Exhibit 10.1  
 LICENSE AGREEMENT  
BETWEEN  
ADHERA THERAPEUTICS, INC  
AND  
MELIOR PHARMACEUTICALS II, LLC  
 July 28, 2021  
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 THIS LICENSE AGREENMENT (this “Agreement”) is made and entered into as of July 28, 2021 (“Effective Date”), by and between Adhera Therapeutics, Inc., with its principal offices at 0000 Xxxxxxxxxx Xxxx, Xxxxx Xxxxx, Xxxxxxxxx 00000 (“Adhera”), and Melior Pharmaceuticals II, LLC., with principal offices located at 000 Xxxxxxxxxx Xxxxx, Xxxxx, XX, XXX ( “Melior”).  
 WITNESSETH:  
 WHEREAS, Melior either owns or controls certain patents and patent applications relating to MLR-1019 as listed in Exhibit A hereto, and has the right to grant licenses for use and commercialization under such patents and patent applications to Adhera;  
 WHEREAS, Melior owns or controls certain technology and know-how relating to MLR-1019 and has the right to grant licenses in respect of such technology and know-how;  
 WHEREAS, Adhera and Melior desire to jointly develop MLR-1019 at Adhera’s expense, provided that any expenses to be incurred in connection with such joint development, including any joint development for the U.S. and Europe, shall be agreed in advance by Adhera;  
 WHEREAS, Adhera desires to obtain an exclusive worldwide license for use and commercialization under such patents, patent applications, technology and know-how; and  
 WHEREAS, Melior desires to grant to Adhera an exclusive worldwide license to make, have made, use, offer for sale, import and sell the commercial products under all of the aforementioned patents, patent applications, technical information and know-how relating to MLR-1019 either by itself or through a third party subject to the terms and conditions of this Agreement.  
 NOW, THEREFORE, in consideration of the premises and the covenants herein contained, the parties agree as follows:  
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 ARTICLE 1. DEFINITIONS  
 The following terms as used herein, when written with an initial capital letter, shall have the meanings ascribed to them below:  
 1.1. “Affiliate” shall mean, with respect to a party to this Agreement, any corporation or non-corporate business entity which controls, is controlled by, or is under common control with such party. A corporation or non-corporate business entity shall be regarded as in control of another corporation if it owns, or directly or indirectly controls, at least fifty (50%) percent of the voting stock of the other corporation, or (a) in the absence of the ownership of at least fifty (50%) percent of the voting stock of a corporation or (b) in the case of a non-corporate business entity, or non-profit corporation, if it possesses, directly or indirectly, the power to direct or cause the direction of the management and policies of such corporation or non-corporate business entity, as applicable.  
 1.2. “Agreement” shall mean this Agreement, including all Exhibits attached to this Agreement.  
 1.3. “Bulk Drug Substance” shall mean the Compounds in bulk form which, if appropriately formulated and finished, would be suitable for preclinical or clinical use or commercial use.  
 1.4. “Bulk Formulation” shall mean the Licensed Product in capsule form or tablet form.  
 1.5. “CMO” shall mean contract manufacturing organization.  
 1.6. “Compounds” shall mean the compound known as MLR-1019, with the chemical name of R-mesocarb, including any salts and esters thereof.  
 1.7. “CRO” shall mean contract research organization.  
 1.8. “CTA” shall mean Clinical Trial Authorization under the EMEA  
 1.9. “DMF” shall mean drug master file  
 1.10. “Dollars” shall mean United States dollars.  
 1.11. “Effective Date” shall mean the date written above.  
 1.12. “EMEA” shall mean the European Medicines Agency or any successor entity thereof.  
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 1.13. “FDA” shall mean the Food and Drug Administration or any successor entity thereof.  
 1.14. “Field” shall mean all therapeutic applications and uses.  
 1.15. “Finished Product” shall mean a Licensed Product in packaged product form suitable for distribution to customers.  
 1.16. “IND” shall mean an Investigational New Drug Application filed with the FDA or its equivalent filed with any other regulatory authority worldwide.  
 1.17. “Indemnitees” shall mean (a) in the case of the indemnity set forth in Section 14.1, Adhera, its Affiliates, officers and employees of any of the foregoing; (b) in the case of the indemnity set forth in Section 14.2, Melior, its Affiliates, officers and employees; and (c) in the case of the Indemnitees referenced in Section 14.3, the parties identified in Subsections 1.17(a) and 1.17(b) above, as applicable.  
 1.18. “Joint Development Committee (JDC)” shall mean the committee described in Article 6 hereof.  
 1.19. “Joint Know-How” shall mean all inventions, discoveries, trade secrets, information, data, formulas, procedures and results which are necessary or useful for the development, registration, manufacturing, using or selling of the Compounds or the Licensed Products which are developed jointly by at least one (1) Adhera employee or person contractually required to assign or license such data and know-how to Adhera and at least one (1) Melior employee or person contractually required to assign or license such data or know-how to Melior during the term of this Agreement. All Joint Know-How shall be owned jointly by the parties hereto.  
 1.20. “Joint Patents” shall mean any patents and patent applications related to the Compounds or the Licensed Products which are jointly developed or made during the term of this Agreement by at least one (1) Adhera employee or person contractually required to assign or grant a license covering such patents or patent applications to Adhera and at least one (1) Melior employee or person contractually required to assign or grant a license covering such patents or patent applications to Melior. All Joint Patents shall be owned jointly by the parties hereto.  
 1.21. “Joint Steering Committee (JSC)” shall mean the committee described in Article 5 hereof.  
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 1.22. “Licensed Product(s)” shall mean any Compound or any pharmaceutical product containing one or more Compounds as an active ingredient, alone or in combination with other active ingredients; process, service, or product, the manufacture, use, or sale of which, is or was covered by a Valid Claim of any of the Melior Patents or incorporates or uses any Melior Know-How.  
 1.23. “Melior Know-How” shall mean all inventions, discoveries, trade secrets, information, experience, data, formulas, procedures and results which are useful for the development, manufacturing and registration of the Compounds or the Licensed Products which are rightfully owned by Melior as of the Effective Date, or which are developed or acquired by Melior during the term of this Agreement including, but not limited to, all manufacturing and synthesis know-how.  
 1.24. “Melior Patents” shall mean all patents and patent applications having patent claims which are necessary or useful for the development, registration, manufacturing, using or selling of the Compounds or Licensed Products, which are owned or controlled by Melior as of the Effective Date, or which are developed or acquired by Melior during the term of this Agreement, including any addition, continuation, continuation-in-part or division thereof or any substitute application thereof; any patent issued with respect to such patent application, any reissue, extension or patent term extension of any such patent, and any confirmation patent or registration patent or patent of addition based on any such patent; and foreign patent or inventor’s certificate with regard thereto. Melior Patents shall include those listed in Exhibit A attached hereto.  
 1.25. “NDA” shall mean a New Drug Application or its domestic equivalent.  
 1.26. “Positive outcome” shall mean (a) the achievement of primary endpoint successfully in the applicable clinical trial or (b) a decision by Adhera to proceed with further development of Licensed Products, following a Phase 2 clinical trial whichever occurs first.  
 1.27. “Registration” shall mean, in relation to any Licensed Product, such approvals by the regulatory authorities in a given country.  
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 1.28. “Up-listing Event” shall mean the registration of Adhera shares on a major stock exchange that provides significantly improved liquidity relative to its current status. Such major stock exchanges shall be Nasdaq or NYSE.  
