

**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): December 30, 2021**

**OVID THERAPEUTICS INC.**

(Exact name of Registrant as Specified in Its Charter)

**Delaware**  
(State or Other Jurisdiction  
of Incorporation)

**001-38085**  
(Commission File Number)

**46-5270895**  
(IRS Employer  
Identification No.)

**1460 Broadway, Suite 15044**  
**New York, New York**  
(Address of Principal Executive Offices)

**10036**  
(Zip Code)

**Registrant's Telephone Number, Including Area Code: 646-661-7661**

**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 the following provisions (see General Instructions A.2. below):

- 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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value \$0.001 per share	OVID	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

**Item 1.01 Entry into a Material Definitive Agreement.**

On December 30, 2021 (the “Effective Date”), Ovid Therapeutics Inc. (the “Company”) entered into a License Agreement (the “License Agreement”) with AstraZeneca AB (“AstraZeneca”), pursuant to which AstraZeneca granted to the Company worldwide exclusive rights to develop and commercialize AstraZeneca’s library of early-stage small molecules targeting the K<sup>+</sup> Cl<sup>-</sup> co-transporter (“KCC2”), including lead candidate OV350 (the “Licensed Compounds”).

The licenses granted to the Company include licenses under AstraZeneca’s patents and know-how covering the Licensed Compounds. The Company is required to use commercially reasonable efforts to conduct development activities for the Licensed Compounds, and following regulatory approval, to commercialize the Licensed Compounds. At the time of proof of clinical efficacy, AstraZeneca will have the right of first negotiation to opt-in to a strategic collaboration.

Pursuant to the License Agreement, the Company agreed to (i) make an upfront payment to AstraZeneca of \$5.0 million in cash within 10 days following the Effective Date, and (ii) issue AstraZeneca 2,272,727 shares (the “License Shares”) of the Company’s common stock, par value \$0.001 per share (“Common Stock”), on the Effective Date or as soon as reasonably practicable thereafter, with the number of shares of Common Stock issued to AstraZeneca determined by dividing (x) \$7,500,000 by (y) the volume-weighted average price of one share of Common Stock on the Nasdaq Global Select Market for the 30 consecutive trading days immediately preceding the Effective Date. Pursuant to the License Agreement, AstraZeneca is eligible to receive potential clinical development milestones of up to \$8.0 million, regulatory milestones of up to \$45.0 million and commercial milestones of up to \$150.0 million. In addition, pursuant to the License Agreement, the Company will be required to pay tiered royalties on net sales by the Company, its affiliates or sublicensees ranging from single digit percentages to 10.0%, subject to certain standard reductions and offsets. Royalties will be payable on a product-by-product and country-by-country basis until the latest of the expiration of the licensed patents covering such product in such country, the expiration of market exclusivity for such product in such country, and a specified number of years from the first commercial sale of such product in such country.

Either party may terminate the License Agreement for the uncured material breach of the other party or in the case of the other party’s insolvency. AstraZeneca may terminate the License Agreement if the Company challenges any of the licensed patents or if the Company permanently ceases development of all products subject to the License Agreement and no such product is being commercialized. The Company may terminate the License Agreement for convenience upon specified notice periods.

The foregoing description of the License Agreement is not complete and is qualified in its entirety by reference to License Agreement, which is attached to this Current Report on Form 8-K as Exhibit 10.1, which is incorporated herein by reference.

**Item 3.02 Unregistered Sales of Equity Securities.**

The information related to the issuance of the License Shares contained in Item 1.01 of this Current Report on Form 8-K is incorporated herein by reference.

As described in Item 1.01, pursuant to the terms of the License Agreement, the Company issued the License Shares to AstraZeneca on the Effective Date. This issuance is and will be exempt from registration under the Securities Act of 1933, as amended (the “Securities Act”), pursuant to Section 4(a)(2) of the Securities Act or Regulation D promulgated thereunder. AstraZeneca represented to the Company that it is an “accredited investor” as defined in Rule 501 of the Securities Act and that the License Shares are being

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acquired for investment purposes and not with a view to, or for sale in connection with, any distribution thereof, and appropriate legends will be affixed to any certificates for the License Shares.

**Item 7.01 Regulation FD Disclosure.**

On January 3, 2022, the Company issued a press release announcing the entry into the License Agreement. A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K.

On January 3, 2022, the Company posted its Corporate Overview presentation, dated January 2022 to the “News & Events” subsection of the “Investors” tab on the Company’s website at [www.ovidrx.com](http://www.ovidrx.com).

The information provided in this Item 7.01, including Exhibit 99.1 hereto, shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act or the Exchange Act, except as expressly set forth by specific reference in such filing.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits.

<u>Exhibit Number</u>	<u>Description</u>
10.1*	<a href="#">License Agreement, dated as of December 30, 2021, by and between the Ovid Therapeutics Inc. and AstraZeneca AB.</a>
99.1	<a href="#">Press Release dated January 3, 2022</a>
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

\* Portions of this exhibit have been omitted pursuant to Rule 601(b)(10) of Regulation S-K.

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## 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.

### **OVID THERAPEUTICS INC.**

By: /s/ Thomas M. Perone  
Thomas M. Perone  
General Counsel & Corporate Secretary

Dated: January 3, 2022

*Certain portions of this exhibit have been omitted pursuant to Rule 601(b)(10) of Regulation S-K. The omitted information is (i) not material and (ii) the type that the Company treats as private or confidential. Information that has been omitted has been noted in this document with a placeholder identified by the mark “[\*\*\*]”.*

**Exhibit 10.1**

***Execution Copy***

**LICENSE AGREEMENT**

**between**

**ASTRAZENECA AB**

**and**

**OVID THERAPEUTICS INC.**

**Dated as of December 30, 2021**

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## **SCHEDULES**

Schedule 1.8 – AstraZeneca Know-How

Schedule 1.9 – AstraZeneca Patents

Schedule 1.56 – Licensed Compounds

Schedule 1.112 – Tufts Information

Schedule 3.8.1 – Inventory

Schedule 7.2.2 – Third Party IP In-Licenses

## LICENSE AGREEMENT

This License Agreement (this “**Agreement**”) is made and entered into effective as of December 30, 2021 (the “**Effective Date**”) by and between AstraZeneca AB, a company incorporated in Sweden under No. 556011-7482, whose registered office is registered at SE-151 85 Södertälje, Sweden and with offices at SE-431 83 Mölndal, Sweden (“**AstraZeneca**”) and Ovid Therapeutics Inc., a Delaware corporation having its principal place of business at Suite 15044, 1460 Broadway, New York, NY 10036 U.S.A. (“**Licensee**”). AstraZeneca and Licensee are sometimes referred to herein individually as a “**Party**” and collectively as the “**Parties**.”

### RECITALS

**WHEREAS**, AstraZeneca owns and controls certain intellectual property rights with respect to the Licensed Compounds (as defined herein) and Licensed Products (as defined herein) in the Territory (as defined herein); and

**WHEREAS**, AstraZeneca wishes to grant a license to Licensee, and Licensee wishes to take, a license under such intellectual property rights to develop and commercialize Licensed Products in the Territory, in each case in accordance with the terms and conditions set forth below.

**NOW, THEREFORE**, in consideration of the premises and the mutual promises and conditions set forth herein and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties, intending to be legally bound, do hereby agree as follows:

### ARTICLE 1 DEFINITIONS

Unless otherwise specifically provided herein, the following terms shall have the following meanings:

**1.1.** “**Affiliate**” means, with respect to a Person, any Person that, directly or indirectly, through one or more intermediaries, controls, is controlled by or is under common control with such first Person at any time for so long as such Person controls, is controlled by or is under common control with such first Person. For purposes of this definition, “control” and, with correlative meanings, the terms “controlled by” and “under common control with” means: (a) the possession, directly or indirectly, of the power to direct the management or policies of a Person, whether through the ownership of voting securities, by contract relating to voting rights or corporate governance or otherwise; or (b) the ownership, directly or indirectly, of more than 50% of the voting securities or other ownership interests of a business entity (or, with respect to a limited partnership or other similar entity, its general partner or controlling entity).

**1.2.** “**Agreement**” has the meaning set forth in the preamble hereto.

**1.3.** “**Alliance Manager**” has the meaning set forth in Section 3.11.

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**1.4.** “**Anti-Corruption Laws**” means the U.S. Foreign Corrupt Practices Act, as amended, the UK Bribery Act 2010, as amended, and any other applicable anti-corruption laws and laws for the prevention of fraud, racketeering, money laundering or terrorism.

**1.5.** “**Applicable Law**” means any applicable laws, rules and regulations of any Governmental Authority, including the FFDCA and the Anti-Corruption Laws.

**1.6.** “**AstraZeneca**” has the meaning set forth in the preamble hereto.

**1.7.** “**AstraZeneca Indemnitees**” has the meaning set forth in Section 8.1.

**1.8.** “**AstraZeneca Know-How**” means all Information Controlled by AstraZeneca or any of its Affiliates as of the Effective Date that is necessary for or useful to the Exploitation of a Licensed Compound or a Licensed Product, which AstraZeneca Know-How is described, contained or disclosed in the documents set forth on **Schedule 1.8**, but excluding any Information to the extent Covered by published AstraZeneca Patents and excluding the Tufts Information.

**1.9.** “**AstraZeneca Patents**” means all Patents Controlled by AstraZeneca or any of its Affiliates as of the Effective Date that are necessary for or useful to the Exploitation of a Licensed Compound or a Licensed Product, which Patents are listed on **Schedule 1.9**, together with all Patents related thereto pursuant to Section 1.77 (i.e., definition of Patents).

**1.10.** “**Auditor**” has the meaning set forth in Section 4.10.1.

**1.11.** “**Breaching Party**” has the meaning set forth in Section 9.2.1.

**1.12.** “**Business Day**” means a day other than a Saturday or Sunday or a day on which banking institutions in New York, New York, U.S.A. are permitted or required to be closed.

**1.13.** “**Calendar Quarter**” means each successive period of three calendar months commencing on January 1, April 1, July 1 or October 1, except that the first Calendar Quarter of the Term shall commence on the Effective Date and end on the day immediately prior to the first to occur of January 1, April 1, July 1 or October 1 after the Effective Date and the last Calendar Quarter shall end on the last day of the Term.

**1.14.** “**Calendar Year**” means each successive period of 12 calendar months commencing on January 1 and ending on December 31, except that the first Calendar Year of the Term shall commence on the Effective Date and end on December 31 of the year in which the Effective Date occurs and the last Calendar Year of the Term shall commence on January 1 of the year in which the Term ends and end on the last day of the Term.

