

### Aerpio Pharmaceuticals, Inc.

27,367,117 Shares

### Common Stock

This prospectus supplement no. 14 supplements the prospectus dated June 23, 2017, relating to the offering and resale of up to 27,367,117 shares of our common stock, par value \$0.0001 per share, that were privately issued to selling stockholders in connection with a merger transaction and a private placement.

This prospectus supplement incorporates into our prospectus the information contained in our attached current report on Form 8-K, which was filed with the Securities and Exchange Commission on June 25, 2018.

You should read this prospectus supplement in conjunction with the prospectus, including any supplements and amendments thereto. This prospectus supplement is qualified by reference to the prospectus except to the extent that the information in the prospectus supplement supersedes the information contained in the prospectus.

This prospectus supplement is not complete without, and may not be delivered or utilized except in connection with, the prospectus, including any supplements and amendments thereto.

Our common stock is presently quoted for trading on the OTC Markets – OTCQB tier, or OTCQB, under the symbol "ARPO." On June 22, 2018, the closing price of our common stock, as quoted on the OTCQB, was \$4.20 per share.

You should carefully consider matters discussed under the caption "Risk Factors" beginning on page 9 of the prospectus.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus supplement or the prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The date of this prospectus supplement is June 25, 2018.

# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

### FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of The Securities Exchange Act of 1934

Date of Report (Date of Earliest Event Reported): June 24, 2018

### **AERPIO PHARMACEUTICALS, INC.**

(Exact name of registrant as specified in its charter)

**Delaware** (State or other jurisdiction of incorporation)

000-53057 (Commission File Number) 61-1547850 (I.R.S. Employer Identification No.)

9987 Carver Road
Cincinnati, OH
(Address of principal executive offices)

revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ⊠

45242 (Zip Code)

Registrant's telephone number, including area code (513) 985-1920

Not Applicable (Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of provisions:	the following
□ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)	
Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)	
Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))	
Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))	
ndicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 or Rule 12b Securities Exchange Act of 1934.	-2 of the
Emerging growth company ⊠	
f an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying wit	h anv new or

#### Item 1.01 Entry into a Material Definitive Agreement

On June 24, 2018, Aerpio Pharmaceuticals, Inc. (the "Company") entered into a License Agreement (the "Agreement"), effective as of June 24, 2018 with a wholly-owned subsidiary of Gossamer Bio, Inc. (including its affiliates, "Gossamer"), under which the Company has granted Gossamer an exclusive, sublicensable license to develop and commercialize AKB-4924 and other structurally related products worldwide, with initial development expected in the indications of induction and maintenance in ulcerative colitis and Crohn's Disease.

Gossamer will be responsible for the development and commercialization of the licensed products, and a joint development committee will be formed to oversee the development and manufacturing activities related to the licensed products. Under the terms of the Agreement, Gossamer is obligated to use its commercially reasonable efforts to develop and commercialize licensed products in at least the United States, two major European countries and Japan for at least one of the initial indications. The Agreement includes an exclusivity provision that prohibits the Company from developing, manufacturing or commercializing, and prohibits Gossamer from clinically developing or commercializing certain HIF stabilizing compounds other than as permitted in the Agreement, which terminates for Gossamer if Gossamer undergoes a change of control.

Pursuant to the terms of the Agreement, Gossamer is required to make an upfront payment to us of \$20 million. The Company is also eligible to receive up to \$55 million in development milestone payments, up to \$85 million in commercial milestone payments, and up to \$260 million in sales milestone payments, with such payments contingent on the achievement of specified milestones with respect to the first licensed product for each of the first two initial indications. The Company is also eligible to receive tiered royalties on sales of licensed products at percentages ranging from a high-single-digit to mid-teens, subject to certain customary reductions. In addition, under certain circumstances, in lieu of receiving the foregoing milestone payments and royalties, the Company may elect to receive a specified percentage of payments received by Gossamer and its stockholders (with some exclusions) in connection with Gossamer's grant of a sublicense or other rights to the licensed products or if Gossamer undergoes a change of control and the value of the transaction exceeds a certain value (provided that Gossamer can prevent the Company from exercising this option if the parent company of Gossamer is the entity undergoing the change of control). Conversely, the Company could be required to accept such a specified percentage of those payments, if Gossamer agrees to pay the Company a certain minimum upon Gossamer and its stockholders being paid. Such amount may be reduced if the subject transaction includes pharmaceutical candidates or products or other named asset categories in addition to the licensed products.

The Agreement expires on a licensed product-by-licensed product and country-by-country basis on the later of fifteen years from the date of first commercial sale or when there is no longer a valid patent claim covering such licensed product in such country. Either party may terminate the Agreement for an uncured material breach by the other party or upon the bankruptcy or insolvency of the other party. Gossamer may terminate the Agreement in the event Gossamer determines there is a potential safety or efficacy issue with the licensed products. The Company may terminate the Agreement if Gossamer institutes certain actions related to the licensed patents. Under certain termination circumstances, the Company would have worldwide rights to the terminated program.

#### Item 8.01. Other Events.

On June 25, 2018, the Company issued a press release announcing its entry into the Agreement. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

#### Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit	
No.	Description

10.1\* License Agreement dated June 24, 2018, by and between Aerpio Pharmaceuticals, Inc. and Gossamer Bio, Inc.

99.1 Press release dated June 25, 2018.

\* Confidential treatment has been requested for portions of this exhibit. These portions have been omitted from this Current Report on Form 8-K and have been filed separately with the SEC.

#### **SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: June 25, 2018

### AERPIO PHARMACEUTICALS, INC.

By: /s/ Stephen J. Hoffman, M.D., Ph.D.
Stephen J. Hoffman, M.D., Ph.D.
Chief Executive Officer

#### LICENSE AGREEMENT

This License Agreement (this "<u>Agreement</u>"), dated as of June \_\_\_, 2018 (the "<u>Effective Date</u>"), is made by and between Aerpio Pharmaceuticals, Inc., a Delaware corporation having business offices at 9987 Carver Road, Suite 420, Cincinnati, OH 45254 ("<u>Aerpio</u>"), and GB004, Inc., a Delaware corporation having business offices at 3013 Science Park Road, Suite 200, San Diego, CA 92121 ("<u>Licensee</u>"). Aerpio and Licensee are sometimes hereinafter referred to each as a "<u>Party</u>" and collectively as the "<u>Parties</u>."

WHEREAS, Aerpio has been engaged in the development of AKB-4924, a compound that binds to HIF prolyl hydroxylase resulting in HIF stabilization, and controls certain patent rights and know-how with respect thereto;

WHEREAS, Licensee desires to obtain exclusive rights under the Aerpio Patent Rights and Aerpio Know-How in order to continue the development thereof and products containing same; and

WHEREAS, the Parties desire to enter into an agreement pursuant to which Aerpio will grant an exclusive license to Licensee under the Aerpio Patent Rights and Aerpio Know-How for Licensee to develop, manufacture and commercialize the Licensed Compound and Licensed Products for initially the indications of induction and maintenance in ulcerative colitis and the induction and maintenance in Crohn's Disease, all on the terms set forth below.

NOW, THEREFORE, the Parties hereby agree as follows:

#### Section 1. Definitions.

For the purpose of this Agreement, the following terms and phrases (and cognates) will have the meanings set forth below:

- 1.1 "Accounting Standards" means generally accepted accounting principles as practiced in the United States or IFRS (International Financial Reporting Standards), in each case, consistently applied.
- 1.2 "Aerpio In-License" means the Non-Exclusive License Agreement by and between Aerpio and The Regents of the University of Colorado (the "UC Regents"), dated November 1, 2016, as amended or restated from time to time. A copy of the Aerpio In-License is attached hereto as Exhibit F.
- 1.3 "Aerpio Know-How" means all Know-How, existing as of the Effective Date or disclosed by Aerpio to the Licensee during Term, Controlled by Aerpio or any of its Affiliates, that is necessary or useful for the research, manufacture, use, sale, offer for sale, importation, development or commercialization of the Licensed Compound or any Licensed Products for use in the Territory in the Field.
- 1.4 "Aerpio Patent Rights" means (a) the patents and patent applications listed in Exhibit A attached hereto and any other patents, patent applications and other patent rights, Controlled by Aerpio or any of its Affiliates, that Cover any Aerpio Know-How, plus (i) all divisionals, continuations, continuations-in-part thereof or any other patent rights claiming priority directly or indirectly to any of the patents or patent applications identified on Exhibit A, and (ii) all patents issuing on any of the foregoing, together with all registrations, re-issues, re-examinations, renewals, supplemental protection certificates and extensions of any of the foregoing, and all foreign counterparts thereof (under this clause (a), collectively, the "Aerpio Core Patent Rights"), (b) any other patents, patent applications and other patent rights, existing as of the Effective Date, Controlled by Aerpio or any of its Affiliates, that are necessary for the manufacture, use, sale, offer for sale or importation of the Licensed Compound or Licensed Products for use in the Territory in the Field.

- 1.5 "Affiliate" of a person or entity means any other person or entity which (directly or indirectly) is controlled by, controls or is under common control with such first person or entity. For the purposes of this definition, the term "control" (including, with correlative meanings, the terms "controlled by" and "under common control with") as used with respect to any entity means (a) in the case of a corporate entity, direct or indirect ownership of voting securities entitled to cast at least fifty percent (50%) of the votes in the election of directors or (b) in the case of a non-corporate entity, direct or indirect ownership of at least fifty percent (50%), including ownership by trusts with substantially the same beneficial interest, of the equity interests with the power to direct the management and policies of such entity, provided that if local law restricts foreign ownership, control will be established by direct or indirect ownership of the maximum ownership percentage that may, under such local law, be owned by foreign interests.
- 1.6 "<u>Change of Control</u>" means with respect to a Party, in one transaction or a series of related transactions, the merger, consolidation, reorganization, business combination, sale of all (or substantially all) of the capital stock (or other equity interests) or assets, the change in voting control (that is, when the equity or other security holders of such Party or Affiliate immediately preceding such transaction(s) hold less than fifty percent (50%) of the outstanding equity or other securities, or less than fifty percent (50%) of the outstanding voting power, respectively, of the ultimate company or entity resulting from such transaction(s) immediately after consummation thereof), liquidation or dissolution, the license, sublicense, sale, assignment or other transfer of all or substantially all of such Party's business or assets to which this Agreement relates, or any other form of acquisition or liquidity event for such Party.
- 1.7 "Commercially Reasonable Efforts" means, with respect to the Licensed Compound or any Licensed Product, that level of efforts and resources commonly dedicated in the pharmaceutical industry by [\*\*\*].
- 1.8 "<u>Commercialization Budget</u>" means the budget for conducting commercialization of any Licensed Product for use in the Territory and in the Field pursuant to the Commercialization Plan during a given calendar year and [\*\*\*].
- 1.9 "<u>Commercialization Plan</u>" means the plan setting forth the activities and timelines relating to the commercialization (and related manufacturing) of any Licensed Product for use in the Territory and in the Field during a given calendar year and the[\*\*\*], including the Commercialization Budget and annual Net Sales forecasts for the Territory.
- 1.10 "<u>Competitive Infringement</u>" means any allegedly infringing activity with respect to an Aerpio Core Patent Right, which activity (i) falls within the scope then in effect of the license granted by Aerpio to Licensee in Section 5.1(a) and (ii) is reasonably expected to reduce the Net Sales of any Licensed Product then being commercialized.
- 1.11 "<u>Confidential Information</u>" means all non-public Know-How, marketing plans, strategies and customer lists, and other non-public information or material that are disclosed or provided by a Party or its Affiliates to the other Party or its Affiliates, regardless of whether any of the foregoing are marked "confidential" or "proprietary" or communicated to the other by the disclosing Party or its Affiliates in oral, written, graphic, or electronic form.
- 1.12 "Confidentiality Agreement" means that certain Bilateral Confidential and Non-Disclosure Agreement, dated August 4, 2017, by and between Aerpio and Licensee d/b/a FSG Bio Inc.

- 1.13 "Control" or "Controlled" means, with respect to any patent right, Know-How, or other intellectual property right, the possession (whether by ownership or license, other than by a license or sublicense granted pursuant to this Agreement) by a Party or its Affiliates of the ability to grant to the other Party a license or access as provided herein to such item, without violating the terms of any agreement or other arrangement with any Third Party or, except for the Aerpio In-License or any patents or patent applications or other intellectual property Covering Aerpio Know-How, being obligated to pay any royalties or other consideration therefor, in existence as of the time such Party or its Affiliates would first be required hereunder to grant the other Party such license or access.
- 1.14 "<u>Cover</u>", "<u>Covered</u>" or "<u>Covering</u>" means, with respect to a particular compound, product or service and a particular issued patent or patent application, that, but for rights granted hereunder, the making, using, importing, offering for sale or selling of such product or service would infringe a Valid Claim in such patent (or patent application, as if such claim has issued).
- 1.15 "<u>Development Budget</u>" means a budget for conducting development pursuant to each Development Plan (a) during a given calendar year and [\*\*\*] and (b) an overall estimate of the budget required for obtaining a first Regulatory Approval of a first Licensed Product for the Indication of such Development Plan.
- 1.16 "Development Plan(s)" means, on an Indication-by-Indication basis, the plan setting forth the activities and timelines relating to the development (and related manufacturing) of the Licensed Compound and Licensed Products in all countries of the Territory for such Indication. An initial draft of each Development Plan for the each of the Initial Indications, as well as any other Indications contemplated for use in the Territory as of the Effective Date, is set forth on Exhibit B-1.
  - 1.17 "EMA" means the European Medicines Agency and any successor agency thereto.
- 1.18 "European Union" or "EU" means the countries of the European Economic Area, as it is constituted on the Effective Date, and as it may be expanded from time to time after the Effective Date.
- 1.19 "Executive Officers" means (a) for Aerpio, the Chief Executive Officer (or a senior executive officer of Aerpio designated by the Chief Executive Officer), and (b) for Licensee, the Chief Executive Officer of Licensee. In the event that the position of any of the Executive Officers identified in this Section 1.19 no longer exists due to a corporate reorganization, corporate restructuring or the like that results in the elimination of the identified position, the applicable Executive Officer will be replaced with another executive officer with responsibilities and seniority comparable to the eliminated Executive Officer.
  - 1.20 "FD&C Act" means the United States Federal Food, Drug and Cosmetic Act, as amended.
  - 1.21 "FDA" means the United States Food and Drug Administration or any successor agency thereto.
  - 1.22 "Field" means all applications.
- 1.23 "First Commercial Sale" means, with respect to any Licensed Product in a given country or region in the Territory, the first sale of such Licensed Product in such country or region (whether or not any pricing or reimbursement approvals or decisions have occurred); provided that sales for clinical studies purposes or compassionate or similar use will not be considered to constitute a First Commercial Sale. For clarity, First Commercial Sale will be determined on a Licensed Product-by-Licensed Product and country-by-country (or region-by-region) basis, as applicable.