 1.29. “Valid Claim” shall mean issued or granted claims of any issued and unexpired patent included among the Melior Patents, which has not been held unenforceable, unpatentable or invalid by a decision of a court or governmental body of competent jurisdiction, which is unappealable or unappealed within the time allowed for appeal, which has not been rendered unenforceable through disclaimer or otherwise or which has not been lost through an interference or opposition proceeding.  
 ARTICLE 2. LICENSES  
 2.1. License Under Melior Patents and Melior Know-How. Melior hereby grants Adhera the exclusive right and license to practice the Melior Patents and the Melior Know-How to develop, have developed, make, have made, use, import, export, offer for sale, sell and have sold Licensed Products (including, but not limited to, Bulk Drug Substance) anywhere in the world. For so long as the license granted to Adhera under this agreement is in effect, Melior forgoes the right to develop, have developed, make, have made, use, import, export, offer for sale, sell and have sold Licensed Products. The initial clinical studies for the Licensed Products shall be conducted under an EMEA CTA to be jointly filed by Melior and Adhera.  
 2.2. Melior Information. Subject to Sections 7.1(a), 7.2 and 8.1, Melior will retain all right, title and interest in, to and under all preclinical data, all clinical data, all pharmaceutical science data, formulations data, and all other supporting data, as well as bulk unformulated and formulated drug product that are related to the Compounds or the Licensed Products developed, owned or controlled by Melior and existing as of the Effective Date. For clarity, any and all information owned by Melior pursuant to this Section 2.2 shall be part of the Melior Know-How.  
 2.3. Adhera Information. Subject to Sections 6.4 (last sentence) and 7.1(b), for so long as the license granted to Adhera under this Agreement is in effect, Adhera will retain all right, title and interest in, to, and under all of the development, preclinical and clinical data relating to the Compounds or the Licensed Products that are generated by Adhera during the course of its performance of this Agreement.  
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 2.4. Melior’s Cooperation. Upon request by Adhera for Melior’s assistance in connection with the recordation of Adhera’s exclusive licenses granted hereunder with the relevant patent authorities, Melior shall cooperate fully with all such requests; provided that Adhera shall reimburse Melior for its out-of-pocket expenses incurred in connection with such cooperation.  
 ARTICLE 3. MILESONE PAYMENTS  
 3.1. Milestone Payments. As consideration for entering into this Agreement, Adhera agrees to pay Melior milestone payments (“Milestone Payments”) in the exact amount specified below (excluding withholding tax) no later than thirty (30) days after the occurrence of the corresponding event designated below, unless Adhera has given Melior notice of termination of this Agreement prior to the occurrence of the applicable milestone.  
 Milestone Milestone Payment  
Last patient enrolled into the Phase 2a study $(US) 250,000  
Positive outcome of the Phase 2a study $(US) 1,500,000  
Initiation of a Phase 3 study $(US)10,000,000  
NDA approval $(US)10,000,000  
Total Milestone Payments $(US) 21,750,000  
 3.2. Taxes. Melior will be responsible for any and all income or other taxes (except withholding tax) owed by Melior and required by applicable law to be deducted from any of the payments made by or on behalf of Adhera to Melior. To the extent any withholding taxes are required to be withheld from any of the payments made by or on behalf of Adhera to Melior by the relevant taxing authorities, Adhera shall withhold and pay all such taxes and shall provide Melior with the written documentation evidencing the payment of such taxes  
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 ARTICLE 4. PAYMENTS  
 4.1. Wire Transfer. All payments to each party shall be made by wire transfer to an account of each party designated by each party from time to time.  
 4.2. Currency Restrictions. Except as hereinafter provided in this Section 4.2, all payments shall be paid in U.S. Dollars.  
 4.3. Overdue Payments. In the event any payment due hereunder is not made when due, the payment shall accrue interest (beginning on the date such payment is due) calculated at the rate of one percent (1%) per month and such payment when made shall be accompanied all interest so accrued. The remittance of such interest shall not foreclose each party from exercising any other rights it may have pursuant to this Agreement because such payment  
 ARTICLE 5. JOINT STEERING COMMITTEE  
 5.1. Appointment of Representatives. As soon as practicable after the Effective Date, Adhera shall appoint three (3) representatives and Melior shall appoint two (2) authorized representatives for a joint steering committee (each a “JSC Representative”). Each party shall provide notice to the other as to the identity of the individual so appointed. Each JSC Representative shall be responsible for communications, other than legal notices, between the parties with respect to the subject matter of this Agreement. Each party may replace its JCS Representative(s) at any time with or without cause by providing written notice to the other party.  
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 5.2. Joint Steering Committee. The JSC Representatives shall comprise the Joint Steering Committee consisting of the three (3) representatives from Adhera and two (2) representatives from Melior, such persons having significant responsibility for the commercialization of MLR-1019, including out-licensing or sub-licensing initiatives.  
 The Joint Steering Committee will meet from time to time at mutually agreeable times via teleconference or in-person, but no less than annually during the term of the Agreement. The JSC Representatives shall set the agenda for each meeting, and each JSC Representative shall determine which regular members of Joint Steering Committee and other representatives of such JSC Representative’s party shall attend in light of the agenda. Each party shall bear its own costs incurred in connection with participation in the Joint Steering Committee. The JSC Representative from Melior shall prepare the meeting minutes whenever Joint Steering Committee is held.  
 5.3. Objective of the Joint Steering Committee. The Primary objective of the Joint Steering Committee will be to oversee the MLR-1019 program under this Agreement and monitor the needs or actions required relating to the commercialization of MLR-1019, including licensing-out or sub-licensing initiatives.  
 Each party agrees to give due consideration to any input received from the other party at such Joint Steering Committee meetings; provided, however, Adhera shall have the final voting right if there is any conflict between Adhera and Melior. Adhera and Melior shall coordinate positively the licensing-out to any third party, and each licensing-out or sublicensing shall comply with the terms and conditions hereunder and the licensing/sublicensing guidelines to be adopted by the Joint Steering Committee.  
 ARTICLE 6. JOINT DEVELOPMENT COMMITTEE  
 6.1. Appointment of Representatives. As soon as practicable after the Effective Date, Adhera shall appoint two (2) representatives and Melior shall appoint three (3) authorized representatives for a joint development committee (each a “JDC Representative”). Each such party shall provide notice to the other as to the identity of the individual so appointed. Each JDC Representative shall be responsible for communications, other than legal notices, between the parties with respect to the subject matter of this Agreement. Each party may replace its JDC Representative(s) at any time for any or no reason by providing written notice to the other party.  
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 6.2. Joint Development Committee. The JDC Representatives shall establish the Joint Development Committee consisting of the two (2) representatives from Adhera and three (3) representatives from Melior, such persons having significant responsibility for the to the development of MLR-1019, including preclinical and clinical programs.  
 The Joint Development Committee will meet from time to time at mutually agreeable times via teleconference or in-person, but no less than semi-annually during the term of the Agreement. The JDC Representatives shall set the agenda for each meeting, and each JDC Representative shall determine which regular members of Joint Development Committee and other representatives of such JDC Representative’s party shall attend in light of the agenda. Each party shall bear its own costs incurred in connection with participation in the Joint Development Committee. The JDC Representative from Adhera shall prepare the meeting minutes whenever a Joint Development Committee is held.  