**1.15.** “**Change of Control**” means, with respect to a Party, any of the following events: (a) any Third Party becomes the beneficial owner, directly or indirectly, as a result of a single transaction or a series of related transactions, of 50% or more of the total voting power of all classes of shares of capital stock or other interests of such Party (or, if applicable, a parent of such Party) then outstanding and normally entitled to vote in the general election of directors of

such Party (“**Voting Stock**”), (b) such Party (or, if applicable, a parent of such Party) consolidates with or merges into a Third Party, or any such Third Party consolidates with or merges into such Party (or, if applicable, a parent of such Party), in either event pursuant to a transaction in which 50% or more of the total voting power of all Voting Stock of the surviving entity then outstanding is not held by the Persons holding at least 50% of the total voting power of all Voting Stock of such Party (or, if applicable, a parent of such Party) outstanding immediately prior to such consolidation or merger; or (c) such Party (or, if applicable, a parent of such Party) conveys, transfers or leases all or substantially all of its assets to a Third Party.

**1.16.** “**Closing**” has the meaning set forth in Section 4.2.

**1.17.** “**Combination Product**” means any product containing a Licensed Product as an active ingredient or component regulated by a Regulatory Authority in combination with one or more other active ingredient or component regulated by a Regulatory Authority that is not a Licensed Product, in any and all forms, presentations, dosages, and formulations.

**1.18.** “**Commercially Reasonable Efforts**” means, with respect to the performance of Licensee’s obligations under this Agreement, as applicable, the carrying out of such obligations using efforts and resources comparable to the efforts and resources commonly used in the research-based biopharmaceutical industry for a company in a similar position and size with similar resources as Licensee at such time for compounds or products of similar market potential at a similar stage in development or product life, as applicable, taking into account efficacy, safety, the competitiveness of the product, alternative products in the marketplace, the patent and other proprietary position of the product, the likelihood of regulatory approval, approved labeling and pricing, availability of capacity to manufacture and supply for development or commercial sale and other relevant scientific, technical, regulatory and commercial factors. In addition, factors beyond the reasonable control of Licensee, including without limitation, regulatory delays, safety findings, unforeseen technical challenges, supply interruptions, and the failure of a product to meet scientific or regulatory endpoints in clinical studies shall be taken into account when determining “Commercially Reasonable Efforts”. “Commercially Reasonable Efforts” shall be determined on a country-by-country (or region-by-region, where applicable) and indication-by-indication basis. In the event that performance of obligations under this Agreement shall be performed by a Sublicensee, the foregoing definition of “Commercially Reasonable Efforts” shall apply *mutatis mutandis* so that Sublicensee’s performance of such obligations, as applicable, shall be measured by efforts and resources commonly used by a company in a similar position and size with similar resources as such Sublicensee (rather than Licensee).

**1.19.** “**Confidential Information**” has the meaning set forth in Section 6.1.

**1.20.** “**Control**” means, with respect to any item of Information, Regulatory Documentation, Patent or other intellectual property right, ownership or possession of the right, whether directly or indirectly and whether by license or otherwise (other than by operation of the license and other grants in Section 2.1), to grant a license, sublicense or other right (including the right to reference Regulatory Documentation) to or under such Information, Regulatory Documentation, material, Patent or other intellectual property right as provided for herein without violating the terms of any agreement with any Third Party.

1.21. “**Controlling Party**” has the meaning set forth in Section 5.5.

1.22. “**Cover**”, “**Covered**” or “**Covering**” means, with respect to a Patent, that, in the absence of a license granted to a Person under a Valid Claim included in such Patent, the Exploitation of a Licensed Compound, Licensed Product or other compound or product, as applicable, by such Person would infringe such Valid Claim (including, if applicable, in the case of a Patent application that is described in clause (b) of the definition of Valid Claim, as if such Valid Claim were issued).

1.23. “**Corporate Names**” means the corporate Trademarks, names and logos of AstraZeneca and its Affiliates, and such other Trademarks, names and logos as AstraZeneca may designate to Licensee in writing from time to time.

1.24. “**Derived**” means [\*\*\*].

1.24.1. [\*\*\*];

1.24.2. [\*\*\*].

1.25. “**Disclosing Party**” has the meaning set forth in Section 6.1.

1.26. “**Dispute**” has the meaning set forth in Section 10.5.1.

1.27. “**Dollars**” or “**\$**” means United States Dollars.

1.28. “**Drug Approval Application**” means a New Drug Application as defined in the FFDCA (“**NDA**”) or any corresponding foreign application in the Territory, including, with respect to the European Union, a Marketing Authorization Application filed with the EMA pursuant to the centralized approval procedure or with the applicable Regulatory Authority of a country in Europe with respect to the mutual recognition or any other national approval, including all amendments and supplements thereto.

1.29. “**Effective Date**” has the meaning set forth in the preamble hereto.

1.30. “**EMA**” means the European Medicines Agency and any successor agency thereto.

1.31. “**EMA Approval**” means the receipt by Licensee, its Affiliate or Sublicensee of all Regulatory Approvals by the EMA required for the commercialization and marketing in the European Union of a Licensed Product.

1.32. “**Encumbrance**” means any lien, mortgage, pledge, option, license, assignment, power of sale, retention of title, right of pre-emption, right of first refusal or security interest of any kind, other than the overriding obligations to the U.S. government, as set forth in Public Law 96-517 (35 U.S.C. §§200-204), as amended, or any similar obligations under the Applicable Law of any other country or jurisdiction.

- 1.33. **“European Union”** means the economic, scientific and political organization of European Union member states as it may be constituted from time to time.
- 1.34. **“Exploit”** means to make, have made, import, use, sell or offer for sale, including to research, develop, commercialize, register, modify, enhance, improve, Manufacture, have Manufactured, hold or keep (whether for disposal or otherwise), formulate, optimize, have used, export, transport, distribute, promote, market or have sold or otherwise dispose of a compound, product or process. **“Exploitation”** means the act of Exploiting a compound or product.
- 1.35. **“FDA”** means the United States Food and Drug Administration and any successor agency thereto.
- 1.36. **“FDA Approval”** means the receipt by Licensee, its Affiliate or Sublicensee of all Regulatory Approvals required for the commercialization in the United States of a Licensed Product.
- 1.37. **“FFDCA”** means the United States Federal Food, Drug, and Cosmetic Act, as amended from time to time, together with any rules, regulations and requirements promulgated thereunder (including all additions, supplements, extensions and modifications thereto).
- 1.38. **“Field”** means all human diagnostic, prophylactic and therapeutic uses.
- 1.39. **“First Commercial Sale”** means, with respect to a Licensed Product and a country, the first sale by a Selling Party for monetary value for use or consumption by the end user of such Licensed Product in such country after approval of a Drug Approval Application for such Licensed Product has been obtained in such country, which sale gives rise to Net Sales. Sales prior to approval of a Drug Approval Application for such Licensed Product in such country, such as so-called “treatment IND sales,” “named patient sales,” and “compassionate use sales,” shall not be construed as a First Commercial Sale.
- 1.40. **“First Negotiation Period”** has the meaning set forth in Section 3.4.1.
- 1.41. **“GAAP”** means, with respect to Licensee or its Affiliates or its or their Sublicensees, United States generally accepted accounting principles, International Financial Reporting Standards or such other similar national standards as Licensee, its Affiliates or its or their Sublicensee adopts for financial reporting purposes, in each case, consistently applied.
- 1.42. **“Generic Competition”** has the meaning set forth in Section 4.4.3(b).
- 1.43. **“Generic Product”** means, with respect to a Licensed Product in a country, any product (including a “generic product” approved by way of an Abbreviated NDA by the FDA (or equivalent regulatory mechanism for another Regulatory Authority)) that is available for commercial sale by a Person (other than Licensee) in such country and (a) in the United States, such product is “therapeutically equivalent,” “comparable,” “biosimilar,” or “interchangeable” with respect to such Licensed Product, as evaluated by the FDA, applying the definition of “therapeutically equivalent” set forth in the preface to the then-current edition of the FDA

publication “Approved Drug Products With Therapeutic Equivalence Evaluations” or any other definitions set forth in the U.S. Code, FDA regulations, or other source of U.S. Applicable Law or (b) outside of the United States, such product meets such substantially equivalent determination by the applicable Governmental Authorities in such country (including, without limitation, a determination that the product is “comparable,” “interchangeable,” “bioequivalent,” or “biosimilar” with respect to such Licensed Product), *provided* that, except to the extent otherwise required by Applicable Law, the determination under the foregoing clause (a) or (b) shall be made without regard to dosage or formulation. A Licensed Product authorized by Licensee or any of its Affiliates or Sublicensees as an authorized generic product whether or not marketed by Licensee or a Third Party will not constitute a Generic Product.

**1.44. “Governmental Authority”** means any federal, state, national, supranational, local, or other government, whether domestic or foreign, including any subdivision, department, agency, instrumentality, authority (including any regulatory authority), commission, board, or bureau thereof, or any court, tribunal, arbitrator or arbitral body, including a patent office or similar authority.

**1.45. “Hatch-Waxman Act”** means the U.S. “Drug Price Competition and Patent Term Restoration Act” of 1984, as set forth at 21 U.S.C. §355(b)(2)(A)(iv) or (j)(2)(A)(vii)(IV).

**1.46. “IND”** means (a) an investigational new drug application filed with the FDA for authorization to commence clinical studies with respect to a product or therapy or any corresponding foreign application in the Territory and (b) all supplements and amendments that may be filed with respect to the foregoing.

**1.47. “Indemnification Claim Notice”** has the meaning set forth in Section 8.3.

**1.48. “Indemnified Party”** has the meaning set forth in Section 8.3.

**1.49. “Information”** means all technical, scientific and other data, know-how, information, inventions, discoveries, trade secrets, ideas, concepts, methods, procedures, designs, compositions, plans, documents, specifications, instructions, protocols, processes, formulae (including as each of the foregoing relates to compositions of matter, cells, cell lines, assays or animal models), expertise, and other technology applicable to development, registration, use, or marketing or to methods of assaying or testing any product or other technology, and all biological, chemical, pharmacological, biochemical, toxicological, pharmaceutical, physical and analytical, pre-clinical, clinical, safety, manufacturing and quality control data and information, including study designs and protocols, assays and biological methodology, expertise, experiments, reports, results, and information relevant to the research, development, use, importation, offering for sale, or sale of, or which may be useful in studying, testing, or developing, any product or other technology, in each case (whether or not confidential, proprietary, patented or patentable) in written, electronic, oral or any other form now known or hereafter developed.

**1.50. “Infringement”** has the meaning set forth in Section 5.3.1.

**1.51. “Initiation”** means, with respect to a clinical study, the first dosing of the first human subject in such clinical study.