- 1.24 "Generic Product" means, with respect to a particular Licensed Product in a country, a generic pharmaceutical product that: (a) contains the same active ingredient as the Licensed Compound in the same chemical form as in such Licensed Product; and (b) is approved for use in such country by a Regulatory Authority through an Abbreviated New Drug Application as defined in the FD&C Act, pursuant to Article 10.1 of Directive 2001/83/EC of the European Parliament and Council of 6 November 2001, or any enabling legislation thereof, or pursuant to any similar abbreviated route of approval in any other countries in the Territory; or (c) (i) contains the same active ingredient as the Licensed Compound in such Licensed Product; and (ii) is approved for use in such country by a Regulatory Authority through a regulatory pathway referencing clinical data first submitted by Licensee or its Affiliates or Sublicensees for obtaining Regulatory Approval for such Licensed Product.
- 1.25 "<u>Governmental Authority</u>" means any United States federal, state or local or any foreign government, or political subdivision thereof, or any multinational organization or authority or any authority, agency or commission entitled to exercise any administrative, executive, judicial, legislative, police, regulatory or taxing authority or power, any court or tribunal (or any department, bureau or division thereof), or any governmental arbitrator or arbitral body.
- 1.26 "IND" means an Investigational New Drug application, clinical study application, clinical trial exemption, or similar application or submission for approval to conduct human clinical investigations filed with or submitted to a Regulatory Authority in conformance with the requirements of such Regulatory Authority.
- 1.27 "Indication" means an application for a label or label expansion indicating the applicable drug for an initial, expanded or additional patient population, or indicating the drug for use in combination with another treatment or drug, in each case that requires a new Pivotal Clinical Trial for Regulatory Approval for such label or label expansion. It is understood and agreed that, notwithstanding anything herein to the contrary, each of the Initial Indications will be treated as separate Indications hereunder for all purposes.
- 1.28 "<u>Initial Indications</u>" means each of the following Indications: (i) induction and maintenance in ulcerative colitis (or similar Indication solely related to inflammatory bowel disease ("<u>IBD</u>")), (ii) induction and maintenance in Crohn's Disease (or similar Indication solely related to IBD), and (iii) any other Indication for which a Development Plan is attached to this Agreement as of the Effective Date.
- 1.29 "Know-How" means know-how, trade secrets, chemical and biological materials, formulations, information, documents, studies, results, data and regulatory approvals, data (including from clinical studies), filings and correspondence, including biological, chemical, pharmacological, toxicological, pre-clinical, clinical and assay data, manufacturing processes and data, specifications, sourcing information, assays, and quality control and testing procedures, whether or not patented or patentable.
- 1.30 "<u>Law</u>" means any federal, state, provincial, local, international or multinational law, statute, standard, ordinance, code, rule, regulation, resolution or promulgation, or any order, writ, judgment, injunction, decree, stipulation, ruling, determination or award entered by or with any Governmental Authority, or any license, franchise, permit or similar right granted under any of the foregoing, or any similar provision having the force or effect of law.
- 1.31 "<u>Licensed Compound</u>" means the compound known as AKB-4924, as further described on Exhibit C, and any solvates (including hydrates), salts, prodrugs, metabolites, acid forms, base forms, polymorphs and crystalline forms thereof.

- 1.32 "<u>Licensed Product</u>" means any pharmaceutical product containing either (a) the Licensed Compound or (b) any other compound that is an active pharmaceutical ingredient whose composition of matter is Covered by the Aerpio Core Patent Rights in each case ((a) and (b)), alone or with other active ingredients, and in all forms, presentations, formulations and dosage forms.
- 1.33 "Licensee Patent Rights" means all patents, patent applications and other patent rights, existing as of the Effective Date or arising during the Term, owned or in-licensed by Licensee or any of its Affiliates as of the Effective Date or during the Term, that have a Valid Claim directed to and Covering [\*\*\*].
- 1.34 "MAA" means (a) a marketing authorization application filed with (i) the EMA under the centralized EMA filing procedure or (ii) a Regulatory Authority in any country of the EU if the centralized EMA filing procedure is not used or (b) any other equivalent or related regulatory submission, in either case to gain approval to market a Licensed Product in any country in the European Union, in each case including, for clarity, amendments thereto and supplemental applications.
  - 1.35 "Major European Country" means any of the United Kingdom, France, Germany, Italy or Spain.
- 1.36 "NDA" means a New Drug Application filed with the FDA (including amendments and supplements thereto) to obtain Regulatory Approval in the United States, or any corresponding applications or submissions filed with the relevant Regulatory Authorities to obtain Regulatory Approvals in any other country or region in the Territory (including any MAA).
- 1.37 "Net Sales" means, with respect to any Licensed Product, the gross amounts invoiced on sales of such Licensed Product by Licensee or any of its Affiliates or Sublicensees to a Third Party, less the following customary deductions, determined in accordance with the Accounting Standards, to the extent specifically and solely allocated to the sale of such Licensed Product and actually taken, paid, accrued, allowed, or included in the gross sales prices with respect to such sales:
  - (a) [\*\*\*]:
  - (b) [\*\*\*]:
  - (c) [\*\*\*]
  - (d) [\*\*\*]:
  - (e) [\*\*\*]; and
  - (f) [\*\*\*].

[\*\*\*]

1.38 "Patent Challenge" means any challenge to the patentability, validity or enforceability of any of the Aerpio Patent Rights (or any claim thereof), including by: (a) filing or pursuing a declaratory judgment action in which any of the Aerpio Patent Rights is alleged to be invalid or unenforceable; (b) citing prior art against any of the Aerpio Patent Rights, or becoming a party to or pursuing an interference; or (c) filing or pursuing any re-examination, opposition, cancellation, nullity or other like proceedings against any of the Aerpio Patent Rights. Notwithstanding the foregoing, any of the following situations shall not be deemed to be a Patent Challenge: (i) any proceeding involving any Aerpio Patent Rights where Licensee, an Affiliate or Sublicensee has been compelled to participate in, or has been involuntarily drawn into, the proceeding by a court, patent office or third party, (ii) routine patent office prosecution where Licensee, an Affiliate or Sublicensee is prosecuting its own patent rights, and (iii) any

situation where Aerpio or its Affiliates assert or file a patent infringement action against Licensee, an Affiliate or Sublicensee under any Aerpio Patent Right outside of the scope of the license grant set forth in Section 5.1(a).

- 1.39 "Phase 1 Clinical Trial" means a human clinical trial of a Licensed Product that would satisfy the requirements of 21 C.F.R. § 312.21(a), or a comparable clinical study prescribed by the relevant Regulatory Authority in a country other than the United States.
- 1.40 "Phase 2 Clinical Trial" means a human clinical trial of a Licensed Product that would satisfy the requirements of 21 C.F.R. § 312.21(b), or a comparable clinical study prescribed by the relevant Regulatory Authority in a country other than the United States.
- 1.41 "Phase 3 Clinical Trial" means a human clinical trial of a Licensed Product that would satisfy the requirements of 21 C.F.R. § 312.21(c), or a comparable clinical study prescribed by the relevant Regulatory Authority in a country other than the United States.
- 1.42 "Pivotal Clinical Trial" means a human clinical trial of a Licensed Product (a) intended to establish that such Licensed Product is safe and effective for its intended use and (b) intended to be sufficient for filing for a Regulatory Approval for such Licensed Product in patients having the disease or condition being studied, solely as evidenced by the acceptance for filing for a Regulatory Approval for such Licensed Product after completion of such clinical trial. For clarity, a Pivotal Clinical Trial is often referred to as a "label enabling" trial.
- 1.43 "Program Transaction" means a (a) Change of Control of Licensee or (b) Subsidiary/Parent Sale, excluding in each case an initial public offering of Licensee or its Affiliate, as applicable.
- 1.44 "Prosecute", "Prosecution" or "Prosecuting" means with respect to any patent rights, (a) to prepare and file patent applications, including re-examinations or re-issues thereof, and represent applicants or assignees before relevant patent offices or other relevant Governmental Authorities during examination, re-examination and re-issue thereof, in appeal processes and interferences, or any equivalent proceedings or any other prosecution activities, (b) to defend all such applications against Third Party oppositions or other challenges (other than any challenges in response to an enforcement against any Competitive Infringement pursuant to Section 7.2 that are not administered by any patent office or like Governmental Authority), (c) to secure the grant of any patents arising from such patent application, (d) to maintain in force any issued patent (including through payment of any relevant maintenance fees), (e) obtain and maintain patent term extension or supplemental protection certificates or their equivalents, and (f) to make all decisions with regard to any of the foregoing activities.
- 1.45 "<u>Regulatory Approval</u>" means, with respect to a country or region in the Territory, approvals, licenses, registrations or authorizations from the relevant Regulatory Authority necessary in order to import, distribute, market or sell a pharmaceutical product (including any Licensed Product) in such country or region, but not including any pricing or reimbursement approvals or decisions.
- 1.46 "<u>Regulatory Authority</u>" means the FDA, the EMA, and any other analogous government regulatory authority or agency involved in granting approvals (including any required pricing or reimbursement approvals) for the development, manufacture or commercialization of any pharmaceutical product (including any Licensed Product) in the Territory.
- 1.47 "Regulatory Filing" means any documentation comprising or relating to or supporting any filing or application with any Regulatory Authority with respect to any compound or product (including the Licensed Compound or any Licensed Product), or its use or potential use in humans,

including any documents submitted to any Regulatory Authority and all supporting data, including INDs and NDAs, and all correspondence with any Regulatory Authority with respect to such compound or product (including minutes of any meetings, telephone conferences or discussions with any Regulatory Authority).

- "Royalty Patent Rights" means the Aerpio Patent Rights and the Licensee Patent Rights. 1.48
- "Sublicensee" means any Affiliate of Licensee or any Third Party in each case that has been granted a sublicense (or an option or right of negotiation or refusal for a sublicense) by Licensee under Section 5.1(a) and in accordance with Section 5.2.
- 1.50 "Subsidiary/Parent Sale" means, with regard to [\*\*\*] any direct or indirect parent Affiliate of Licensee, any transaction, [\*\*\*] that would constitute a Change of Control [\*\*\*].
- "Transaction Payments" means all consideration in any form, including merger consideration, equity or other securities purchase price, exercise price, option purchase price, option fee, upfront, marketing, distribution, franchise, milestone, royalties or license payments, profit shares, fees, bonuses or other payments, paid (directly or indirectly) to, or for the benefit of, Licensee, its Affiliates, or equity or other security holders (or former equity or other security holders) of Licensee or any of its Affiliates from any Sublicensees or other Third Parties solely with respect to any (a) grant of license or other rights by Licensee or any of its Affiliates to the Licensed Compound or any Licensed Product, including any distribution rights or any sublicense under any of the Aerpio Patent Rights or Aerpio Know-How (other than by any Program Transaction) or (b) Program Transaction, in each case provided that to the extent that the consideration from any such transaction includes contingent payments related to future events or release of escrowed amounts, such payments and amounts shall be included as Transaction Payments only as and when such payments and amounts are received (directly or indirectly) by or on behalf of Licensee or its Affiliates or such equity or other security holders (or former equity or other security holders). Not included in Transaction Payments shall be any consideration attributable to the sale or transfer of physical assets, leases or inventory, and with respect to clause (a) (but not clause (b)) above, the following will not be treated as Transaction Payments: (i) payments to reimburse Licensee for research or development activities or for patent prosecution costs specific to any Licensed Product, and (ii) payments made for debt or securities of Licensee up to fair market value (with any premium on debt or securities included as "Transaction Payments" hereunder).
  - 1.52 "Territory" means worldwide.
  - "Third Party" means any person or entity other than Licensee or Aerpio or any of their respective Affiliates.
- "Valid Claim" means (a) a claim of an issued and unexpired patent, which claim has not been held invalid or unenforceable by a court or other government agency of competent jurisdiction from which no appeal can be or has been taken and has not been held or admitted to be invalid or unenforceable through re-examination or disclaimer, opposition procedure, nullity suit or otherwise and (b) a claim of any patent application that has been pending for fewer than seven (7) years after the earliest priority date of such patent application.

The following additional defined terms have the meanings set forth in the section indicated:

**Defined Term** AAA Section 11.8(b) Additional Third Party Licenses Section 6.3(d) Aerpio Introductory Paragraph

Section

Defined Term	Section
Aerpio Core Patent Rights	Section 1.4
Aerpio Indemnitees	Section 9.5(a)
Affected Party	Section 10.4
Agreement	Introductory Paragraph
Alliance Manager	Section 2.2(f)
Bankruptcy Event	Section 10.4
Claim	Section 9.5(c)
CREATE Act	Section 7.1(e)
Disclosing Party	Section 8.1(a)
Effective Date	Introductory Paragraph
Hatch-Waxman Time Period	Section 7.2(b)
Indemnitee	Section 9.5(c)
Indemnitor	Section 9.5(c)
Issuing Party	Section 8.2(c)
JDC	Section 2.2(a)
Licensee	Introductory Paragraph
Licensee Indemnitees	Section 9.5(b)
Losses	Section 9.5(a)
Milestone Events	Section 6.2
Milestone Payments	Section 6.2
Party	Introductory Paragraph
Receiving Party	Section 8.1(a)
Release	Section 8.2(c)
Reversion IP	Section 10.6(d)
Reviewing Party	Section 8.2(c)
Royalty Term	Section 6.3(b)
SEC	Section 1.6
Sublicense	Section 5.2(b)
Term	Section 10.1
20% Amount	Section 6.4(a)
Working Group	Section 2.2(a)

#### Section 2. Development.

2.1 <u>General</u>. The JDC's overall responsibility shall be to encourage and facilitate ongoing cooperation between the Parties with respect to the development activities contemplated by this Agreement and to coordinate the development of the Licensed Products for the Indications covered by each Development Plan.

### 2.2 <u>Joint Development Committee</u>.

(a) Formation; Purposes. Within thirty (30) days after the Effective Date, Aerpio and Licensee will establish a joint development committee (the "JDC") composed of no more than three (3) representatives of each Party. The JDC will have responsibility for (i) reviewing and overseeing the overall progress of development and manufacturing activities under this Agreement with respect to Licensed Products for use in the Territory and in the Field, including oversight of the various budgets and activities, (ii) overseeing the implementation of all development operational

aspects of the arrangements established by this Agreement, and (iii) forming various working group(s) (each, a "Working Group") to oversee particular projects or activities from time to time and delegating to such Working Group(s) such operational responsibilities as the JDC may determine necessary or desirable. In conducting its activities, including in the allocation of activities to the Parties under each Development Plan, the JDC will operate and make its decisions consistent with the terms of this Agreement.

- (b) *Membership*. The JDC will be composed of an equal number of representatives appointed by each of Aerpio and Licensee. Each Party will have the right, but not be obligated, to appoint the same number of representatives to the various Working Groups as are appointed by the other Party; however, each Party will have collectively one vote, as set forth in Section 2.2(e)(i), regardless of the number or representatives from each Party. The Parties may from time to time change the size of the JDC. Each Party may replace JDC and any Working Group representatives at any time upon written notice to the other Party. The JDC and the various Working Groups will be co-chaired by one designated representative of each Party. The co-chairpersons of each committee and Working Group will not have any greater authority than any other representative on the committee or Working Group. The co-chairperson of Licensee will be responsible for: (a) calling meetings; (b) preparing and circulating an agenda in advance of each meeting, provided that the co-chairperson will include any agenda items proposed by either Party on such agenda; (c) ensuring that all decision-making is carried out in accordance with the voting and dispute resolution mechanisms set forth in this Agreement; and (d) preparing and issuing minutes of each meeting within thirty (30) days thereafter. Each Party may designate the same individual as a representative on more than one committee or Working Group, and such individual may be an employee or consultant of such Party or any of its Affiliates. Each Party will be responsible for all costs and expenses incurred by it in participating in the JDC and any Working Groups.
- (c) Meetings of the JDC and Working Groups. The JDC will hold meetings at such times as the JDC will determine, but in no event will such meetings of the JDC be held less frequently than once every six (6) months during the Term for so long as the JDC exists. Each Working Group will hold meetings at such times as the Working Group agrees, or as the JDC directs. Each of the JDC and the Working Groups may meet in person or by audio or video conference as the Parties may mutually agree. Other representatives of the Parties, their Affiliates and Third Parties involved in the development, manufacture or commercialization of the Licensed Compound and Licensed Products may attend such meetings of the JDC or Working Groups as nonvoting observers. The JDC and Working Groups may upon agreement meet on an ad hoc basis between regularly scheduled meetings in order to address and resolve time-sensitive issues within their purview that may arise from time to time. No action taken at a meeting of the JDC or any Working Group will be effective unless a representative of each Party is present or participating. Neither Party will unreasonably withhold attendance of at least one representative of such Party at any meeting of a committee or Working Group for which reasonable advance notice was provided.
  - (d) JDC Specific Responsibilities. The JDC will:
  - (i) review and discuss the research and development activities for the Licensed Compound and Licensed Products;
  - (ii) review and discuss the implementation of each Development Plan and the corresponding Development Budget;
- (iii) review and discuss each Development Plan, including the corresponding Development Budget set forth therein, on an annual basis, including new Development Plans and corresponding Development Budgets, and review and discuss amendments and updates to each Development Plan and corresponding Development Budget;