 6.3. Objective of the Joint Development Committee. The Primary objective of the Joint Development Committee will be to oversee the MLR-1019 Program, and monitor and decide the needs or actions required relating to the development of MLR-1019, including preclinical and clinical programs, but not limited to;  
 (a) providing a forum for protocol and development plan review;  
(b) discussing the regulatory strategy, filing and activities;  
(c) determining plans for proceeding to phase 2b study based on the results of the phase 2a study;  
(d) determining additional preclinical study or clinical study;  
(e) coordinating the production of the Finished Product, Bulk Formulation and Bulk Drug Substance; and  
(f) providing the budget for each of the above.  
 Each party agrees to give due consideration to any input received from the other party at such Joint Development Committee meetings; provided, however, Melior shall have the final voting right if there is any conflict between Adhera and Melior.  
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 Adhera will bear the costs associated with MLR-1019 development for Phase 2a and Phase 2b studies via direct payment of all invoices from CRO, CMO or hospitals pursuant to the terms and conditions of the agreements in effect with each of CRO, CMO or hospitals. In addition, upon the JDC’s reasonable judgment that engagement of external toxicologists and/or outside consultants for regulatory approval is necessary, Adhera will bear the cost of such engagement. For clarity, all such toxicologists and consultants shall be engaged as independent contractors and shall be paid on an hourly basis. A phase 2a study referred to herein involves a treatment of Xxxxxxxxx’x disease subjects in Eastern European countries such as Bulgaria, Romania and/or Moldova. The clinical protocol that is envisioned is exemplified by the protocol synopsis provided in Exhibit 2. Adhera will use commercially reasonable efforts (a) to ensure that the execution of this development plan progresses without delay and (b) to develop, receive all necessary regulatory approvals to market and sell, and commercialize Licensed Products. Melior will use commercially reasonable efforts to work with CRO’s, CMO’s and consultants, selected by the JDC, to progress the development plan on a schedule set forth by the JDC.  
 6.4. Exchange of Study Results and Data. Each party shall submit a report detailing the results, information and data of each non-clinical and clinical study which it performs to the other party within thirty (30) days after completion of the final statistical analyses of the results of such study. Such results, information and data may include information related to the manufacturing of the Licensed Product, information relating to the patent protection surrounding the Licensed Products as well as regulatory status and correspondence with regulatory agencies. All data furnished by one party to the other party under this Agreement shall be deemed Confidential Information of the party furnishing such data. Notwithstanding the immediately preceding sentence, each party may copy, use and supply and otherwise commercialize such data, free of charge, such as in their and their INDs, and/or NDAs or similar documents used for regulatory, development, product approval and marketing purposes.  
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 6.5. Publications. Each party reserves the right to publish or publicly present the results of its own development activities in respect of the Licensed Products (the “Results”). The party proposing to publish or publicly present the Results (the “publishing party”) will, however, submit a draft of any proposed manuscript, abstract, speech, transparencies, presentation materials and press releases to the other party (the “non-publishing party”) form comments at least thirty (30) days prior to submission for publication or oral presentation, except, in the case of press releases, where applicable law, in the reasonable opinion of the publishing party, requires such press release to be issued within time constraints which would make such review impractical. The non-publishing party shall notify the publishing party in writing within fifteen (15) days of receipt of such draft whether such draft contains Information (as hereinafter defined) of the non-publishing party which it considers to be confidential under the provisions of Article 15 hereof, or information that if published would have an adverse effect on a patent application for which non-publishing party has initial patent prosecution responsibility pursuant to Article 11 of this Agreement. In the latter case, the non-publishing party shall have the right to request a delay and the publishing party shall delay such publication for a period not exceeding sixty (60) days. In any such notification the non-publishing party shall indicate with specificity its suggestions regarding the manner and degree to which the publishing party may disclose such information. The publishing party shall have the final authority to determine the scope and content of any publication, provided that such authority shall be exercised with reasonable regard for the interests of the non-publishing party, except that no publication will contain any Information disclosed by the non-publishing party to the publishing party without the non-publishing party’s prior written permission. Each party shall cause its Affiliates, as the case may be, to comply with the requirements of this Section 6.5 with respect to any of their proposed publications.  
 ARTICLE 7. TRANSFER OF KNOW-HOW; TECHNICAL ASSISTANCE  
 7.1. Transfer by Melior. (a) Within thirty (30) days following the Effective Date, Melior shall supply Adhera with all Melior Know-How, including, but not limited to pharmacology, toxicology, preclinical testing, clinical testing, CMC data, batch records, trials and studies, safety and efficacy, manufacturing information, analytical and quality control. Melior shall also supply Adhera with copies of all study reports prepared with respect to the Licensed Products. With respect to any Melior Know-How developed by Melior during the term of this Agreement, such disclosure will be made at least on a quarterly basis or sooner, if practicable.  
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 (b) Any data and information generated by Melior will be given free to Adhera, and its Affiliates for regulatory purposes or other issues associated with any Licensed Product. Similarly, any data and information generated by Adhera will be given free to Melior and its Affiliates for regulatory purposes or other issues associated with any Licensed Product.  
 7.2. Technical Assistance. In order to obtain regulatory approval, Melior shall, upon request by Adhera, provide Adhera with reasonable cooperation and assistance, consistent with the other provisions hereof, in connection with the transfer of Melior Know-How. Such assistance may include, but is not limited to, development of the formulations of the Licensed Products; procurement of supplies and raw materials; initial developmental and production batch manufacturing runs; process, specification and analytical methodology design and improvement; and, in general, such other assistance as may contribute to the efficient application by Adhera of the Melior Know-How. In this regard, Melior agrees to make appropriate employees of Melior reasonably available to assist Adhera, and Melior agrees to provide reasonable numbers of appropriate Adhera personnel with access during normal business hours to the appropriate personnel and operations of Melior for such periods of time as may be reasonable in order to familiarize Adhera personnel with the Melior Know-How as applied by Melior. Such technical assistance shall include but not be limited to the following:  
 (i) Melior shall (A) provide Adhera with access to any and all Drug Master File(s) or counterparts thereof in any countries (“DMF”) of Melior relating to the manufacture of Bulk Drug Substance existing as of the Effective Date; (B) reasonably cooperate with Adhera in obtaining access to and letters of authorization to refer to the DMFs of Melior’s subcontractors which are, or will be, supplying any Bulk Drug Substance, Finished Product. (ii) Within thirty (30) days after the Effective Date, Melior shall provide Adhera with copies of all documentation in Melior’s possession, including all correspondence between Melior and its subcontractors, regarding the manufacture of the Bulk Drug Substance which would be necessary or useful to assist Adhera in the commercial production of Bulk Drug Substance or to support Registration of the Licensed Products. (iii) Melior shall provide Adhera with access to any and all communication with relative regulatory authorities in any countries as of the Effective Date. (iv) Melior shall provide Adhera with testing data for other applicable regulatory authorities in any countries. Testing shall include, but not limited to, long term stability test based on ASEAN ICH condition (30 Celcius±2Celsius/75%±5%RH for 3 years). However, the procedural details of such testing shall be discussed by Joint Development Committee.  
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 7.3. Language of Disclosures. All disclosures pursuant to this Agreement will be in English.  
