dose patients enrolled in the Study through completion of the Clinical Protocol, as required, by the applicable Regulatory Authority and/or Applicable Law.

i) Theralase® shall refer to the applicable Ferring Study identification number in all Study reports, reports of SAEs, Adstiladrin® requests and other material submissions or communications with Ferring related to the Clinical Protocol.

j) Subject to Section 5.2(e), each Party shall:
   i) Use CRE and contribute such resources as are necessary to conduct the activities contemplated by this Agreement; and
   ii) Act in good faith in performing its obligations under this Agreement and each Related Agreement to which it is a Party.

k) Promptly following execution of this Agreement, the Parties shall enter into a safety data exchange agreement upon customary terms and conditions.

2.2 Management

a) The Parties agree to form a JDC, comprised of three (3) representatives each from the Parties.

b) The JDC shall be responsible for reviewing and approving: regulatory submissions, Clinical Protocol amendments, Study Data, clinical safety and efficacy reviews, publications and publication strategy, and other related activities or documentation of the Study, pursuant to this Agreement, except for activities under, and pursuant to, Article 6 (Intellectual Property).

c) Each Party shall designate an AM (as defined in Article 1) who shall be responsible collectively to undertake the following recommended activities as agreed to by the Parties:
   i) Prepare and distribute an agenda and any required support materials to each JDC member to review reasonably in advance of the Quarterly meeting;
   ii) Coordinate activities and facilitate the exchange of information between the Parties with respect to the Study; and
   iii) Summarize and present in executive format the latest Study Data, which, by way of example, may include:
      A) CSS status (launch, enrolling, termination)
      B) Enrolled and planned patient enrollment by CSS
      C) Quarterly safety and efficacy data
      D) AE, SAE and SADR reports
      E) DSMB reports
      F) Deviations and waivers from the Clinical Protocol
      G) Recommended amendments to the Clinical Protocol
      H) Study Drug(s) supply issues
      I) Clinical, regulatory or communication issues regarding the Study
      J) Open, closed and pending Study issues
      K) Other related information
      iv) Record meeting minutes for subsequent distribution to all JDC members
      v) Present any other topics or issues relating to the Study

d) The JDC shall meet a minimum four (4) times per year, Quarterly, with the Parties agreeing to the timing of the meetings during the first meeting of the JDC. The JDC may meet in person or by means of teleconference, internet conference, videoconference or similar means.

e) In the case of an AE, SAE or SADR which requires discussion amongst the JDC members, any JDC member can request their respective AM to schedule an ad hoc JDC meeting for discussion of the matter, and as required, along with supporting documentation of a review from the

independent Data Safety Monitoring Board ("**DSMB**"). Reporting requirements are outlined under Section 2.3 below of the contract.

f) Quorum of the meeting shall be at least 2 out of 3 members from each Party for a duly constituted meeting.

g) In the event that the JDC does not mutually agree on a material issue raised during the JDC meeting, and, after good faith efforts, fails to reach consensus, then the issue and any required supporting materials shall be elevated to the Study Executive Manager ("**SEM**") for each Party for discussion and resolution. In the event such escalation to the SEMs does not result in resolution or consensus, the respective SEMs will elicit the help of an agreed upon Third Party organization (expert versed in the specific field that pertains to the material issue) to assist the SEMs in resolving the matter (such Third Party organization, the "**Mediator**"). Notwithstanding anything to the contrary contained herein, no Party or any Mediator shall have the right to finally resolve a dispute pursuant to this Section without agreement of the other Party in a manner that would (i) adopt or effect any amendment of the Study Procedure (which must be mutually approved by both Parties), (ii) impose any obligations on such other Party beyond those for which such other Party is responsible under this Agreement or the then-current Study Procedure, (iii) diminish such other Party's rights under this Agreement or (iv) increase such other Party's financial obligations under the Study Procedure.

2.3 Reporting

a) Theralase®, as the Sponsor of the Study, will manage all Study Drug safety reporting activities for the Study.

b) Theralase® will notify Ferring of any SAEs, SADRs, reports of exposure during pregnancy (maternal or paternal) or reports of suspected transmission of an infectious agent according to the Clinical Protocol, within twenty four (24) hours of being made aware of it by the CSSs via Theralase®'s standard SAE reporting form (or equivalent) delivered by fax or e-mail to the Ferring AM and to Ferring's Medical Information Call Center ("**MICC**") by contacting the Ferring SAE Reporting Contact identified below:

SAE/DSUR Review (Theralase)	**Independent Data Monitoring & Safety Board**
Ferring — AE Reporting Contact:	**Redacted:** Commercially sensitive information.
E-mail:	
MICC Phone:	

c) Each Party shall not collect, use or disclose Personal Data obtained in the course of performing the pharmacovigilance activities under this Section 2.3, but if required will only use the Personal Data to the extent required for purposes of complying with the regulatory obligations as described in this Agreement, the Clinical Protocol, Applicable Law or by court order. Both Parties will use electronic, physical and other safeguards appropriate to the nature of the information to prevent any use or disclosure of Personal Data, other than as provided for by this Agreement and permitted under the ICF. The Parties will also take reasonable precautions to protect such Personal Data from accidental, unauthorized or unlawful alteration or destruction. Each Party will notify the other Party promptly of any accidental, unauthorized or unlawful destruction, loss, alteration, disclosure of or access of such Personal Data.

d) Theralase® will promptly make available to Ferring, through the AM, upon request, such redacted records that Theralase® controls, as is necessary, or useful to perform medical assessment of any AE, SAE or SADR associated with the use of Adstiladrin® or Ruvidar® reported during the Study.

e) Theralase® shall perform case level reconciliation to confirm that Ferring has received all reports required under this Agreement. The collective AMs shall communicate Quarterly to compile a reconciliation report of patients who have received the Study Procedure and those contained in the Study database and to provide any missing documentation.

f) As Sponsor, Theralase® will be responsible for submitting annual aggregate report submissions to Regulatory Authorities for the Study; provided that Theralase® has previously provided such draft report submissions to Ferring reasonably in advance for its comments, which comments shall be reasonably incorporated, and Theralase® will provide Ferring with the final version of any aggregate report at the time of submission. Theralase® will also submit appropriate safety letters or safety reports to PIs, IRB and authorized Regulatory Authorities in accordance with Applicable Law.

g) In the event that Ferring produces any DSUR in respect to Adstiladrin®, Ferring will provide Theralase® copies of the executive summary and any line listings of SADRs extracted from the final DSUR for information purposes to assist Theralase® in generation of their own clinical study aggregate report. Theralase® agrees not to forward such Ferring DSUR information to any Third Party, except to its Affiliates, consultants, advisors and contractors, under obligations of confidentiality for generation of a clinical study aggregate report or as otherwise permitted with respect to Ferring Confidential Information under Article 9.

h) If Theralase® determines there is a significant Safety Issue or significant Safety Signal arising in a clinical study that may be associated with Adstiladrin®, Ruvidar® or the combination thereof, Theralase® will disclose such information to Ferring promptly after such determination.

i) Ferring will notify Theralase® of any significant Safety Issues or significant Safety Signal relating to Adstiladrin® promptly after such determination by Ferring.

j) Promptly following Study Completion, Theralase® shall provide to Ferring an electronic draft of the top-line results memorandum and an electronic draft of the final report of the results of the Study. Ferring shall have fifteen (15) days after receipt of such results memorandum and thirty (30) days after receipt of such final report to provide comments thereon. Theralase® shall consider any comments provided by Ferring on either document and shall not include any statements in either document relating to the Ferring Study Drug or the Ferring Study Data that have not been approved by Ferring. Theralase® shall deliver to Ferring a final version of each such document promptly following finalization thereof.

2.4 Conduct

a) Subject to the Study Procedure and the terms of this Agreement (including Section 5.2(e)), each Party shall use CRE on a timely basis to:

i) Perform and fulfill its respective activities for the Study, Clinical Protocol and Agreement in an effective manner consistent with prevailing standards;

ii) Supply the quantities of its Study Drug in accordance with Article 4, as required, to conduct the Study;
iii) Conduct and pursue completion of the Study in accordance with the Clinical Protocol, Agreement and Third-Party agreements;
iv) Provide sufficient resources, funding and Personnel to conduct and perform the Study; and
v) Perform its duties for the Study in accordance with Applicable Law; including, the applicable standards of GCP, GLP and GMP.

Article 3: License Grants

3.1 Grant by Ferring

Subject to the terms of this Agreement, Ferring hereby grants, and shall cause its Affiliates to grant, to Theralase® a worldwide, non-exclusive, non-transferable, royalty-free license (with the right to sublicense solely pursuant to the terms of and subject to the limitations of Section 3.3) under the Intellectual Property and Technology that is Controlled by Ferring to use Adstiladrin® solely to the extent necessary to discharge Theralase®'s obligations under this Agreement with respect to the conduct of the Study in the Territory.

3.2 Grant by Theralase®

Subject to the terms of this Agreement, Theralase® hereby grants, and shall cause its Affiliates to grant, to Ferring a worldwide, non-exclusive, non-transferable, royalty-free license (with the right to sublicense solely pursuant to the terms of and subject to the limitations of Section 3.3) under the Intellectual Property and Technology that is Controlled by Theralase® to use Ruvidar® and the TLC-3200 solely to the extent necessary to discharge Ferring's obligations under this Agreement with respect to the conduct of the Study in the Territory.

3.3 Sublicensing

a) Subject to the terms and conditions of this Agreement, each Party shall have the right to grant sublicenses or covenants not to sue under the licenses granted to it under Section 3.1, Section 3.2 or Section 3.4, as applicable, to Affiliates and to Third Parties, for an Affiliate or a Third Party to perform its duties with respect to the conduct of the Study and to assist such Party in carrying out its responsibilities with respect to the Study.

b) With regard to any such sublicenses permitted and made under this Agreement:

i) the sublicensees, except Affiliates, shall be subject to written agreements that bind such sublicensees to obligations that are consistent with a Party's obligations under this Agreement; including, confidentiality and non-use provisions no less restrictive than those set forth in herein and provisions regarding IP that ensure that the Parties will have the rights provided under this Agreement to any IP related to their Study Drug and/or the Combined Therapy created by such sublicensee;
ii) each Party shall provide written notice to the other Party of any such sublicense or proposed covenant not to sue (and obtain approval for sublicenses or covenant not to sue to Third Parties other than CSSs, such approval to not be unreasonably conditioned, withheld, or delayed); and

iii) the licensing Party shall remain liable to the other Party for all actions of the sublicensing Party's sublicensees.

3.4 Mutual Freedom to Operate

Subject to the terms of this Agreement, Theralase® hereby grants to Ferring a worldwide, non-exclusive, non-transferable, royalty-free, fully paid-up, irrevocable, perpetual license (with the right to sublicense solely pursuant to the terms of and subject to the limitations of Section 3.3) to **Theralase®**'s Background Intellectual Property solely for the purposes of using, selling, offering for sale or importing Ferring's Study Drug (including components thereof).

Subject to the terms of this Agreement, Ferring hereby grants to Theralase® a worldwide, non-exclusive, non-transferable, royalty-free, fully paid-up, irrevocable, perpetual license (with the right to sublicense solely pursuant to the terms of and subject to the limitations of Section 3.3) to Ferring's Background Intellectual Property solely for the purposes of using, selling, offering for sale or importing Theralase®'s Study Drug (including components thereof).