1.52. “**Invalidity Claim**” has the meaning set forth in Section 5.5.

1.53. “**Inventory**” has the meaning set forth in Section 3.8.1.

1.54. “**Invoiced Sales**” has the meaning set forth in the definition of “Net Sales.”

1.55. “**Knowledge**” means the knowledge of those members of the Global Intellectual Property Group within the legal department of AstraZeneca and its Affiliates (and any other patent attorney employed or hired by AstraZeneca or its Affiliates) who worked on matters involving any of the Licensed Compounds prior to the Effective Date; in each case, after reasonable inquiry of each such member’s files and records.

1.56. “**Licensed Compound**” means each of the K<sup>+</sup> Cl<sup>-</sup> co-transporter (“**KCC2**”) activator compounds designated as [\*\*\*] (each of which is more specifically described on Schedule 1.56 attached hereto) and any other compound Covered by AstraZeneca Patents, together with and any salt, ester, hydrate, solvate, isomer, enantiomer, free acid form, free base form, crystalline form, co-crystalline form, amorphous form, racemate, polymorph, chelate, stereoisomer, tautomer or optically active form of any of the foregoing. For the purposes of this Agreement, Licensed Compounds shall include all [\*\*\*].

1.57. “**Licensed Product**” means any product that is comprised of or contains a Licensed Compound [\*\*\*], alone or in combination with one or more other active ingredients, in any and all forms, presentations, dosages and formulations.

1.58. “**Licensed Product Agreement**” means, with respect to a Licensed Product, any agreement entered into by and between Licensee or any of its Affiliates or its or their respective Sublicensees, on the one hand and one or more Third Parties, on the other hand, that is necessary or reasonably useful for the Exploitation of such Licensed Product in the Field in the Territory, including (a) any agreement pursuant to which Licensee, its Affiliates or its or their Sublicensees receives any license or other rights to Exploit such Licensed Product, (b) supply agreements pursuant to which Licensee, its Affiliates or its or their Sublicensees obtain or will obtain quantities of such Licensed Product, (c) clinical study agreements, (d) contract research organization agreements and (e) service agreements.

1.59. “**Licensee**” has the meaning set forth in the preamble hereto.

1.60. “**Licensee Indemnitees**” has the meaning set forth in Section 8.2.

1.61. “**Licensee Know-How**” means all Information Controlled by Licensee or any of its Affiliates or its or their Sublicensees as of the Effective Date or that is developed by Licensee or any of its Affiliates or its or their Sublicensees after the Effective Date and at any time during the Term that is (a) not generally known and (b) reasonably necessary for the Exploitation of a Licensed Compound or a Licensed Product, but excluding any Information to the extent Covered by published Licensee Patents.

1.62. “**Licensee Patents**” means all of the Patents Controlled by Licensee or any of its Affiliates or its or their Sublicensees as of the Effective Date or at any time during the Term

that are reasonably necessary (or, with respect to Patent applications, would be reasonably necessary if such Patent applications were to issue as Patents) for the Exploitation of a Licensed Compound or a Licensed Product.

**1.63.** “**License Shares**” has the meaning set forth in Section 4.2.

**1.64.** “**Losses**” has the meaning set forth in Section 8.1.

**1.65.** “**Major Market**” has the meaning set forth in Section 5.3.1.

**1.66.** “**Manufacture**” and “**Manufacturing**” means all activities related to the production, manufacture, processing, filling, finishing, packaging, labeling, shipping and holding of a product or any intermediate thereof, including process development, process qualification and validation, scale-up, pre-clinical, clinical and commercial manufacture and analytic development, product characterization, stability testing, quality assurance and quality control.

**1.67.** “**Material Anti-Corruption Law Violation**” means a violation of an Anti-Corruption Law relating to the subject matter of this Agreement by or on behalf of Licensee of any of its Affiliates or its or their Sublicensees that would, if it were publicly known, in the reasonable view of AstraZeneca, have a material adverse effect on AstraZeneca or any of its Affiliates or on the reputation of AstraZeneca or any of its Affiliates because of its relationship with Licensee.

**1.68.** “**Milestone Event**” means each of the events identified as a milestone event in Section 4.3.1 or Section 4.3.3.

**1.69.** “**NDA**” has the meaning set forth in the definition of “Drug Approval Application.”

**1.70.** “**Negotiation Period**” has the meaning set forth in Section 3.4.2.

**1.71.** “**Net Sales**” means, with respect to a Licensed Product for any period, the gross amount billed or invoiced by Licensee, its Affiliates or its or their Sublicensees (each, a “**Selling Party**”) to Third Parties for sales of such Licensed Product (the “**Invoiced Sales**”), less the deductions for:

**1.71.1.** trade, quantity, prompt settlement and other discounts (including chargebacks and allowances), retroactive price reductions and rebates actually allowed and taken by any Third Party (including but not limited to Governmental Authorities, purchasers, reimbursers, customers, distributors, wholesalers, managed care organizations or similar organizations and entities);

**1.71.2.** amounts repaid or credited by reason of rejection, return or recall of goods, damaged goods, rebates or bona fide price reductions;

**1.71.3.** freight, packing, handling, postage, shipping, insurance and other reasonable transportation expenses to the extent that such items are incurred by a Selling Party in transporting Licensed Product to a Third Party and included in the gross amount invoiced;

**1.71.4.** all taxes (other than income taxes), duties and similar governmental charges, levies, imposts and withholdings (including customs, VAT, sales and excise duties) related to or imposed on the importation, use or sale of Licensed Product and any other similar governmental charges levied on, absorbed, determined and/or imposed with respect to importation, use, or sale of the Licensed Product;

**1.71.5.** rebates and similar payments made with respect to sales paid for by any Governmental Authority, such as, by way of illustration and not in limitation of the Parties' rights hereunder, Federal or state Medicaid, Medicare or similar state program or equivalent foreign governmental program;

**1.71.6.** the portion of administrative fees or other similar payments or allowances paid during the relevant time period to group purchasing organizations, reimbursers, customers, distributors, wholesalers, managed care organizations, pharmaceutical benefit managers or other similar organizations or entities relating to such Licensed Product;

**1.71.7.** that portion of the annual fee on prescription drug manufacturers imposed by the Patient Protection and Affordable Care Act, Pub. L. No. 111-148 (as amended) that a Selling Party allocates to sales of the Licensed Products in accordance with such Selling Party's standard policies and procedures, consistently applied across its products, as applicable; and

**1.71.8.** amounts written off by reason of uncollectible debt, *provided* that, if the debt is thereafter paid, the corresponding amount shall be added to the Net Sales of the period during which it was paid.

Any of the deductions listed above that involves a payment by a Selling Party shall be taken as a deduction in the Calendar Quarter in which the payment is accrued by such Selling Party. For purposes of determining Net Sales, a Licensed Product shall be deemed to be sold when invoiced. Net Sales shall be determined on, and only upon and following, the first sale by a Selling Party to a non-Sublicensee Third Party. Transfers, dispositions, or disposals of a Licensed Product for or use of a Licensed Product for pre-clinical or clinical purposes or as free samples shall not give rise to any deemed sale under this definition. The transfer or distribution of a Licensed Product among any of Licensee and its Affiliates and its and their Sublicensees (and their Affiliates) shall not be considered a sale for purposes of this definition, unless and until such Licensed Product is resold to a Third Party in a transaction that is included in Net Sales.

Subject to the above, Net Sales shall be calculated in accordance with the standard internal policies and procedures of a Selling Party, which must be in accordance with GAAP.

In the event that a Licensed Product is sold in any country in the form of a Combination Product, Net Sales of such Combination Product shall be adjusted by multiplying actual Net Sales of such Combination Product in such country calculated pursuant to the foregoing definition of "Net Sales" by the fraction  $A/(A+B)$ , where A is the average invoice price in such country of any Licensed Product that contains the same Licensed Compound(s) as such

Combination Product as its sole active ingredient(s), if sold separately in such country and B is the average invoice price in such country of each product that contains active ingredient(s) other than the Licensed Compound(s) contained in such Combination Product as its sole active ingredient(s) if sold separately in such country; *provided* that the invoice price in a country for each Licensed Product that contains only the Licensed Compound(s) and each product that contains solely active ingredient(s) other than the Licensed Compound(s) included in the Combination Product shall be for a quantity comparable to that used in such Combination Product and of substantially the same class, purity and potency or functionality, as applicable. If either such Licensed Product that contains the Licensed Compound(s) as its sole active ingredient or a product that contains the active ingredient(s) (other than the Licensed Product) in the Combination Product as its sole active ingredient(s) is not sold separately in a particular country, the Parties shall negotiate in good faith a reasonable adjustment to Net Sales in such country that takes into account the medical contribution to the Combination Product of and all other factors reasonably relevant to the relative value of, the Licensed Compound(s), on the one hand and all of the other active ingredient(s) collectively, on the other hand.

In the case of pharmacy incentive programs, hospital performance incentive programs, chargebacks, disease management programs, similar programs or discounts on portfolio product offerings, all rebates, discounts and other forms of reimbursements shall be allocated among products on the basis on which such rebates, discounts and other forms of reimbursements were actually granted or, if such basis cannot be determined, in accordance with Selling Party's existing allocation method; *provided* that any such allocation shall be done in accordance with Applicable Law, including any price reporting laws, rules and regulations.

**1.72.** "Neurology Field" means all human diagnostic, prophylactic and therapeutic uses in neurology.

**1.73.** "Non-Breaching Party" has the meaning set forth in Section 9.2.1.

**1.74.** "Non-Prosecuting Party" has the meaning set forth in Section 5.2.2.

**1.75.** "Notice Period" has the meaning set forth in Section 9.2.1.

**1.76.** "Party" and "Parties" have the meanings set forth in the preamble hereto.

**1.77.** "Patents" means:

(a) all national, regional and international patents and patent applications, including provisional and non-provisional patent applications;

(b) all patent applications that claim priority to any patent or patent application in clause (a), including divisionals, continuations, continuations-in-part, provisionals, converted provisionals and continued prosecution applications;

(c) any and all patents that have issued or in the future issue from the foregoing patent applications ((a) and (b)), including utility models, petty patents, innovation patents and design patents and certificates of invention; and

(d) any and all extensions or restorations by existing or future extension or restoration mechanisms, including revalidations, reissues, re-examinations or any other post-grant proceedings and extensions (including any supplementary protection certificates and the like) of the foregoing patents or patent applications ((a), (b) and (c)).