 ARTICLE 8. SUPPLY OF BULK DRUG SUBSTANCE, BULK FORMULATION AND FINISHED PRODUCTS  
 8.1. Supply for Pre-clinical and Clinical Use. In case that Melior keeps raw material manufactured by Melior before the Effective Date Melior shall supply laboratory quantities of such raw materials to Adhera at Adhera’s request free of charge. And Melior shall supply raw materials and finished products for the phase IIa clinical study under this agreement in case that Melior keeps raw material manufactured by Melior before the Effective Date.  
 ARTICLE 9. LICENSED PRODUCT PROGRAM PURCHASE OPTION  
 9.1. If Adhera has completed the necessary steps to affect an Up-listing Event then Adhera will have the option at such time to purchase all rights, otherwise held by Melior, for Licensed Products.  
 9.2. The full purchase consideration by Adhera shall be the issuance of 10% of Adhera common shares (adjusted for stock splits), based upon the number of outstanding shares following the Up-listing Event plus a 2.5% royalty of future gross product sales.  
 9.3. Further terms and conditions of the asset purchase by Adhera from Melior, including any possible Melior involvement with further clinical development, will be set forth in a separate definitive purchase agreement.  
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 ARTICLE 10. SAFETY INFORMATION EXCHANGE  
 10.1. Adverse Effect. The parties shall establish and implement a procedure for the mutual exchange of adverse effects reports and safety information concerning the Licensed Product to compliance with applicable law and regulatory guidelines. The detail of the operating procedure shall be separately agreed by the parties.  
 ARTICLE 11. PATENT PROSECUTION  
 11.1. Patent Prosecution and Maintenance. Melior shall be responsible, and use best efforts to prosecute Patents in each of countries including, but not limited to, US, Canada, the EPO and Asia. Melior shall keep Adhera informed as to all developments with respect to Melior Patents. Adhera shall be afforded reasonable opportunities to advise Melior and cooperate with Melior in such prosecution and maintenance. Once Patents would be issued, Melior shall use best efforts, to maintain the Patents in force and in good standing.  
 11.2. Patent Costs. For so long as the license granted to Adhera under this Agreement is in effect, Adhera will reimburse Melior for costs related to prosecuting and maintaining Melior’s patent portfolio for MLR-1019 which shall be incurred from the Effective Date. Invoices, including reasonable substantiation thereof, shall be submitted once in respect of each fiscal quarter as promptly as practicable after the end of such quarter. Payments shall be due net thirty (30) days from the date of invoice. For the avoidance of doubt, reimbursement by Adhera for new patent registrations shall be subject to prior agreement between the parties depending on the jurisdiction.  
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 11.3. Joint Patents. With respect to Joint Patents: (a) all patent applications, patents and intellectual property with respect thereto shall be jointly owned by Adhera and Melior; (b) Adhera shall be free to use such patent application and patents in the Territory and Melior shall be free to use such patent applications and patents, in each event, without any payment therefore; (c) each party agrees to consult with the other party and to give due and reasonable consideration to the other party’s position in determining the territorial scope of patent filings and the prosecution and maintenance of resulting patent rights based on Joint Patents; and Neither Party shall assign or transfer any such Joint Patents to a Third Party without the prior written consent of the other Party.  
 ARTICLE 12. INFRINGEMENT  
 12.1. Each Party shall promptly report in writing to each other Party during the term of this Agreement any: (i) known infringement or suspected infringement of any of the Melior Patent Rights in the Field; or (ii) unauthorized use or misappropriation of the Melior Technology Rights in the Field by a Third Party of which it becomes aware, and shall provide each other Party with all available evidence supporting said infringement, suspected infringement or unauthorized use or misappropriation. Within 30 days after Melior becomes, or is made, aware of any of the foregoing, it shall decide whether or not to initiate an infringement or other appropriate suit and shall advise Adhera of its decision in writing. The inability of Melior to decide on a course of action within such 30-day period shall for purposes of this Agreement be deemed a decision not to initiate an infringement or other appropriate suit.  
 12.2. Within sixty (60) days after Melior becomes, or is made, aware of any infringement, suspected infringement or unauthorized use or misappropriation by a third party in the Field, as provided in Section 12.1 above, and provided that Melior shall have advised Adhera of its decision to file suit within the 30-day period provided in Section 12.1 above, Melior shall have the right to initiate an infringement or other appropriate suit anywhere in the world against such Third Party. Melior shall provide Adhera with an opportunity to make suggestions and comments regarding such suit and shall promptly notify Adhera of the commencement of such suit. Melior shall keep Adhera promptly informed of, and shall from time to time consult with Adhera regarding, the status of any such suit and shall provide Adhera with copies of all documents filed in, and all written communications relating to, such suit.  
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 12.3. Melior shall select counsel for any suit referred to in Section 12.2 above who shall be reasonably acceptable to Adhera. Melior shall, except as provided below, pay all expenses of the suit, including, without limitation, attorneys’ fees and court costs. Adhera, in its sole discretion, may elect, within 60 days after the receipt by Adhera from Melior of notice of the commencement of such litigation, to contribute to the costs incurred by Melior in connection with such litigation in an amount not to exceed 50 percent of such costs. Any damages, settlement fees or other consideration for past infringement received as a result of such litigation shall be shared by Melior and Adhera pro rata based on their respective sharing of the costs of such litigation. If necessary Adhera shall join as a party to the suit but shall be under no obligation to participate except to the extent that such participation is required as the result of being a named party to the suit. Adhera shall have the right to participate and be represented in any suit by its own counsel at its own expense. Melior shall not settle any such suit involving rights of Adhera without obtaining the prior written consent of Adhera, which consent shall not be unreasonably withheld.  
 12.4. In the event that Melior does not inform Adhera of its intent to initiate an infringement or other appropriate suit within the 30-day period provided in Section 12.1 above, or does not initiate such an infringement other appropriate action within the 60-day period provided in Section 12.2 above, Adhera shall have the right, at its expense, to initiate an infringement or other appropriate suit in the Territory only. In exercising its rights pursuant to this Section 12.4, Adhera shall have the sole and exclusive right to select counsel and shall pay all expenses of the suit including without limitation attorneys’ fees and court costs. If necessary, Melior shall join as a party to the suit, at its own expense, and shall participate only to the extent that such participation is required as a result of its being a named party to the suit or being the holder of any patent at issue or being the owner of any Melior Technology Rights at issue. At Adhera’s request, Melior shall offer reasonable assistance to Adhera in connection therewith at no charge to Adhera except for reimbursement of reasonable out-of-pocket expenses incurred in rendering such assistance. Without limiting the generality of the preceding sentence, Melior shall cooperate fully in order to enable Adhera to institute any action hereunder. Melior shall have the right to be represented in any such suit by its own counsel at its own expense. Any settlement or other consideration for past infringement received as a result of litigation shall be the sole property of Adhera.  