- (iv) review and discuss non-clinical research or development of the Licensed Compound and Licensed Products;
- (v) review and discuss clinical development of the Licensed Compound and Licensed Product in all Indications subject of a Development Plan, including clinical study design, clinical study endpoints, clinical methodology and monitoring requirements; and
- (vi) perform such other functions as are assigned to it in this Agreement or as are appropriate to further the purposes of this Agreement as agreed in writing by the Parties.
  - (e) JDC Decision-Making.
- (i) Other than as set forth herein, in order to make any decision required of it hereunder with respect to any approval, the JDC must have present (in person, by videoconference or telephonically) at least one member of each Party. The Parties will endeavor to make decisions of the JDC by consensus.
- (ii) The JDC will attempt in good faith to resolve any disputes or failure to agree by unanimous consent (with each Party having one vote). If the JDC cannot resolve such dispute or failure to agree within thirty (30) days of the matter being referred to it, such matter will be resolved pursuant to Section 11.8(a) by referral directly to a senior executive of each Party designated by such Party's Executive Officer (but not Section 11.8(b)). If such matter is not resolved pursuant to the dispute resolution process set forth in Section 11.8(a), then Licensee will have the tie-breaking vote, provided that no decision by Licensee may be in conflict with any of the terms of this Agreement (including by amending or increasing any obligations on Aerpio or any of its Affiliates or by granting any licenses or other rights to Licensee or any of its Affiliates that, in each case, are not expressly set forth in this Agreement).
- (iii) Notwithstanding anything herein to the contrary, with respect to any decision to be made by any of the JDC or the various Working Groups, each Party will exercise its voting right (including Licensee's tie-breaking vote of Section 2.2(e)(ii)) in good faith and in a manner consistent with its obligations under this Agreement, including Sections 2.4(a) and 3.1(a).
  - (iv) Neither the JDC nor any Working Group will have the authority to amend or modify this Agreement.
  - (f) Alliance Managers. Each Party will designate a single alliance manager for all of the activities contemplated under this Agreement ("Alliance Manager"). Such Alliance Managers will be responsible for the day-to-day worldwide coordination of the arrangements contemplated by this Agreement and will serve to facilitate communication between the Parties. Such Alliance Managers will have experience and knowledge appropriate for managers with such project management responsibilities. Each Party may change its designated Alliance Manager from time to time upon notice to the other Party.
  - (g) *Term*. The JDC, and any Alliance Manager relationship described in Section 2.2(f), will continue until the initial Regulatory Approval of the initial Licensed Product in the United States or a Major European Country, unless otherwise agreed by the Parties in writing, provided that Aerpio may, at its sole discretion, elect to dissolve the JDC or the Alliance Manager at any time.

(h) Notwithstanding anything to the contrary herein, Licensee may, in its sole discretion, dissolve the JDC or any Working Groups or Alliance Manager in the event of a Change of Control of Aerpio.

#### 2.3 <u>Development Plan; Amendments; Development Responsibilities.</u>

- (a) Development Plan. The global development of the Licensed Products, including pre-clinical development activities, will be governed on an Indication-by-Indication basis by a Development Plan, and Licensee agrees to conduct (and to cause its Affiliates and Sublicensees to conduct) all of Licensee's development activities relating to the Licensed Products in accordance with each Development Plan at Licensee's sole cost and expense. The terms of and activities set forth in each Development Plan will at all times be designed to be in compliance with all applicable Law and to be conducted in accordance with professional and ethical standards customary in the pharmaceutical industry.
  - (b) Development Budget. A Development Budget will be included in each Development Plan.
  - (c) Updating and Amending Each Development Plan.
- (i) The JDC will review each Development Plan and develop updates as necessary. Upon the JDC's preliminary approval, such updates will be submitted to Licensee for its internal budgeting process with a target for final approval by the JDC. No amendments to updates to any Development Plan (including the corresponding Development Budget), nor any new Development Plan (with corresponding Development Budget), will be effective without the approval of the JDC.
- (ii) Exhibit B-2 sets for the Development Budgets for the initial Development Plans set forth in Exhibit B-1, and those Development Budgets include a high-level forecast of anticipated budget amounts and associated timelines for the applicable development.

#### 2.4 <u>Development Efforts; Manner of Performance; Reports.</u>

- (a) Development Efforts. Licensee will use Commercially Reasonable Efforts to develop, and seek Regulatory Approval for, Licensed Products containing the Licensed Compound [\*\*\*]. All other development and commercialization efforts with respect to the Licensed Compound and Licensed Products shall be at the discretion of Licensee. Without limiting the generality of the foregoing, Licensee will use Commercially Reasonable Efforts to perform, or cause others to perform, each Development Plan as set forth therein (including in accordance with the applicable Development Budget and timelines set forth therein). Licensee will conduct, and will cause its Affiliates and Sublicensees to conduct (as applicable), all research and development activities in good scientific manner and in compliance with applicable Law, including Laws regarding environmental, safety and industrial hygiene, and GLP, GCP, current standards for pharmacovigilance practice, and all applicable requirements relating to the protection of human subjects.
- (b) *Responsibility; Cost and Expense*. As between the Parties, Licensee will be solely responsible, at its sole cost and expense, for all research and development activities under this Agreement (including the performance of each Development Plan), and all associated manufacturing.
- (c) *Development Reports*. In the event that Licensee has not received Regulatory Approval for a Licensed Product in [\*\*\*], Licensee will prepare and maintain, and will cause each of its Affiliates and Sublicensees to prepare and maintain (as applicable), reasonably complete and accurate records regarding the development activities on the Licensed Compound or Licensed Products that have been performed. Each calendar year, Licensee will provide to Aerpio a written

progress report that includes information of Licensee and its Affiliates and Sublicensees regarding accrual, site initiation, progress on protocol writing, meeting requests and briefing documents, in the case of clinical or regulatory activities, and in other cases such information as is reasonably necessary to convey a reasonably comprehensive understanding of the status of the applicable research or development activity. In addition to the foregoing, Licensee will immediately provide notice to Aerpio in the event that the development of the Licensed Compound or any of the Licensed Products, or any Indications in development, is suspended or terminated, or if any significant adverse events have occurred, as defined by the applicable Regulatory Authority.

- (d) Aerpio Know-How Transfer and Technical Assistance.
- (i) Know-How Transfer. During the [\*\*\*] period following the Effective Date, Aerpio will endeavor to provide to Licensee all tangible embodiments of all Aerpio Know-How in its possession and Control, including one (1) electronic copy of all documents, data or other information in Aerpio's Control to the extent that such documents, data or other information describe or contain Aerpio Know-How (including any clinical studies on the Licensed Compound).
- (ii) *Technical Assistance*. During the six (6) month period following the Effective Date, Aerpio will reasonably cooperate with Licensee to provide (i) up to two hundred fifty (250) hours of technical assistance without charge to Licensee (with travel and accommodation expenses to be borne by Licensee) and (ii) any additional hours of technical assistance as Licensee may reasonably request, for which Licensee will pay Aerpio a rate of [\*\*\*] for C-level executives, [\*\*\*] for VP-level employees and [\*\*\*] for other employees, in each case per hour of such technical assistance and reimburse Aerpio for all out-of-pocket expenses incurred in providing such technical assistance under this clause (ii), in each case to facilitate the transfer of development efforts related to the Licensed Compound and Licensed Products. Such cooperation will include providing Licensee with reasonable access by teleconference or in-person at Aerpio's facilities to Aerpio personnel involved in the development of the Licensed Compound and Licensed Products to provide Licensee with a reasonable level of technical assistance and consultation in connection with the transfer of Aerpio Know-How.
- (iii) Aerpio agrees that, during the Term and subject to Section 8.4, any Aerpio Know-How disclosed to or required to be disclosed to Licensee shall be treated as Licensee Confidential Information hereunder (in addition to being treated as Aerpio Confidential Information), but only to the extent any such Aerpio Know-How relates solely to the Licensed Compound and is not excepted from the confidentiality obligations pursuant to Section 8.1(b). Notwithstanding the foregoing or anything else contained herein, Licensee may publish or otherwise disclose Aerpio Know-How to the extent reasonably related to any Licensed Compound or Licensed Products.

#### 2.5 Regulatory Filings and Regulatory Approvals.

- (a) *Responsibility; Cost and Expense.* As between the Parties, Licensee will solely be responsible, at its sole cost and expense, for seeking and attempting to obtain all Regulatory Approvals for the Licensed Products for use in the Territory and in the Field, including in accordance with each Development Plan.
- (b) *Ownership of Regulatory Approvals*. As between the Parties, Licensee will own all Regulatory Filings and Regulatory Approval for the Licensed Products for use in the Territory and in the Field filed by Licensee or any of its Affiliates or Sublicensees.
- (c) Regulatory Cooperation. Licensee will provide, and will cause its Affiliates and Sublicensees to provide (as applicable), Aerpio with advance drafts of any material documents or other material correspondence pertaining to Regulatory Approvals, including any proposed labeling, that is

planned to be submitted to any Regulatory Authority. Aerpio may provide comments regarding such documents and other correspondence prior to their submission, which comments Licensee and its Affiliates and Sublicensees will consider in good faith. Licensee will provide, and will cause its Affiliates and Sublicensees to provide (as applicable), Aerpio with copies of all material submissions it makes to, and all material correspondence it receives from, a Regulatory Authority pertaining to a Regulatory Approval. Notices, copies of submissions and correspondence, and other materials to be given in advance as provided in this Section 2.5(c) will be provided at least [\*\*\*] in advance unless circumstances necessitate a shorter time period, and in any event not less than a reasonable time in advance under the circumstances. For clarity, during the Term, Aerpio shall have no right to, and shall not, make any regulatory filings related to the Licensed Compound or Licensed Products or otherwise interact with any Regulatory Authorities with respect to the Licensed Compound or Licensed Product, unless compelled or involuntarily required by Law.

#### Section 3. Commercialization.

#### 3.1 Commercialization Efforts; Manner of Performance; Reports; Pricing; Markings.

- (a) *Commercialization Efforts*. Licensee will use Commercially Reasonable Efforts to commercialize Licensed Products for use in the Territory and in the Field in those countries and for those Indications for which Regulatory Approval (and, if applicable, pricing or reimbursement approval or decision) has been obtained. Without limiting the generality of the foregoing, Licensee will use Commercially Reasonable Efforts to execute and to perform, or cause to be performed, the Commercialization Plan.
- (b) *Responsibility; Cost and Expense.* As between the Parties, Licensee will be solely responsible, at its sole cost and expense, for all commercialization activities under this Agreement (including under the Commercialization Plan), and all associated manufacturing.
- (c) *Commercialization Reports*. Licensee will prepare and maintain and will cause its Affiliates and Sublicensees to prepare and maintain (as applicable), reasonably complete and accurate records regarding the commercialization activities for Licensed Products. Each calendar quarter, Licensee will provide to Aerpio a written progress report that describes commercialization activities that Licensee and its Affiliates and Sublicensees has performed or caused to be performed since the last progress report submitted.
- (d) *Pricing and Reimbursement*. As between the Parties, Licensee will be responsible for and have the exclusive right to seek and obtain pricing and reimbursement approvals for the Licensed Products for use in the Territory and in the Field.
- (e) *Commercialization Markings*. All promotional materials, packaging and product labeling for Licensed Products will contain to the extent not prohibited by applicable Law, the corporate name of Aerpio (in a form and manner to be provided by Aerpio), and further will indicate that the Licensed Product was in-licensed from Aerpio.

#### 3.2 Commercialization Plan and Budget.

(a) *Commercialization Plan*. Licensee will develop a Commercialization Plan that sets forth the commercialization activities to be undertaken with respect to Licensed Products for use in the Territory and in the Field (which may set forth commercialization activities for use in the Territory and in the Field on a regional basis, rather than a country-by-country basis, defining the regions in a manner consistent with Licensee's internal procedures). Licensee will use Commercially Reasonable Efforts to commercialize the Licensed Compound and Licensed Products in accordance

with the Commercialization Plan and this Agreement. The Commercialization Plan (including the Commercialization Budget) will be provided to Aerpio and will be updated at least annually by Licensee. The terms of and activities set forth in the Commercialization Plan will at all times be designed to be in compliance with all applicable Law and to be conducted in accordance with professional and ethical standards customary in the pharmaceutical industry.

(b) *Commercialization Budget*. The Commercialization Budget will be included in the Commercialization Plan and will be a written budget setting forth the budgeted amounts for costs with respect to activities set forth in the Commercialization Plan during the then-current calendar year and [\*\*\*], broken down by calendar quarter for the then current calendar year. The Commercialization Budget also will include a breakout of costs by functional area or category (and may set forth budgets for commercialization activities in the Territory on a regional basis, rather than a country-by-country basis, defining the regions in a manner consistent with Licensee's internal procedures).

#### Section 4. Manufacturing.

Licensee will be solely responsible, at its sole cost and expense, for manufacturing and supplying the worldwide requirements for the research, development and commercialization of the Licensed Compound and Licensed Products for use in the Territory and in the Field. The manufacturing contracts of Aerpio for the Licensed Compound or Licensed Products listed on Exhibit G hereto will be assigned to Licensee within [\*\*\*] of the Effective Date. Notwithstanding the foregoing, upon request by Licensee within [\*\*\*] of the Effective Date, Aerpio shall sell to Licensee at Aerpio's cost of goods plus delivery costs some or substantially all quantities (as requested by Licensee) of the Licensed Compound or Licensed Product in its possession.

#### Section 5. Licenses and Other Rights.

#### 5.1 Exclusive License Grants.

- (a) Aerpio Patents and Aerpio Know-How. Subject to the terms and conditions of this Agreement, Aerpio hereby grants to Licensee a non-transferable (except in accordance with Section 11.1), exclusive (even as to Aerpio), royalty- and milestone-bearing license, with the right to sublicense in accordance with Section 5.2 only, under the Aerpio Patent Rights and Aerpio Know-How, to make, have made, use, sell, offer to sell, import, develop, and commercialize the Licensed Compound and the Licensed Products, for use in the Territory and in the Field.
- (b) *INDs*. Subject to the terms and conditions of this Agreement, Aerpio hereby grants to Licensee a non-transferable (except in accordance with Section 11.1), exclusive (even as to Aerpio), royalty- and milestone-bearing right of reference, with the right to grant further rights of reference only to those person or entities that have been granted a sublicense by Licensee under the license grant in Section 5.1(a) in compliance with Section 5.2, to the INDs listed on Exhibit D, solely for the Licensed Compound and Licensed Products, for use in the Territory and in the Field.
- (c) Aerpio In-License. Subject to the terms and conditions of this Agreement and the Aerpio In-License, Aerpio hereby grants to Licensee and its Affiliates a non-transferable (except in accordance with Section 11.1), royalty- and milestone-bearing (solely as set forth in Section 6 of this Agreement) sublicense, with no right to sublicense further, under the Licensed Patents (as defined in the Aerpio In-License), of the non-exclusive rights under those Licensed Patents granted to Aerpio under the Aerpio In-License, up to but not more than the scope and term of the license granted by Aerpio to Licensee under Section 5.1(a) (and in any event not more than what was granted to Aerpio under the Aerpio In-License). At Licensee's reasonable request, Aerpio will grant to Licensee's

Sublicensees a sublicense under the Aerpio In-License equivalent to the grant above, subject to this Section 5.1(c) and the remainder of this Agreement and pursuant to a mutually agreeable written agreement, without any requirements for further consideration or additional obligations. Subject to the terms and conditions of this Agreement, the foregoing sublicense by Aerpio to Licensee will be exclusive as to Aerpio but, for clarity, not the UC Regents per the Aerpio In-License, and save for the continuing right to grant sublicenses in accordance with the immediately preceding sentence. Any sublicense under the Aerpio In-License is subject to the terms of this Agreement and the Aerpio In-License (including Article 4 thereof), and further and without limitation, Section 4.3 thereof (and the provisions of the Aerpio In-License identified therein) are hereby incorporated by reference and made applicable to Licensee as a sublicensee for the benefit of the UC Regents. It is understood and agreed that Licensee and no other sublicensee of Aerpio under the Aerpio In-License will be a third party beneficiary of the Aerpio In-License. For clarity, any sub-license under Section 5.1(a) under the Aerpio In-License will be subject to the terms and conditions of the Aerpio In-License and this Section 5.1(c). Aerpio represents and warrants that Licensee will not be obligated to make any payments to UC Regents under the Aerpio In-License. Aerpio shall be liable for any and all payments that may become due to UC Regents under the Aerpio In-Licensee's activities under this Agreement, including any activities related to the development or commercialization of Licensed Products.