3.5 No Implied Licenses

Unless and except as specifically set forth in this Agreement, neither Party shall acquire any license or other IP interest, by implication or otherwise, in any IP of the other Party; including, Confidential Information disclosed to it under this Agreement or under any Patent Rights Controlled by the other Party or its Affiliates.

Article 4: Study Drug Manufacture and Supply

4.1 Study Drug Manufacture and Supply

Subject to the Study Procedure and the terms of this Agreement (including Section 5.2(e)), the Parties shall be responsible, at their sole cost and expense for:

a) Manufacturing, packaging and labelling (or having Manufactured, packaged or labelled) GMP-grade quantities of their Study Drug sufficient to support the Study.

b) Payment of any Third-Party License Payments that may be due based on the Manufacture, supply or use of their Study Drug.

c) Obtaining any other drug required for the use of their Study Drug in the Study.

d) Shipping their Study Drug to the CSSs, on a timely basis.

e) Delivering COAs and any other documents specified in the Supply and Quality Documentation; including, documentation necessary to allow the Parties to compare the Study Drug COA to the Study Drug specifications.

f) Maintaining Regulatory compliance of the quality of the Study Drug at the time the Study Drug is delivered to the CSSs.

g) Subject to Section 4.4, cooperating in accordance with Applicable Law to minimize indirect taxes (such as value added tax, sales tax, consumption tax and other similar taxes) related to the Study Drug in connection with this Agreement.

h) Prompt notice of any Manufacturing and supply issues with respect to their Study Drug or any defects or Manufacturing problems identified with respect to their Study Drug supplied to the CSSs that may adversely impact the conduct or timelines of the Study. In the event of a supply interruption or shortage of their Study Drug, as determined by internal processes and policies ("**Shortage**"), such that the responsible Party reasonably believes that they will not be able to fulfill their supply obligations under this Agreement, the responsible Party will provide prompt written notice to the other Party (including the quantity of Study Drug that the Party reasonably estimates it will be able to supply) and, upon request, the Parties will promptly discuss such situation through their AMs; including, how the quantities of the Study Drug that the Party is able to supply under this Agreement will be allocated within the Study. Notwithstanding anything to the contrary contained herein, in the event of a Shortage of the Study Drug, the responsible Party will have sole discretion, subject to Applicable Law, to determine the quantity of Study Drug it will be able to supply as a result of such Shortage. The responsible Party will not be deemed to be in breach of this Agreement for failure to supply their Study Drug hereunder as a result of a Shortage. Upon a Shortage, the AMs will discuss on how to resolve the issue to allow the Study to continue.

4.2 Study Drug Use

a) The Parties agree that the Study Drugs, supplied by the respective Parties, under this Agreement will be used solely for the Study, as specified in the Clinical Protocol and for no other purpose; including, as a reagent or tool to facilitate its internal research efforts, for any commercial purpose or for other clinical or non-clinical research unrelated to the Study.

b) Except as may be required or expressly permitted by the Clinical Protocol or the Supply and Quality Documentation, the recipient of the Study Drug shall not perform and shall not allow any Third Party to perform any analytical testing on the supplied Study Drug.

4.3 Supply and Quality Documentation

a) The Parties shall supply their Study Drugs directly to the CSSs for use in the Study, in accordance with a supply agreement, to be negotiated in good faith by the Parties on customary terms and conditions ("**Supply and Quality Documentation**"). The Supply and Quality Documentation shall outline the roles and responsibilities relative to the quality of the Study Drug(s) in support of the Study. It shall include the responsibility for quality elements that includes a COA as well as exchanged GMP documents and certifications required to release the Study Drug for the Study. In addition, the Supply and Quality Documentation shall detail the documentation required for each shipment of Study Drug supplied to the CSSs for use in the Study. Notwithstanding anything to the contrary herein, Ferring shall only be obligated to supply Adstiladrin® in the manner, dose, packaging, and form that Ferring generally supplies Adstiladrin® to Third Parties from time-to-time.

b) The estimated supply and delivery details will be outlined in the Supply and Quality Documentation and will be updated by the Parties by mutual agreement, as required, based on patient enrollment.

c) Theralase® will promptly inform Ferring of any change in patient enrollments and Ferring will endeavor to accommodate any change in the supply quantities requested by Theralase®, as long as it does not unduly disrupt Ferring's ongoing business activities.

4.4 Customs Valuation

The Study will be conducted in the Territory. The country shipped to in the Territory will be used as the basis for customs valuation for the shipping of the Study Drug to CSSs.

4.5 Designated Supply Contact

Each Party will designate Personnel ("**Designated Supply Contact**") that a Party may contact to assist with coordinating supplies and facilitating the resolution of any issues or concerns arising in connection with the supply of the Study Drug for use in the Study.

Adstiladin® Commercial Product Supply Contact:
Redacted: Commercially sensitive information

CSS Contact for Adstiladrin Order Placement:
Redacted: Commercially sensitive information

Article 5: Responsibilities

5.1 Theralase® Responsibilities

Theralase® shall, subject to the terms of the Clinical Protocol and this Agreement manage and be responsible for the conduct of the Study; including, timelines and contingency planning. In particular, and not in limitation to the foregoing, Theralase® shall perform, by itself, or in conjunction with Third Parties (e.g.: CSSs, CROs, PIs and others), the following operational matters ("**Operational Matters**") with respect to the Study:

a) Compile, amend and file all necessary Study Regulatory Documentation with Regulatory Authority(ies), maintaining and acting as Sponsor of Record as provided in 21 CFR 312.50 (and applicable comparable Canadian laws and Applicable Laws in other countries) with responsibility, unless otherwise delegated in accordance with 21 CFR 312.52 (and applicable comparable Canadian laws and Applicable Laws in other countries), for the Study and making all required submissions to Regulatory Authorities on a timely basis.

b) Conduct clinical study start-up activities, communicating with and obtaining approval from PIs and IRBs for the Clinical Protocol and ICF, in addition to approval from the PI and CSS for the CRA and associated budget and other relevant documents for the Study, as applicable, as well as patient recruitment and retention activities.

c) Registration of the Study on www.clinicaltrials.gov or other public registry in the Territory in which such Study is being conducted, in accordance with Applicable Law and in accordance with its internal policies relating to clinical study registration.

d) Provide Ferring with reasonable advance written notice of scheduled meetings or other pre-planned non-written communications with a Regulatory Authority, to allow Ferring the opportunity to participate in each such meeting. In such case, Theralase® will endeavor to provide Ferring reasonable advance notice (and no less than three (3) Business Days' advance notice where practicable) of such meeting for the opportunity to review and provide feedback on the Study Regulatory Documentation and correspondence to be supplied and if inconsistent

with the Clinical Protocol, approve all submissions and written correspondence with a Regulatory Authority that relates to Adstiladrin®.

e) Select, negotiate and approve contracts, manage and compensate CROs or vendors based on the timely completion and quality of contract deliverables in the performance of the Study.

f) For CSSs, compile, negotiate and submit for approval CRAs, ICFs and IRB submissions, ensuring that they do not conflict with the terms of this Agreement.

g) Ensure that each ICF identifies all potential Study risks for both Study Drugs and the Study Procedure detailing risk of patient injury / death and listing all known AEs, SAEs or SADRs minimizing liability for the Parties. In the case of patient injury / death, Theralase® will lead the investigation into root cause and advise Ferring accordingly of the steps taken by Theralase® to address the situation.

h) Provide Ferring with access to and use of Study Data and other information and documents, as required.

i) Do not impose a financial obligation, whether direct, indirect or contingent, upon Ferring that is not set forth in this Agreement or Applicable Law.

j) Retain each of the Parties' respective IP Rights in and access to the Intellectual Property and Technology that is Controlled by Ferring, Study Data, Samples, Adstiladrin® and Study consistent with this Agreement.

k) Comply with Applicable Law.

l) Provide Ferring available DSMB reports for the Study.

m) Inform and update Ferring on a Quarterly basis on the overall Study progress and any other Study-related matters involving safety, efficacy or toxicology, with significant issues to be communicated promptly after Theralase® becomes aware of them.

n) Manage the implementation and maintenance of a Global Safety Database for collecting, evaluating and reporting SAEs, safety data and pharmacovigilance information from the Study.

o) Analyze the Study Data in a timely fashion and provide Ferring with access to the Study Data on a Quarterly basis:
    i) CSRs (safety and efficacy)
    ii) Statistical analysis (Final CSR only)
    iii) DSMB reports
    iv) eCRF for all patients enrolled in the Study
    vi) EDC access
    vii) SAP for the Study

p) CSS collection of Samples, as specified in the Clinical Protocol.

q) Receive and timely address inquiries from the CSSs, PIs and their research teams.

r) Supply Ruvidar® and the TLC-3200 directly to CSSs at no additional cost.

s) **Redacted:** Commercially sensitive information.

t) Such other responsibilities as may be agreed to by the Parties.

5.2 Ferring Responsibilities

Subject to the Study Procedure and the terms of this Agreement (including Section 5.2(e)), Ferring shall be responsible for the following activities:

a) Manufacture and supply GMP-grade quantities of Adstiladrin®, in a timely fashion, for direct delivery to the CSS, as further described in Article 4 above and as specified in the Supply and Quality Documentation.

b) Provide necessary GMP information and documentation (including the IB) that enables the PI to administer Adstiladrin® safely and effectively in the Study.

For additional clinical support in the administration of Adstiladrin®, the PI or their team are able to contact:

PI Clinical Support Contact:	**Redacted:** Commercially sensitive information.
Position:	
E-mail:	
Cell Phone:	

c) To the extent necessary for the conduct of the Study, provide a Right of Cross-Reference to the relevant Regulatory Documentation for Adstiladrin®, as set forth in Section 2.1(h), if applicable, to the Ferring IB for Adstiladrin® (and updates thereto) as provided in Section 2.1(f).

d) Supply Adstiladrin® directly to CSSs at no additional cost, per Appendix B.

e) **Redacted:** Commercially sensitive information.

f) Such other responsibilities as may be agreed to by the Parties.

5.3 Other Clinical Studies

Subject to the terms of this Agreement, either Party shall be entitled to conduct any additional clinical study(ies) not involving the other Party's Study Drug, as it may determine in its sole discretion, except as it relates to the Confidential Information of the other Party.

5.4 Potential Subsequent Studies

During the Term of this Agreement, each of the Parties agrees to discuss in good faith additional clinical study(ies) and additional clinical condition(s), incorporating Adstiladrin®, Ruvidar®, Rutherrin®, TLC-3200 or X-ray. If the Parties jointly agree to conduct any further Subsequent Study, this Agreement and the Supply and Quality Documentation shall be amended to provide for the Subsequent Study under the terms thereof. For clarity, no Party shall be obligated to collaborate with the other Party or agree on terms with the other Party with respect to any Subsequent Study (or other collaboration opportunities).