**1.78.** “**Payment**” has the meaning set forth in Section 4.7.1.

**1.79.** “**Payment Statement**” has the meaning set forth in Section 4.5.

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

**1.81.** “**Phase 1 Clinical Study**” means a human clinical study of a product in any country, the principal purpose of which is a preliminary determination of safety in healthy individuals or patients, that would satisfy the requirements of 21 C.F.R. 312.21(a), or a similar clinical study prescribed by the relevant Regulatory Authorities or Applicable Law in a country other than the United States.

**1.82.** “**Phase 2 Clinical Study**” means a human clinical study of a product in any country that would satisfy the requirements of 21 C.F.R. 312.21(b) and that is designed or intended to explore a variety of doses, dose response, and duration of effect and to generate initial evidence of clinical safety and activity in a target patient population, or a similar clinical study prescribed by the relevant Regulatory Authorities or Applicable Law in a country other than the United States.

**1.83.** “**Phase 3 Clinical Study**” means a human clinical study of a product in any country that would satisfy the requirements of 21 C.F.R. 312.21(c) and that is designed or intended to (a) establish that the product is safe and efficacious for its intended use, (b) define warnings, precautions and adverse reactions that are associated with the product in the dosage range to be prescribed, and (c) support Regulatory Approval for such product.

**1.84.** “**Positive Biomarker Readout**” means an EEG reading or documentation of seizure reduction.

**1.85.** “**Product Trademarks**” means the Trademarks used or to be used by Licensee or its Affiliates or its or their Sublicensees for the commercialization of Licensed Products in the Territory (excluding, in any event, any Corporate Names and any other Trademarks that consist of or include any corporate name or corporate logo of either Party or any of its Affiliates or its or their (sub)licensees (or Sublicensees)).

**1.86.** “**Prosecuting Party**” has the meaning set forth in Section 5.2.2.

**1.87.** “**Receiving Party**” has the meaning set forth in Section 6.1.

**1.88. “Regulatory Approval”** means, with respect to a country in the Territory, any and all approvals (including Drug Approval Applications), licenses, registrations or authorizations of any Regulatory Authority necessary to commercially distribute, sell or market a Licensed Product in such country, including, where applicable, (a) pricing or reimbursement approval in such country, (b) any prerequisite Manufacturing approval or authorization related thereto) and (c) labeling approval.

**1.89. “Regulatory Authority”** means the FDA in the United States, the EMA in the European Union, and any other Governmental Authority that regulates or otherwise exercises authority in its applicable jurisdiction over the testing, development, manufacture, use, storage, import, transport, promotion, marketing, distribution, offer for sale, sale, or other commercialization of pharmaceutical products in a given jurisdiction.

**1.90. “Regulatory Documentation”** means: all (a) applications (including all INDs and Drug Approval Applications), registrations, licenses, authorizations and approvals (including Regulatory Approvals); and (b) correspondence and reports submitted to or received from Regulatory Authorities (including minutes and official contact reports relating to any communications with any Regulatory Authority) and all supporting documents with respect thereto, including all adverse event files and complaint files, in each case ((a) and (b)) relating to a Licensed Compound or a Licensed Product.

**1.91. “Regulatory Exclusivity Period”** means, with respect to each Licensed Product in any country in the Territory, a period of exclusivity (other than Patent exclusivity) granted or afforded by Applicable Law or by a Regulatory Authority in such country that confers exclusive marketing rights with respect to such Licensed Product in such country or prevents another Person from using or otherwise relying on any data supporting the approval of the Drug Approval Application for such Licensed Product to support an application for regulatory approval of another product for any indication without the prior written consent of the Drug Approval Application holder.

**1.92. “Representatives”** has the meaning set forth in Section 7.5.

**1.93. “Resolution Auditor”** has the meaning set forth in Section 4.11.

**1.94. “Royalty”** has the meaning set forth in Section 4.4.

**1.95. “Royalty Term”** means, with respect to each Licensed Product and each country in the Territory, the period beginning on the date of the First Commercial Sale of such Licensed Product in such country and ending on the latest to occur of: (a) the expiration of the last-to-expire AstraZeneca Patent Covering the sale of such Licensed Product in such country; (b) the expiration of the Regulatory Exclusivity Period for such Licensed Product in such country; and (c) the [\*\*\*] anniversary of the First Commercial Sale of such Licensed Product in such country.

**1.96. “Selling Party”** has the meaning set forth in the definition of “Net Sales.”

**1.97. “Senior Officer”** means, with respect to AstraZeneca, its Vice President for Neuroscience R&D, and with respect to Licensee, its Chief Executive Officer.

**1.98.** “**Sublicensee**” means a Person, other than an Affiliate of Licensee, that is granted a sublicense by Licensee or its Affiliate under the grants in Section 2.1, as provided in Section 2.2, for the Exploitation of Licensed Products by Licensee under this Agreement.

**1.99.** “**Subscription Agreement**” has the meaning set forth in Section 4.2.

**1.100.** “**Tax**” or “**Taxation**” means any form of tax or taxation, levy, duty, charge, social security charge, contribution, or withholding of whatever nature (including any related fine, penalty, surcharge or interest) imposed by, or payable to, a Tax Authority.

**1.101.** “**Tax Authority**” means any government, state or municipality, or any local, state, federal or other fiscal, revenue, customs or excise authority, body or official anywhere in the world, authorized to levy Tax.

**1.102.** “**Term**” has the meaning set forth in Section 9.1.

**1.103.** “**Termination Notice**” has the meaning set forth in Section 9.2.1.

**1.104.** “**Territory**” means the entire world.

**1.105.** “**Third Party**” means any Person other than AstraZeneca, Licensee and their respective Affiliates.

**1.106.** “**Third Party Claims**” has the meaning set forth in Section 8.1.

**1.107.** “**Third Party Infringement Claim**” has the meaning set forth in Section 5.4.

**1.108.** “**Third Party IP In-Licenses**” has the meaning set forth in Section 7.3.3.

**1.109.** “**Third Party Patent Right**” has the meaning set forth in Section 5.6.

**1.110.** “**Trademark**” means any word, name, symbol, color, designation or device or any combination thereof that functions as a source identifier, including any trademark, trade dress, brand mark, service mark, trade name, brand name, logo or business symbol, whether or not registered.

**1.111.** “**Tufts Agreement**” means [\*\*\*].

**1.112.** “**Tufts Information**” means the Information set forth on **Schedule 1.112** that was generated by Tufts under the Tufts Agreement.

**1.113.** “**United States**” or “**U.S.**” means the United States of America and its territories and possessions (including the District of Columbia and Puerto Rico).

**1.114.** “**Valid Claim**” means (a) a claim of any issued and unexpired Patent whose validity, enforceability or patentability has not been affected by (i) irretrievable lapse, abandonment, revocation, dedication to the public, disclaimer, or admission by the patentee or its

Affiliate, or (ii) a holding, finding or decision of invalidity, unenforceability or non-patentability by a Governmental Authority that has competent jurisdiction, such holding, finding or decision being final and unappealable or unappealed within the time allowed for appeal or (b) a claim of a pending Patent application that was filed and is being prosecuted in good faith, for a period of no more than [\*\*\*] years from the date on which such application was filed, and has not been abandoned or finally disallowed without the possibility of appeal or re-filing of the application.

1.115. “VAT” has the meaning set forth in Section 4.7.2.

1.116. “Voting Stock” has the meaning set forth in the definition of “Change of Control.”

## ARTICLE 2 GRANT OF RIGHTS

2.1. **Grants to Licensee.** Subject to Section 2.2 and Section 2.3 and the other terms and conditions of this Agreement, AstraZeneca hereby grants to Licensee an exclusive (including with regard to AstraZeneca and its Affiliates) right and license (or sublicense), with the right to grant sublicenses in accordance with Section 2.2, under the AstraZeneca Patents and the AstraZeneca Know-How, to Exploit Licensed Compounds [\*\*\*] and Licensed Products in the Field in the Territory.

2.2. **Sublicenses.** Licensee shall have the right to grant sublicenses (or further rights of reference), through multiple tiers of sublicensees, under the licenses granted in Section 2.1, to its Affiliates and other Persons; *provided* that any such sublicenses shall be (a) subject to the requirements of this Section 2.2, and (b) consistent with the terms and conditions of this Agreement. Licensee shall (x) incorporate terms and conditions sufficient to enable Licensee to comply with this Agreement into agreements with a Sublicensee under which such a sublicense is granted, and (y) provide AstraZeneca an appropriately redacted copy of any sublicense agreement executed by Licensee and a Sublicensee no later than 14 days after the execution thereof. Upon termination of this Agreement under Section 9.2, if any Sublicensee is not then in default under its sublicense agreement with Licensee such that Licensee would have a termination right thereof, each such Sublicensee shall obtain a direct license from AstraZeneca on the terms and conditions as set forth in the applicable sublicense agreement with Licensee (*provided* that the payment terms therein shall be at least as favorable to AstraZeneca as those set forth herein) unless such Sublicensee opts out of obtaining such direct license by giving AstraZeneca written notice thereof within 30 days after the effective date of termination of this Agreement.

2.3. **Limitations Applicable to License Grants.** Except as expressly provided herein, AstraZeneca grants Licensee no other right or license, including any rights or licenses to the AstraZeneca Patents, the AstraZeneca Know-How, the AstraZeneca Corporate Names or any other Patent, Trademark or other intellectual property rights.

**ARTICLE 3**  
**TRANSITION, DEVELOPMENT, REGULATORY AND COMMERCIALIZATION ACTIVITIES**

**3.1. Know-How Transfer.** As soon as reasonably practicable on or after the Effective Date, and in no event later than [\*\*\*] after such date, AstraZeneca will deliver to Licensee the AstraZeneca Know-How, as described on **Schedule 1.8**, and each Party shall bear its own costs and expenses in connection therewith. For a period of [\*\*\*] after the Effective Date and at no cost to the Licensee, AstraZeneca shall reasonably cooperate to facilitate the transition of the AstraZeneca Know-How from AstraZeneca to Licensee.

**3.1.1.** [\*\*\*].

**3.2. Development.**

**3.2.1. Diligence.** After the Effective Date, as between the Parties, and for clarity, excluding the Know-How Transfer to be performed by AstraZeneca under Section 3.1, Licensee shall be solely responsible for all aspects of the development of the Licensed Compound and Licensed Products in the Field in the Territory. Licensee shall use Commercially Reasonable Efforts to develop, and obtain and maintain Regulatory Approvals for, Licensed Products for use in the Field throughout the Territory. Licensee shall perform or cause to be performed its development activities hereunder in good scientific manner and in compliance with all Applicable Law by allocating sufficient time, effort, equipment, and skilled personnel to complete such development activities.

**3.2.2. Development Costs.** Licensee shall be responsible for all of its costs and expenses in connection with the development of, and obtaining and maintaining Regulatory Approvals for, the Licensed Products for use in the Field in the Territory.