(d) *Scope Clarification*. The licenses and other rights granted in this Section 5.1 and the remainder of this Agreement will not grant or create (by implication, estoppel or otherwise) any license or right under any Aerpio Patent Rights, Aerpio Know-How, INDs listed on Exhibit D, or under the Aerpio In-License, to research, develop, manufacture or commercialize, make, use, sell, offer to sell or import any molecule that is not a Licensed Compound or any other molecule Covered by the Aerpio Patent Rights (including any other therapeutically active molecule in any Licensed Product).

#### 5.2 Sublicenses.

- (a) Licensee may grant sublicenses (or any option or right of negotiation or refusal for a sublicense) of the license granted under Section 5.1(a) and the rights granted under Section 5.1(b) only as follows:
- (i) to any Affiliate of Licensee as a Sublicensee hereunder, provided such sublicense (or any option or right of negotiation or refusal for a sublicense) only remains in effect for as long as such Sublicensee remains an Affiliate of Licensee;
- (ii) to non-Affiliated Third Parties that are clinical research organizations, contract manufacturers, contract laboratory organizations, and other similar organizations that support the development and commercialization of the Licensed Compound and Licensed Products on a fee-for-service basis as Sublicensees hereunder, provided that such sublicenses (or options or rights of negotiation or refusal for a sublicense) include obligations of confidentiality and non-use of Aerpio Patent Rights, Aerpio Know-How and Confidential Information of Aerpio substantially in accordance with the terms of this Agreement; and
- (iii) to other non-Affiliated Third Parties as a Sublicensee hereunder, provided that only one (1) such non-Affiliated Third Party may be a Sublicensee at any given time in any given geographic area in the Territory.

- (b) Each sublicense (or any option or right of negotiation or refusal for a sublicense) granted by a Licensee to a non-Affiliated Third Party pursuant to this Section 5.2 is required to (i) be in writing; and (ii) be subject and subordinate to, and consistent with, the terms and conditions of this Agreement. Licensee will provide Aerpio with a copy of each agreement containing any such sublicense (or any option or right of negotiation or refusal for a sublicense) within thirty (30) days of execution. No sublicense (or any option or right of negotiation or refusal for a sublicense) will diminish, reduce or eliminate any obligation of Licensee under this Agreement, and Licensee will remain responsible for its obligations under this Agreement and will be responsible for the performance of the relevant Sublicensee as if such Sublicensee were "Licensee" hereunder. Each sublicense (or any option or right of negotiation or refusal for a sublicense) granted by Licensee to any rights licensed to it hereunder will, at the option of Aerpio, either be (i) assigned to Aerpio or (ii) terminate immediately upon the termination of the license under Section 5.1(a) from Aerpio to Licensee.
- 5.3 <u>License Limitations</u>. Except as expressly set forth in this Agreement, no licenses or other rights are granted or created hereunder to use any patent right, Know-How or other intellectual property rights owned or in-licensed by Aerpio or any of its Affiliates or licensors. All licenses and other rights are or will be granted only as expressly provided in this Agreement, and no other licenses or other rights is or will be created or granted hereunder by implication, estoppel or otherwise.

#### 5.4 Exclusivity.

- (a) During the Term, Aerpio will not (either alone or with any of its Affiliates), directly or indirectly, develop, manufacture or commercialize, or collaborate with, enable or otherwise authorize, license, sublicense, or otherwise grant any right to any Third Party, to develop, manufacture or commercialize, any compound that primarily binds to HIF prolyl hydroxylase resulting in HIF stabilization anywhere in the Territory.
- (b) During the Term, Licensee will not (either alone or with any of its Affiliates), directly or indirectly, [\*\*\*], enable or otherwise authorize, license, sublicense, or otherwise grant any right to any Third Party, to [\*\*\*], any compound (except for Licensed Compounds and any compound contained in Licensed Products) that [\*\*\*].

#### Section 6. Payment.

6.1 <u>Initial License Fee</u>. Licensee will pay to Aerpio within five (5) days after the Effective Date a one-time payment in cash of twenty million U.S. dollars (\$20,000,000), which payment will be non-refundable and non-creditable and not subject to set-off.

6.2 <u>Milestone Payments</u>. As set forth in the following table, Licensee will make the following payments in cash (the "<u>Milestone Payments</u>") to Aerpio upon achievement of each of the milestone events set forth in the tables below (the "<u>Milestone Events</u>") by Licensee or its Affiliates or Sublicensees. Each Milestone Payment will be payable by Licensee to Aerpio within [\*\*\*] after the achievement of the corresponding Milestone Event with respect to the first Licensed Product in each of the first and second Initial Indications. Such payments will be non-refundable and non-creditable and not subject to set-off.

"Clinical Development Milestones"

"M":1----- F-----

"Milestone Event"	"Milestone Payment"
Initiation (i.e., first patient, first dosing) of first Phase 2 Clinical Trial for the first Licensed Product for the first Initial Indication to achieve such milestone	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

For clarity, each Clinical Development Milestone payment is due only once regardless of the number of Licensed Products developed by Licensee.

If the first [\*\*\*] for the first Licensed Product for the first [\*\*\*] in the foregoing table is skipped [\*\*\*], then the [\*\*\*] for the first Licensed Product for the [\*\*\*] will be deemed to have been achieved upon the achievement of [\*\*\*] for the first Licensed Product [\*\*\*].

#### "Commercial Milestones"

"Milestone Event"	"Milestone Payment"
First Commercial Sale in the United States following achievement of Regulatory Approval by the FDA for the first Licensed Product for the first Initial Indication to achieve such milestone	[***]
First Commercial Sale in the United States following achievement of Regulatory Approval by the FDA for the first Licensed Product for the second Initial Indication to achieve such milestone	[***]
First Commercial Sale in a Major European Country following achievement of Regulatory Approval by the EMA for the first Licensed Product for the first Initial Indication to achieve such milestone	[***]
First Commercial Sale in a Major European Country following achievement of Regulatory Approval by the EMA for the first Licensed Product for the second Initial Indication to achieve such milestone	[***]
First Commercial Sale in Japan following achievement of Regulatory Approval in Japan for the first Licensed Product for the first Initial Indication to achieve such milestone	[***]
First Commercial Sale in Japan following achievement of Regulatory Approval in Japan for the first Licensed Product for the second Initial Indication to achieve such milestone	[***]

For clarity, each Commercial Milestone payment is due only once regardless of the number of Licensed Products developed by Licensee.

#### "Sales Milestones"

"Milestone Event"	"Milestone Payment"
First achievement of [***] of annual Net Sales of all Licensed Products in the Territory in a particular Calendar Year	[***]
First achievement of [***] of annual Net Sales of all Licensed Products in the Territory in a particular Calendar Year	[***]
First achievement of [***] of annual Net Sales of all Licensed Products in the Territory in a particular Calendar Year	[***]
First achievement of [***] of annual Net Sales of all Licensed Products in the Territory in a particular Calendar Year	[***]

For clarity, each Sales Milestone payment is due only once regardless of the number of Licensed Products commercialized by Licensee or the number of times the Sales Milestone is met.

#### 6.3 Royalties.

(a) *Royalties*. Licensee will pay to Aerpio running royalties in cash at the graduated royalty rates specified in the following table with respect to the aggregate annual worldwide Net Sales of all Licensed Products in a calendar year:

Aggregate Annual Worldwide Net Sales of All <u>Licensed Products in a calendar year</u>	Royalty Rate
Portion of cumulative Calendar Year Net Sales of Licensed Products in the Territory up to and including [***]	[***]
Portion of cumulative Calendar Year Net Sales of Licensed Products in the Territory between [***]	[***]
Portion of cumulative Calendar Year Net Sales of Licensed Products in the Territory between [***]	[***]
Portion of cumulative Calendar Year Net Sales of Licensed Products in the Territory exceeding [***]	[***]

The applicable royalty rate will be calculated as provided in this Section 6.3(a) by reference to the aggregate annual worldwide Net Sales of all Licensed Products. By way of example, [\*\*\*].

- (b) *Royalty Term.* The royalties due under Section 6.3(a) will be payable on Net Sales from the First Commercial Sale of a particular Licensed Product until the later of, on a country-by-country basis, (i) the date of expiration of the last-to-expire Valid Claim of any Aerpio Patent Right (including any applicable patent term extension) that Covers the manufacture, use, sale, offer for sale or importation of such Licensed Product in such country, (ii) [\*\*\*], or (iii) fifteen (15) years from such First Commercial Sale of such Licensed Product in such country (the "**Royalty Term**").
- (c) Only One Royalty. Only one royalty will be due with respect to the sale of the same unit of Licensed Product. Only one royalty will be due hereunder on the sale of the same unit of Licensed Product even if more than one claim of the Royalty Patent Rights Covers such Licensed Product.
- (d) *Anti-Stacking*. In the event that Licensee reasonably determines that it is necessary for Licensee to obtain a license to any patent rights from a Third Party to commercialize (including to make, have made, use, sell, offer for sale, have sold or import any Licensed Product for such commercialization) ("**Additional Third Party Licenses**") and Licensee obtains such an Additional Third Party Licensee, then Licensee may deduct from the royalty payment that would otherwise have been due to Aerpio, an amount equal to [\*\*\*] of the royalties actually paid to such Third Party under such Additional Third Party Licensee by Licensee to commercialize (including to make, have made, use, sell, offer for sale, have sold or import for such commercialization, as applicable) such Licensed Product, provided that pursuant to this Section 6.3(d) the royalties owed by Licensee to Aerpio for a particular Licensed Product shall not be reduced to less than [\*\*\*] of the amount otherwise owed.
- (e) *Know-How Royalty*. In countries in the Territory where a Licensed Product is not Covered by a Valid Claim of a Royalty Patent Right (*i.e.*, under clause (i) of Section 6.3(b)), Licensee shall pay royalties on Net Sales of such Licensed Products in such countries with respect to the Royalty Term at royalty rates that shall be set at [\*\*\*] of the applicable royalty rate determined according to Section 6.3(a), mutatis mutandis.
- (f) *Generic Competition*. In the event that, on a Licensed Product-by-Licensed Product and country-by-country basis, a Generic Product(s) is commercially available with respect to such Licensed Product in such country and the combined market share for such Generic Product(s) is [\*\*\*].
- (a) *Payment Floor*. In no event will any credits, deductions or reductions permitted to be taken under this Agreement against any particular royalty payment owed to Aerpio under this Section 6.3 (including under Section 6.3(d) or 6.3(e) or 6.3(f)) act to reduce such payment by more than [\*\*\*] (or by more than [\*\*\*] if the reduction set forth in Section 6.3(f) is then in effect) than would otherwise be payable hereunder in absent of any such credits, deductions or reductions. Further, save for the permitted reductions pursuant to Section 6.3(d), 6.3(e), and 6.3(f), all royalties payable hereunder shall be non-refundable and non-creditable and not subject to set-off.

#### 6.4 Transaction Payments.

(a) Within [\*\*\*] before or after the signing of any transaction that will (or could) give rise to any [\*\*\*] payment in excess of [\*\*\*] (a "Qualifying Transaction"), Licensee will notify Aerpio of such Qualifying Transaction and provide Aerpio under confidentiality with (i) documentation regarding the nature and amount of any Transaction Payments, including any upfront payments, (ii) Licensee's good faith calculation of the amount and projected payment dates of those Transaction Payments, (iii) a calculation of [\*\*\*] of the Transaction Payments (including the

projected payment dates), with the only reductions allowed from such [\*\*\*] as permitted by Sections 1.51 and 6.4(d), or for taxes pursuant to Section 6.5(e), in each case if applicable (such [\*\*\*] of those Transaction Payments, the "[\*\*\*]"), (iv) the expected date of the signing of such transaction, or if the signing has already occurred, the expected closing of such transaction, and (v) notification of whether Licensee is exercising its option pursuant to Section 6.4(b).

- (b) For any Qualifying Transaction, Licensee shall have the option in its sole discretion to pay Aerpio the greater of (1) [\*\*\*] or (2) the [\*\*\*] of any upfront Transaction Payment, within [\*\*\*] days after closing the Qualifying Transaction (or such earlier or later date when such upfront Transaction Payment is received (directly or indirectly) by or on behalf of Licensee, its Affiliates, or equity or other security holders (or former equity or other security holders) of Licensee or any of its Affiliates), and Aerpio will no longer be paid any amounts under Sections 6.2 and 6.3 accruing after the notification is provided to Aerpio pursuant to Section 6.4(a), subject to such Qualifying Transaction closing and (i) Licensee providing to Aerpio all of the final documentation regarding such transaction, (ii) Aerpio receiving all of the [\*\*\*] for such Qualifying Transaction (but subject to and based upon the last sentence of this Section 6.4(b)), and (iii) if applicable, the Parties compliance with Section 6.4(d). To the extent the actual upfront Transaction Payment for such transaction is less than [\*\*\*], the portion of such [\*\*\*] payment that is in excess of the [\*\*\*] of such upfront Transaction Payment shall be creditable against any future [\*\*\*] payments arising from any future Transaction Payments received (directly or indirectly) by or on behalf of Licensee, its Affiliates, or equity or other security holders (or former equity or other security holders) of Licensee or any of its Affiliates for such Qualifying Transaction, but only as and within [\*\*\*] of any Transaction Payments for such Qualifying Transaction actually being received (directly or indirectly) by or on behalf of Licensee or its Affiliates or such equity or other security holders (or former equity or other security holders).
- (c) For any Qualifying Transaction for which Licensee does not exercise its rights pursuant to Section 6.4(b), within [\*\*\*] following the notification pursuant to Section 6.4(a), Aerpio will have the option in its sole discretion to elect by written notice to Licensee to be paid the [\*\*\*], and upon making such election, and provided that Aerpio is paid at least [\*\*\*] of the [\*\*\*] of the upfront payment amount provided pursuant to clause 6.4(a) (i), then Aerpio's election will be irrevocable and Aerpio will no longer be paid any amounts under Sections 6.2 and 6.3 accruing after the notification is provided to Aerpio pursuant to Section 6.4(a), subject to such Qualifying Transaction closing and (i) Licensee providing to Aerpio all of the final documentation regarding such transaction and (ii) Aerpio receiving all of the [\*\*\*] for such Qualifying Transaction (but subject to and based upon the last sentence of this Section 6.4(c)), and (iii) if applicable, the Parties compliance with Section 6.4(d). In the event that Licensor exercises its option under this Section 6.4(c) to receive the applicable[\*\*\*], Licensee is obligated to pay, and will pay, to Aerpio such [\*\*\*] for such Qualifying Transaction, but only as and within [\*\*\*] of any Transaction Payments for such Qualifying Transaction actually being received (directly or indirectly) by or on behalf of Licensee or its Affiliates or such equity or other security holders (or former equity or other security holders).
- (d) If Licensee is reasonably of the view that any transaction subject to Section 6.4 includes consideration attributable to any physical assets, leases or inventory, or pharmaceutical products or drug candidates in addition to consideration attributable to the Licensed Compound and Licensed Products, [\*\*\*], the portion of the consideration reasonably attributable to the Licensed Compound and Licensed Products that will be the amount of the Transaction Payment that is subject to such [\*\*\*] payment to Aerpio. If Licensee elects to exercise its option in Section 6.4(b), [\*\*\*] on the

portion of the consideration reasonably attributable to the Licensed Compound and Licensed Products that will be the amount of the Transaction Payment that is subject to such[\*\*\*] payment to Aerpio [\*\*\*]. If the parties cannot agree on the [\*\*\*].