5.5 Records and Audits

Ferring shall have the right, during the Term and for three (3) years thereafter, to arrange with Theralase® for Ferring's representatives to visit the offices and laboratories of Theralase® and any of its approved Third Party subcontractors that perform any of Theralase®'s activities hereunder, during normal business hours and upon reasonable advance notice, to discuss such activities and related records, in detail. Additionally, Ferring and its representatives may conduct compliance audits of Theralase® or its Affiliates and such Third Party subcontractors and their respective facilities to ensure compliance with this Agreement; including, compliance with Applicable Law and the Clinical Protocol; provided that Ferring shall (a) provide written notice of at least ten (10) Business Days with respect to such audits; and (b) conduct such audits during normal business hours, using reasonable efforts to not unreasonably interfere with Theralase® or its applicable Affiliates' or Third Party subcontractors' operations. Ferring will be fully responsible for its and its representatives' acts or omissions and for ensuring its representatives are bound to all applicable confidentiality and other requirements of this Agreement.

In addition to the above, Theralase® shall maintain, and shall cause its Affiliates to maintain, materially complete and accurate records in sufficient detail to permit Ferring to confirm the accuracy of the calculation of Eligible Costs under this Agreement. Upon reasonable prior written notice (not to be less than sixty (60) days' prior written notice), but not more than once per calendar year, such records in Theralase®'s possession or control shall be made available during regular business hours at such place or places where such records are customarily kept, for a period of twelve (12) months from the end of the calendar year to which they pertain for examination (provided that no period may be audited more than once) at the expense of Ferring by an independent certified public accountant selected by Ferring and reasonably acceptable to Theralase®, for the sole purpose of verifying the accuracy of the financial reports and correctness of the payments furnished by Theralase® pursuant to this Agreement. All records made available for inspection or audit shall be deemed to be Confidential Information of Theralase®. The accounting firm will disclose to Ferring only whether the payments are correct or incorrect and the specific details concerning any discrepancies. No other information will be provided to Ferring without the prior consent of Theralase®, unless disclosure is required by Applicable Laws or judicial order. Theralase® is entitled to require the accounting firm to execute a reasonable confidentiality agreement prior to commencing any such audit. The accounting firm shall provide a copy of its report and findings to both Parties. Any amounts shown to be owed by Ferring, but unpaid shall be paid within thirty (30) days from the accountant's report. Any amounts shown to have been overpaid by Ferring shall be refunded within thirty (30) days from the accountant's report. Ferring shall bear the full

cost of such audit and no interest shall be paid on any underpayment or overpayment of amounts, unless such audit discloses an overpayment by Ferring of more than ten percent (10%) of the amount paid by Ferring with respect to the Eligible Costs matter under review, in which case Theralase® shall bear the full cost of such audit and shall pay interest on overpayments at a rate equal to ten percent (10%) per annum. The audit rights set forth in this Section 5.5 shall survive the Term for a period of twelve (12) months.

Article 6: Intellectual Property

6.1 Background Intellectual Property

Subject to Section 3.4, no term or provision of this Agreement shall grant a Party any right(s) or interest to or in the other Party's Background Intellectual Property, or any variations or improvements thereof. For clarity, any IP related to the Study Drug of the respective Party is and will remain the property of the respective Party.

6.2 Foreground Intellectual Property

Subject to Sections 6.3 and 8.2:

All IP and/or Invention(s) arising out of the Agreement (without regard to whether it was conceived and/or reduced to practice on behalf of one or both Parties), to the extent specifically relating to a Party's Study Drug (including compositions of matter or formulations of such Study Drug and methods of use or manufacture of such Study Drug as a monotherapy) and to the extent not specifically relating to either (i) the other Party's Study Drug, or (ii) the Combined Therapy, will be the IP and Patent Rights of such Party.

If applicable, the other Party shall assign and hereby assigns (and shall cause its Affiliates and contractors to assign) its right, title and interest in any Invention(s) and Patent Rights to the Party to whom rights are assigned in accordance with this Section 6.2. The other Party shall execute such further documents and provide other assistance as may be reasonably requested by the Party to perfect the Party's Patent Rights in the Invention(s), at the Party's expense. The Party to whom rights are assigned in accordance with this Section 6.2 shall have the sole right, but not the obligation, to prepare, file, prosecute (including any proceedings relating to reissues, reexaminations, protests, interferences, oppositions, post-grant reviews or similar proceedings and requests for patent extensions) and maintain any Patent Rights at its own expense.

6.3 Joint Intellectual Property

Subject to Section 8.2, any IP and/or Invention(s) arising out of the Agreement that are: (a) conceived and/or reduced to practice by both Parties and not involving any Study Drug(s) or (b) conceived and/or reduced to practice by either Party and specifically relating to a Combined Therapy, will be the IP and Patent Rights of both Parties (such IP, "**Joint Intellectual Property**", and such Patent Rights, "**Joint Patent Rights**").

Joint Intellectual Property and Joint Patent Rights shall be jointly owned by the Parties and both Parties shall have the right to freely exploit the Joint Intellectual Property and Joint Patent Rights, both within and outside the scope of this Agreement, without accounting or any other obligation to the other Party (except as expressly set forth in this Section 6.3 with regard to the filing, prosecution, maintenance and enforcement of Joint Patent Rights) and each Party may use, exploit and grant licenses (with right to

sublicense) to Third Parties under its interest in such Joint Intellectual Property and Joint Patent Rights. Theralase®, using outside counsel acceptable to both Parties, shall be responsible, at its sole discretion, for preparing and prosecuting Patent applications and maintaining Patents within the Joint Patent Rights. Theralase® shall keep Ferring advised as to material developments and steps to be taken with respect to prosecuting any such Joint Patent Rights and shall furnish Ferring with copies of applications for such Joint Patent Rights, amendments thereto and other related correspondence to and from patent offices and permit Ferring a reasonable opportunity to review and offer comments prior to submitting such applications and correspondence to the applicable governmental authority. Ferring shall reasonably assist and cooperate in obtaining, prosecuting and maintaining the Joint Patent Rights. Notwithstanding the foregoing clause, Theralase® shall not take any position in a submission to a patent office concerning Joint Intellectual Property that interprets the scope of a Patent Right Controlled by Ferring without the prior written consent of Ferring, provided that Ferring has notified Theralase® in writing of the existence and scope of such Ferring Patent Right. Theralase® shall be reimbursed for any costs and expenses incurred in prosecuting Joint Patent Rights and the subsequent maintenance of Joint Patent Rights by Ferring such that Ferring shall be responsible for up to 50% of such costs. On a monthly basis, Theralase® shall invoice Ferring such amounts and Ferring shall pay Theralase® such invoiced amounts within thirty (30) days after receipt of an invoice.

The Parties shall discuss in good faith the countries in which the Joint Patent Rights will be filed. In case one of the two Parties decides that the Joint Patent Right should not be filed or maintained in a given country (and also elects not to reimburse the other Party for 50% of the costs of prosecution and maintenance of such Joint Patent Right in said country), then the other Party shall have the right to file, prosecute and maintain such Joint Patent Right in said country in its own name and at its own expense upon the prior consent of the other Party, which shall not be unreasonably withheld, conditioned or delayed. In this case, the Party who decides that a Joint Patent Right should not be filed or maintained and who also decides not to reimburse the other Party for its share of the costs of for a given country shall promptly assign its rights to the Joint Patent Right in said country to the Party ("**Filing Party**"), who wishes to file or maintain said Joint Patent Right in said country and the Filing Party shall grant, and hereby grants, to the other Party an irrevocable, perpetual, fully-paid, non-exclusive license, with the right to grant and authorize sublicenses, under such Joint Patent Rights to make, have made, use, sell, offer for sale, import and exploit products and services in said country. The Party who does not wish to file or maintain a Joint Patent Right in any country shall assist in the timely provision of all documents required under national provisions to register said assignment of Patent Rights with the corresponding national authorities at the sole expenses of the Party, who wishes to file or maintain such Joint Patent Right in that given country. If the Parties cannot agree with respect to the decision to file or maintain a Joint Patent Right within twenty (20) Business Days, subsequent to the initiation of the Parties' good faith efforts to resolve any disagreement, then either Party (whichever files first) shall have the right to file or maintain any Joint Patent Right in the names of both Parties, provided that:

(i) any such Joint Patent Right shall be jointly owned by the Parties and subject to the freedom to use and operate under such Joint Patent Right as set forth in Section 6.3;

(ii) such prosecuting Party obtains the prior consent of the non-prosecuting Party, which consent shall not be unreasonably withheld or delayed; and

(iii) the non-prosecuting party reimburses the prosecuting party for its 50% share of the patent prosecution costs.

6.4 Disclosure and Assignment of Inventions - Ownership of Independent Patent Rights

Each Party shall disclose promptly to the other Party in writing and on a confidential basis all Inventions, prior to any public disclosure or filing of Patent Rights and allow sufficient time for comment by the other Party. In addition, each Party shall, and does hereby, assign, and shall cause its Affiliates and

contractors to so assign, to the other Party, without additional compensation, such right, title and interest in and to any Inventions as well as any Patent Rights and other IP Rights with respect thereto, as is necessary to fully effect, as applicable, the sole ownership provided for in Section 6.2 and the joint ownership provided for in Section 6.3. Each Party shall ensure that each of its Personnel and contractors conducting activities under this Agreement has a written obligation to assign all right, title and interest in and to all Inventions and all IP Rights therein to such Party. Except for the license granted in Sections 3.1, 3.2 and 3.4, nothing in this Agreement shall be construed to grant or transfer to any Party any rights of the other Party related to the other Party's Study Drug Patent Rights, which shall be the sole and exclusive property of the other Party.

6.5 Infringement of Patent Rights by Third Parties

a) Each Party shall promptly notify the other Party in writing of any Infringement of Joint Patent Rights, of which it becomes aware.

b) For all Infringements of a Party's Patent Rights anywhere in the world, the responsible Party Controlling such Patent Rights shall have the exclusive right to prosecute such Infringements as it may determine in its sole and absolute discretion and that Party shall bear all related expenses and retain all related recoveries. The other Party shall reasonably cooperate with the Party or its designee, at the Party's request and expense, in any such action.

c) For all Infringements of Joint Patent Rights anywhere in the world, the Party controlling prosecution of such Joint Patent Rights shall have the exclusive right to prosecute such Infringements as it may determine in its sole and absolute discretion and the Parties shall split all related expenses evenly (50/50) and retain all related recoveries evenly (50/50). The other Party shall reasonably cooperate with the Party or its designee at the Party's request and expense, in any such action.