**3.2.3. Development Records.** Licensee shall, and shall cause its Affiliates and its and their Sublicensees to, maintain, in good scientific manner, complete and accurate books and records pertaining to development of Licensed Products hereunder. Such books and records shall reasonably (a) be appropriate for patent and regulatory purposes, (b) be in material compliance with Applicable Law, (c) reflect all work done and results achieved in the performance of its development activities hereunder, (d) record only such activities and not include or be commingled with records of activities outside the scope of this Agreement and (e) be retained by Licensee for at least [\*\*\*] after the expiration or termination of this Agreement in its entirety or for such longer period as may be required by Applicable Law.

**3.2.4. Development Reports.** No later than [\*\*\*] following the end of each Calendar Year during which Licensee is conducting development activities hereunder, Licensee shall provide AstraZeneca with a written report describing such development activities it has performed, or caused to be performed, since the preceding report (or the Effective Date, with respect to the first report), and a description of its development activities in process and the future activities it expects to initiate during the following [\*\*\*] period. Each such report shall contain sufficient detail to enable AstraZeneca to assess Licensee's compliance with its obligations set

forth in Section 3.2.1, including: (a) Licensee's, or its Affiliates' or its or their Sublicensees' activities with respect to achieving Regulatory Approvals of Licensed Products in the Territory and (b) clinical study results and results of other developments. AstraZeneca acknowledges and agrees that any forward looking activities and information in any such report are to be based on Licensee's good faith plans, objectives and expectations, may not be completed or achieved, and will be subject to change.

**3.3. AstraZeneca Services.** Prior to any exercise of the right of first negotiation pursuant to Section 3.4, Licensee and AstraZeneca may from time to time discuss opportunities to utilize AstraZeneca's in-house expertise and capabilities for development of Licensed Compounds and Licensed Products to the extent possible and for which AstraZeneca has capacity. If requested by Licensee, AstraZeneca may elect, at AstraZeneca's sole discretion, to support Licensee's development activities for Licensed Compounds and Licensed Products, and, upon any such election by AstraZeneca, the Parties would negotiate in good faith the terms and conditions of any such engagement to be memorialized in a separate written agreement between the Parties.

#### **3.4. AstraZeneca's Right of First Negotiation.**

**3.4.1.** AstraZeneca shall have an exclusive, one-time right of first negotiation to buy into Licensee's program for development and commercialization of Licensed Compounds and Licensed Products, which right shall be exercisable by AstraZeneca within [\*\*\*] (the "**First Negotiation Period**") after Licensee provides AstraZeneca with a report of the final results of the first Phase 2 Clinical Study of a Licensed Product.

**3.4.2.** If, within the First Negotiation Period, AstraZeneca notifies in writing Licensee of its desire to negotiate an opt-in right, the Parties agree to exclusively negotiate in good faith for a period of [\*\*\*] from the date AstraZeneca gives notice to Licensee (the "**Negotiation Period**") to enter into a definitive agreement for joint development and commercialization of Licensed Compounds and Licensed Products on commercially reasonable terms mutually agreed to by the Parties.

**3.4.3.** If the definitive agreement is not agreed within the Negotiation Period, Licensee shall then have the right to commence discussions and enter into definitive agreement(s) with Third Parties in relation to the further Exploitation of Licensed Compounds and Licensed Products.

#### **3.5. Regulatory Activities.**

**3.5.1. Regulatory Approvals.** Licensee shall have the sole right to prepare, obtain and maintain Drug Approval Applications (including the setting of the overall regulatory strategy therefor), other Regulatory Approvals and other submissions (including INDs) and to conduct communications with the Regulatory Authorities, for the Licensed Products in the Field in the Territory in its name.

**3.5.2. Recalls, Suspensions or Withdrawals.** Licensee shall notify AstraZeneca promptly (but in no event later than 2 Business Days) following its determination that any event, incident or circumstance has occurred that Licensee has determined would result in the

need for a recall, market suspension or market withdrawal of a Licensed Product in the Field in the Territory and shall include in such notice the reasoning behind such determination and any supporting facts. As between the Parties, Licensee shall be solely responsible for handling any recall, market suspension or market withdrawal in the Field in the Territory at its sole cost and expense; *provided* that prior to any implementation of such a recall, market suspension or market withdrawal, Licensee shall consult with AstraZeneca and shall consider AstraZeneca's comments in good faith. If a recall, market suspension or market withdrawal is mandated by a Regulatory Authority in the Territory, as between the Parties, Licensee shall initiate such a recall, market suspension or market withdrawal in compliance with Applicable Law.

**3.5.3. Global Safety Database.** Licensee shall establish, hold and maintain (at Licensee's sole cost and expense) the global safety database for the Licensed Products.

**3.6. Commercialization.**

**3.6.1. Commercialization Costs.** As between the Parties, Licensee shall be solely responsible for commercialization of the Licensed Products in the Field in the Territory at its own cost and expense.

**3.6.2. Diligence.** Licensee shall use Commercially Reasonable Efforts to commercialize the Licensed Products throughout the Territory so as to maximize Net Sales throughout the Territory.

**3.6.3. Booking of Sales; Distribution.** Licensee, its Affiliates, or its or their Sublicensees shall invoice and book sales, establish all terms of sale (including pricing and discounts) and warehouse and distribute the Licensed Products in the Field in the Territory and perform or cause to be performed all related services. Licensee, its Affiliates, or its or their Sublicensees shall handle all returns, recalls or withdrawals (in accordance with Section 3.5.2), order processing, invoicing, collection, distribution and inventory management with respect to the Licensed Products in the Territory.

**3.6.4. Commercialization Records.** Licensee shall maintain complete and accurate books and records pertaining to commercialization of the Licensed Products hereunder, which shall be in compliance with Applicable Law and reasonably reflect all work done and results achieved in the performance of its commercialization activities. Such records shall be retained by Licensee for at least [\*\*\*] after the expiration or termination of this Agreement in its entirety or for such longer period as may be required by Applicable Law.

**3.6.5. Commercialization Reports.** No later than [\*\*\*] following the end of each Calendar Year during which Licensee is conducting commercialization activities hereunder, Licensee shall provide AstraZeneca with a written report describing such commercialization activities it has performed, or caused to be performed, since the preceding report (or the Effective Date, with respect to the first report) and a description of the future activities it expects to initiate during the following [\*\*\*] period. Each such report shall contain sufficient detail to reasonably enable AstraZeneca to assess Licensee's compliance with its obligations set forth in Section 3.6.2. AstraZeneca acknowledges and agrees that any forward

looking activities and information in any such report are to be based on Licensee's good faith plans, objectives and expectations, may not be completed or achieved, and will be subject to change.

**3.7. Statements and Compliance with Applicable Law.** Licensee shall, and shall cause its Affiliates to, comply, in all material respects, with all Applicable Law with respect to the Exploitation of Licensed Products.

**3.8. Supply of Licensed Products.**

**3.8.1.** AstraZeneca hereby sells and assigns to Licensee all of its right, title and interest in and to the amounts of the Licensed Compounds and Licensed Products set forth on **Schedule 3.8.1** (the "**Inventory**"). In connection with the transfer of AstraZeneca Know-How under Section 3.1, AstraZeneca shall deliver or, in case any of the Inventory is owned by an Affiliate of AstraZeneca, shall have the applicable Affiliate deliver the Inventory to Licensee (or its designee) at a facility designated by Licensee at such time as requested by Licensee. AstraZeneca represents, warrants and covenants that all Inventory provided to Licensee under this Section shall be stored and maintained by AstraZeneca prior to delivery to Licensee (or its designee) in accordance with AstraZeneca's standard procedures. EXCEPT AS PROVIDED IN THIS SECTION, LICENSEE AGREES THAT ALL SUCH INVENTORY IS PROVIDED "AS IS" AND WITHOUT ANY WARRANTIES, EXPRESS OR IMPLIED.

**3.8.2. Responsibility.** Licensee may use the Inventory provided by AstraZeneca solely for the development of Licensed Products pursuant to this Agreement and shall not make any Inventory available to any Third Party except as expressly permitted herein. As between the Parties, Licensee shall have the sole responsibility for, at its expense, Manufacturing (or having Manufactured) and supplying the Licensed Compounds and Licensed Products for its development and commercialization activities in the Territory. AstraZeneca shall be under no obligation to Manufacture (or have Manufactured) Licensed Compounds.

**3.9. Subcontracting.** Licensee may subcontract with a Third Party to perform any or all of its obligations hereunder (including by appointing one or more distributors); *provided* that Licensee shall be responsible for the acts or omissions of its subcontractors in performing services for Licensee or its Affiliates which would constitute a breach by Licensee hereunder.

**3.10. Information Sharing Conferences.** Licensee shall convene meetings between that Parties at least twice each Calendar Year to share updates and progress of the development and commercialization of Licensed Products. Such information sharing conferences may be held by phone, videoconference or in person at such times and in such manner as mutually agreed by the Parties.

**3.11. Alliance Managers.** Within [\*\*\*] after the Effective Date, each Party shall, by written notice to the other Party, appoint one individual to serve as such Party's alliance manager under this Agreement (each, an "**Alliance Manager**"). The Alliance Managers shall, in addition to such other responsibilities as the Parties may agree in writing after the Effective Date, (a) discuss and supervise the development and commercialization of the Licensed Compounds and

the Licensed Products in the Field in the Territory (b) coordinate the Parties' activities under this Agreement, and (c) work together to manage and facilitate the communication between the Parties under this Agreement, including scheduling of information sharing conferences contemplated by Section 3.10 and resolution (in accordance with the terms of this Agreement) of issues between the Parties that arise in connection with this Agreement. Each Party may replace its Alliance Manager at any time by notifying the other Party in writing of such replacement. The Alliance Managers shall not have final decision-making authority with respect to any matter under this Agreement.

**ARTICLE 4  
PAYMENTS AND RECORDS**

**4.1. Upfront Cash Payment.** Licensee shall pay AstraZeneca a non-refundable and non-creditable upfront amount in cash equal to \$5,000,000. On the Effective Date, AstraZeneca shall provide an invoice to Licensee for the upfront cash payment due, which amount shall be payable by Licensee no later than ten days following the Effective Date.