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 ARTICLE 13. WARRANTIES AND REPRESENTATIONS  
 13.1. Warranties and Representations of Melior. Melior warrants and represents the following as of the date hereof:  
 (a) Melior hereby represents and warrants that: (i) Melior has the authority to grant to Adhera all of the rights granted hereunder; (ii) Melior has licensed, owns or controls all rights to the Melior Patents and the Melior Know-How; and (iii) Melior is unaware of any rights superior to Melior Patent and Melior Know-How which would prevent Adhera from fully exercising the rights licensed to it herein;  
 (b) Exhibit A is a complete list of all patents and patent applications included in the Melior Patents as of the Effective Date;  
 (c) it is not aware of any material facts which it has not disclosed to Adhera regarding the manufacture, use or sale of any Licensed Product or the practice of any inventions included in the Melior Patents or the use of the Melior Know-How by Adhera including without limitation any material facts regarding the possibility that such manufacture, use, sale or practice might infringe any third party’s know-how, patent rights or other intellectual property in the Territory;  
 (d) it is aware of no third party using or infringing all or any of the Melior Patents in derogation of the rights granted pursuant to this Agreement;  
 (e) it is aware of no third party claim to any rights in the Melior Patents or the Melior Know-How;  
 (f) it is aware of no pending interference or opposition proceeding or litigation or any communication which threatens an interference or opposition proceeding or litigation before any patent office, court, or any other governmental entity or court in any jurisdiction in regard to the Melior Patent; and  
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 (g) it is not aware of any action or proceeding, pending or threatened, with respect to Licensed Products, including without limitation the conduct of any clinical trials, manufacturing activities or other activities, that questions the validity of this Agreement or any action taken by Melior in connection with the execution of this Agreement. There are no material unsatisfied judgments or outstanding orders, injunctions, decrees, stipulations or awards (whether rendered by a court, an administrative agency or by an arbitrator) against Melior with respect to Licensed Product, including without limitation the conduct of any clinical trials, manufacturing activities or other activities.  
 13.2. Warranties and representations by Adhera. Adhera represents and warrants that it has, or will obtain, the skill and expertise in the technical areas relating to the Melior Patents and Melior Know-How to make or have made an evaluation of the capabilities, safety, utility and commercial application of the Melior Patent and the Melior Know-How.  
 13.3. Warranties and Representations of Each Party. Each party hereto warrants and represents to: (a) the other that it is free to enter into this Agreement (including the receipt of all corporate authorizations) and to carry out all of the provisions hereof, including, its grant to the other of the licensed described in Article 2; (b) to its knowledge, there is no failure to comply with, no violation of or any default under, any law, permit or court order applicable to it which might have a material adverse effect on its ability to execute, deliver and perform this Agreement or on its ability to consummate the transactions contemplated hereby; and (c) it shall comply with laws and regulations relating to the performance of its obligations or the exercise of its rights hereunder including, those relating to the manufacture, processing, producing, use, sale, or distribution of Licensed Products; and that it shall not take any action which would cause it or the other party to violate such laws and regulations.  
 13.4. Intellectual Property.  
 (i) The Melior Patents and Melior Know-How constitute all intellectual property controlled by Melior that is necessary or useful to manufacture, develop, use or commercialize the Licensed Product, and to the knowledge of Melior there is not any other intellectual property necessary for such purposes that is not controlled by Melior;  
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 (ii) All patents within the Melior Patents are in full force and effect, valid, subsisting and, in the case of issued patents, enforceable, and inventorship of the Melior Patents is properly identified on such Melior Patents. None of the Melior Patents is currently involved in any interference, reissue, reexamination, or opposition proceeding, and neither Melior nor any of its Affiliates has received any written notice from any person, or has knowledge, of such actual or threatened proceeding;  
 (iii) There are no actions or proceedings (including any inventorship challenges) pending or, to the knowledge of Melior, threatened with respect to any of the Melior Patents, Melior Know-How, Compound or Licensed Products nor have any such actions or proceedings been brought or, to the knowledge of Melior, threatened during the past five (5) years, in each case which have not been resolved without impairment of Melior’s rights in and to any of the Melior Patents, Melior Know-How, Compound Licensed Products and without the obligation to pay any royalties or other amounts to any third party with respect to the use of such technology or the sale of such products;  
 (iv) All official fees, maintenance fees and annuities for the Melior Patents have been paid through the Effective Date.  
 13.5. Exclusivity. For so long as the license granted to Adhera under this agreement is in effect, Melior shall not enter into a Transaction in the field of Xxxxxxxxx’x disease therapeutics, as hereinafter defined, with a company, organization, partnership or any other person, firm or entity unless otherwise agreed to by Adhera, which consent shall not be unreasonably withheld.  
 “Transaction” shall include but is not limited to any financing collaboration, distribution revenues, earn-outs, sales, out-licensing, purchases, debt, royalties, merger acquisition, transfer of cash or non-cash assets, disposition of capital stock by way of tender or exchange offer, partnership or any other joint or collaborative venture, research collaboration, material transfer, sponsored research or similar transaction or agreements.  
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 ARTICLE 14. INDEMNIFICATION  
 14.1. Adhera’s Indemnification. Subject to compliance by the Indemnitees with the provisions set forth in Section 14.3, Adhera shall defend, indemnify, and hold harmless the Indemnitees, from and against any and all demands, losses, liabilities, expenses, and damages including investigative costs, court costs and reasonable attorneys’ fees (collectively, the “Liabilities”) arising in connection with any and all charges, complaints, actions, suits, proceedings, hearings, investigations, claims, demands, judgments, orders, decrees, stipulations or injunctions by a third party (each, a “Third Party Claim”) resulting from any and all personal injury (including death) and property damage caused or contributed to, in whole or in part, by manufacture, testing, design, use, sale, or labeling of any Licensed Products, regulatory action related to such products, or the practice of the Melior Patents or Melior Know-How by Adhera or its Affiliates except to the extent that such Liabilities result from the negligence or willful misconduct of Melior or are an item for which Melior must indemnify Adhera pursuant to Section 14.2.  
 14.2. Melior’s Indemnification. Subject to compliance by the Indemnitees with the provisions set forth in Section 14.3, Melior shall indemnify and hold harmless the Indemnitees from and against any and all Liabilities arising in connection with any Third Party Claim resulting from: (a) any breach by Melior of any of its representations, warranties, covenants set forth in this Agreement; (b) Melior’s (or its agent’s, contractor’s or other designee’s) failure to comply with cGMP, applicable product specifications or applicable law in connection with the manufacture of any Licensed Product supplied to Adhera hereunder; (c) the negligence, recklessness or intentional acts or omissions of Melior or its Affiliates, or subcontractors, and their respective directors, officers, employees and agents, except to the extent that such Liabilities result from the negligence or willful misconduct of Adhera or are an item for which Adhera must indemnify Melior pursuant to Section 14.1. Melior’s obligations under this Article shall survive expiration or termination of this Agreement for any reason.  
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 14.3. Indemnification Procedures. Any Indemnitee which intends to claim indemnification under this Article shall, promptly after becoming aware thereof, notify the party from whom it is seeking indemnification (the “Indemnitor”) in writing of any matter in respect of which the Indemnitee or any of its employees intend to claim such indemnification. The Indemnitee shall permit, and shall cause its employees to permit, the Indemnitor, at its discretion, to settle any such matter and agrees to the complete control of such defense or settlement by the Indemnitor; provided, however, that such settlement does not adversely affect the Indemnitee’s rights hereunder or impose any obligations on the Indemnitee in addition to those set forth herein in order for it to exercise such rights. No such matter shall be settled by such Indemnitee without the prior written consent of the Indemnitor and neither the Indemnitor nor the Indemnitee shall be responsible for any legal fees or other costs incurred other than as provided herein. The Indemnitee and its employees shall cooperate fully with the Indemnitor and its legal representatives in the investigation and defense of any matter covered by the applicable indemnification. The Indemnitee shall have the right, but not the obligation, to be represented by counsel of its own selection and expense.  