6.6 Infringement of Third-Party Rights

a) If the activities relating to the Study become the subject of a claim of infringement of a Patent Right, copyright or other proprietary right or trade secret misappropriation by a Third Party pertaining to the Territory, the Party first having notice of the claim shall promptly notify the other Party and, without regard to which Party is charged with said infringement, the Parties shall promptly meet to discuss the claim.

b) If both Parties are charged with infringement pursuant to a claim described in Section 6.5(b), each Party shall have the right to defend itself against such claim and the Parties shall discuss in good faith defending such claim jointly. If only one Party is charged with infringement, such Party will have the first right, but not the obligation to defend such claim. If the charged Party does not commence actions to defend such claim within twenty (20) Business Days, after request by the other Party to do so, then the other Party shall have the right, but not the obligation, to defend any such claim to the extent such claim pertains to the other Party's Study Drug. In any event, the non-defending Party shall reasonably cooperate with the Party conducting the defense of the claim and shall have the right to participate with separate counsel at its own expense and the defending Party shall consider comments and suggestions on strategy for defending the action by the non-defending Party in good faith. The Party defending the claim shall bear the cost and expenses of the defense of any such Third Party infringement claim and shall have sole rights to any recovery. If the Parties jointly defend the claim, the Parties shall bear the costs evenly (50/50) in the defense of the Third Party infringement claim; provided, however,

that, notwithstanding the foregoing, if the claim relates solely to one Party's Study Drug, such Party will bear one hundred percent (100%) of the costs and expenses of the defense of such claim and shall have the sole right, but not the obligation, to defend, settle and otherwise handle the disposition of such claim. Neither Party shall enter into any settlement concerning activities under this Agreement or the Study that affects the other Party's rights under this Agreement or imposes any obligations on the other Party; including, any admissions of wrongdoing on behalf of the other Party, without the other Party's prior written consent, not to be unreasonably withheld or delayed, except that a Party may settle any claim that solely relates to its Study Drug without the consent of the other Party as long as the other Party's rights under this Agreement are not adversely impacted (in which case, it will obtain the other Party's prior written consent, not to be unreasonably withheld or delayed). If any claim described in this Section 6.6(b) is subject to a Party's indemnification obligations under Article 11, then Article 11 shall govern such claim and not this Section 6.6(b).

6.7 Study Regulatory Documentation

Subject to the license and other rights granted by each Party to the other Party pursuant to this Agreement, Theralase® shall solely own all right, title and interest in and to the Study Regulatory Documentation; provided, however, that Ferring shall retain sole and exclusive ownership of any Ferring Regulatory Documentation that is submitted with or cross-referenced in the Study Regulatory Documentation. Theralase® shall retain sole and exclusive ownership of any Theralase® Regulatory Documentation that is submitted with or referenced in the Study Regulatory Documentation. This Section 6.7 is without limitation of any other disclosure obligations under this Agreement.

6.8 No Other Use

Except as expressly provided in Section 6.1, the Parties agrees not to make or file any Patent Rights application based on or containing the other Party's Confidential Information and to give no assistance to any Third Party for such application without the other Party's prior written authorization.

6.9 Joint Research Agreement

The Parties acknowledge and agree that this Agreement is a "Joint Research Agreement" as defined in 35 USC § 100 (h).

Article 7: Costs and Expenses

7.1 Manufacturing and IP Costs

Expenses incurred as described in Article 4 (Study Drug Manufacture and Supply) and Article 6 (Intellectual Property) shall be borne or shared by the Parties as provided in such Articles.

7.2 Study Costs

For all out-of-pocket expenses actually paid by a Party or its Affiliates to any Third Party (other than those expenses set forth in Section 7.1) that are directly attributable or reasonably allocable to the conduct of the Study ("**Eligible Costs**"), it is understood that:

a) Each Party will be responsible for its own internal costs and expenses in the provision of its Study Drug in accordance with this Agreement (including all Manufacturing, acceptance and release testing).

b) Each Party shall be solely responsible for all of its own internal costs (including costs of Personnel, external consultants or individual independent contractors) incurred by such Party or any of its Affiliates.

c) **Redacted:** Commercially sensitive information.

7.3 Study Drug Supply

Subject to the terms and conditions of this Agreement, each Party will use CRE to supply, or cause to be supplied, its Study Drug in the quantities and on the timelines as determined by the AMs, for use in the Study. The respective AM of each Party shall coordinate the supply of its respective Study Drug under this Agreement.

Notwithstanding the foregoing, or anything to the contrary herein, if a Party is unable to supply its respective Study Drug in a timely manner, under the terms of this Agreement, then the respective AMs shall meet to discuss how to best resolve the situation, either:

i) reschedule the patient's Study Procedure;
ii) if the Study Drug in shortage is outside the Study Procedure time window, then issue a waiver to the CSS to allow for the Study Drug to arrive to treat the patient;
iii) discontinue that particular Study Procedure for the patient; or
iv) remove the patient from the Study.

7.4 Third Party License Payments

If the conduct of the Study requires a Third-Party License Payment with respect to the Manufacture, supply and use of a Party's Study Drug, then the responsible Party shall pay any such Third-Party License Payment at its sole cost and expense.

Article 8: Records and Study Data

8.1 Records

Each Party shall maintain complete and accurate records of their work conducted with respect to the Study and all Results (e.g.: information, data, data analyses, reports, records, methods, processes, practices, formulae, instructions, skills, techniques, procedures, experiences and developments CRFs, AE reports) ("**Study Data**") made by or provided to either Party, or by the Parties together, in the course of such Party's efforts with respect to the Study; including, any Statistical Analysis Plan and any bioanalysis plan to be conducted pursuant to the Clinical Protocol or otherwise agreed to by the Parties. Such records shall fully and properly reflect all work done and Results achieved in the performance of the Study in sufficient detail and in good scientific manner appropriate for patent and regulatory purposes.

8.2 Ownership of Study Data

Ferring shall own the Study Data to the extent that it specifically relates to Adstiladrin® ("**Ferring Study Data**") and Theralase® shall own the Study Data to the extent that it specifically relates to Ruvidar® ("**Theralase® Study Data**"). Both Parties shall jointly own any Study Data that does not specifically relate only to Ruvidar® or Adstiladrin® ("**Combined Study Data**"). Each Party shall, and does hereby, assign, and shall cause its Affiliates to so assign, to the other Party, without additional compensation, such right, title and interest in and to any Study Data as is necessary to fully effect the foregoing and agrees to execute all instruments as may be reasonably necessary to effect same.

8.3 Use of Study Data

a) Use of a Party's Own Study Data

Ferring may use and analyze the Ferring Study Data for any purpose without obligation or accounting to Theralase®, who shall hold the Ferring Study Data in confidence pursuant to this Agreement. Theralase® may use and analyze the Theralase® Study Data for any purpose without obligation or accounting to Ferring, who shall hold Theralase® Study Data in confidence pursuant to this Agreement.

b) Use of Combined Study Data

Each Party and their respective Affiliates and (sub)licensees shall have the right to use and analyze the Combined Study Data:

i) in connection with the independent development, commercialization or exploitation of the respective Study Drugs (alone or in combination with other drugs and/or other pharmaceutical agents) and/or for inclusion in the safety database for each Party, in each case without the consent of, or any obligation to account to the other Party.

ii) to conduct studies with Samples pursuant to Section 8.5, where the Results of all analyses or uses shall be owned by the Parties; including, any IP arising out of same, in accordance with this Agreement. The Party's and their respective Affiliates and (sub)licensees shall be entitled to use the Combined Study Data during and following the Term to:

A) make regulatory filings, meet regulatory requirements and seek approval for the respective Study Drug, either alone or as part of the Combined Therapy;
B) evaluate the safety and efficacy of the Combined Therapy and their respective Study Drug;
C) promote indications based on, and to disseminate, the Combined Study Data for their benefit, either alone or as part of the Combined Therapy, where permitted by and in accordance with Applicable Law; provided that nothing in the foregoing is intended or shall be construed as granting a Party any right or license, expressly or impliedly to make, have made, use, sell, offer for sale, or import the other Party's Study Drug; and
D) include in Patent Right filings made in the course of the prosecution of Patent Rights that do not Cover any of the composition of matter of their Study Drug, its Manufacture or formulation, or method of use of their Study Drug.

Each Party hereby grants to the other Party and their respective Affiliates and (sub)licensees a Right of Cross-Reference to Regulatory Documentation Controlled by them and the Study Regulatory Documentation for their Study Drug or the Combined Therapy for the sole purpose of enabling the

Parties and their Affiliates and sublicensees to exercise their rights under clause (i) of this Section 8.3(b), which right shall survive any expiration or termination of this Agreement.

c) No Other Uses

All other uses of Combined Study Data by either Party are limited solely to those permitted by this Agreement and neither Party may use such Study Data for any other purpose without the consent of the other Party during and after the Term.

8.4 Access to Study Data

Subject to the provisions of Sections 8.1, each Party shall have access to the Combined Study Data. The relevant Party shall make such Study Data in its possession available to the other Party within a reasonable period, after such Study Data is available to or generated by the applicable Party.

8.5 Samples

a) Samples shall be jointly owned by the Parties (to the extent not owned by the patient and/or the respective CSS). Any such Samples shall be collected in accordance with the Clinical Protocol, GCP guidelines and applicable ICFs. Upon Ferring's request, Theralase® shall provide copies of such ICFs for Ferring's review and Theralase® will in good faith consider any Ferring comments regarding modifications to such ICF templates, in all cases prior to use at any CSS. Except as set forth in the Clinical Protocol, neither Party shall be permitted to use such Samples for any purpose without the prior written consent of the other Party, which consent shall not be unreasonably withheld, with the terms of such use to be set forth in a written agreement between the Parties setting forth the Samples to be used and any appropriate terms/restrictions on such use. For clarity, Theralase® shall have the right, without further consent of Ferring, to use and study any such Samples as set forth in the Clinical Protocol, it being understood that if the Clinical Protocol does not reference specific assays to be utilized in the analysis of any such Samples and such analysis will be in the discretion of Theralase®. Except for IP pertaining solely to Adstiladrin®, which shall be owned by Ferring, any data and IP arising out of such Samples shall be owned by the Party conducting such study using same, provided that, to the extent that any such data or IP relating solely to the Combined Therapy (or biomarkers solely for use with the Combined Therapy), shall be considered Combined Therapy Study Data, Combined Therapy Inventions and/or Combined Therapy Patent Rights, as the case may be. All Samples, including Samples for pharmacokinetics ("**PK**") and Adenosine DeAminase ("**ADA**") serum analysis will be stored for future use in Theralase®'s Sample repository, unless the Parties mutually agree that Ferring would store such samples, provided that, if the Party holding the Samples determines that it no longer has a use for the Samples and the other Party determines that it does, then the Samples shall, subject to Applicable Law and the terms of the signed ICFs, be transferred to the other Party and may be used solely thereafter by the other Party. If neither Party has any further use for the Samples, then the remaining Samples will be destroyed pursuant to the respective Party's SOPs for sample retention and destruction, subject to the terms of and permission(s) granted in the ICFs signed by the patients contributing the Samples in the Study.

b) If required by a Regulatory Authority, as part of the Clinical Protocol or related bioanalysis plan, Ferring will use commercially reasonable efforts to arrange for Theralase® to use Ferring's preferred Third Party vendor for bioanalytical work of Samples from Study patients treated with Adstiladrin®. Such vendor(s) will provide the Results of their bioanalytical work of such Samples to the Parties, which Results will be included in the final CSR, along with the bioanalytical work

of Ruvidar® and Adstiladrin® performed by or on behalf of Theralase®. This bioanalysis will qualify as Eligible Costs. For the avoidance of doubt, all bioanalytical Results for Adstiladrin® and Ruvidar® are deemed Study Data.