- (e) Notwithstanding the foregoing in this Section 6.4, if the ultimate parent Affiliate of Licensee undergoes a Change of Control (where the reference to "Party" in such "Change of Control" definition refers to such parent entity), Licensee may by written notice to Aerpio notify Aerpio that this Section 6.4 will not apply to such Change of Control, [\*\*\*].
- (f) All such payments to Aerpio under this Section 6.4 will be [\*\*\*]. For clarity, Aerpio shall not be entitled to receive any [\*\*\*] payments for any transaction that is not a Qualifying Transaction.

#### 6.5 Payment Terms.

- (a) *Manner of Payment*. All payments to be made by Licensee hereunder will be made in United States dollars by wire transfer to such bank account as Aerpio may designate.
- (b) Reports and Royalty Payments. Subsequent to the First Commercial Sale anywhere in the Territory and for as long as royalties are due under Section 6.3(a), Licensee will furnish to Aerpio a written report, within [\*\*\*] days after the end of each calendar quarter, showing the amount of Net Sales of Licensed Products and royalty due for such calendar quarter. Royalty payments for each calendar quarter will be due at the same time as such written report for the calendar quarter. The report will include, at a minimum, the following information for the applicable calendar quarter, each listed by product and by country of sale: (i) Net Sales for such Licensed Products sold by Licensee, Affiliates and Sublicensees; (ii) the royalties and Milestone Payments owed to Aerpio, listed by category; and (iii) the computations for any applicable currency conversions pursuant to Section 6.5(d). All such reports will be treated as Confidential Information of Licensee.
- (c) Records and Audits. Licensee will keep, and will cause each of its Affiliates and Sublicensees to keep (as applicable), adequate books and records of accounting for the purpose of calculating all amounts due to Aerpio hereunder. For [\*\*\*] next following the end of the calendar year to which each will pertain, such books and records of accounting (including those of Licensee's Affiliates and Sublicensees, as applicable) will be made available for inspection at reasonable times and upon reasonable notice by an independent certified accountant selected by Aerpio, and which is reasonably acceptable to Licensee, for the sole purpose of inspecting the amounts due to Aerpio under this Agreement. In no event will such inspections be conducted hereunder more frequently than once every [\*\*\*] or cover more than [\*\*\*] prior to the date of request for inspection. Such accountant must have executed and delivered to Licensee and its Affiliates and Sublicensees, as applicable, a confidentiality agreement as reasonably requested by Licensee, which will include provisions limiting such accountants's disclosure to Aerpio to only whether the royalty reports are correct or incorrect and the amount of any discrepancy. The results of such inspection, if any, will be binding on both Parties if not disputed within [\*\*\*] following receipt by the Parties of the inspection report. Any such dispute over an inspection report shall be subject to the dispute resolution procedure of Section 11.8, and no payment shall be required until the dispute is resolved. If it is determined that Licensee underpaid, Licensee shall pay to Aerpio such amount it was determined to have underpaid plus interest as provided in Section 6.5(g) within thirty [\*\*\*] of such determination. If it is determined that Licensee overpaid, Aerpio shall pay to Licensee within [\*\*\*] days of notification of the results of such inspection. Any undisputed overpayments will be fully creditable against amounts payable in subsequent payment periods. Aerpio will pay for such

inspections, except that in the event there is any upward adjustment in amounts payable for any calendar year shown by such inspection of more than the greater of (i) [\*\*\*] and (ii) [\*\*\*] of the amount paid, Licensee will reimburse Aerpio for any reasonable out-of-pocket costs of such accountant. Any underpayments or overpayments under this Section 6.5(c) will be subject to the currency exchange provisions set forth in Section 6.5(d) as applied to the calendar quarter during which the payment obligations giving rise to such underpayment or overpayment were incurred by Licensee.

- (d) *Currency Exchange*. With respect to Net Sales invoiced in United States dollars, the Net Sales and the amounts due to Aerpio hereunder will be expressed in United States dollars. With respect to Net Sales invoiced in a currency other than United States dollars, the Net Sales will be expressed in the domestic currency of the entity making the sale, together with the United States dollars equivalent, calculated using the official rate of exchange of such domestic currency as quoted in the Wall Street Journal, New York edition, for the last business day of the calendar quarter for which payment is made.
- (e) *Taxes*. Aerpio shall be liable for all income and other taxes (including interest) imposed upon any payments made by Licensee to Aerpio under this Section 6 or otherwise pursuant to this Agreement. Licensee may withhold from payments due to Aerpio amounts for payment of any withholding tax that is required by Law to be paid to any taxing authority with respect to such payments. Licensee will provide Aerpio all relevant documents and correspondence, and will also provide to Aerpio any other cooperation or assistance on a reasonable basis as may be necessary to enable Aerpio to claim exemption from such withholding taxes and to receive a refund of such withholding tax or claim a foreign tax credit. Licensee will give proper evidence from time to time as to the payment of any such tax. The Parties will cooperate with each other in seeking deductions under any double taxation or other similar treaty or agreement from time to time in force. Such cooperation may include Licensee making payments from a single source in the U.S., where possible.
- (f) *Blocked Payments*. In the event that, by reason of applicable Law in any country, it becomes impossible or illegal for Licensee to transfer, or have transferred on its behalf, payments owed Aerpio hereunder, Licensee will promptly notify Aerpio of the conditions preventing such transfer and such payments will be deposited in local currency in the relevant country to the credit of Aerpio in a recognized banking institution designated by Aerpio or, if none is designated by Aerpio within a period of thirty (30) days, in a recognized banking institution selected by Licensee, as the case may be, and identified in a written notice given to Aerpio.
- (g) *Interest Due*. Licensee will pay Aerpio interest on any payments that are not paid on or before the date such payments are due under this Agreement at a rate of [\*\*\*] per month or the maximum applicable legal rate, if less, calculated on the total number of days payment is delinquent.
- 6.6 <u>Mutual Convenience</u>. The royalty and other payment obligations set forth hereunder have been agreed to by the Parties for the purpose of reflecting and advancing their mutual convenience, including the ease of calculating and paying royalties and other amounts to Aerpio. Licensee hereby stipulates to the fairness and reasonableness of such royalty and other payments obligations and covenants not to allege or assert (and to require its Affiliates not to allege or assert) that any such royalty or other payments obligations are unenforceable or illegal in any way, and to include such covenant in any sublicense agreement.

#### Section 7. Patent Prosecution, Infringement and Extensions.

#### 7.1 Prosecution and Maintenance.

- (a) By the Parties Jointly. Promptly after the Effective Date, Aerpio will provide Licensee with copies of the prosecution files for all patents and patent applications listed on Exhibit A. The Parties will cooperate in the Prosecution of the Aerpio Core Patent Rights, and Licensee will have final decision making authority for those Prosecution activities. Licensee will act as the lead party and the party of record with each applicable Governmental Authority, and Licensee will select counsel reasonably acceptable to Aerpio (such acceptance not to be unreasonably withheld) in the Territory for those Prosecution activities (which counsel, for clarity, will represent Licensee but not the Parties jointly). Each Party will provide to the other Party copies of any papers relating to the Prosecution of Aerpio Core Patent Rights promptly upon receipt, or reasonably in advance of their filing, for the other Party to review and comment thereon, and Licensee will consider any Aerpio's comments in good faith. Licensee and its counsel will prepare the first draft of all papers for submission. Each Party (and its counsel) will have the right to review, and all reasonable comments will be accepted on, those papers. Licensee will be solely responsible for all costs and expenses incurred in connection with those Prosecution activities. Aerpio will be responsible for any costs and expenses incurred by or on behalf of Aerpio. In Prosecuting the Aerpio Core Patent Rights, the Parties will endeavor to the extent practicable to maximize the patent term and patent protection for the Licensed Compound and Licensed Products.
- (b) By Aerpio. In no event will any of the Aerpio Core Patent Rights fail to be filed or be permitted to lapse or be abandoned in any country, or no new patent application be filed claiming priority to a patent application with the Aerpio Core Patent Rights before such patent application's issuance, or extended, without Aerpio first being given an opportunity to assume full responsibility for the continued Prosecution of such Aerpio Core Patent Rights, unless such failure to file, lapse, abandonment or filing is jointly agreed upon by the Parties. In the event that the Parties acting jointly cannot agree on whether or not to file or continue the Prosecution of or extend a patent application or patent within the Aerpio Core Patent Rights in any country at least [\*\*\*] prior to any filing deadline or pending lapse or abandonment thereof, Aerpio will have the right, but not the obligation, to assume sole responsibility for the Prosecution of such patent rights, with counsel of Aerpio's own choice, by delivery by Aerpio of written notice to Licensee of its election to assume such sole responsibility. Upon Aerpio's delivery of the foregoing written notice, any such patent applications and patents will no longer be considered "Aerpio Patent Right" hereunder and will be excluded from the license granted to Licensee under Section 5.1. Aerpio will assume sole responsibility for all costs and expenses arising from the Prosecution activities of such patent applications and patents.
  - (c) Patent Extensions; Orange Book Listings; Patent Certifications.
- (i) Patent Term Extension. If elections with respect to obtaining patent term extension or supplemental protection certificates or their equivalents in any country with respect to any Licensed Product becomes available, upon Regulatory Approval or otherwise, the Parties will discuss in good faith which issued patent to extend, and Licensee will have final decision making authority for which issued patent to extend, provided that the only patent rights owned or in-licensed by Aerpio or any of its Affiliates that may be extended by Licensee by operation of this Agreement are those Aerpio Core Patent Rights that Cover the applicable Licensed Product.
- (ii) *Data Exclusivity and Orange Book Listings*. With respect to data exclusivity periods (such as those periods listed in the Orange Book (including any available pediatric extensions) or periods under national implementations of Article 10.1(a)(iii) of Directive 2001/EC/83, and all

equivalents in any country), Licensee, in consultation with Aerpio, will seek and maintain all such data exclusivity periods that may be available for any of the Licensed Products. The Parties will discuss in good faith which Aerpio Patent Rights, if any, will be listed in the Orange Book or any similar patent listing in any country with respect to the Licensed Products, and Licensee will have final decision making authority for which patents will be listed.

- (iii) Notification of Patent Certification. Each Party will notify and provide the other Party with copies of any allegations of alleged patent invalidity, unenforceability or non-infringement of an Aerpio Patent Right pursuant to a Paragraph IV Patent Certification by a Third Party filing an Abbreviated New Drug Application, an application under §505(b)(2) of the FD&C Act, or any other similar patent certification by a Third Party, and any foreign equivalent thereof. Such notification and copies will be provided within five (5) business days after a Party receives such certification, and will be sent to the other Party' address set forth in Section 11.7.
  - (d) *Cooperation*. Each Party will reasonably cooperate with the other Party in the Prosecution of the Aerpio Core Patent Rights. Such cooperation includes promptly executing all documents, or requiring inventors, subcontractors, employees and consultants and agents of such Party and its Affiliates, and for Licensee, Sublicensees, to execute all documents, including declarations and assignments, as reasonable and appropriate so as to enable the Prosecution of any such Aerpio Core Patent Rights in any country.
  - (e) *CREATE Act.* Notwithstanding anything to the contrary in this Agreement, each Party will have the right to invoke the Cooperative Research and Technology Enhancement Act of 2004, 35 U.S.C. § 103(c)(2)-(c)(3) (the "<u>CREATE Act</u>") when exercising its rights under this Agreement, but only with the prior written consent of the other Party. In the event that a Party intends to invoke the CREATE Act, once agreed to by the other Party as required by the preceding sentence, it will notify the other Party and the other Party will cooperate and coordinate its activities with such Party with respect to any filings or other activities in support thereof.

#### 7.2 Enforcement.

- (a) By Licensee. In the event that Aerpio or Licensee becomes aware of any actual or suspected Competitive Infringement of any Aerpio Core Patent Right within the scope of the license grant in Section 5.1, such Party will notify the other Party promptly, and following such notification, the Parties will confer. Licensee will have the initial right, but will not be obligated, to bring an infringement action with respect to such Competitive Infringement at its own expense, in its own name and under its own direction and control, or settle any such action or proceeding. Aerpio will reasonably assist Licensee in any action or proceeding being prosecuted if so requested, and will be named in or join such action or proceeding if requested by Licensee, and if so requested by Licensee, Licensee will bear all of Aerpio's related legal costs and expenses. If Aerpio otherwise elects to be represented by its own legal counsel, Aerpio will bear all of Aerpio's related legal costs and expenses.
- (b) *By Aerpio*. If Licensee elects not to bring any action for a Competitive Infringement described in Section 7.2(a) within [\*\*\*] after the becoming aware of such suspected Competitive Infringement, (and in all events at least [\*\*\*] before the end of the applicable Hatch-Waxman Time Period, as defined below), then Aerpio may bring such action at its own expense, in its own name and under its own direction and control, subject to the following: Licensee will reasonably assist Aerpio in any action or proceeding being defended or prosecuted if so requested, and will join such action or proceeding at its own expense if requested by Aerpio. Licensee will have the right to participate in any such action or proceeding with its own counsel at its own expense. For purposes of this Agreement, "Hatch-Waxman Time Period" means the applicable period of time during which a

patent holder or licensee has the right to file an infringement suit to maintain certain rights and privileges upon receipt of Paragraph IV Patent Certification by a Third Party filing an Abbreviated New Drug Application or an application under § 505(b)(2) of the FD&C Act, or any other similar patent certification by a Third Party, or any foreign equivalent thereof.

- (c) *Withdrawal*. If either Party brings an action or proceeding under this Section 7.2 and subsequently ceases to pursue or withdraws from such action or proceeding (other than by settlement), it will promptly notify the other Party and the other Party may substitute itself for the withdrawing Party under the terms of this Section 7.2.
- (d) Damages. In the event that either Party exercises the rights conferred in this Section 7.2 and recovers any damages or other sums in such action or proceeding or in settlement thereof, such damages or other sums recovered will first be applied to all out-of-pocket costs and expenses incurred by the Parties in connection therewith (including attorney's fees), unless expressly not reimbursable hereunder. If such recovery is insufficient to cover all such costs and expenses of both Parties, the controlling Party's costs will be paid in full first before any of the other Party's costs. If after such reimbursement any funds will remain from such damages or other sums recovered, such funds will be allocated as follows: (i) to the extent such recovery reflects lost profits damages, Licensee will retain such lost profits recovery, less the amounts that would otherwise be payable to Aerpio by treating such lost profits recovery as "Net Sales" with respect to such Licensed Product; (ii) to the extent such recovery reflects reasonable royalty damages or other payments and Licensee is the controlling Party, [\*\*\*]; and (iii) to the extent such recovery reflects reasonable royalty damages or other recoveries and Aerpio is the controlling Party, [\*\*\*].
- (e) Settlement of Litigation. No settlement, consent judgment or other final disposition of an action for infringement or validity or misappropriation may be entered into as to any Aerpio Core Patent Rights without the prior written consent of Licensee, which consent shall not be unreasonably withheld.
- 7.3 <u>Patent Marking</u>. Licensee will mark, and will cause all of its Affiliates and Sublicensees to mark, Licensed Products with all Aerpio Patent Rights in accordance with applicable Law, which marking obligation will continue for as long as required under applicable Law.