 ARTICLE 15. CONFIDENTIALITY  
 15.1. Treatment of Confidential Information. Except as otherwise provided hereunder, during the term of this Agreement and for a period of five (5) years thereafter:  
 (a) Adhera and its Affiliates shall retain in confidence and use only for purposes of this Agreement, any written or oral confidential information and data supplied by or on behalf of Melior under this Agreement; and  
 (b) Melior and its Affiliates shall retain in confidence and use only for purposes of this Agreement any written and oral confidential information and data supplied by or on behalf of Adhera to Melior under this Agreement.  
 For Purposes of this Agreement, all such confidential information and data which a party is obligated to retain in confidence shall be called “Information.”  
 15.2. Right to Disclose. To the extent that it is reasonably necessary to fulfill its obligations or exercise its rights under this Agreement, or any rights which survive termination or expiration hereof, each party may disclose Information to its Affiliates, consultants, outside contractors, actual or prospective investors, and clinical investigators on condition that such entities or persons agree in writing:  
 (a) to keep the Information confidential for a period of at least five (5) years from the date of disclosure by such party to the same extent as such party is required to keep the Information confidential; and  
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 (b) to use the Information only for those purposes for which the disclosing party is authorized to use the Information.  
 Each party or its Affiliates, as applicable, may disclose Information to the government or other regulatory authorities to the extent that such disclosure (i) is necessary for the prosecution and enforcement of patents, of authorizations to conduct preclinical or clinical trials to commercially market Licensed Products, provided such party is then otherwise entitled to engage in such activities in accordance with the provisions of this Agreement, or (ii) is legally required.  
 15.3. Release from Restrictions. The obligation not to disclose or use Information shall not apply to any part of such Information that:  
 (a) is or becomes patented (but the existence of a patent shall only permit disclosure and not, unless otherwise provided hereunder, use), published or otherwise part of the public domain, other than by unauthorized acts of the party obligated not to disclose such Information (for purposes of this Article 16 the “receiving party”) or its Affiliates in contravention of this Agreement; or  
 (b) is disclosed to the receiving party or its Affiliates by a third party provided that such Information was not obtained by such third party directly or indirectly from the other party to this Agreement; or  
 (c) prior to disclosure under the Confidentiality Agreement or this Agreement, as the case may be, was already in the possession of the receiving party, its Affiliates, provided that such Information was not obtained directly or indirectly from the other party to this Agreement; or  
 (d) result from research and development by the receiving party or its Affiliates, independent of disclosure from the other party to this Agreement; or  
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 (e) is required by law to be disclosed by the receiving party, provided that in the case of disclosure in connection with any litigation, the receiving party uses reasonable efforts to notify the other party immediately upon learning of such requirement in order to give the other party reasonable opportunity to oppose such requirement; or  
 (f) Adhera and Melior agree in writing may be disclosed.  
 ARTICLE 16. TERM AND TERMINATION  
 16.1. Term. Unless sooner terminated as otherwise provided in this Agreement, the term of this Agreement shall commence on the Effective Date and shall continue until the date of expiration of the last-to-expire of the Melior Patents, including any renewals or extensions thereof.  
 16.2. Termination by Default. If either party defaults in the performance of, or fails to be in compliance with, any material agreement, condition or covenant of this Agreement, the non-defaulting party may terminate this Agreement with respect to the defaulting party if such default or noncompliance shall not have been remedied, or, in the event the default or non-compliance cannot be remedied within such period, reasonable steps shall not have been initiated to remedy the same, within sixty (60) days after receipt by the defaulting party of a written notice thereof from the non-defaulting party. In the event of any termination of this Agreement due to Melior’s breach of any provision of this Agreement, all right, title, interest in and to Melior Know-how that have been developed at Adhera’s expense up to the effective date of such termination shall be hereby transferred and assigned to Adhera. Adhera shall have the right to use Melior’s know-how as well as Joint Patents and Joint Know-How free of charge under this Agreement for the regulatory purpose after termination of this agreement.  
 16.3. Termination by Adhera without any cause. Adhera shall have the right to terminate this Agreement by giving Melior sixty (60) days’ prior written notice thereof. In the case of the termination pursuant to Article 16.3, Melior shall have the right to use Joint Patents and Joint Know-How as well as Adhera Information free of charge under this agreement.; provided that if such termination occurs while either the Phase 2a or Phase 2b trial is enrolling patients or before all follow-up visits for such studies have been completed, Adhera must continue to fund in accordance with the terms and conditions of its contracts in effect with each of CRO, CMO or hospitals.  
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 16.4. Termination due to Insolvency. Either party may terminate this Agreement if, at any time after the Effective Date, the other party (i) commences any insolvency, receivership or bankruptcy proceedings or any other proceedings for the settlement of such party’s debts or such proceeding is commenced against such party by a third party and is not dismissed within 60 days of commencement (each an “Insolvency Event”); (ii) such party makes an assignment for the benefit of creditors, or (iii) the dissolution or cessation of business by such party. Upon the occurrence of an Insolvency Event affecting Melior, all right, title and interest in and to Melior Know-how developed after the Effective Date at Adhera’s expense under this Agreement shall be hereby transferred and assigned to Adhera.  
 16.5. Merger / Change of Control. In the event of a merger or change of control of Melior, Adhera’s obligation to pay for any expenses shall immediately terminate, but Adhera’s commercial license and right of using data which Melior has at this event shall continue in effect. Further, in the event of a merger or change of control of Melior, Melior (or the third party acquiring the controlling interest in Melior as a result of such merger or change of control) shall reimburse Adhera for any and all expenses borne by Adhera in connection with any and all development work under this Agreement up to the effective date of such merger or change of control.  
 16.6. License-out by Melior. If Melior enters into a license agreement in breach of this Agreement with any third party without the prior written approval from Adhera, any such license agreement shall be null and void and without any legal effect.  
 16.7. Failure to Continue Commercially Reasonable Efforts. If Adhera fails to maintain commercially reasonable efforts for the continued development of the Licensed Products then Adhera’s licensed rights for commercial use and development shall terminate.  
 16.8. Failure to Affect an Up-listing Event. If Adhera fails to affect an Up-listing Event within 12 months after the parties receive a CTA from the EMEA, then Adhera’s commercial license and rights for using data shall terminate.  
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 16.9. Survival of Obligations; Return of Confidential Information. Notwithstanding any termination of this Agreement, the obligations of the parties with respect to the protection and nondisclosure of Confidential Information (Section 15) and product liability indemnification as well as any other provisions which by their nature are intended to survive any such termination, shall survive and continue to be enforceable. Upon any termination or expiration of this Agreement, each Party shall promptly return to the other Party all written Confidential Information and all copies thereof, of such other Party.  
 16.10. Effect of Termination. In the event of any expiration or termination pursuant to this Article 16, neither party shall have any remaining rights or obligations under this Agreement other than as provided below:  
 (a) Each party will have the right to receive all payments accrued prior to the effective date of termination;  
 (b) termination or expiration of this Agreement for any reason shall have no effect on the parties’ rights or obligations under Articles 12, 14 and 15, or their respective rights in Joint Patents and Joint Know-How;  
 (c) the parties’ shall retain any other remedies for breach of this Agreement they may otherwise have.  
 (d) after termination of this Agreement, Melior can obtain the rights to use the Joint Know-How, Joint Patents and Adhera Information.  