Article 9: Confidentiality

9.1 Confidential Information

a) Any Confidential Information relating to Adstiladrin®, Ruvidar® or the conduct of the Study previously disclosed by the Parties pursuant to the Agreement shall be treated as Confidential Information for the purposes of this Agreement. All written, visual, oral and electronic data, information, know-how or other proprietary information or materials, both technical and non-technical, disclosed by one Party to the other Party pursuant to this Agreement, and disclosed in the manner specified herein, that:
   i) if in tangible form, is labeled in writing as "proprietary" or "confidential" (or similar reference); and
   ii) if in oral or visual form, is identified as proprietary or confidential or for internal use only at the time of disclosure or within twenty (20) Business Days; thereafter, shall be deemed the **Confidential Information** of the Disclosing Party and all Study Data and Inventions shall be the Confidential Information of the Party (or Parties) owning such Study Data or Invention (as provided in Section 8.2 with regard to Study Data and Article 6 with regard to Inventions).

b) For purposes of this Agreement, regardless of which Party discloses such Confidential Information to the other:
   i) all Intellectual Property, Inventions and Technology Controlled by Theralase® and Theralase® Regulatory Documentation shall be Confidential Information of Theralase® and Ferring shall be the Receiving Party with respect thereto; and
   ii) all Inventions and Technology Controlled by Ferring, and Ferring Regulatory Documentation shall be Confidential Information of Ferring and Theralase® shall be the Receiving Party with respect thereto.

c) The Parties agree that the terms of this Agreement shall be treated as Confidential Information of both Parties and thus may be disclosed only as permitted by Section 9.3. Except as required by Applicable Law, each Party agrees not to issue any press release or public statement disclosing information relating to this Agreement or the transactions contemplated hereby or the terms hereof without the prior written consent of the other Party, except as permitted by a press release ("**Press Release**"), which provides information on the primary aspects of the Agreement, agreed to in writing by the Parties in accordance with Section 9.4.

d) Except to the extent expressly authorized in this Article 9 or as otherwise agreed in writing by the Parties, each Party agrees that, for the Term and for a period of 1 year thereafter, it shall:
   i) keep confidential and shall not publish or disclose, and shall not use for any purpose other than as expressly provided for in this Agreement, any Confidential Information of the other Party; including, information related to this Agreement or the transactions contemplated hereby or the terms hereof;
   ii) treat the other Party's Confidential Information with the same degree of care that the receiving Party uses for its own confidential information, but in no event with less than a reasonable degree of care; and

iii) reproduce the disclosing Party's Confidential Information solely to the extent necessary or reasonably useful to accomplish the Receiving Party's obligations under this Agreement or exercise the Receiving Party's rights to use and disclose such Confidential Information, as expressly provided for in this Agreement, with all such reproductions being considered the Disclosing Party's Confidential Information. Notwithstanding anything to the contrary in this Section 9.1, and subject to Section 8.3, the Receiving Party may disclose the Disclosing Party's Confidential Information to its employees, consultants, agents or permitted (sub)licensees solely on a need-to-know basis for the purpose of fulfilling the Receiving Party's obligations under this Agreement or exercising the Receiving Party's rights to use and disclose such Confidential Information as expressly provided for in this Agreement; provided, however, that:

A) any such Personnel, consultants, agents or permitted (sub)licensees are bound by obligations of confidentiality and non-use at least as restrictive as those set forth in this Agreement; and

B) the Receiving Party remains liable for the compliance of such Personnel, consultants, agents or permitted (sub)licensees with such obligations. Each Receiving Party acknowledges that in connection with its and its representatives examination of the Confidential Information of the Disclosing Party, the Receiving Party and its representatives may have access to material, non-public information, and that the Receiving Party is aware, and will advise its representatives who are informed as to the matters that are the subject of this Agreement, that State and Federal laws, including United States securities laws, may impose restrictions on the dissemination of such information and trading in securities when in possession of such information. Each Receiving Party agrees that it will not, and will advise its representatives who are informed as to the matters that are the subject of this Agreement to not, purchase or sell any security of the Disclosing Party on the basis of the Confidential Information to the extent such Confidential Information constitutes material nonpublic information about the Disclosing Party or such security.

e) Combined Therapy Study Data shall be treated as Confidential Information of each Party and shall not be disclosed to Third Parties except to the extent it falls within the exceptions set forth in Section 9.2 below, is authorized under this Section 9.1 or Section 9.3, is required to be filed with a Regulatory Authority or included in a product's label or package insert, is reasonably necessary to be disclosed in order for a Party to exercise its rights under Section 8.3(b) or 8.3(c) or it is disclosed as permitted pursuant to Section 9.4.

9.2 Exceptions

The obligations in Section 9.1 shall not apply with respect to any portion of Confidential Information that the Receiving Party can demonstrate by contemporaneous tangible records or other competent proof:

a) was already known to the Receiving Party (or its Affiliates), other than under an obligation of confidentiality, either:
   i) at the time of disclosure by the Disclosing Party; or
   ii) at the time that it was generated hereunder;

b) was generally available to the public or otherwise part of the public domain either:
   i) at the time of its disclosure to the Receiving Party; or
   ii) at the time that it was generated hereunder;

c) became generally available to the public or otherwise part of the public domain after its disclosure and other than through any act or omission of the Receiving Party in breach of this Agreement;

d) was disclosed to the Receiving Party (or its Affiliates), other than under an obligation of confidentiality, by a Third Party who had no obligation to the Disclosing Party not to disclose such information to others; or

e) was independently discovered or developed by the Receiving Party (or its Affiliates) without the use of, or reference to, the Confidential Information of the Disclosing Party.

9.3 Authorized Disclosure

Notwithstanding any other provision of this Agreement, each Party may disclose Confidential Information of the other Party to the extent such disclosure is reasonably necessary in the following instances:

a) filing or prosecuting Patent Rights pursuant to Section 6.2 and 6.3;

b) prosecuting or defending litigation, or pursuant to an order of a court or governmental entity;

c) complying with Applicable Law or the rules or regulations of any securities exchange on which such Party's stock is listed;

d) disclosure, in connection with the performance of this Agreement, to Affiliates, permitted (sub)licensees, contractors, IRBs, CROs, academic institutions, consultants, agents, investigators, Personnel and contractors engaged by CSSs and PIs involved with the Study, each of whom prior to disclosure must be bound by terms of confidentiality and non-use at least as protective of Confidential Information as those set forth in this Article 9;

e) disclosure of the Combined Therapy Study Data, Combined Therapy Inventions and Combined Therapy Patent Rights to Regulatory Authorities in connection with the development and obtaining of regulatory approval of the Combined Therapy, Ruvidar® or Adstiladrin®;

f) disclosure of relevant safety information contained within the Combined Therapy Study Data to PIs, IRBs and Regulatory Authorities that are involved in other clinical studies of Ruvidar® or Adstiladrin® and in the event of a Material Safety Issue, to Third Parties that are collaborating with either Party, respectively in the conduct of such other clinical studies of Ruvidar® or Adstiladrin®, in each case solely to the extent necessary for the conduct of such clinical studies and/or to comply with Applicable Law and regulatory requirements; or

g) if such disclosure is necessary to comply with a Party's or its applicable Affiliate's obligations under licenses of Background Intellectual Property.

Notwithstanding the foregoing, if a Party is required or otherwise intends to make a disclosure of any other Party's Confidential Information pursuant to Article 9.3, it shall give advance notice to such other

Party of such impending disclosure and endeavor in good faith to secure confidential treatment of such Confidential Information and/or reasonably assist the Party that owns such Confidential Information in seeking a protective order or other confidential treatment.

9.4 Press Releases and Publications

a) The Parties shall jointly agree, through the JDC, to the content and timing of all public communications with respect to this Agreement, press releases, Q&As and the content of, and wording for, any listing of the Study required to be listed on a public database or other public registry such as www.clinicaltrials.gov, except for a Press Release, which shall be issued after execution of this Agreement on an agreed upon date. For clarity, if either Party terminates this Agreement pursuant to Section 12.4, the Parties shall mutually agree upon any external communication related to such termination, which shall not include the rationale for such termination unless and to the extent mutually agreed to by the Parties. Notwithstanding the foregoing in this Section 9.4(a), either Party shall be permitted to publicly disclose information that such Party determines in good faith is necessary to be disclosed to comply with Applicable Law or the rules or regulations of any securities exchange on which such Party's stock may be listed or pursuant to an order of a court or governmental entity.

b) Theralase® and Ferring agree to collaborate, through and subject to JDC approval, to publicly disclose, publish or present:

i) top-line Results from the Study, limited, if possible, to avoid jeopardizing the future publication of the Study Data at a scientific conference or in a scientific journal, as soon as reasonably practicable, the safety and efficacy Results and conclusions that are material to either Party under applicable securities laws; and

ii) the conclusions and outcomes ("**Results**") of the Study at a scientific conference as soon as reasonably practicable following the database lock date for such Study, subject in each case to the following terms and conditions:

A) the Party proposing to disclose, publish or present the Results shall deliver to the other Party a copy of the proposed disclosure, publication or presentation at least twenty (20) Business Days before submission to a Third Party;

B) the reviewing Party shall determine whether any of its Confidential Information that may be contained in such disclosure, publication or presentation should be modified or deleted, whether to file a patent application on any Invention Controlled by Theralase® or Ferring or any Invention relating to the Combined Therapy disclosed therein;

C) the disclosure, publication or presentation shall be delayed for an additional twenty (20) Business Days (i.e.: a total of forty (40) Business Days from the initial proposal) if the reviewing Party reasonably requests such extension to allow time for the preparation and filing of relevant patent applications consistent with the terms of this Agreement; and

D) if the reviewing Party reasonably requests modifications to the disclosure, publication or presentation to prevent the disclosure of Confidential Information of the reviewing Party, the publishing Party shall edit such publication to prevent the disclosure of such Confidential Information prior to submission of the disclosure, publication or presentation. In the event of a

disagreement as to content, timing and/or venue or forum for any disclosure, publication or presentation of the Results, such Dispute ("**Publication Dispute**") shall be referred to the SEMs; provided that, in the absence of agreement after such good faith discussions and upon expiration of the additional twenty (20) Business Days period:

a) Academic collaborators or CSSs engaged by Theralase® in connection with the performance of the Study may publish Combined Therapy Study Data obtained by such academic collaborator or CSS solely to the extent that such ability to publish such Combined Therapy Study Data is set forth in an agreement between Theralase® and such academic collaborator or CSS relating to the conduct of the Study
b) The publishing Party may proceed with the disclosure, publication or presentation provided that such disclosure, publication or presentation is consistent with its internal publication guidelines and customary industry practices for the publication of similar data and does not disclose the Confidential Information of the other Party, other than the Results or Study Data.
c) Authorship of any publication shall be determined based on the accepted standards used in peer-reviewed academic journals at the time of the proposed disclosure, publication or presentation.
d) The Parties agree that they shall make reasonable efforts to prevent publication of a press release that could jeopardize the future publication of Study Data at a scientific conference or in a scientific journal, but in no way will this or any other provision of this Agreement supersede the requirements of any Applicable Law or the rules or regulations of any securities exchange or listing entity on which a Party's stock is listed; specifically, Ontario Securities Commission Continuous Disclosure Obligations NI 51-102 or any such rule or regulation that may require a Party to make public disclosures about interim Results of the Study.

c) Theralase® agrees to include in all permitted press releases, presentations and publications it makes related to the Study, specific mention of Adstiladrin® and the support and involvement of Ferring. Ferring agrees to include in all permitted press releases, presentations and publications it makes related to the Study specific mention of Ruvidar® and the support and involvement of Theralase®.