#### Section 8. Confidential Information and Publicity.

#### 8.1 Confidentiality.

- (a) Confidential Information. Except as expressly provided herein, each of the Parties agrees that, for itself and its Affiliates, and during the Term and for a period of ten (10) years thereafter, a Party and its Affiliates (the "Receiving Party") receiving Confidential Information of the other Party or its Affiliates (the "Disclosing Party") will (i) not disclose such Confidential Information to any Third Party without the prior written consent of the Disclosing Party, except for disclosures expressly permitted below, and (ii) not use such Confidential Information for any purpose except those licensed or otherwise authorized or permitted by this Agreement.
- (b) *Exceptions*. The obligations in Section 8.1(a) will not apply with respect to any portion of the Confidential Information that the Receiving Party can show by competent proof:
  - (i) is publicly disclosed by the Disclosing Party, either before or after it is disclosed to the Receiving Party hereunder;
- (ii) was known to the Receiving Party or any of its Affiliates, without any obligation to keep it confidential or any restriction on its use, prior to disclosure by the Disclosing Party;

- (iii) is subsequently disclosed to the Receiving Party or any of its Affiliates by a Third Party lawfully in possession thereof and without any obligation to keep it confidential or any restriction on its use;
- (iv) is published by a Third Party or otherwise becomes publicly available or enters the public domain, either before or after it is disclosed to the Receiving Party; or
- (v) has been independently developed by employees or contractors of the Receiving Party or any of its Affiliates without the aid, application or use of Confidential Information of the Disclosing Party.
  - (c) *Authorized Disclosures*. The Receiving Party may disclose Confidential Information belonging to the Disclosing Party to the extent (and only to the extent) such disclosure is reasonably necessary in the following instances:
- (i) subject to Section 8.2 (including the exceptions provided therein), by either Party in order to comply with applicable Law (including any securities Laws or regulation or rules of a securities exchange) or with a legal or administrative proceeding;
- (ii) by either Party, in connection with prosecuting or defending litigation, making regulatory filings, and Prosecuting Aerpio Core Patent Rights in accordance with Section 7;
- (iii) by Licensee, to its Affiliates, potential and future Sublicensees, permitted acquirers or assignees under Section 11.1, subcontractors, investment bankers, investors, lenders, and each of Licensee's and its Affiliates' respective directors, employees, contractors and agents; and
- (iv) by Aerpio to its Affiliates, permitted acquirers or assignees under Section 11.1, subcontractors, investment bankers, investors (including royalty purchasers), lenders, and each of Aerpio's and its Affiliates' respective directors, employees, contractors and agents,

provided that (A) with respect to Section 8.1(c)(i) or 8.1(c)(ii), where reasonably possible, the Receiving Party will notify the Disclosing Party of the Receiving Party's intent to make any disclosure pursuant thereto sufficiently prior to making such disclosure so as to allow the Disclosing Party adequate time to take whatever action it may deem appropriate to protect the confidentiality of the information to be disclosed, and (B) with respect to Sections 8.1(c)(iii) and 8.1(c)(iv), each of those named people and entities must be bound prior to disclosure by confidentiality and non-use restrictions at least as restrictive as those contained in this Section 8 (other than investment bankers, investors and lenders, who must be bound prior to disclosure by commercially reasonable obligations of confidentiality). Further, with respect to Section 8.1(c)(i), in the event either Party intends to make a disclosure pursuant thereto, the other Party will have a reasonable time period to review and comment on the proposed disclosure or filing that relates to this Agreement (including the right to request redaction of material terms to the extent permitted by any applicable Law), and the Party intending to make such disclosure will consider in good faith any reasonable comments thereon provided by the other Party.

#### 8.2 Terms of this Agreement; Publicity.

- (a) *Terms of this Agreement.* The Parties agree that the terms of this Agreement will be treated as Confidential Information of both Parties, and thus may be disclosed only as permitted by this Section 8.
- (b) *Restrictions*. Except as otherwise contemplated by this Section 8, neither Party to this Agreement will originate any publicity, news release or other public announcement, written or oral, relating to this Agreement, the transactions contemplated hereby or the terms hereof, or the existence of any arrangement between the Parties, without the prior written consent of the other Party, whether named in such publicity, news release or other public announcement or not, except as required by applicable Law.

- (c) Review. In the event either Party (the "Issuing Party") desires to issue any publicity, new release or other public announcement relating to this Agreement or the transactions contemplated hereby or the terms hereof, the Issuing Party will provide the other Party (the "Reviewing Party") with a copy of the proposed release, announcement or statement (the "Release"). The Issuing Party will specify with each such Release, taking into account the urgency of the matter being disclosed, a reasonable period of time within which the Reviewing Party may provide any comments on such Release and if the Receiving Party fails to provide any comments during the response period called for by the Issuing Party, the Reviewing Party will be deemed to have consented to the issuance of such Release; provided, however, that as it relates to the disclosure of the results of any clinical trial conducted by Licensee or any health or safety matter related to a Licensed Product, each Party acknowledges that announcements may need to be made on extremely short notice, and although a Party will endeavor to provide the other Party adequate time for such a review, such Party will be free to make necessary public disclosures as promptly as it deems necessary and appropriate. If the Reviewing Party provides any comments, the Parties will consult on such Release and work in good faith to prepare a mutually acceptable Release. If the Reviewing Party does not provide its consent, not to be unreasonably withheld, to the issuance of the Release, the Issuing Party will not issue the Release except as required by Law (including to comply with any securities Laws or regulation or rules of a securities exchange) or as otherwise expressly set forth herein. Each Party acknowledges and agrees that the other Party may submit this Agreement to the SEC and if a Party does submit this Agreement to the SEC, such Party agrees to consult with the other Party with respect to the preparation and submission of, a confidential treatment request for this Agreement. Licensee acknowledges that Aerpio is a publicly traded company and, as such, is legally obligated to make timely disclosures of all material events relating to its business, and will be required to file this Agreement with the SEC. If a Party is required by Law to make a disclosure of the terms of this Agreement in a filing with or other submission to the SEC, and it is understood and agreed that Aerpio will need to make such public filing with the SEC, (i) such Party has provided copies of the disclosure to the other Party reasonably in advance to the extent practicable under the circumstances, (ii) such Party has promptly notified the other Party in writing of such requirement and any respective timing constraints, and (iii) such Party has given the other Party a reasonable time under the circumstances from the date of notice by such Party of the required disclosure to comment upon, request confidential treatment or approve such disclosure, then such Party will have the right to make such public disclosure at the time and in the manner reasonably determined by its counsel to be required by Law. Notwithstanding anything to the contrary herein, it is hereby understood and agreed that if a Party seeking to make a disclosure to the SEC as set forth in this Section 8.2, and the other Party provides comments within the respective time periods or constraints specified herein or within the respective notice, the Party seeking to make such disclosure or its counsel, as the case may be, will in good faith (A) consider incorporating such comments and (B) use reasonable efforts to incorporate such comments, limit disclosure or obtain confidential treatment to the extent reasonably requested by the other Party.
- (d) Press Release Regarding Execution of the Agreement. The Parties agree to issue the joint press release in Exhibit E promptly following the Effective Date.
- 8.3 <u>Relationship to the Confidentiality Agreement</u>. This Agreement supersedes the Confidentiality Agreement, provided that all "Confidential Information" disclosed or received by the Parties thereunder will be deemed "Confidential Information" hereunder and will be subject to the terms and conditions of this Agreement.

- 8.4 <u>Publications</u>. In order to protect its investment hereunder, Licensee may elect to maintain the confidentiality of its Confidential Information, and may request that Aerpio maintain the confidentiality of the Aerpio Know-How that relates primarily to the Licensed Compound and Licensed Products, until applications for patent rights have been filed with respect thereto. Accordingly, Aerpio shall not, and shall cause each of its Affiliates not to, make any publications or public disclosures regarding any Licensee Confidential Information, or Aerpio Know-How that relates primarily to the Licensed Compound or Licensed Products, without Licensee's prior written consent, for, in the case of Aerpio Know-How, up to [\*\*\*] from Licensee first being notified of any such proposed publication or public disclosure, and in all events subject to any disclosure required by applicable Law.
- 8.5 <u>Clinical Trials</u>. For clarity, Licensee shall have the right to publish the results or summaries of results of any clinical trials conducted with respect to a Licensed Product in its sole discretion and without needing the consent of Aerpio.
- 8.6 <u>Remedies</u>. Each Party shall be entitled to seek, in addition to any other right or remedy it may have, at law or in equity, a temporary injunction, without the posting of any bond or other security, enjoining or restraining the other Party from any violation or threatened violation of this Section 8.

#### Section 9. Warranties; Limitations of Liability; Indemnification.

- 9.1 <u>Aerpio Representations and Warranties</u>. Except as set forth on Schedule 9.1, Aerpio represents and warrants to Licensee that as of the Effective Date:
  - (a) Aerpio is duly organized, validly existing and in good standing under the laws of the jurisdiction in which it is organized, and it has full right and authority to enter into this Agreement and to grant the licenses and other rights to Licensee as herein described.
  - (b) This Agreement has been duly authorized by all requisite corporate action, and when executed and delivered will become a valid and binding contract of Aerpio enforceable against Aerpio in accordance with its terms, subject to applicable bankruptcy, insolvency, reorganization, moratorium and other Law affecting creditors' rights generally from time to time in effect, and to general principles of equity.
  - (c) The execution, delivery and performance of this Agreement does not conflict with any other agreement, contract, instrument or understanding, oral or written, to which Aerpio is a party, or by which it is bound, nor will it violate any applicable Law.
  - (d) All necessary consents, approvals and authorizations of all Governmental Authorities and other persons or entities required to be obtained by Aerpio in connection with the execution and delivery of this Agreement and the performance of its obligations hereunder have been obtained.
  - (e) There is no litigation, proceeding or investigation pending or threatened against or involving Aerpio in any court or before any agency or regulatory body which could adversely affect Aerpio's ability or right to enter into this Agreement.
  - (f) Neither Aerpio, nor to the knowledge of Aerpio any of its employees, independent contractors or consultants or agents or officers: (i) has ever been debarred or is subject to debarment or convicted of a crime for which a person could be debarred before a Regulatory Authority under applicable Laws, or (ii) has ever been under indictment for a crime for which a person could be debarred under such Laws.

- (g) Aerpio is the sole and exclusive owner of the entire right, title and interest in and to the Aerpio Core Patent Rights and the Aerpio Know-How free and clear of all liens and other encumbrances, security interests, options and licenses.
- (h) Aerpio is the non-exclusive licensee of the Aerpio In-License, and holds such license for such patent rights free and clear of all liens and other encumbrances, security interests, options and licenses. The Aerpio In-License is in full force and effect and neither Aerpio nor, to the knowledge of Aerpio, UC Regents is in breach of the Aerpio In-License, and neither party to that agreement has accused the other party of being in breach of Aerpio In-License.
- (i) The Aerpio Patent Rights and the Licensed Patents (as defined in the In-License Agreement) constitute all the patents and patent applications owned or Controlled by Aerpio that Cover (or could Cover upon issuance of the patent application) the Licensed Compound.
- (j) Aerpio has the right to grant the licenses and rights in the Aerpio Patent Rights and grant the sublicense in the Licensed Patents (as defined in the In-License Agreement) it purports to grant to Licensee hereunder.
- (k) During the Term, Aerpio shall maintain the Aerpio In-License in good standing and shall not take any action, or omit to take any action (including making necessary payments), which would result in a breach or early termination of the Aerpio In-License or any rights thereunder. Aerpio covenants that it shall not amend, modify or supplement the terms of, or waive any rights under, the Aerpio In-License that would adversely impact Licensee's rights hereunder without the prior written consent of Licensee, such consent not to be unreasonably withheld, delayed or conditioned. Aerpio shall promptly notify Licensee upon receipt by Aerpio of any notice from UC Regents of any actual or alleged breach under the Aerpio In-License and Aerpio shall endeavor to cure any such breach within the allotted cure period and if it is unwilling or unable to do so, Aerpio shall timely notify Licensee and Licensee shall have the right to cure such breach on Aerpio's behalf.
- (l) There are no adverse actions, suits or claims pending or, to the knowledge of Aerpio, threatened against Aerpio in any court or by or before any governmental entity with respect to the Licensed Compound, the Aerpio Patent Rights, or the Aerpio Know-How and, to the knowledge of Aerpio, there are no Third Party patents that would reasonably be expected to give rise to such actions, suits or claims. No Third Party has challenged the ownership, inventorship, scope, duration, validity, enforceability, priority or right to use the Licensed Compound, the Aerpio Patent Rights, or the Aerpio Know-How (other than in connection with routine patent office prosecution), and, to the knowledge of Aerpio, there is no basis for any such challenge.
- (m) Except for the matter with UC Regents that resulted in the Aerpio In-License, Aerpio has not initiated or been involved in any proceedings or claims in which it alleges that any Third Party is or was infringing or misappropriating the Aerpio Patent Rights or Aerpio Know-How, nor have any proceedings been threatened by Aerpio, nor, to the knowledge of Aerpio, is there any basis for any such proceeding.
- (n) To the knowledge of Aerpio and notwithstanding 35 U.S.C. § 271(e) or any comparable Laws, the research, development, manufacture, use or sale of the Licensed Compound does not infringe or misappropriate any patent rights, know-how rights, or other intellectual property rights of any Third Party.
  - (o) Aerpio has provided to Licensee complete and accurate copies of each of the manufacturing agreements listed on Exhibit G.

For purposes of this Agreement, "to the knowledge of Aerpio" (and like phrases) will mean the actual knowledge as of the Effective Date of the individuals listed on Schedule 9.1(a), with no duty of inquiry other than inquiry of (i) Aerpio's current officers, directors, employees, consultants and legal counsel and (ii) the individuals listed on Schedule 9.1(b).

- 9.2 <u>Licensee Representations and Warranties</u>. Licensee represents and warrants to Aerpio that as of the Effective Date:
- (a) Licensee is duly organized, validly existing and in good standing under the laws of jurisdiction in which it is organized, and it has full right and authority to enter into this Agreement and to accept the rights and licenses granted as herein described.
- (b) This Agreement has been duly authorized by all requisite corporate action, and when executed and delivered will become a valid and binding contract of Licensee enforceable against Licensee in accordance with its terms, subject to applicable bankruptcy, insolvency, reorganization, moratorium and other Law affecting creditors' rights generally from time to time in effect, and to general principles of equity.
- (c) The execution, delivery and performance of this Agreement does not conflict with any other agreement, contract, instrument or understanding, oral or written, to which Licensee is a party, or by which it is bound, nor will it violate any applicable Law.
- (d) All necessary consents, approvals and authorizations of all Governmental Authorities and other persons or entities required to be obtained by Licensee in connection with the execution and delivery of this Agreement and the performance of its obligations hereunder have been obtained.
- 9.3 <u>Disclaimer</u>. EXCEPT AS EXPRESSLY SET FORTH HEREIN, NEITHER AERPIO NOR LICENSEE MAKES ANY REPRESENTATION OR WARRANTY OF ANY KIND, EITHER EXPRESS OR IMPLIED, WITH RESPECT TO ANY AERPIO PATENT RIGHTS, AERPIO KNOW-HOW, PATENT RIGHTS LICENSED TO AERPIO UNDER THE AERPIO IN-LICENSE, INDs LISTED ON EXHIBIT D, THE LICENSED COMPOUND, OR ANY LICENSED PRODUCTS, INCLUDING ANY WARRANTIES OF VALIDITY OR ENFORCEABILITY OF ANY PATENTS, TITLE, QUALITY, MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, PERFORMANCE OR NONINFRINGEMENT OF ANY THIRD PARTY PATENTS OR OTHER INTELLECTUAL PROPERTY RIGHTS.
- 9.4 <u>Performance by Affiliates and Subcontractors</u>. Each Party will have the right to utilize the services of its Affiliates or Third Party subcontractors in connection with the performance of the activities for which it is responsible under the Development Plan or the Commercialization Plan; provided, however, that such Party will remain responsible under this Agreement for the performance and compliance of such Affiliates and Third Party subcontractors and will, if required, grant sublicenses to them in compliance with the terms of this Agreement. The Party utilizing such subcontractors also will ensure that such Affiliate or Third Party is subject to obligations protecting and limiting use and disclosure of Confidential Information, the Licensed Compound, Licensed Products, patent rights and Know-How at least to the same extent as set forth under this Agreement.

#### 9.5 <u>Indemnification</u>.

(a) *Licensee Indemnity*. Licensee hereby agrees to indemnify, defend and hold Aerpio and its Affiliates, and their respective employees, directors, agents and consultants, and their respective successors, heirs and assigns and representatives ("Aerpio Indemnitees") harmless from and

against all claims, liability, threatened claims, damages, expenses (including reasonable attorneys' fees), suits, proceedings, losses or judgments, whether for money or equitable relief, of any kind, including but not limited to death, personal injury, illness, product liability or property damage or the failure to comply with applicable Law (collectively, "Losses"), arising from any Third Party claim due to (i) the research, development, commercialization (including promotion, advertising, offering for sale, sale or other disposition), transfer, importation or exportation, manufacture, labeling, handling or storage, or use of, or exposure to, the Licensed Compound or any Licensed Products by or for Licensee or any of its Affiliates, Sublicensees, subcontractors, agents and consultants; or (ii) Licensee's (or its Affiliates' and Sublicensees') use or practice of Aerpio Patent Rights and Aerpio Know-How; or (iii) any material breach of any obligation, representation or warranty of Licensee hereunder; or (iv) Licensee's (or its Affiliates' and Sublicensees') gross negligence, recklessness or willful misconduct, except, in each case, to the extent that such Losses arise from (A) infringement or misappropriation of patent or other intellectual property rights or know-how by any Aerpio Indemnitees, (B) the gross negligence, recklessness or willful misconduct of any Aerpio Indemnitees, or (C) any material breach of any obligation, representation or warranty of Aerpio hereunder.