**4.2. Upfront Equity Payment.** Licensee shall issue to AstraZeneca a number of newly issued, fully-paid and non-assessable shares of Licensee's common stock determined by dividing (a) \$7,500,000 by (b) the volume-weighted average price of one share of Licensee's common stock on the Nasdaq Capital Market for the 30 Business Days immediately preceding the Effective Date, as reported by Bloomberg L.P. (the "**License Shares**"). Concurrently with the execution and delivery of this Agreement, AstraZeneca and Licensee shall execute a subscription agreement ("**Subscription Agreement**") for the purchase and sale of the License Shares. AstraZeneca shall provide an invoice to Licensee for the upfront equity payment due, which amount shall be payable by Licensee by issuance of the License Shares on the Effective Date or as soon as reasonably practicable thereafter (the "**Closing**"). At the Closing, Licensee shall deliver, or cause to be delivered, an irrevocable instruction to its transfer agent to (i) issue the License Shares to AstraZeneca in book-entry form effective as of the Effective Date, and (ii) deliver evidence of the issuance thereof to AstraZeneca.

**4.3. Milestones.**

**4.3.1. Development and Regulatory Milestones.** Licensee shall pay AstraZeneca each of the following non-refundable, non-creditable milestone payments upon the first achievement of the corresponding Milestone Event as set forth below in accordance with Section 4.3.2:

Development or Regulatory Milestone Event	Development or Regulatory Milestone Payment
[***]	[***]

Development or Regulatory Milestone Event	Development or Regulatory Milestone Payment
[***]	[***]
[***]	[***]
[***]	[***]

Each milestone payment in this Section 4.3.1 shall be payable only once upon the first achievement of the applicable Milestone Event and no amounts shall be due and payable for subsequent or repeated achievements of such Milestone Event, whether by the same or any subsequent Licensed Product. If, at any time, the achievement of a Milestone Event described in this Section 4.3.1 has occurred with respect to which a payment is due hereunder and any payment for a logically antecedent Milestone Event in this Section 4.3.1 (excluding, for the avoidance of doubt, any milestone event with respect to [\*\*\*) has not been due or been paid, then each such skipped milestone payment shall become due and payable concurrently with the milestone payment for the Milestone Event with respect to which payment is due.

**4.3.2. Invoicing.** Licensee shall give AstraZeneca written notice of the achievement of each Milestone Event in Section 4.3.1 no later than [\*\*\*) after such achievement. AstraZeneca shall submit an invoice promptly, but no more than [\*\*\*) following receipt of such notice, to Licensee for the full amount of the corresponding milestone payment, which amount shall be payable within [\*\*\*) after the receipt of the invoice.

**4.3.3. Commercial Milestones.** Licensee shall pay AstraZeneca each of the following non-refundable, non-creditable milestone payments after the achievement of the corresponding Milestone Event:

Commercial Milestone Event	Milestone Payment
[***)	[***)
[***)	[***)
[***)	[***)

If more than one of the foregoing Milestone Events of this Section 4.3.3 is achieved in a given Calendar Year, Licensee shall pay to AstraZeneca a separate milestone payment with respect to each such Milestone Event that is achieved in such Calendar Year. Each milestone payment in this Section 4.3.3 shall be payable only once upon the first achievement of such Milestone Event and no amounts shall be due and payable for subsequent or repeated achievements of such Milestone Event.

**4.3.4. Notice and Payment.** Licensee shall give AstraZeneca written notice of the achievement of each Milestone Event in Section 4.3.3 no later than [\*\*\*] after the close of the Calendar Quarter in which such Milestone Event was achieved. Following receipt of such notice, AstraZeneca shall submit an invoice promptly, but no more than [\*\*\*] following receipt of such notice, to Licensee for the full amount of the corresponding milestone payment. Each such milestone payment shall be payable [\*\*\*] after receipt of the invoice. Licensee shall provide along with the payment a written statement of the calculation of Net Sales for each Licensed Product in each country in the Territory (including such amounts expressed in local currency and as converted to Dollars). If, notwithstanding the fact that Licensee has not provided AstraZeneca such notice, AstraZeneca believes that any such Milestone Event has been achieved, it shall so notify Licensee in writing and the Parties shall promptly meet and discuss in good faith whether such Milestone Event has been achieved. Any dispute under this Section 4.3.4 regarding whether or not a Milestone Event has been achieved shall be subject to resolution in accordance with Section 10.5.

**4.4. Royalties.**

**4.4.1. Royalty Rates.** Licensee shall pay AstraZeneca a royalty based on Net Sales of each Licensed Product in the Field in the Territory during each Calendar Year during the Royalty Term at the following rates set forth below in this Section 4.4.1 (as adjusted by the other terms of this Section 4.4, each, a “**Royalty**”), in accordance with Section 4.5.

Portion of aggregate Net Sales of all Licensed Products in the Territory during a Calendar Year	Royalty Rate
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

**4.4.2.** [\*\*\*].

**4.4.3. Royalty Reduction.**

(a) **Royalty Stacking.** If Licensee or any of its Affiliates believes that it is necessary to obtain a license to Exploit such Licensed Product to avoid infringement of the intellectual property rights owned or controlled by a Third Party, Licensee may deduct from any Royalty due on the Net Sales of such Licensed Product for a Calendar Year [\*\*\*] of the license fees, royalties, or other amounts paid by Licensee or its Affiliates to such Third Party for such Calendar Year for the grant or maintenance of such license.

(b) **Reduction for Generic Competition.** In the event that one or more Generic Products with respect to a Licensed Product are commercially available in a given country in the Territory (“**Generic Competition**”) in a given Calendar Quarter, then Licensee shall be entitled to deduct [\*\*\*] from the Royalty due to AstraZeneca with respect to such Licensed Product in such country if Net Sales of such Licensed Product in such country in such Calendar Quarter [\*\*\*], such deduction to be made in such Calendar Quarter and thereafter in each Calendar Quarter during the Royalty Term in which there is Generic Competition with respect to such Licensed Product in such country.

(c) [\*\*\*].

**4.4.4. No Multiple Royalties.** No multiple royalties will be due because any Licensed Product is Covered by more than one Valid Claim of the AstraZeneca Patents. In such case, Licensee shall pay only one Royalty at the applicable rate pursuant to Section 4.4.1, as adjusted pursuant to Section 4.4.3, as applicable.

**4.4.5. Royalty Term.** Licensee shall have no obligation to pay any Royalty with respect to Net Sales of any Licensed Product in any country after the last day of the month in which the Royalty Term for such Licensed Product in such country expires.

**4.5. Royalty Payments and Reports.** Licensee shall calculate all amounts payable to AstraZeneca pursuant to Section 4.4.1 at the end of each Calendar Quarter, which amounts shall be converted to Dollars, in accordance with Section 4.6. Licensee shall provide a written statement (a “**Payment Statement**”) that includes such calculation to AstraZeneca in writing within [\*\*\*] of the end of the Calendar Quarter, which Payment Statement shall include, on a Licensed Product-by-Licensed Product basis, the amount of Invoiced Sales, Net Sales and deductions taken to arrive at Net Sales attributable to each Licensed Product in each country in the Territory during the applicable Calendar Quarter (including such amounts expressed in local currency and as converted to Dollars) and a calculation of the amount of Royalty payment due on such Net Sales for such Calendar Quarter. Following receipt of such Payment Statement, AstraZeneca shall submit an invoice promptly, but no more than [\*\*\*] following receipt of such Payment Statement, to Licensee for the full amount of the corresponding Royalty payment. Licensee shall pay to AstraZeneca the Royalty amounts due with respect to a given Calendar Quarter within [\*\*\*] after the receipt of the invoice. Without limiting the generality of the foregoing, Licensee shall require its Affiliates and Sublicensees to account for their Net Sales and provide reports with respect thereto, as if such sales were made by Licensee.

**4.6. Mode of Payment; Offsets.** All payments to AstraZeneca under this Agreement shall be made by deposit of Dollars in the requisite amount to such bank account as AstraZeneca may from time to time designate by notice to Licensee. For the purpose of calculating any sums due under this Agreement (including the calculation of Net Sales expressed in currencies other than Dollars), Licensee shall convert any amount expressed in a foreign currency into Dollar equivalents using its, its Affiliate’s or Sublicensee’s, as applicable, standard conversion methodology consistent with GAAP. Except as otherwise expressly permitted under Sections 4.4.3 and 7.3.3, Licensee shall have no right to offset, set off or deduct any amounts from or against the amounts due to AstraZeneca hereunder.

#### 4.7. Taxes.

**4.7.1. General.** The milestone payments and royalties payable by Licensee to AstraZeneca pursuant to this Agreement (each, a “**Payment**”) shall be paid free and clear of any and all taxes, except for any withholding Taxes required by Applicable Law as set forth below. Except as provided in this Section 4.7, AstraZeneca shall be solely responsible for paying any and all Taxes (other than withholding Taxes required by Applicable Law to be deducted from Payments and remitted by Licensee) levied on account of, or measured in whole or in part by reference to, any Payments it receives. Licensee shall deduct or withhold from the Payments any Taxes that, in its good faith judgment, it is required by Applicable Law to deduct or withhold. Notwithstanding the foregoing, if AstraZeneca is entitled under any applicable Tax treaty to a reduction of rate of, or the elimination of, applicable withholding Tax, it may deliver to Licensee or the appropriate Governmental Authority (with the assistance of Licensee to the extent that this is reasonably required and is requested in writing) the prescribed forms necessary to reduce the applicable rate of withholding or to relieve Licensee of its obligation to withhold such Tax and Licensee shall apply the reduced rate of withholding or dispense with withholding, as the case may be; *provided* that Licensee has received evidence of AstraZeneca’s delivery of all applicable forms (and, if necessary, its receipt of appropriate governmental authorization) at least 15 days prior to the time that the Payments are due. If, in accordance with the foregoing, Licensee withholds any amount, it shall pay to AstraZeneca the balance when due, make timely payment to the proper Taxing authority of the withheld amount and send to AstraZeneca proof of such payment within 10 days following such payment. No later than ten days after the Effective Date, AstraZeneca shall provide Licensee with a properly executed United States Internal Revenue Service Form W-9 or Form W-8, as applicable (with AstraZeneca to provide an updated form as soon as any relevant change in circumstance would cause the form on file with Licensee to no longer be current or accurate).

**4.7.2. Value Added Tax.** Notwithstanding anything contained in Section 4.7.1, this Section 4.7.2 shall apply with respect to value added tax (“**VAT**”). All Payments are exclusive of VAT. If any VAT is chargeable in respect of any Payments, Licensee shall pay VAT at the applicable rate in respect of any such Payments following the receipt of a VAT invoice in the appropriate form issued by AstraZeneca in respect of those Payments, such VAT to be payable on the later of the due date of the payment of the Payments to which such VAT relates and [\*\*\*] after the receipt by Licensee of the applicable invoice relating to that VAT payment. The Parties will issue invoices for all amounts due under this Agreement consistent with indirect Tax requirements.