9.5 Compliance with Sunshine Laws

a) For purposes of compliance with reporting obligations under Sunshine Laws, as between the Parties, Theralase® represents that it is not, as of the Effective Date, subject to reporting obligations under the Sunshine Laws; therefore, as between the Parties, Ferring will report payments or other transfers of value (as defined in the Sunshine Laws, "**POTV**") made by Theralase® or the CRO related to the conduct of the Study and any applicable associated contractor engagements, as required under the Sunshine Laws for the Study. Ferring shall request delayed publication for any reported POTV for clinical studies sponsored by Theralase®, as permitted under the Sunshine Laws and if consistent with Ferring's normal business practices. In the event that Theralase® becomes responsible for reporting POTV for clinical studies sponsored by it, in a given country during the Term, Theralase® shall provide written notification

to Ferring and the Parties will meet to confer to discuss how they wish to handle reporting thereafter. Interpretation of the Sunshine Laws for purposes of reporting any POTV by a Party shall be in such Party's sole discretion so long as the interpretation complies with Applicable Law.

b) Theralase®:
   i) Will provide (to the extent in the possession of Theralase®), or will utilize CRE to obligate and ensure that each CRO and other applicable Third Party contractors for the Study provides, Ferring with any information requested by Ferring as Ferring may reasonably determine is necessary for Ferring to comply with its reporting obligations under Sunshine Laws (with such amounts paid to, or at the direction of, healthcare providers, teaching hospitals and/or any other persons for whom POTVs must be reported under Sunshine Laws to be reported to Ferring within a reasonable time period specified by Ferring); and
   ii) Will reasonably cooperate with and will utilize CRE to obligate and ensure that each CRO and other applicable Third Party contractors for the Study reasonably cooperates with Ferring in connection with its compliance with such Sunshine Laws. The form in which Theralase® provides any such information shall be mutually agreed, but sufficient to enable Ferring to comply with its reporting obligations and Ferring may disclose any information that it believes is necessary to comply with Sunshine Laws.

Without limiting the foregoing, Ferring shall have the right to allocate POTVs in connection with this Agreement, in any required reporting under Sunshine Laws in accordance with its normal business practices. These obligations shall survive the expiration and termination of this Agreement to the extent necessary for Ferring to comply with Sunshine Laws. Theralase® shall not be required to provide any information to Ferring that is subject to disclosure pursuant to Theralase®'s own obligations under the Sunshine Laws.

c) For purposes of this Section 9.5, "**Sunshine Laws**" shall mean Applicable Laws requiring collection, reporting and disclosure of POTVs to certain healthcare providers, entities and individuals. These Applicable Laws may include relevant provisions of the U.S. Patient Protection and Affordable Health Care Act of 2010 and implementing regulations thereunder.

9.6 Destruction of Confidential Information

Upon expiration or termination of the Agreement, the Receiving Party shall, upon request by the Disclosing Party, destroy or return all of the Disclosing Party's Confidential Information relating solely to its Study Drug as monotherapy, but not to the Combined Therapy or the Combined Therapy Study Data, in its possession; provided; however, that the Receiving Party shall be entitled to retain one (1) copy of Confidential Information solely for record-keeping purposes and shall not be required to destroy any Confidential Information required, or reasonably necessary, to be retained for any clinical study activities that continue after expiration or termination, or off-site computer files created during automatic system back up, which are subsequently stored securely by the Receiving Party.

9.7 Non-Solicitation of Employees

Each Party agrees that, during the Term of the Agreement and for one (1) year thereafter, neither it nor any of its Affiliates shall recruit, solicit or induce any employee of the other Party directly involved in the development or other activities conducted by the other Party under this Agreement to terminate their employment with such other Party and become employed by or consult for such other Party, whether or

not such employee is a full-time employee of such other Party, and whether or not such employment is pursuant to a written agreement or is "at-will". For purposes of the foregoing, "recruit", "solicit" or "induce" shall not be deemed to mean:

a) Circumstances where an employee of one Party initiates contact with the other Party or any of its Affiliates with regard to possible employment; or
b) General solicitations of employment, not specifically targeted at employees of a Party or any of its Affiliates; including, responses to general advertisements.

Article 10: Representations and Warranties

10.1 Authority and Binding Agreement

Each Party represents and warrants to the other Party that:

a) it has the corporate power, authority and legal right to enter into this Agreement and perform its obligations hereunder;
b) it has taken all necessary corporate action on its part required to authorize the execution and delivery of the Agreement and the performance of its obligations hereunder; and
c) the Agreement has been duly executed and delivered on behalf of such Party and constitutes a legal, valid and binding obligation of such Party that is enforceable against it in accordance with its terms subject to bankruptcy, insolvency, reorganization, arrangement, winding-up, moratorium and similar laws of general application affecting the enforcement of creditors' rights generally and subject to general equitable principles; including, the fact that the availability of equitable remedies, such as injunctive relief or specific performance, is in the discretion of the court.

10.2 No Conflicts

Each Party represents and warrants to the other Party that, to the best of its knowledge, it has not entered as of the Effective Date, and shall not enter, into any agreement with any Third Party that is in conflict with the rights granted to the other Party under this Agreement and has not taken any action that would in any way prevent it from granting the rights granted to the other Party under this Agreement or that would otherwise materially conflict with or adversely affect the rights granted to the other Party under this Agreement.

10.3 Litigation

Each Party represents and warrants to the other Party, to the best of its knowledge as of the Effective Date, it is not aware of any pending or threatened litigation (and has not received any communication) that alleges that its activities related to this Agreement have violated or that by conducting the activities as contemplated in this Agreement it would violate, any of the IP Rights of any other Person, after giving effect to the license grants in this Agreement.

10.4 No Adverse Proceedings

Each Party represents and warrants to the other Party that, except as otherwise notified to the other Party, as of the Effective Date, there is no pending or, to the knowledge of such Party, threatened, against such Party, any claim, suit, action or governmental proceeding that would, if adversely determined, materially impair the ability of such Party to perform its obligations under this Agreement.

10.5 Consents

Each Party represents and warrants to the other Party that, to the best of its knowledge, all necessary consents, approvals and authorizations of all regulatory and governmental authorities and other Persons:

a) Required as of the Effective Date to be obtained by such Party in connection with the execution and delivery of this Agreement have been obtained or will be obtained prior to such execution and delivery; and
b) Required to be obtained by such Party in connection with the performance of its obligations under this Agreement have been obtained or will be obtained prior to such performance.

10.6 No Debarment

Each Party hereby certifies to the other that it has not used and will not use the services of any Person disqualified, debarred, banned, subject to debarment or convicted of a crime for which a Person could be debarred by the FDA under 21 U.S.C. 335a, as amended or subject to a similar sanction of any other Regulatory Authority, in any capacity in connection with any of the services or work provided under the Study and that this certification may be relied upon in any applications to the FDA or any other Regulatory Authority. It is understood and agreed that this certification imposes a continuing obligation upon each Party to notify the other promptly of any change in the truth of this certification. Upon request by a Party, the other Party agrees to provide a list of Persons used to perform the services or work provided under any activities conducted for or on behalf of such Party or any of its Affiliates pursuant to this Agreement who, within the five (5) years preceding the Effective Date or subsequent to the Effective Date, were or are convicted of one of the criminal offenses required by 21 U.S.C. 335a, as amended, to be listed in any application for approval of an abbreviated application for drug approval.

10.7 Compliance with Applicable Law

Each Party represents and warrants to the other Party that it shall comply with all Applicable Law of the country or other jurisdiction, or any court or agency thereof, applicable to the performance of its activities hereunder or any obligation or transaction hereunder; including, those pertaining to the production and handling of drug products, such as those set forth by the Regulatory Authorities, as applicable, and the applicable terms of this Agreement in the performance of its obligations hereunder.

10.8 Affiliates

Each Party represents and warrants to the other Party that, to the extent the IP, Regulatory Documentation or Technology licensed by it hereunder are Controlled by its Affiliates or a Third Party, it has the right to use, and has the right to grant (sub)licenses to the other Party to use, such IP, Regulatory Documentation or Technology in accordance with the terms of this Agreement.

10.9 Ethical Business Practices

Each Party represents and warrants to the other Party that neither it nor its Affiliates will make any payment, either directly or indirectly, of money or other assets; including, the compensation such Party derives from this Agreement (collectively "**Payment**"), to government or political party officials, officials of International Public Organizations, candidates for public office, or representatives of other businesses or persons acting on behalf of any of the foregoing (collectively "**Officials**"), where such Payment would constitute violation of any law; including, the Foreign Corrupt Practices Act of 1977, 15 U.S.C. §§ 78dd-1,

et seq. In addition, regardless of legality, neither it nor its Affiliates will make any Payment either directly or indirectly to Officials, if such Payment is for the purpose of improperly influencing decisions or actions with respect to the subject matter of this Agreement. All activities will be conducted in compliance with the U.S. False Claims Act and the U.S. Anti-Kickback Statute.

10.10 Accounting

Each Party represents and warrants to the other Party that all transactions under the Agreement shall be properly and accurately recorded in all material respects on its books and records and that each document upon which entries in such books and records are based is complete and accurate in all material respects.

10.11 Study Drug Safety Issues

Each Party represents and warrants that, to the best of its knowledge as of the Effective Date, it is not aware of any material safety or toxicity issues with respect to its Study Drug that is not reflected in the IB or ICF for its Study Drug existing as of the Effective Date.

10.12 Compliance with Licensor Agreements

Each Party will use, and will cause its Affiliates to use, CRE to comply with its obligations under any agreements entered into by it or its Affiliates with a Third Party under which it is licensed any IP Rights or Confidential Information relating to a Study Drug and not to voluntarily terminate the same to the extent necessary for the Study to be conducted and completed in accordance with the terms of this Agreement and for the other Party to receive the rights and benefits provided to it under this Agreement.

10.13 Disclaimer of Warranty

The express representations and warranties stated in this Article 10 are in lieu of and the Parties do hereby disclaim all other representations and warranties, express, implied or statutory; including, warranties of merchantability, fitness for a particular purpose or use and non-infringement of Third Party IP rights.

Article 11: Indemnification

11.1 Indemnification

Each Party ("**Indemnifying Party**") hereby agrees to defend, hold harmless and indemnify ("**Indemnify**") the other Party, their Affiliates, agents, directors, officers, employees or subcontractors ("**Indemnitees**") from and against any and all liabilities, expenses and/or losses; including, reasonable legal expenses and attorneys' fees ("**Losses**") resulting from Third Party suits, claims, actions or demands ("**Third Party Claim**") to the extent that they arise or result from:

a) the negligence or intentional misconduct of any Party or any (sub)licensee conducting activities on behalf of the Party under this Agreement;
b) any breach by the Party of any provision of this Agreement;
c) any injury or death, other than resulting from a known AE, SAE or SADR, to a patient in the Study to the extent caused by the Party's Study Drug; or
d) the use by a Party, its Affiliates, contractors or (sub)licensees of Combined Therapy Study Data, Study Data, or Joint Intellectual Property, other than with respect to Third Party

Claims that are covered under Section 6.5; but excluding, in each case ((a) through (d)), any such Losses to the extent arising or resulting from a cause or event for which the Indemnitee is obligated to Indemnify the Indemnified Party pursuant to this Section 11.1.