- (b) Aerpio Indemnity. Aerpio hereby agrees to indemnify, defend and hold Licensee and its Affiliates, and their respective employees, directors, agents and consultants, and their respective successors, heirs and assigns and representatives ("Licensee Indemnitees") harmless from and against all Losses arising from any Third Party claim due to (i) the research, development, transfer, importation or exportation, manufacture, labeling, handling or storage, or use of, or exposure to, the Licensed Compound or any Licensed Products by or for Aerpio or any of its Affiliates, Sublicensees, subcontractors, agents and consultants before, during, or after the Term; or (ii) Aerpio's (or its Affiliates' and Sublicensees') use or practice of Aerpio Patent Rights and Aerpio Know-How; or (iii) any material breach of any obligation, representation or warranty of Aerpio hereunder; or (iv) Aerpio's (or its Affiliates' and licensees') gross negligence, recklessness or willful misconduct, except, in each case, to the extent that such Losses arise from (A) infringement or misappropriation of patent or other intellectual property rights or know-how by any Licensee Indemnitees, (B) the gross negligence, recklessness or willful misconduct of any Licensee Indemnitees, or (C) any material breach of any obligation, representation or warranty of Licensee hereunder.
- (c) Indemnification Procedure. A claim to which indemnification applies under Section 9.5(a) or Section 9.5(b) will be referred to herein as a "Claim". If any person or entity (each, an "Indemnitee") intends to claim indemnification under this Section 9.5, the Indemnitee will notify the other Party (the "Indemnitor") in writing promptly upon becoming aware of any claim that may be a Claim (it being understood and agreed, however, that the failure by an Indemnitee to give such notice will not relieve the Indemnitor of its indemnification obligation under this Agreement except and only to the extent that the Indemnitor is actually prejudiced as a result of such failure to give notice). The Indemnitor will have the right to assume and control the defense of such Claim at its own expense with counsel selected by the Indemnitor and reasonably acceptable to the Indemnitee; provided however that an Indemnitee will have the right to retain its own counsel, with the fees and expenses to be paid by the Indemnitee, if representation of such Indemnitee by the counsel retained by the Indemnitor would be inappropriate due to actual or potential differing interests between such Indemnitee and any other Party represented by such counsel in such proceedings. If the Indemnitor does not assume the defense of such Claim as aforesaid, the Indemnitee may defend such Claim but will have no obligation to do so. The Indemnitee will not settle or compromise any Claim without the prior written consent of the Indemnitee's interests, without the prior written consent of the Indemnitee, which consent, in each case, will not be unreasonably withheld. The Indemnitee will

reasonably cooperate with the Indemnitor at the Indemnitor's expense and will make available to the Indemnitor all pertinent information under the control of the Indemnitee, which information will be subject to Section 8.

- 9.6 Insurance. Each Party shall maintain in full force and effect during the Term and for a period of [\*\*\*] after expiration or termination of this Agreement, worker's compensation and general liability insurance coverage all in such amounts and with such scope of coverages as are customary in the industry for companies of like size and activities, and, in addition, Licensee shall maintain clinical trial liability and product liability insurance coverage in amounts no less that: (a) clinical trials coverage in a minimum amount of [\*\*\*] combined single limit per occurrence and in the aggregate and (b) product liability coverage, in a minimum amount of [\*\*\*] combined single limit per occurrence and in the aggregate. The policies of insurance required by this Section 9.6 will be issued by an insurance carrier with an A.M. Best rating of "A" or better. Licensee will name Aerpio as an additional insured under such policies. Upon written request, each Party shall provide evidence of such insurance to the other Party and ensure that the other Party will receive no less than thirty (30) days' notice of any cancelation, non-renewal or material change in such coverage. The coverage limits set forth herein will not create any limitation on Licensee's liability to Aerpio under this Agreement.
- 9.7 <u>Licensee Planned Structure</u>. As of the Effective Date, Licensee does not have any rights to any pharmaceutical products or drug candidates other than the Licensed Compound and Licensed Products and is wholly owned by its ultimate parent Affiliate, Gossamer Bio, Inc.

#### Section 10. Term, Termination and Survival.

- 10.1 Term. This Agreement will become effective as of the Effective Date and, unless sooner terminated in accordance with the terms hereof or by mutual written agreement of the Parties, will continue on a country-by-country and Licensed Product-by-Licensed Product basis until the end of the period during which royalties are due hereunder on Net Sales of such Licensed Product in such country (the "Term"). Upon the end of such period for such Licensed Product in such country, the license grant contained in Section 5.1(a) will become perpetual, royalty-free and fully paid up with respect to such Licensed Product in such country.
- 10.2 <u>Termination for Safety or Efficacy</u>. Notwithstanding anything contained herein to the contrary, Licensee shall have the right to terminate this Agreement at any time in its sole discretion in the event of potential safety or efficacy concerns affecting the Licensed Compound or Licensed Product. Any termination under this Section 10.2 shall be accomplished by Licensee giving [\*\*\*] advance written notice to Aerpio.
- 10.3 <u>Termination for Material Default</u>. Either Party will have the right to terminate this Agreement upon delivery of written notice to the other Party in the event of any material default in the performance by such other Party of any of such other Party's material obligations under this Agreement, provided that such default has not been cured [\*\*\*], or, in the event such default results in a failure to make any material payment when due hereunder, [\*\*\*], after written notice thereof is given by the non-defaulting Party to the defaulting Party specifying the nature of the alleged default.
- 10.4 <u>Termination for Insolvency</u>. To the extent permitted by Law, upon the filing or institution of bankruptcy, reorganization, liquidation or receivership proceedings, or upon an assignment of a substantial portion of the assets for the benefit of creditors (a "<u>Bankruptcy Event</u>") by either Party, Aerpio, in the case of a Bankruptcy Event by Licensee, or Licensee, in the case of a Bankruptcy Event by Aerpio, may terminate this Agreement; provided, however, that, in the case of any involuntary bankruptcy proceeding, such right to terminate will only become effective if the subject Party consents to the

involuntary bankruptcy or such proceeding is not dismissed within [\*\*\*] after the filing thereof. All rights and licenses granted under or pursuant to this agreement are and shall otherwise be deemed to be, for purposes of Section 365(n) of the U.S. Bankruptcy Code or any analogous provisions in any other country or jurisdiction, licenses of right to "intellectual property" as defined under Section 101 of the U.S. Bankruptcy Code and Licensee as licensee under this Agreement and Aerpio will retain and may fully exercise all of their rights and elections under the U.S. Bankruptcy Code and foreign equivalents, including that upon commencement of a bankruptcy proceeding by or against such Party undergoing a bankruptcy proceeding (the "Affected Party.") under the U.S. Bankruptcy Code or foreign equivalents, the non-Affected Party will be entitled to complete duplicates of or complete access to, as such non-Affected Party deems appropriate, any Know-How and patent and other intellectual property rights and all embodiments hereof licensed or to be transferred to such non-Affected Party hereunder by the Affected Party. Such Know-How, rights and embodiments will be promptly delivered to the non-Affected Party (a) upon any such commencement of a bankruptcy proceeding and upon written request thereof by the non-Affected Party, unless the Affected Party elects to continue to perform all of its obligations under this Agreement, or (b) if not delivered under the foregoing clause (a), upon the rejection of this Agreement by or on behalf of the Affected Party upon written request therefore by the non-Affected Party. This Section 10.4 is without prejudice to any rights the non-Affected Party may have arising under the U.S. Bankruptcy Code, foreign equivalents or other Law.

## 10.5 Termination by Aerpio for Patent Challenge.

- (a) Aerpio will have the right to terminate this Agreement upon written notice to Licensee in the event that Licensee or any of its Affiliates or Sublicensees directly or indirectly asserts a Patent Challenge; provided that with respect to any such Patent Challenge by any non-Affiliate Sublicensee, Aerpio will not have the right to terminate this Agreement under this Section 10.5 if Licensee (i) causes such Patent Challenge to be terminated or dismissed or (ii) terminates such Sublicensee's sublicensee to the Aerpio Patent Rights being challenged by the Sublicensee, in each case within [\*\*\*] of Aerpio's notice to Licensee under this Section 10.5. In the event Licensee or any of its Affiliates intends to assert a Patent Challenge in any forum, not less than [\*\*\*] prior to making any such assertion, Licensee will provide to Aerpio a written disclosure of such assertion. Notwithstanding the foregoing, Aerpio's termination right under this Section 10.5 will not apply to any Affiliate of Licensee that first becomes an Affiliate of Licensee after the Effective Date, where such Affiliate of Licensee was undertaking activities in connection with a Patent Challenge prior to such Affiliate first becoming an Affiliate of Licensee: provided however that Licensee uses commercially reasonable efforts to cause such Patent Challenge to terminate within [\*\*\*] of such Affiliate first becoming an Affiliate of Licensee.
- (b) In lieu of exercising its rights to terminate under this Section 10.5, Aerpio may elect upon written notice [\*\*\*], which election will be effective retroactively to the date of the commencement of the Patent Challenge.
- (c) Licensee acknowledges and agrees that this Section 10.5 is reasonable, valid and necessary for the adequate protection of Aerpio's interest in and to the Aerpio Patent Rights, and that Aerpio would not have granted to Licensee the licenses under those Aerpio Patent Rights, without this Section 10.5. Aerpio will have the right, at any time in its sole discretion, to strike this Section 10.5 (or any portion thereof) from this Agreement, and Aerpio will have no liability whatsoever as a result of the presence or absence of this Section 10.5 (or any struck portion thereof).

## 10.6 Effect of Termination.

- (a) If this Agreement terminates for any reason (other than expiration), except as may otherwise be agreed in writing by the Parties, Licensee will be responsible at its own expense for an orderly wind-down, in accordance with accepted pharmaceutical industry norms and ethical practices, of any then on-going clinical studies hereunder for which it has responsibility. Licensee will consider in good faith any reasonable request from Aerpio that Licensee continue, at Aerpio's cost and expense, any ongoing clinical studies at the time of termination, except if safety issues would put patients at risk. Aerpio reserves the right to continue any ongoing clinical studies for any Licensed Products at its own expense at such time as Licensee is no longer responsible therefor.
- (b) If this Agreement terminates for any reason (other than expiration), Licensee and its Affiliates and Sublicensees will have [\*\*\*] thereafter in which to dispose of any inventory of Licensed Compound or Licensed Product, subject to the payment to Aerpio of any royalties or other amounts due hereunder thereon.
- (c) If this Agreement terminates for any reason (other than expiration), all licenses and other rights granted by Aerpio to Licensee hereunder will automatically terminate (including any sublicenses to Licensee or any Sublicensees under the Aerpio In-License), and Licensee and its Affiliates and Sublicensees will have no further rights to practice or reference any Aerpio Patent Rights, Aerpio Know-How or INDs listed on Exhibit D (except as expressly permitted by Sections 10.6(a) and 10.6(b)). Each Party will promptly return to the other Party (or as directed by such other Party destroy and certify to such other Party in writing as to such destruction) all of such other Party's Confidential Information that are in such Party's (or its Affiliates' or in the case of Licensee's Sublicensees') possession or control, save that such Party will have the right to retain (i) one (1) copy of intangible Confidential Information of such other Party for legal purposes, and (ii) any of the foregoing that such Party retains any license or other right hereunder. Licensee and its Affiliates and Sublicensees will not continue to develop, manufacture or commercialize the Licensed Compound or any Licensed Products.
- (d) If this Agreement is terminated by Licensee pursuant to Section 10.2 or by Aerpio pursuant to Sections 10.3 or 10.4 or 10.5 (but solely with respect to a Patent Challenge of Aerpio Core Patent Rights), [\*\*\*]. Licensee will provide to Aerpio, at [\*\*\*] cost and expense, one (1) copy of the foregoing (including all other documents necessary to [\*\*\*] (including all completed and ongoing clinical studies)) and all documents contained in or referenced in any such items, [\*\*\*].
- (e) If this Agreement is terminated by Licensee pursuant to Section 10.2 or by Aerpio pursuant to Sections 10.3 or 10.4 or 10.5 (but solely with respect to a Patent Challenge of Aerpio Core Patent Rights), [\*\*\*].
  - (f) If this Agreement terminates for any reason (other than expiration), [\*\*\*].
- (g) As compensation for the rights and licenses of Aerpio set forth in Sections 10.6(d) and 10.6(e), if before termination of this Agreement by Licensee pursuant to Section 10.2 or by Aerpio pursuant to Sections 10.3 or 10.4 or 10.5 (but solely with respect to a Patent Challenge of Aerpio Core Patent Rights) [\*\*\*].
- 10.7 <u>Survival</u>. In addition to the termination consequences set forth in Section 10.6, the following provisions will survive expiration or termination of this Agreement for any reason: Section 1, Section 5.3, Section 6 (but only with respect to payments accrued before any such expiration or termination), Section 8, Sections 9.3, 9.4, 9.5 and 9.6, Section 10 and Section 11. Expiration or termination of this Agreement for any reason will not relieve the Parties of any liability or obligation

which accrued hereunder prior to the effective date of such termination or expiration, nor preclude either Party from pursuing all rights and remedies it may have hereunder or at law or in equity, with respect to any breach of this Agreement nor prejudice either Party's right to obtain performance of any obligation. All other rights and obligations will terminate upon termination or expiration of this Agreement.

#### Section 11. General Provisions.

# 11.1 Assignment.

- (a) This Agreement may not be assigned by either Party, nor may either Party delegate its obligations or otherwise transfer licenses or other rights created by this Agreement, except as expressly permitted hereunder or otherwise without the prior written consent of the other Party, which consent will not be unreasonably withheld; provided that without consent (i) Licensee may assign this Agreement in full to (x) an Affiliate of Licensee, provided that Licensee will remain fully liable for the performance of its obligations under this Agreement by such Affiliate, and further that such assignee Affiliate will assign this Agreement in full back to Licensee at such time as such assignee Affiliate is no longer an Affiliate of Licensee, or (y) its successor in connection with a Change of Control of Licensee, and (ii) Aerpio may assign this Agreement in full to (m) an Affiliate of Aerpio, provided that Aerpio will remain fully liable for the performance of its obligations under this Agreement by such Affiliate, and further that such assignee Affiliate will assign this Agreement in full back to Aerpio at such time as such assignee Affiliate is no longer an Affiliate of Aerpio, or (n) its successor in connection with a Change of Control of Aerpio. Each Party will provide prompt written notice to the other Party of any such permitted assignment.
- (b) Notwithstanding anything to the contrary in this Agreement, Aerpio may sell, transfer, lend or assign its rights to any Third Party(ies) to receive payments under Section 6, and Aerpio may disclose Confidential Information of Licensee to one or more Third Parties in connection with any such assignment to enable the Third Party(ies) to evaluate and monitor any such purchase or loan; provided that Licensee shall only be obligated to send payments due hereunder to not more than two entities.
- (c) Any permitted assignee will assume all assigned obligations of its assignor under this Agreement. The terms and conditions of this Agreement will inure to the benefit of, and be binding upon, the legal representatives, successors and permitted assigns of the Parties.
- 11.2 <u>Limited Right to Set-Off</u>. Without limiting Licensee's rights under law or in equity, Licensee may exercise a right of set-off against any and all amounts paid by Licensee pursuant to Section 9.1(k) to cure a breach of the Aerpio In-License by Aerpio.
- 11.3 <u>Change of Control of Aerpio</u>. Notwithstanding anything to the contrary herein: (a) no patent rights, Know-How or other intellectual property rights not Controlled by Aerpio or any of its Affiliates before a Change of Control of Aerpio will be deemed Controlled for purposes of this Agreement after such Change of Control, provided that any patent right that claims priority, directly or indirectly, to any other patent right first Controlled by Aerpio or any of its Affiliates before such Change of Control will be deemed Controlled by Aerpio thereafter no matter when such patent right is filed or issued, and (b) only those assets (including those items described in clause (a) above) of Aerpio and its Affiliates (before a Change of Control) that are in existence at the time of Change of Control will be subject to Section 5.4.
- 11.4 <u>Severability</u>. If any one or more of the provisions contained in this Agreement is held invalid, illegal or unenforceable in any respect, the validity, legality and enforceability of the remaining provisions contained herein will not in any way be affected or impaired thereby, unless the absence of the

invalidated provision(s) adversely affects the rights of the Parties. The Parties will in such an instance use their reasonable best efforts to replace the invalid, illegal or unenforceable provision(s) with valid, legal and enforceable provision(s) which, insofar as practical, implement the purposes of this Agreement.