**4.7.3.** [\*\*\*].

**4.7.4. Prevention of Facilitation of Tax Evasion.**

(a) Each Party represents, warrants and undertakes that neither it nor its Affiliates shall commit a tax evasion facilitation offence under Part 3 of the UK Criminal Finances Act 2017 in connection with or attributable to this Agreement or the transactions contemplated hereby.

(b) Each Party shall promptly report to the other Party any apparent breach of Section 4.7.4(a) and shall (i) answer, in reasonable detail, any written or oral inquiry from the other Party related to its and its Affiliates compliance with Section 4.7.4(a), (ii) facilitate the interview of employees of such Party by the other Party (or any agent of such Party) at any reasonable time specified by the inquiring Party related to such Party's compliance with Section 4.7.4(a) and (iii) co-operate with the inquiring Party and any Governmental Authority in relation to any investigation relating to the matters referred to in Section 4.7.4(a), in all cases, as reasonably required to enable that other Party to comply with its undertaking in Section 4.7.4.

**4.8. Interest on Late Payments.** If any undisputed payment due to either Party under this Agreement is not paid on or before the date such payment is due under this Agreement, then such paying Party shall pay interest thereon at an annual rate equal to the lesser of (a) [\*\*\*] of interest as reported in the Wall Street Journal on the date applicable payment was due and (b) the maximum rate permitted under Applicable Law. Any interest will accrue from day to day and is calculated based on the actual number of days elapsed from the payment due date to the actual payment date and a year of 360 days.

**4.9. Financial Records.** Licensee shall, and shall cause its Affiliates and its and their Sublicensees to, keep complete and accurate financial books and records pertaining to the commercialization of Licensed Products hereunder, in all material respects, which are reasonably necessary for the calculation of payments based on Net Sales to be made to AstraZeneca hereunder, and retain such records at least [\*\*\*] following Licensee's delivery of the Payment Statement with respect to the applicable Calendar Quarter.

**4.10. Audit.**

**4.10.1.** At the reasonable request and sole expense of AstraZeneca within [\*\*\*] after receiving any Payment Statement, Licensee shall permit a qualified, independent certified public accountant designated by AstraZeneca and reasonably acceptable to Licensee ("**Auditor**"), upon reasonable but not less than [\*\*\*] prior written notice to Licensee, to audit Licensee's applicable books and records maintained pursuant to Section 4.9 solely to ensure the accuracy of such Payment Statement and Royalty payment made hereunder. The Auditor must conduct such audit during Licensee's normal business hours in a manner designed to minimize disruption of Licensee's normal business operations and complete such audit within a reasonable period of time after commencing such audit. All information and materials made available to or otherwise obtained or prepared by or for the Auditor in connection with such audit will be deemed Licensee's Confidential Information and will be subject to the Auditor's entry, prior to conducting the audit, into a written agreement with Licensee containing confidentiality and restricted use obligations at least as restrictive as those set out in Article 6. AstraZeneca may not exercise this right more than once in any [\*\*\*] period and the Auditor may only disclose to AstraZeneca information limited to the accuracy of the audited Payment Statement and any deficiency in the payment made, or any overpayment, and no other information or materials made available to or otherwise obtained or prepared by or for the Auditor in connection with such audit. AstraZeneca shall not compensate the Auditor (in whole or in part) contingent on the outcome of the audit.

**4.10.2.** AstraZeneca shall provide to Licensee a copy of the Auditor's audit report within 30 days of AstraZeneca's receipt of the report. If such report shows that payments made by Licensee are deficient, subject to Section 4.7.1, Licensee shall pay AstraZeneca the deficient amount within 30 days after Licensee's receipt of the audit report, or, except to the extent Licensee disputes such deficiency in good faith (in which event Licensee may withhold payment of such disputed amount, subject to resolution of such dispute). If the report shows that payments made by Licensee were in excess of the required payment, AstraZeneca shall promptly pay Licensee the excess amount at the time it provides the copy of the Auditor's audit report to Licensee. If the Auditor's audit report shows that payments made by Licensee are deficient by more than [\*\*\*] of the amount due for the audited period, Licensee shall promptly reimburse AstraZeneca for its reasonable, documented out-of-pocket costs of such audit.

**4.10.3.** The failure of AstraZeneca to request an audit or verification of any Payment Statement during the 36 month period after receipt of such Payment Statement is deemed acceptance by AstraZeneca of the accuracy of such Payment Statement and the payments made by Licensee in accordance with such Payment Statement and, thereafter, AstraZeneca's audit rights under this Section 4.10.3 shall no longer apply with respect to such Payment Statement, the payments made by Licensee in accordance with such Payment Statement and any facts or circumstances to which such Payment Statement and payments relate.

**4.11. Audit Dispute.** In the event of a dispute with respect to any audit under Section 4.10, AstraZeneca and Licensee shall work in good faith to resolve the disagreement. If the Parties are unable to reach a mutually acceptable resolution of any such dispute within 30 days, the dispute shall be submitted for resolution to a qualified, independent certified public accounting firm jointly selected by each Party's certified public accountants or to such other Person as the Parties shall mutually agree (the "**Resolution Auditor**"). The decision of the Resolution Auditor shall be final and the costs of such arbitration as well as the initial audit shall be borne between the Parties in such manner as the Resolution Auditor shall determine. Not later than 10 days after such decision and in accordance with such decision, Licensee shall pay the additional amounts or AstraZeneca shall reimburse the excess payments, as applicable.

## **ARTICLE 5 INTELLECTUAL PROPERTY**

### **5.1. Ownership of Intellectual Property.**

**5.1.1. Ownership of Technology.** As between the Parties, (a) Licensee shall own and retain all right, title and interest in and to any and all Information and inventions that are conceived, discovered, developed or otherwise made by or on behalf of a Party or its Affiliates or its or their respective (sub)licensees (or Sublicensee(s)), as applicable, under or in connection with this Agreement during the Term, whether or not patented or patentable and any and all Patents and other intellectual property rights with respect thereto; and (b) each Party shall own and retain all right, title and interest in and to any and all other Information, inventions, Patents and other intellectual property rights that are owned or otherwise controlled (other than pursuant to the license grants set forth in Section 2.1) by such Party or its Affiliates or its or their (sub)licensees (or Sublicensees) (as applicable) outside of this Agreement.

**5.1.2. United States Law.** The determination of whether Information and inventions are conceived, discovered, developed or otherwise made by a Party or any of its Affiliates for the purpose of allocating proprietary rights (including Patent, copyright or other intellectual property rights) therein, shall, for purposes of this Agreement, be made in accordance with Applicable Law in the United States as such law exists as of the Effective Date irrespective of where such conception, discovery, development or making occurs.

**5.1.3. Assignment Obligation.** Each Party shall cause all Persons who perform activities for such Party under this Agreement or who conceive, discover, develop or otherwise make any Information or inventions by or on behalf of such Party or its Affiliates or its or their respective (sub)licensees (or Sublicensees) under or in connection with this Agreement to be under an obligation to assign (or, if such Party is unable to cause such Person to agree to such assignment obligation despite such Party's using commercially reasonable efforts to negotiate such assignment obligation, then to grant an exclusive license under) their rights in any Information and inventions resulting therefrom to such Party, except where Applicable Law requires otherwise and except in the case of governmental, not-for-profit and public institutions that have standard policies against such an assignment (in which case, a suitable license or right to obtain such a license, shall be obtained).

**5.1.4. Ownership of Product Trademarks.** As between the Parties, Licensee shall own all right, title and interest to the Product Trademarks in the Territory.

**5.1.5. Ownership of Corporate Names.** As between the Parties, AstraZeneca shall retain all right, title and interest in and to its Corporate Names.

## **5.2. Maintenance and Prosecution of Patents**

**5.2.1. In General.** As between the Parties, Licensee shall have the first right, but not the obligation, to prepare, file, prosecute and maintain the AstraZeneca Patents, including any related interference, re-issuance, re-examination and opposition proceedings with respect thereto, worldwide, in each case, at its sole cost and expense and through counsel of its choice. If, as between the Parties, Licensee decides not to prepare, file, prosecute or maintain any of the AstraZeneca Patents in a country in the Territory, Licensee shall provide reasonable prior written notice to AstraZeneca of such intention and AstraZeneca shall thereupon have the right, in its sole discretion, to assume the control and direction of the preparation, filing, prosecution and maintenance of such AstraZeneca Patent at its sole cost and expense in such country. AstraZeneca shall promptly execute such documents and take such further actions as may be necessary or requested by Licensee to grant Licensee or its designee the rights to control, and to assist Licensee or its designee in, the preparation, filing, prosecution and maintenance of the AstraZeneca Patents.

**5.2.2. Cooperation.** Each Party shall, and shall cause its Affiliates to, assist the other Party at the reasonable request of the other Party from time to time in connection with its activities set forth in Section 5.2.1. The Party that has the right to prepare, file, prosecute and maintain the AstraZeneca Patents (the "**Prosecuting Party**") shall (a) keep the other Party (the "**Non-Prosecuting Party**") reasonably informed of all steps to be taken in the preparation and prosecution of all applications filed by it pursuant to Section 5.2.1, (b) furnish the Non-Prosecuting

Party with copies of material filings with any patent office relating to prosecution and maintenance of such patent application, and (c) to the extent reasonably practicable, permit the Non-Prosecuting Party an opportunity to offer its comments on such material filings before making a submission to a patent office, which comments the Prosecuting Party shall consider in good faith. The Non-Prosecuting Party shall offer its comments, if any, promptly.

**5.2.3. Patent Term Extension and Supplementary Protection Certificate.** As between the Parties, Licensee shall have the sole right to make decisions regarding and to apply for, patent term extensions, in the Territory with respect to the AstraZeneca Patents, including in the United States with respect to extensions pursuant to 35 U.S.C. §156 et. seq. and in other jurisdictions pursuant to supplementary protection certificates, and in all jurisdictions with respect to any other extensions that are now or become available in the future, wherever applicable, in each case including whether or not to do so. AstraZeneca shall provide prompt and reasonable assistance, as requested by Licensee, including by taking such action as patent holder as is required under any Applicable Law to obtain such extension or supplementary protection certificate.

**5.2.4. Patent Listings.** As between the Parties, Licensee shall have the sole right to make decisions regarding and make all filings with Regulatory Authorities in the Territory with respect to the AstraZeneca Patents, including as required or allowed (a) in the United States, in the FDA's Orange Book and (b) in the European Union, under the national implementations of Article 10.1(a)(iii) of Directive 2001/EC/83 or other international equivalents. To the extent reasonably practicable, Licensee shall reasonably consult with AstraZeneca to determine the course of action with respect to such filings.