11.2 Indemnification Procedure

Each Party's agreement to Indemnify the Indemnitees is conditioned on the performance of the following by the Party seeking indemnification:

a) providing written notice to the Indemnifying Party of any Loss and/or Third Party Claim of the types set forth in Section 11.1 promptly and in any event within twenty (20) Business Days, after the Party seeking indemnification has knowledge of such Loss and/or Third Party Claim; provided that, any delay in complying with the requirements of this clause (a) will only limit the Indemnifying Party's obligation to the extent of the prejudice caused to the Indemnifying Party by such delay;
b) permitting the Indemnifying Party to assume full responsibility to investigate, prepare for and defend against any such Loss and/or Third Party Claim;
c) providing reasonable assistance to the Indemnifying Party, at the Indemnifying Party's expense, in the investigation of, preparation for and defense of any Loss and/or Third Party Claim; and
d) not compromising or settling such Loss and/or Third Party Claim without the Indemnifying Party's written consent, such consent not to be unreasonably withheld or delayed.

11.3 Separate Defense of Claims

In the event that the Parties cannot agree as to the application of Sections 11.1 and/or 11.2 to any particular Loss, the Parties may conduct separate defenses of such Loss. Each Party further reserves the right to claim indemnity from the other in accordance with Sections 11.1 and/or 11.2 upon resolution of the underlying claim, notwithstanding the provisions of Section 11.2(b).

11.4 Insurance

Each Party shall maintain commercially reasonable levels of insurance or other adequate and commercially reasonable forms of protection or self-insurance to satisfy its indemnification obligations under this Agreement. Each Party shall provide the other Party with written notice at least twenty (20) Business Days prior to the cancellation, non-renewal or material change in such insurance or self-insurance, which would materially adversely affect the rights of the other Party hereunder. The maintenance of any insurance shall not constitute any limit or restriction on damages available to a Party under this Agreement.

11.5 Limitation of Liability

Neither Party shall be liable to the other Party for indirect, incidental, consequential or special damages; including, lost profits, arising from or relating to this Agreement and/or such Party's performance hereunder, regardless of any notice of the possibility of such damages and regardless of the cause of action, whether in contract, tort, breach of warranty or otherwise. Nothing in this Section 11.5 is intended to limit or restrict the indemnification rights or obligations of a Party under Sections 11.1 or 11.2, a Party's liability for it breaches of the Data Protection Terms or confidentiality obligations in Article 9, or a Party's liability for such Party's negligence or willful misconduct.

Article 12: Term and Termination

12.1 Term

This Agreement shall be effective as of the Effective Date and, unless terminated earlier pursuant to Sections 12.2, 12.3 or 12.4 or any other termination right expressly stated in this Agreement, it shall continue in effect until delivery of final documents by Theralase® pursuant to Section 2.3(j) ("**Term**").

12.2 Termination for Material Breach

a) **Notice and Cure Period**

If a Party ("**Breaching Party**") is in material breach of its obligations under this Agreement, the other Party ("**Non-Breaching Party**") shall have the right to give the Breaching Party notice specifying the nature of such material breach. The Breaching Party shall have a period of twenty (20) Business Days after receipt of such notice to cure such material breach ("**Cure Period**") in a manner reasonably acceptable to the Non-Breaching Party. For the avoidance of doubt, this provision is not intended to restrict in any way either Party's right to notify the other Party of any other breach or to demand the cure of any other breach.

b) **Termination Right**

The Non-Breaching Party shall have the right to terminate this Agreement, upon written notice, in the event that the Breaching Party has not cured such material breach within the Cure Period; provided however, that if such breach is capable of cure, but cannot be cured within the Cure Period and the Breaching Party commences actions to cure such material breach within the Cure Period and thereafter diligently continue such actions, the Breaching Party shall have an additional twenty (20) Business Days to cure such breach. If a Party contests such termination pursuant to the Dispute resolution procedures under Section 13.3, such termination shall not be effective until a conclusion of the Dispute resolution procedures in Section 13.3, as applicable, resulting in a determination that there has been a material breach that was not cured within the Cure Period, which Cure Period shall be tolled for the period from notice of such Dispute until resolution of such Dispute pursuant to Section 13.3 or abandonment of such Dispute by the disputing Party.

12.3 Termination for Bankruptcy

Either Party may terminate this Agreement if, at any time, the other Party files in any court or agency pursuant to any statute or regulation of any state, country or jurisdiction, a petition in bankruptcy or insolvency or for reorganization or for an arrangement or for the appointment of a receiver or trustee of such other Party or of such other Party's assets, or if the other Party proposes a written agreement of composition or extension of its debts or if the other Party is served with an involuntary petition against it, filed in any insolvency proceeding and such petition is not dismissed or stayed within twenty (20) Business Days after the filing thereof or if the other Party proposes or is a party to any dissolution or liquidation or if the other Party makes an assignment for the benefit of its creditors.

12.4 Termination Due to Material Safety Issue - Clinical Hold

a) Either Party shall have the right to terminate this Agreement immediately, after meeting and discussing with the other Party in good faith as described in the following sentence, upon written notice if it deems it necessary to protect the safety, health or welfare of patients enrolled

in the Study due to the existence of a Material Safety Issue. In the event of a termination due to a Material Safety Issue, prior to the terminating Party providing written notice, each Party's safety committee shall, to the extent practicable, meet and discuss in good faith the safety concerns raised by the terminating Party and consider in good faith the input, questions and advice of the non-terminating Party, but should any Dispute arise in such discussion, the Dispute resolution processes set forth in Section 13.3 shall not apply to such Dispute and the terminating Party shall have the right to issue such notice and such termination shall take effect without the Parties first following the procedures set forth in Section 13.3.

b) If a Clinical Hold with respect to either of the Party's Study Drugs should arise at any time after the Effective Date, the Parties will meet and discuss the basis for the Clinical Hold, how long the Clinical Hold is expected to last and how they might address the issue that caused the Clinical Hold. If, after twenty (20) Business Days of discussions following the Clinical Hold, either Party reasonably concludes that the issue adversely impacts the Study and is not solvable or that unacceptable and material additional costs/delays have been and/or will continue to be incurred in the conduct of the Study, then such Party may immediately terminate this Agreement.

12.5 Effect of Termination

Upon expiration or termination of this Agreement:

a) The licenses granted to each Party to conduct the Study in Sections 3.1 and 3.2 and any sublicenses granted under Section 3.3 shall terminate;
b) The Parties shall use reasonable efforts to wind down activities under this Agreement in a reasonable manner and avoid incurring any additional expenditures or non-cancellable obligations; provided that, in the case of termination pursuant to Section 12.4, Theralase® may continue to dose patients enrolled in the Study through completion of the Clinical Protocol, if dosing is required by the applicable Regulatory Authority(ies) and/or Applicable Law. Any such wind-down activities will include the return to Ferring, or destruction, of any Adstiladrin® provided to Theralase® and not consumed in the Study, except in the event that Theralase® terminates this Agreement pursuant to Section 12.2 or 12.3, in which case Theralase® shall continue to have the right to use any Adstiladrin® provided to Sponsor for the conduct of the Study.
c) Each Party shall promptly deliver to the other Party, any Study Data belonging to such other Party, including copies of Combined Study Data jointly owned by the Parties, in the format reasonably requested by such other Party.

12.6 Survival

The following Articles and Sections of this Agreement and all definitions relating thereto shall survive any expiration or termination of this Agreement for any reason: Article 1 (Definitions), Section 3.4 (Mutual Freedom to Operate), Section 3.5 (No Implied Licenses), Section 5.5 (Audits), Article 6 (Intellectual Property), Section 8.2 (Ownership of Study Data), Section 8.3 (Use of Study Data), Section 8.5(a) (Samples), Article 9 (Confidentiality), Section 10.13 (Disclaimer of Warranty), Article 11 (Indemnification), Section 12.5 (Effect of Termination), Section 12.6 (Survival), and Article 13 (Miscellaneous).

Article 13: Miscellaneous

13.1 Entire Agreement

The Parties acknowledge that this Agreement shall govern all activities of the Parties with respect to the Study from the Effective Date forward. This Agreement; including, the Appendices hereto and together with the Supply and Quality Documentation, sets forth the complete, final and exclusive Agreement between the Parties concerning the subject matter hereof and supersedes 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 in this Agreement. All Appendices attached hereto are incorporated herein as part of this Agreement.

13.2 Governing Law

This Agreement shall be governed and construed in accordance with the internal laws of the State of Delaware, USA; excluding, any choice of law rules that may direct the application to the laws of another jurisdiction.

13.3 Dispute Resolution

a) The Parties' AMs (for clinical and regulatory matters) and the Parties' Designated Supply Contacts (for supply matters) shall attempt in good faith to resolve any Dispute or concern that either Party may bring to the other Party's attention.

b) In the event of any Dispute, controversy or claim arising out of, relating to or in connection with any provision of this Agreement ("**Dispute**"), other than a Publication Dispute or a Dispute as to whether a Material Safety Issue exists, that cannot be resolved by the applicable Designated Contacts of each Party after a period of five (5) Business Days, then upon the request of either Party by written notice, the Parties shall refer such Dispute to the SEMs. This Agreement shall remain in effect during the pendency of any such Dispute. In the event that no resolution is made by the SEMs in good faith negotiations within five (5) Business Days after such referral to them, then:

   i) If such Dispute constitutes an Arbitration Matter, such Dispute shall be resolved through arbitration in accordance with the remainder of Section 13.3; provided, however, that with respect to any such Arbitration Matter Dispute that relates to a matter described in Section 13.4, either Party shall have the right to seek an injunction or other equitable relief without waiting for the expiration of a five (5) Business Days period;

   ii) If such Dispute constitutes a Publication Dispute, the specific Dispute resolution processes contained in Section 9.4 will apply; and

   iii) If such Dispute regards the supply, quality or compliance with specifications of a Party's Study Drug, that Party shall have the final say regarding such Dispute; provided that:

      A) that Party shall have no authority to amend, change or waive compliance with this Agreement, which matters may be approved only by the written consent of both Parties; and

B) all determinations made by that Party shall be consistent with the terms of this Agreement.

If a Dispute that constitutes an Arbitration Matter remains unresolved after escalation to the Study Executive Managers as described above, either Party may refer such matter to arbitration as described herein. Any arbitration of an Arbitration Matter under this Agreement shall be conducted under the auspices of the American Arbitration Association by a panel of three (3) arbitrators pursuant to that organization's Commercial Arbitration Rules then in effect.

c) The fees and expenses of the arbitrators shall be borne in equal shares by the Parties. Each Party shall bear the fees and expenses of its legal representation in the arbitration. The arbitral tribunal shall not reallocate either the fees and expenses of the arbitrators or of the Parties' legal representation. The arbitration shall be held in New York, New York, which shall be the seat of the arbitration. The language of the arbitration shall be English.