- 11.5 <u>Cumulative Remedies</u>. All rights and remedies of the Parties hereunder will be cumulative and in addition to all other rights and remedies provided hereunder or available by agreement, at Law or otherwise.
- 11.6 Amendment; Waiver. This Agreement may not be modified, amended or rescinded, in whole or part, except by a written instrument signed by the Parties; provided that any unilateral undertaking or waiver made by one Party in favor of the other will be enforceable if undertaken in a writing signed by the Party to be charged with the undertaking or waiver. No delay or omission by either Party hereto in exercising any right or power occurring upon any noncompliance or default by the other Party with respect to any of the terms of this Agreement will impair any such right or power or be construed to be a waiver thereof. A waiver by either of the Parties of any of the covenants, conditions or agreements to be performed by the other will not be construed to be a waiver of any succeeding breach thereof or of any other covenant, condition or agreement herein contained.
- 11.7 <u>Notices</u>. All notices which are required or permitted hereunder shall be in writing and sufficient if delivered personally, sent by facsimile (and promptly confirmed by personal delivery, registered or certified mail or overnight courier), sent by nationally-recognized overnight courier or sent by registered or certified mail, postage prepaid, return receipt requested, addressed as follows:

If to Licensee, to: GB004, Inc.

3013 Science Park Road

Suite 200

San Diego, CA 92121 Attention: General Counsel

With a required copy to:

Latham & Watkins LLP

12670 High Bluff Drive San Diego, CA 92130

Attn: Steven T. Chinowsky, Esq. Facsimile: (858) 523-5450 Email: steven.chinowsky@lw.com

If to Aerpio, to: Aerpio Pharmaceuticals, Inc.

9987 Carver Road, Suite 420 Cincinnati, OH 45242

Attention: CEO

With a required copy to: Goodwin Procter LLP

100 Northern Avenue Boston, MA 02210

Attention: Kingsley L. Taft, Esq.

or to such address as each Party may hereafter designate by notice to the other Party. A notice will be deemed to have been given on the date it is received by all required recipients for the noticed Party.

## 11.8 Dispute Resolution.

- (a) In the event of any dispute between the Parties under this Agreement, the Parties will first attempt in good faith to resolve such dispute by negotiation and consultation between themselves. In the event that such dispute is not resolved on an informal basis within [\*\*\*] days, either Party may, by written notice to the other, have such dispute referred to a senior executive of each Party designated by such Party's Executive Officer, which senior executives will meet in person if requested by either such senior executive and attempt in good faith to resolve such dispute by negotiation and consultation for a [\*\*\*] day period following receipt of such written notice. If such senior executives do not resolve such dispute within such [\*\*\*] day period, either Party may refer the matter to the Parties' Executive Officers for attempted resolution, whereupon the Parties' Executive Officers will meet in person, if requested by either such Executive Officer and attempt in good faith to resolve such dispute by negotiation and consultation for a thirty (30) day period following such referral.
- (b) Subject to Section 2.2(e)(ii), if the Executive Officers do not resolve such dispute within such [\*\*\*] day period, either Party may at any time thereafter submit such dispute to be finally settled by arbitration administered in accordance with the Commercial Arbitration Rules of the American Arbitration Association ("AAA") in effect at the time of submission. The arbitration will be heard and determined by three (3) arbitrators. Licensee and Aerpio will each appoint one (1) arbitrator and the third arbitrator will be selected by the two (2) Party-appointed arbitrators, or, failing agreement within [\*\*\*] days following the date of receipt by the respondent of the claim, by the AAA. Such arbitration will take place in New York, NY. The award shall be made within [\*\*\*] months of the filing of the notice of arbitration, and the arbitrator(s) shall agree to comply with this schedule before accepting appointment. However, this time limit may be extended by agreement of the Parties or by the arbitrator(s) if necessary. The arbitration award so given will be a final and binding determination of the dispute, and will be fully enforceable in any court of competent jurisdiction. Costs of arbitration are to be divided by the Parties in the following manner: Licensee will pay for the arbitrator it chooses, Aerpio will pay for the arbitrator it chooses, and the costs of the third arbitrator will be divided equally between the Parties. Except in a proceeding to enforce the results of the arbitration or as otherwise required by Law, neither Party nor any arbitrator may disclose the existence, content or results of any arbitration hereunder without the prior written consent of both Parties. Notwithstanding this Section 11.8(b), any dispute between the Parties under this Agreement regarding the scope, validity, enforceability of infringement of any patent rights will subject to Section 11.8(a) and thereafter not this Section 11.8(b) but rather any court or other forum.
- (c) Notwithstanding the dispute resolution procedures set forth in this Section 11.8, in the event of an actual or threatened breach hereunder, the aggrieved Party may seek equitable relief (including restraining orders, specific performance or other injunctive relief) in any court or other forum, without first submitting to any dispute resolution procedures hereunder.
- (d) Notwithstanding the provisions of this Section 11.8, disputes relating to intellectual property rights, including disputes relating to the ownership, inventorship, enforceability, validity or scope of patent or other intellectual property rights, or other disputes for which a Party wishes to seek injunctive or other equitable relief, but not any disputes under Section 6.4, shall not be subject to the terms of this Section 11.8 and may be submitted for resolution to a court of competent jurisdiction, and without the necessity of posting a bond for such disputes seeking injunctive or other equitable relief (each, an "Excluded Claim"). The Parties agree that any dispute concerning an Excluded Claim that cannot be resolved by the Parties will be subject to the exclusive jurisdiction of the U.S. federal or New York state courts within the New York counties of New York, and the Parties

hereby submit to, and waive any objection to, personal jurisdiction and venue in such courts for such purpose, and both Parties waive any right they may have under applicable law or otherwise to a right to a trial by jury for such purpose.

- 11.9 <u>Governing Law</u>. This Agreement will be governed by and construed in accordance with the laws of the State of New York, without regard to its conflicts of law provisions; provided that any dispute relating to the scope, validity, enforceability or infringement of any patent rights will be governed by, and construed and enforced in accordance with, the substantive laws of the jurisdiction from which such patent rights arose.
- 11.10 Relationship of the Parties. Each Party is an independent contractor under this Agreement. Nothing contained herein is intended or is to be construed so as to constitute Aerpio and Licensee as partners, agents or joint venturers. Neither Party will have any express or implied right or authority to assume or create any obligations on behalf of or in the name of the other Party or to bind the other Party to any contract, agreement or undertaking with any Third Party. There are no express or implied third party beneficiaries hereunder (except for Licensee Indemnitees other than Licensee and Aerpio Indemnitees other than Aerpio for purposes of Sections 9.5(a) or 9.5(b), as applicable).
- 11.11 <u>Entire Agreement</u>. This Agreement (along with the Exhibits) contains the entire understanding of the Parties with respect to the subject matter hereof and supersedes and replaces any and all previous arrangements and understandings, including the Confidentiality Agreement, whether oral or written, between the Parties with respect to the subject matter hereof.
- 11.12 <u>Headings</u>. The captions to the several Sections hereof are not a part of this Agreement, but are merely guides or labels to assist in locating and reading the several Sections hereof.
- 11.13 <u>Waiver of Rule of Construction</u>. Each Party has had the opportunity to consult with counsel in connection with the review, drafting and negotiation of this Agreement. Accordingly, the rule of construction that any ambiguity in this Agreement will be construed against the drafting Party will not apply.
- 11.14 <u>Interpretation</u>. Whenever any provision of this Agreement uses the term "including" (or "includes"), such term will be deemed to mean "including without limitation" (or "includes without limitations"). "Herein," "hereby," "hereunder," "hereof" and other equivalent words refer to this Agreement as an entirety and not solely to the particular portion of this Agreement in which any such word is used. The term "or" means "and/or" hereunder. All definitions set forth herein will be deemed applicable whether the words defined are used herein in the singular or the plural. Unless otherwise provided, all references to Sections and Exhibits in this Agreement are to Sections and Exhibits of this Agreement. References to any Sections include Sections and subsections that are part of the related Section (e.g., a section numbered "Section 5.2" would be part of "Section 5", and references to "Section 5.2" would also refer to material contained in the subsection described as "Section 5.2(a)").
- 11.15 <u>Counterparts; Facsimiles or PDF</u>. This Agreement may be executed in one (1) or more counterparts, each of which will be deemed an original and all of which together will constitute one and the same instrument. Facsimile or PDF execution and delivery of this Agreement by either Party will constitute a legal, valid and binding execution and delivery of this Agreement by such Party.

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IN WITNESS WHEREOF, the Parties have caused this License Agreement to be executed by their respective duly authorized representatives as of the Effective Date.

# AERPIO PHARMACEUTICALS, INC.

By: /s/ Stephen Hoffman

(Signature)
Name: Stephen Hoffman
Title: Chief Executive Officer

**GB004, INC.** 

By: /s/ Christian Waage

(Signature)
Name: Christian Waage
Title: Treasurer & Secretary

# **EXHIBIT A**

# **AERPIO PATENT RIGHTS**

	Application		
Country	Number	Filing Date	Patent Number
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# **EXHIBIT B-1**

# INITIAL DEVELOPMENT PLANS

[\*\*\*]

# **EXHIBIT B-2**

# INITIAL DEVELOPMENT BUDGETS

[\*\*\*]

# **EXHIBIT C**

# LICENSED COMPOUND

AKB-4924

# EXHIBIT D

# LICENSED COMPOUND INDs

# **Canada**

• [\*\*\*]

# **United States**

• [\*\*\*]

# **EXHIBIT E**

PRESS RELEASE

# **EXHIBIT F**

# **AERPIO IN-LICENSE**

# **EXHIBIT G**

# ASSIGNED MANUFACTURING AGREEMENTS

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	SCHEDULE 9.1(a)
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	SCHEDULE 9.1(b)
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# Aerpio Announces Exclusive License Agreement with Gossamer Bio for AKB-4924, a First in Class Hypoxia-Inducible Factor-1 Alpha Stabilizer in Development for Inflammatory Bowel Disease

CINCINNATI, OH & SAN DIEGO, CA — (BUSINESS WIRE) — Aerpio Pharmaceuticals, Inc. (OTCQB:ARPO), today announced an exclusive global license agreement with a wholly owned subsidiary of Gossamer Bio, Inc., GB004, Inc. ("Gossamer"), for the development and commercialization of Aerpio's HIF-1 alpha stabilizer, AKB-4924, along with other related compounds. The arrangement combines Aerpio's deep understanding of HIF biology with Gossamer's experience in inflammation, immunology and inflammatory bowel disease (IBD) drug development.

AKB-4924 (to be known as GB004) is an investigational hypoxia-inducible factor-1 alpha (HIF-1 alpha) stabilizer in development for IBD. Unlike other HIF stabilizers in clinical development, which stabilize HIF-2 and stimulate erythropoiesis, GB004 preferentially stabilizes HIF-1 alpha, and has profound anti-inflammatory and mucosal wound healing effects in animal models of IBD. Based on pre-clinical study results, GB004 has demonstrated several potential advantages over existing therapies for the treatment of IBD, including a possible superior efficacy and safety profile and once-daily oral route of administration. To date, Aerpio has conducted a Phase 1, single ascending dose study which found GB004 to be safe and well-tolerated. In May 2018, Aerpio initiated a 24-subject, Phase 1, multiple ascending dose study to further assess the pharmacokinetics, safety and tolerability of GB004 in healthy volunteers.

Under the terms of the license agreement, Gossamer will pay Aerpio \$20 million up front, potential development, regulatory, and sales milestones of up to \$400 million, and royalties on worldwide net sales, which range from a high single digit to mid-teen percentage of net sales. Gossamer will be responsible for the remaining development, regulatory, and commercialization expenses for GB004.

"Gossamer is the ideal partner to maximize the potential of GB004 in IBD," said Stephen Hoffman, MD, PhD, Chief Executive Officer of Aerpio. "The Gossamer team has a demonstrated track record of successful therapeutic development in IBD, specifically the

development of Ozanimod in multiple sclerosis and IBD, as evidenced by the sale of Receptos to Celgene in 2015 for \$7.2 billion. Our partnership allows us to focus our resources on our ophthalmology and diabetes programs currently in development at Aerpio."

Faheem Hasnain, Gossamer Bio's Chairman and Chief Executive Officer, stated "We are pleased to have found GB004 after thoroughly assessing a substantial number of opportunities. This program represents an important addition to the Gossamer portfolio of drug candidates aiming to address unmet medical needs."

Sheila Gujrathi, MD, Gossamer Bio's President and Chief Operating Officer, said "The HIF-1 alpha stabilization mechanisms represent truly novel biology with multiple putative benefits and a potential paradigm-changing approach to treating IBD patients."

## **About Aerpio Pharmaceuticals**

Aerpio Pharmaceuticals, Inc. is a biopharmaceutical company focused on advancing first-in-class treatments for ocular diseases. The Company's lead compound, AKB- 9778, is a small molecule activator of the Tie2 pathway and is in clinical development for diabetic retinopathy. For more information please visit www.aerpio.com.

#### **About Gossamer Bio**

Gossamer Bio, Inc. is a biopharmaceutical company focused on discovering, developing, and commercializing immunology-based therapeutics in the autoimmune, allergy/inflammation, immuno-oncology and fibrosis disease areas. Gossamer's goal is to create a business that allows value creation and capture at the individual asset level, long-term sustainability, and continuity, while ultimately helping to improve the lives of patients.

## About AKB-4924 (GB004)

GB004, a selective stabilizer HIF-1 alpha, is being developed for the treatment of inflammatory bowel disease. HIF-1 alpha is involved in mucosal wound healing and the reduction of inflammation in the gastrointestinal tract. Aerpio has completed a single ascending dose clinical trial of GB004 in healthy volunteers and has initiated a multiple ascending dose study in healthy volunteers.

#### **Forward Looking Statements**

This press release contains forward-looking statements. Statements in this press release that are not purely historical are forward-looking statements. Such forward-looking statements include, among other things, the timeline of, and other developmental plans for, GB004 for inflammatory bowel disease or otherwise, and the therapeutic potential of the Company's product candidates, including GB004, and the Company's partnership with Gossamer Bio. Actual results could differ from those projected in any forward-looking statements due to several risk factors. Such

factors include, among others, that the Company's partnership with Gossamer Bio may not yield the intended benefits, the availability of funding needed to continue to develop GB004 or other product development plans, the inherent uncertainties associated with the FDA and drug development process, competition in the industry in which the Company operates and overall market conditions. These forward-looking statements are made as of the date of this press release, and the Company assumes no obligation to update the forward-looking statements, or to update the reasons why actual results could differ from those projected in the forward-looking statements, except as required by law. Investors should consult all the information set forth herein and should also refer to the risk factor disclosure set forth in the reports and other documents the Company files with the SEC available at www.sec.gov.

#### **Investor Contacts:**

Aerpio Pharmaceuticals, Inc. Michael Rogers Chief Financial Officer mrogers@aerpio.com

## Gossamer Bio, Inc.:

Bryan Giraudo Chief Financial Officer bgiraudo@gossamerbio.com

### **Media Contacts:**

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