 ARTICLE 17. ASSIGNMENT  
 17.1. Assignment by Either Party. Neither Party may assign its rights or obligations hereunder without the prior written consent of each other Party other than in connection with a Change of Control of such Party, and any assignment made in breach of this Section 17.1 shall be null and void. For clarity, neither Party shall assign or transfer its rights and obligations hereunder, whether by operation of law, contract or otherwise (including in connection with the insolvency or bankruptcy affecting such Party) without the prior written consent of the other Party, except in connection with a Change of Control of the Party.  
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 ARTICLE 18. DISPUTE RESOLUTION AND ARBITRATION  
 18.1. Initial Resolution. In the case of any disputes between the parties arising from this Agreement, and in case this Agreement does not provide a solution for how to resolve such disputes, the parties shall discuss and negotiate in good faith a solution acceptable to both parties and in the spirit of this Agreement. If after negotiating in good faith pursuant to the foregoing sentence, the parties fail to each agreement within thirty (30) days, then the Chief Executive Officer of Melior and the Chief Executive Officer of Adhera shall discuss in good faith an appropriate resolution to the dispute. If these executives fail, after good faith discussions not to exceed thirty (30) days, to reach an amicable agreement then the parties shall submit to binding arbitration pursuant to Section 18.2 (“Arbitration”). The date of submission of the matter to substrate shall be the “Dispute Date”.  
 18.2. Arbitration. This Agreement shall be governed by and interpreted in accordance with the laws of Delaware without regard to its or any other jurisdiction’s choice of law rules that would result in the application of the laws of any jurisdiction other than Delaware. Any controversy or claim arising out of or relating to this Agreement shall be finally settled by arbitration administered by the American Arbitration Association in accordance with its Commercial Arbitration Rules, and judgment on the award rendered by the arbitrator(s) may be entered in any court having jurisdiction thereof. The arbitration shall be conducted in Pennsylvania, before a tribunal of three arbitrators, of whom one shall be nominated by Melior and one shall be nominated by Adhera, and the third one shall be selected by the foregoing two nominees. The arbitration proceedings shall be in English. All decisions of the arbitration tribunal shall be final and binding on the Parties and shall be enforceable in accordance with their terms. Each party shall bear the expenses and costs of the Arbitrator selected by party. The third Arbitrator shall be compensated for services rendered at the prevailing hourly rate of compensation and reimbursed for any expenses incurred in connection with rendering such services. The non-prevailing party shall bear the costs and expenses of compensation and reimbursement for the third Arbitrator.  
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 ARTICLE 19. GENERAL PROVISIONS  
 19.1. Damages. EXCEPT FOR A BREACH OF CONFIDENTIALITY OBLIGATIONS UNDER THIS AGREEMENT OR WILLFUL BREACH OF THIS AGREEMENT, IN NO EVENT SHALL EITHER PARTY BE LIABLE TO THE OTHER PARTY FOR ANY CONSEQUENTIAL, INCIDENTAL, INDIRECT, PUNITIVE OR EXEMPLARY DAMAGES EVEN IF ADVISED OF THE POSSIBLE OF THE SAME.  
 19.2. Independent Contractors. It is understood and agreed that the parties hereto are independent contractors and are engaged in the operation of their own respective businesses, and neither party hereto is to be considered the agent of the other party for any purpose whatsoever, and neither party shall have any authority to enter into any contracts or assume any obligations for the other party nor make any warranties or representations on behalf of that other party.  
 19.3. Publicity. The parties agree to issue mutual press releases concerning their entry into this Agreement, with the content of such releases to be approved (which consent shall not be unreasonably withheld or delayed) in advance by the parties. In all other respects, except as required by law, neither party shall use the name of the other party in any publicity release without the prior written permission of such other party, which shall not be unreasonably withheld. The other party shall have a reasonable opportunity to review and comment on any such proposed publicity release. Except as required by law, neither party shall publicly disclose the terms of this Agreement or issue any publicity release with regard thereto unless expressly authorized to do so by the other party which authorization shall be agreed upon  
 19.4. Governing Law. This Agreement and all amendments, modifications, alterations, or supplements hereto, and the rights of the parties hereunder, shall be construed under and governed by the laws of Delaware, exclusive of its conflicts of laws principles.  
 19.5. Entire Agreement. This Agreement, together with the Exhibits attached hereto, constitutes the entire agreement between Melior and Adhera with respect to the subject matter hereof and shall not be modified, amended or terminated, except as herein provided or except by another agreement in writing executed by the parties hereto. Upon the Effective Date, the Confidentiality Agreement shall terminate.  
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 19.6. Waiver. No provision of this Agreement may be waived except by a writing signed by the party entitled to the benefit thereof, and no such waiver of any provision hereof in one instance shall constitute a waiver of any other provision or of such provision in any other instance. No omission, delay or failure on the part of any party hereto in exercising any rights hereunder will constitute a waiver of such rights or of any other rights hereunder.  
 19.7. Severability. All rights and restrictions contained herein may be exercised and shall be applicable and binding only to the extent that they do not violate any applicable laws and are intended to be limited to the extent necessary so that they will not render this Agreement illegal, invalid or unenforceable. If any provision or portion of any provision of this Agreement, not essential to the commercial purpose of this Agreement, shall be held to be illegal, invalid or unenforceable by a court of competent jurisdiction, it is the intention of the parties that the remaining provisions or portions thereof shall constitute their agreement with respect to the subject matter hereof, and all such remaining provisions, or portions thereof, shall remain in full force and effect. To the extent legally permissible, any illegal, invalid or unenforceable provision of this Agreement shall be replaced by a valid provision which shall implement the commercial purpose of the illegal, invalid or unenforceable provision. In the event that any provision essential to the commercial purpose of this Agreement is held to be illegal, invalid or unenforceable and cannot be replaced by a valid provision which will implement the commercial purpose of this Agreement, this Agreement and the rights granted herein shall terminate  
 19.8. Force Majeure.  
 (a) Any delays in, or failure of performance of, any party to this Agreement, shall not constitute a default hereunder, or give rise to any claim for damages, if and to the extent caused by occurrences beyond the control of the party affected, including, but not limited to, acts of God, strikes or other concerted acts of workmen, civil disturbances, fires, floods, explosions, riots, war, rebellion, sabotage, acts of governmental authority or failure of governmental authority to issue licenses or approvals which may be required(“Force Majeure”).  
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 (b) The party asserting the Force Majeure shall promptly notify the other party of the event constituting Force Majeure and of all relevant details of occurrence and where appropriate an estimate of how long such Force Majeure event shall continue.  
 (c) If such Force Majeure event continues thereafter and in any event, the parties shall consult with each other in order to find a fair solution and shall use all reasonable endeavors to minimize the consequences of such Force Majeure.  
 19.9. Counterparts. This Agreement may be executed in one or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.  
 19.10. Notices. All notices, statements, and reports required to be given under this Agreement shall be in writing and shall be deemed to have been given upon delivery in person or, when deposited (a) in the mail in the country of residence of party giving the notice, registered or certified postage prepaid or with a professional courier service (e.g., FedEx or UPS or DHL), and addressed as follows:  
 To Adhera: Adhera Therapeutics, Inc   
 0000 Xxxxxxxxxx Xxxxxxx  
 Xxxxx Xxxxx, XX 00000   
 Attn: Xxxxxx Xxxxxxxxxx   
 Tel:   
 Fax:   
 E-mail: xxxxxxxxxxx@xxxxxxxxxxx.xxx   
 To Melior: Melior Pharmaceuticals II, LLC   
 000 Xxxxxxxxxx Xxxxx   
 Xxxxx, XX 00000   
 Attn: Xxxxxx Xxxxxx   
 Tel.: (000)000-0000 xxx 000   
 Fax.: (000)000-0000   
 E-mail: xxxxxxx@xxxxxxxxxxxxxxx.xxx   
 Any party hereto may change the address to which notices to such party are to be sent by giving notice to the other party at the address and in the manner provided above. Any notice may be given, in addition to the manner set forth above, by facsimile or e-mail, provided that the party giving such notice obtains acknowledgment by facsimile or e-mail that such notice has been received by the party to be notified. Notices made in this manner shall be deemed to have been given when such acknowledgment has been transmitted. Any provision of this Section 19.10 to the contrary notwithstanding, any notice to Melior shall be effective if given as to Melior prescribed above by Adhera, despite any failure to deliver copies as prescribed above.  