13.4 Injunctive Relief

Notwithstanding anything herein to the contrary, a Party may seek an injunction or other injunctive relief from any court of competent jurisdiction in order to prevent immediate and irreparable injury, loss or damage on a provisional basis. For the avoidance of doubt, if either Party:

a) discloses Confidential Information of the other Party other than as permitted under Article 9;
b) uses the other Party's Study Drug or Technology in any manner other than as expressly permitted under this Agreement; or
c) otherwise is in material breach of this Agreement and such material breach could cause immediate harm to the value of the other Party's Study Drug, then the other Party shall have the right to seek an injunction or other equitable relief precluding the Party from continuing its activities related to the Study without waiting for the conclusion of the Dispute resolution procedures under Section 13.3.

13.5 Force Majeure

The Parties shall be stayed from the performance of their obligations under this Agreement, other than the payment of monies owed to the other Party, 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 stay shall be continued for 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 mean acts of God, pandemics, epidemics, strikes or other concerted acts of workers, civil disturbances, fires, earthquakes, acts of terrorism, floods, explosions, riots, war, rebellion, sabotage or failure or default of public utilities or common carriers or similar conditions beyond the control of the Parties.

13.6 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 if such notice is timely and is:

a) Mailed by first class certified or registered mail, postage prepaid, return receipt requested;

b) Sent by express delivery service; or
c) Personally delivered.

Unless otherwise specified in writing, the mailing addresses of the Parties shall be as described below.

For Theralase®: Theralase® Technologies Inc.
41 Hollinger Road
Toronto, Ontario, M4B 3G4, Canada
Attention: Roger DuMoulin-White
President and Chief Executive Officer

For Ferring: **Redacted:** Commercially sensitive information.

Any such communication shall be deemed to have been received when delivered. It is understood and agreed that this Section 13.6 is not intended to govern the day-to-day business communications necessary between the Parties in performing their duties, in due course, under the terms of this Agreement.

13.7 No Waiver – Modifications

It is agreed that no waiver by a Party hereto of any breach or default of any of the covenants or agreements herein set forth shall be deemed a waiver as to any subsequent and/or similar breach or default. No amendment, modification, release or discharge shall be binding upon the Parties unless in writing and duly executed by authorized representatives of both Parties.

13.8 No Strict Construction

This Agreement has been prepared jointly and shall not be strictly construed against either Party. No presumption as to construction of this Agreement shall apply against either Party with respect to any ambiguity in the wording of any provision(s) of this Agreement irrespective of which Party may be deemed to have authored the ambiguous provision(s).

13.9 Independent Contractor

The Parties are independent contractors of each other, and the relationship between the Parties shall not constitute a partnership, joint venture or agency. Neither Party shall be the agent of the other or have any authority to act for, or on behalf of, the other Party in any matter.

13.10 Assignment - Licensees

a) **Assignment**

Neither Party may assign or transfer this Agreement or any rights or obligations hereunder without the prior written consent of the other Party, except that a Party may make such an assignment without the other Party's consent to:

i) an Affiliate;
ii) a Third Party that merges with, consolidates with or acquires substantially all of the assets or voting control of the assigning Party; or
iii) a Third Party that acquires all the rights of the assigning Party to the respective Party's Study Drug. If assigned or transferred to an Affiliate, the assigning/transferring

Party shall remain jointly and severally responsible and liable with the assignee/transferee Affiliate for the assigned rights and/or obligations. If assigned to a Third Party, 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 assignment or attempted assignment by any Party in violation of the terms of this Section 13.10(a) shall be null and void and of no legal effect.

b) **Licensees**

If a Party grants a Third Party a license to develop and commercialize its Study Drug on a worldwide basis or in any geographic region and/or for all purposes or a limited field ("**Licensee**"), such Party will obtain the Licensee's agreement to abide by the terms of this Agreement as and to the extent necessary in order for its obligations hereunder to be fulfilled in the same manner as the licensing Party and in such event the licensing Party may exercise its rights granted hereunder (including rights to use Study Data and practice Inventions) through the Licensee.

13.11 Headings

The captions to the several Sections and Articles hereof are not a part of this Agreement, but are included merely for convenience of reference only and shall not affect its meaning or interpretation.

13.12 Counterparts

This Agreement may be executed in two (2) or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one (1) and the same instrument. This Agreement may be executed by facsimile or electronic (e.g.: PDF) signatures and such signatures shall be deemed to bind each Party hereto as if they were an original signature.

13.13 Severability

If any provision of this Agreement is held to be illegal, invalid or unenforceable under any present or future law and if the rights or obligations of a Party under this Agreement will not be materially and adversely affected thereby:

a) such provision shall be fully severable;
b) this Agreement shall be construed and enforced as if such illegal, invalid or unenforceable provision had never comprised a part hereof;
c) the remaining provisions of this Agreement shall remain in full force and effect and shall not be affected by the illegal, invalid or unenforceable provision or by its severance herefrom; and
d) in lieu of such illegal, invalid or unenforceable provision, there shall be added automatically as a part of this Agreement a legal, valid and enforceable provision as similar in terms to such illegal, invalid or unenforceable provision as may be possible and reasonably acceptable to the Parties.

13.14 Further Assurance

Each Party shall duly execute and deliver, or cause to be duly executed and delivered, such further instruments and do and cause to be done such further acts and things; including, the filing of such

assignments, agreements, documents and instruments, as may be necessary or as the other Party may reasonably request in order to perfect any license, assignment or other transfer or any properties or rights under, or pursuant, to this Agreement.

13.15 No Benefit to Third Parties

The representations, warranties and agreements set forth in this Agreement are for the sole benefit of the Parties and their successors and permitted assigns and they shall not be construed as conferring any rights on any other parties.

13.16 Construction

a) **General**

Except as otherwise explicitly specified to the contrary:

i) references to a Section, Article or Exhibit means a Section or Article of, or Exhibit to, this Agreement and all subsections thereof, unless another agreement is specified;
ii) references to a particular statute or regulation include all rules and regulations promulgated thereunder and any successor statute, rules or regulations then in effect, in each case; including, the then-current amendments thereto;
iii) words in the singular or plural form; include, the plural and singular form, respectively;
iv) the terms “including,” “include(s),” “such as,” and “for example” used in this Agreement mean; including, the generality of any description preceding such term and will be deemed to be followed by “without limitation”; and
v) the words “hereof,” “herein,” “hereunder,” “hereby” and derivative or similar words refer to this Agreement. No presumption as to construction of this Agreement shall apply against either Party with respect to any ambiguity in the wording of any provision(s) of this Agreement irrespective of which Party may be deemed to have authored the ambiguous provision(s).

b) **No Response**

Except as expressly set forth in this Agreement, where a provision of this Agreement provides for a Party to respond within a designated period following written notice from the other Party and if such Party fails to respond, then the failure to respond shall not be deemed to create or imply:

i) that the non-responding Party agrees or disagrees with the proposed action to be taken by the other Party;
ii) any amendment, change or waiver of the terms of this Agreement; or
iii) any consent that an action proposed to be taken may be taken if it conflicts with the terms of this Agreement and/or waiver of any rights it may have to seek remedies at law or in equity for breach of this Agreement as a result of the action taken.

c) **Reprints - References in Publication**

Consistent with Applicable Law; including, copyright law, each Party may use, refer to and disseminate reprints of scientific, medical and other published articles and materials from journals, conferences or symposia relating to the Study that discloses the name of a Party, provided; however, that such use does not constitute an endorsement of any commercial product or service by the other Party.

In Witness Whereof, the Parties, intending to be legally bound hereby, have caused this Agreement to be executed by their duly authorized representatives as of the Effective Date.

Ferring Pharmaceuticals Inc.	**Theralase® Technologies Inc.**
By: _____	By: _____
Name: _____	Name: _____
Title: _____	Title: _____
Date: _____	Date: _____

By: _____

Name: _____

Title: _____

Date: _____

Appendix A
Clinical Protocol Summary

Clinical Study

Theralase® Technologies Inc. and Ferring Pharmaceuticals will conduct a collaborative Phase II clinical study of Intravesical Photo Dynamic Therapy with Adstiladrin® in Patients diagnosed with BCG-Unresponsive NMIBC CIS (with or without resected papillary disease (Ta, T1)) or Who Are Intolerant to BCG Therapy. The study sponsor, Theralase®, plans this phase II, open-label, single-arm, multi-center clinical study primarily in the United States, and then subject to written agreement by the Parties, in Canada or any other country designated by the JDC.

Appendix B
Supply of Adstiladrin

Ferring shall provide Adstiladrin® to the CSS, as authorized by Theralase®, in the form of commercially available packaged and labelled vials and the CSS shall use, store, transport, handle and dispose of Adstiladrin® in accordance with Ferring's Standard Operating Procedure ("**SOP**") and Applicable Law.

Ferring will deliver Adstiladrin® to the CSS on a specified day specified by Theralase® at no additional cost. Title for Adstiladrin® shall transfer from Ferring to the CSS upon Delivery.

All costs associated with the subsequent transportation, cold storage, warehousing and distribution of Adstiladrin® shall be borne by Theralase®.

Theralase® will, or will cause the specific CSS to:

i) Take Delivery of the shipped Adstiladrin®
ii) Keep complete and accurate records pertaining to the use and disposition of Adstiladrin®; including, records relating to its storage, shipping (cold chain), in-transport temperature recorder(s), receipt verification, chain-of-custody activities and usage and inventory reconciliation
iii) Make the records described in subsection (ii) and such other documentation as may be reasonably requested by Ferring available for review by Ferring for the purpose of conducting investigations for the determination of Adstiladrin® safety or efficacy and Theralase®'s compliance with this Agreement with respect to Adstiladrin®.

Theralase® is solely responsible for supplying (including all Manufacturing, acceptance and release testing) Ruvidar® for the Study and the subsequent handling, storage, transportation, warehousing and distribution of all Ruvidar®. Theralase® shall ensure that all such activities are conducted in compliance with Applicable Law.

Theralase® shall:

i) Use Adstiladrin® solely for purposes of performing the Study
ii) Not use Adstiladrin® in any manner that is inconsistent with this Agreement or for any commercial purpose. Theralase® shall not reverse engineer, reverse compile, disassemble or otherwise attempt to derive the composition or underlying information, structure or ideas of Adstiladrin® and in particular shall not analyze Adstiladrin® by physical, chemical or biochemical means except as necessary to perform its obligations hereunder.

Product Specifications:
A certificate of analysis shall accompany each shipment of Adstiladrin® to the CSS which will be stored in the Trial Master File ("**TMF**") at the CSS.

Changes to Manufacturing:
Each Party may make changes from time to time to its Study Drug or the Manufacturing Site, in its sole determination.

How to Order:
Detailed ordering instructions for Adstiladrin® will be provided directly to Theralase®, who will be responsible for ensuring these procedures are followed and implemented at the ordering sites.

Appendix C
Countries Approved for the Combination Clinical Study

Ferring shall provide Adstiladrin® to the CSSs in the form of commercially available packaged and labelled vials for use in the Study initially in the United States. Should Adstiladrin® be approved by Health Canada at a future date, subject to Ferring's decision to commercialize Adstiladrin® in Canada, Adstiladrin® may be made available for expansion of the Study in CSSs located in Canada. Accordingly, Territory shall mean the United States and, subject to Ferring's decision above, Canada.

Appendix D
Data Protection Terms

The Parties agree to discuss in good faith appropriate Data Protection Terms to be agreed upon after execution of the Agreement, as needed.