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 IN WITNESS WHEREOF, Adhera and Melior have caused this Agreement to be signed by their duly authorized representatives, under seal, as of the day and year indicated above.  
 ADHERA THERAPEUTICS, INC.  
 By Xxxxxx Xxxxxxxxxx  
 Title: President & CEO  
 MELIOR PHARMACEUTICALS II, LLC  
 By: Xxxxxx Xxxxxx  
 Title: President & CEO  
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 Exhibit A: Melior Patents  
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 Exhibit B: Exemplary Clinical Protocol Synopsis for Anticipated Phase 0x Xxxxx  
 XX-000 XXXXXXXX XXXXXXXX  
Protocol Number MP2-201  
 Protocol Title A Multi-center, Double Blind, Randomized, Placebo-controlled, Flexible Dose-Escalagion, Phase IIa Study of MLR-1019 in Xxxxxxxxx’x Patients With L-DOPA Induced Dyskinesias  
 Clinical Phase II  
 Sponsor Melior Pharmaceuticals II, LLC  
 Study Centers   
Approximately 10 sites distributed in the Bulgaria and Romania .  
 Study Period   
12 weeks  
Subjects will be screened for inclusion /exclusion criteria within 7 days of first dose  
 Study Objectives   
Primary Objective  
 ● To assess the safety and tolerability of MLR-1019 in Xxxxxxxxx’x patients.  
 Secondary Objectives  
 ● To evaluate the potential dose-response relationship of MLR-1019 on L-DOPA induced dyskinesia in Xxxxxxxxx’x patients over a period of 12 weeks.  
 ● To assess the effect of MLR-1019 on reducing parkinsonian symptoms when given orally b.i.d to subjects with L-DOPA induced dyskinesia over a period of 12 weeks.  
 ● To assess the effect of MLR-1019 on excessive daytime sleepiness associated with Xxxxxxxxx’x disease when given orally b.i.d to subjects with L-DOPA induced dyskinesia over a period of 12 weeks.  
 Study Population Xxxxxxxxx’x disease patients with L-DOPA induced dyskinesia  
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 Study Design   
This study is a randomized, double blind, placebo-controlled, parallel group, flexible dose-escalation, study of MLR-1019 in Xxxxxxxxx’x patients with L-DOPA induced dyskinesia. Following an initial screening visit, subjects fulfilling the study inclusion and exclusion criteria will be randomized 3:1 to one of 2 study arms and receive either 5 mg MLR-1019 x.xx. or placebo. Placebo tablets will be identical in appearance to those of MLR-1019.  
 After 4 weeks of treatment, subjects receiving 5mg will a) remain on the same dose, b) switched to 10mg, or c) switched to placebo based upon clinical global impression-efficacy index (CGI-EI) rating scale. After an additional 4 weeks of treatment subject receiving 10 mg will a) remain on the same dose, b) switched to 20mg, or c) switched to 5mg based upon clinical global impression-efficacy index (CGI-EI) rating scale.  
 Subjects will visit the research facility at weekly intervals (+/- 2 days) for assessments of tolerability, safety and efficacy.  
 Number of Subjects   
Approximately 80 subjects will be enrolled (60 subjects initially in 5mg arm, 20 subjects initially in placebo arm).  
 Key Inclusion Criteria   
1) Male or Female aged over 30 years,  
2) Diagnosis of Xxxxxxxxx’x disease consistent with the criteria of the UKPD Brain Bank  
3) Xxxxxxxxx’x disease (PD), treated with L-Dopa, with a documented history of predictable moderate to severe dyskinesias for a period of at least three months  
4) A stable anti-parkinsonian treatment regimen for at least four weeks  
 Exclusion Criteria   
1) Atypical parkinsonian syndromes,  
2) Drug-induced Parkinsonism,  
3) Neuroleptic treatment within the previous 3 months,  
4) Surgical or Duodopa treatment for PD  
5) Advanced, severe or unstable disease (other than PD) or evidence of dementia that may interfere with the study outcome evaluations, in judgement of investigator,  
6) Female subjects of childbearing potential without effective contraception  
7) History of drug or alcohol abuse within previous 12 months.  
8) Exclusionary medications: benzodiazepines or other sleep aids  
 Route and Dosage Form  
 Oral, capsules  
 Dosage   
0 mg, 5 mg, 10 mg, 20mg  
 Duration of Treatment   
The total duration of MLR-1019 treatment or placebo is 12 weeks.  
 Primary Endpoints   
● Safety - descriptive list of adverse events by treatment group,  
● Tolerability of MLR-1019 as measured by ability to complete the study on the assigned dosage, and by major changes in xxxxx xxxxx, laboratory values, and electrocardiogram adverse events leading to study drug discontinuation.  
● Efficacy – Anti-dyskinetic efficacy as measured by UDysRS  
 Secondary Endpoints   
● Anti-dyskinetic efficacy as measured by the modified AIMS (Abnormal Involuntary Movement Scale) total score at 1-week intervals  
● Anti-dyskinetic efficacy as measured by the Xxxx-Xxxx Activities of Daily Living Dyskinesia Scale (LFADLDS)  
● Total ON- and OFF-times and ON-time with dyskinesia and with troublesome dyskinesias (patient diary)  
● Number and duration of diurnal involuntary sleep episodes of severe sleepiness (patient diary)  
● Anti-dyskinetic efficacy as measured by items 32, 33 and 34 of Part IV of the Unified Xxxxxxxxx’x Disease Rating Scale (UPDRS)  
● Change from baseline on patient’s Total Unified Xxxxxxxxx’x Disease Rating Scale (UPDRS) Score from Baseline to 4 Weeks  
● Change from baseline on patient’s Epworth Sleepiness Scale scores (ESS) Subject and Clinician Global Impression of Change for dyskinesia (SGI-C and CGI-C) using a 7-point Likert Scale (ranging from “very much improved” to “very much worse”)  
● Tolerability of MLR-1019 as measured by ability to complete the study on the assigned dosage and by changes in xxxxx xxxxx, laboratory values, electrocardiogram, and adverse events leading to study drug discontinuation  
 Proposed Statistical analysis:   
● Because this is an exploratory study to assess tolerability and safety as primary goals, formal power and sample size computations have not been performed.  
● A Repeated Measures Mixed Model will be employed to assess the change from baseline to final visit in UDysRS, modified AIMS, CGI-C, UPDRS, and ESS.  
● Proportion of patients experiencing improvement in UDysRS.  
● Frequency and Severity of reported AEs among treatment groups will be assessed descriptively.  
● All statistical analysis will be performed using SAS® software  
 This study will be conducted in compliance with ICH/GCP guidelines.  
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