### **5.3. Enforcement of Patents.**

**5.3.1. Notice.** Each Party shall promptly notify the other Party in writing of, but in no event later than 30 days after the earlier of receiving written notice or, to the actual knowledge of any of a Party's patent attorneys with responsibility for Licensed Products, becoming aware of, (a) any known infringement of the AstraZeneca Patents or misappropriation of AstraZeneca Know-How in the U.S., Canada, Japan, Germany, UK, Italy, France, Spain, or China (each, a "**Major Market**"); (b) any pending declaratory judgment, opposition, or similar action or proceeding alleging the invalidity, unenforceability, or non-infringement of AstraZeneca Patents and/or AstraZeneca Know-How; or (c) any certification filed under the Hatch-Waxman Act claiming that any AstraZeneca Patents are invalid or unenforceable or claiming that any AstraZeneca Patents would not be infringed by the making, use, offer for sale, sale or import of a product for which an application under the Hatch-Waxman Act is filed or any equivalent or similar certification or notice in any other jurisdiction in the Territory, in each case ((a), (b) and (c)) of which such Party becomes aware (an "**Infringement**"), and such Party shall provide the other Party with all available evidence supporting such Infringement.

**5.3.2. Enforcement of Patents.** As between the Parties, Licensee shall have the first right, but not the obligation, to prosecute any Infringement with respect to the AstraZeneca Patents and/or AstraZeneca Know-How, including as a defense or counterclaim in connection with any Third Party Infringement Claim, and, in each case, control the conduct thereof in the name of AstraZeneca, Licensee or both as may be required by Applicable Law, at Licensee's

sole cost and expense, using counsel of Licensee's choice; *provided* that if Licensee does not take commercially reasonable steps to prosecute such an Infringement in any Major Market (a) within [\*\*\*] following the first notice provided above under Section 5.3.1 with respect to such Infringement or (b) *provided* such date occurs after the first such notice of such Infringement is provided, [\*\*\*] before the time limit, if any, set forth in appropriate laws and regulations for filing of such actions, whichever comes first, then Licensee shall so notify AstraZeneca and AstraZeneca may prosecute such Infringement at its sole cost and expense.

**5.3.3. Cooperation.** If a Party is entitled to and pursues an action against an Infringement in accordance with this Section 5.3, (a) the other Party shall, and shall cause its Affiliates to, cooperate fully, including being joined as a necessary party to such action, providing access to relevant documents and other evidence and making its employees available at reasonable business hours, (b) such Party pursuing any action against an Infringement shall reasonably consult with the other Party as to the strategy for such action and (c) such Party shall consider in good faith any comments from the other Party and shall keep the other Party reasonably informed of any steps taken with respect to such action.

**5.3.4. Settlement.** The Party that is entitled to and pursues an action against an Infringement in accordance with this Section 5.3 shall have the right to control and enter into any settlement, consent judgment or other voluntary disposition of such action; *provided* that no settlement shall be entered into without the prior consent of the other Party (which consent shall not be unreasonably withheld, conditioned or delayed) if such settlement would adversely affect the rights of the other Party or any of its Affiliates concerning the AstraZeneca Patents and/or AstraZeneca Know-How or impose any costs or liability on or involve any admission by, the other Party or any of its Affiliates.

**5.3.5. Cost Recovery.** Each Party shall bear its own costs and expenses relating to any Infringement action commenced pursuant to this Section 5.3; *provided* that the pursuing Party shall reimburse the other Party for the reasonable out-of-pocket costs and expenses incurred by the other Party for any assistance requested by the pursuing Party for such action. Except as otherwise agreed by the Parties in connection with a cost sharing arrangement, any recovery realized as a result of any suit, action or other proceeding described above in this Section 5.3 or from any counterclaim or similar claim asserted in a proceeding described below in Section 5.4, whether by way of settlement or otherwise, shall be applied in the following order of priority: first, the Party assisting the pursuing Party shall be reimbursed for all reasonable out-of-pocket costs and expenses incurred by such assisting Party in connection with such proceeding; second, the pursuing Party shall be reimbursed for all costs and expenses in connection with such proceeding, including attorneys' fees; and third any remainder shall be deemed Net Sales and retained by Licensee, subject to Royalty payments to AstraZeneca hereunder.

**5.4. Infringement Claims by Third Parties.** Each Party shall promptly notify the other Party in writing of, but in no event later than 30 days after the earlier of receiving written notice or, to the actual knowledge of any of a Party's patent attorneys with responsibility for Licensed Products, becoming aware of, any threatened or actual claim, action, suit or proceeding by a Third Party against Licensee, or any of its Affiliates or its or their Sublicensees relating to the infringement of such Third Party's Patents or unauthorized use or misappropriation of such Third

Party's Information, based upon an assertion or claim arising out of the research, development, commercialization or Manufacture of a Licensed Product in the Territory pursuant to this Agreement by Licensee or any of its Affiliates or its or their Sublicensees (such claim, action, suit or proceeding, a "**Third Party Infringement Claim**"), including any defense or counterclaim in connection with an Infringement action initiated pursuant to Section 5.3 As between the Parties, Licensee shall be responsible for defending any such Third Party Infringement Claim, and control the conduct thereof, at its sole cost and expense, using counsel of Licensee's choice. AstraZeneca may participate in any such Third Party Infringement Claim, with counsel of its choice at its sole cost and expense; *provided* that Licensee shall control such Third Party Infringement Claim. AstraZeneca shall, and shall cause its Affiliates to, assist and cooperate with Licensee, as Licensee may reasonably request from time to time, in connection with its activities set forth in this Section 5.4, including where necessary, furnishing a power of attorney solely for such purpose or joining in, or being named as a necessary party to, such Third Party Infringement Claim, providing access to relevant documents and other evidence and making its employees available at reasonable business hours; *provided* that Licensee shall reimburse AstraZeneca for its reasonable and verifiable out-of-pocket costs and expenses incurred in connection therewith. Licensee shall keep AstraZeneca reasonably informed of all material developments in connection with any such Third Party Infringement Claim. Any damages, or awards, including royalties incurred or awarded in connection with any Third Party Infringement Claim defended under this Section 5.4 shall be borne by Licensee.

**5.5. Invalidity or Unenforceability Defenses or Actions.** Each Party shall promptly notify the other Party in writing of, but in no event later than 30 days after the earlier of receiving written notice or, to the actual knowledge of any of a Party's patent attorneys with responsibility for Licensed Products, becoming aware of, any threatened or actual claim, action, suit or proceeding by a Third Party asserting that any AstraZeneca Patent relating to a Licensed Product is invalid or otherwise unenforceable (such claim, action, suit or proceeding, an "**Invalidity Claim**"), whether as a defense in an infringement action brought by Licensee or AstraZeneca pursuant to Section 5.3, in a declaratory judgment action or in a Third Party Infringement Claim brought against Licensee or AstraZeneca. As between the Parties, Licensee shall have the first right, but not the obligation, to defend and control the defense of the Invalidity Claim at its sole cost and expense, using counsel of Licensee's choice. For purposes of this Section 5.5, the Party defending an Invalidity Claim pursuant to the foregoing sentence shall be the "**Controlling Party**." With respect to any such Invalidity Claim in the Territory, the non-Controlling Party may participate in such Invalidity Claim with counsel of its choice at its sole cost and expense; *provided* that the Controlling Party shall retain control of the defense in such Invalidity Claim. If the Controlling Party or its designee elects not to defend or control the defense of the applicable AstraZeneca Patent in an Invalidity Claim, then the non-Controlling Party may conduct and control the defense of any such Invalidity Claim at its sole cost and expense. The non-Controlling Party in such an Invalidity Claim shall, and shall cause its Affiliates to, cooperate fully, including being joined as a party plaintiff in such action, providing access to relevant documents and other evidence and making its employees available at reasonable business hours; *provided* that the Controlling Party shall reimburse the non-Controlling Party for its reasonable and verifiable out-of-pocket costs and expenses incurred in connection therewith. The Controlling Party shall consider in good faith any comments from the non-Controlling Party and shall keep the non-Controlling Party reasonably informed of any steps taken with respect to such action.

**5.6. Third Party Patent Rights.** If in the reasonable opinion of Licensee, the Exploitation of a Licensed Compound or a Licensed Product in the Field and in the Territory by Licensee, any of its Affiliates or any of its or their Sublicensees infringes or is reasonably expected to infringe any Patent of a Third Party in any country in the Territory (such right, a “**Third Party Patent Right**”), then, as between the Parties, Licensee shall have the first right, but not the obligation, to negotiate and obtain a license from such Third Party to such Third Party Patent Right as necessary or desirable for Licensee or its Affiliates or its or their Sublicensees to Exploit such Licensed Compound or Licensed Product in the Field in such country; *provided* that as between the Parties, subject to Section 4.4.3, Licensee shall bear all expenses incurred in connection therewith, including any royalties, milestones or other payments incurred under any such license.

## ARTICLE 6 CONFIDENTIALITY AND NON-DISCLOSURE

**6.1. Confidentiality Obligations.** At all times during the Term and for a period of [\*\*\*] following termination or expiration of this Agreement in its entirety, but with respect to trade secrets, for so long as such constitutes and is protected under Applicable Law as a trade secret, each Party shall, and shall cause its officers, directors, employees and agents to, keep confidential and not publish or otherwise disclose to a Third Party and not use, directly or indirectly, for any purpose, any Confidential Information of the other Party, except to the extent such disclosure or use is expressly permitted by the terms of this Agreement. “**Confidential Information**” means any non-public, confidential, or proprietary information provided by or on behalf of one Party (the “**Disclosing Party**”) to the other Party (the “**Receiving Party**”) in connection with this Agreement, whether in oral, written, electronic, or other form or media, whether prior to, on or after the Effective Date, whether or not such information is marked, designated, or otherwise identified as “confidential”, including any information that, due to the nature of its subject matter or circumstances surrounding its disclosure, would reasonably be understood to be confidential or proprietary. Information relating to the terms of this Agreement (subject to Section 6.4), information relating to any Licensed Compound or Licensed Product (including the Regulatory Documentation) or any development or commercialization of any Licensed Compound or Licensed Product, any know-how with respect thereto developed by or on behalf of the Disclosing Party or its Affiliates (including Licensee Know-How and AstraZeneca Know-How, as applicable) or the scientific, regulatory or business affairs or other activities of either Party shall be deemed the Confidential Information of such Party, as applicable. Notwithstanding the foregoing, the terms of this Agreement shall be deemed to be the Confidential Information of both Parties and both Parties shall be deemed to be the Receiving Party and the Disclosing Party with respect thereto. Notwithstanding the foregoing, the confidentiality and non-use obligations under this Section 6.1 with respect to any Confidential Information shall not apply to any information that:

**6.1.1.** was, is or hereafter becomes part of the public domain by public use, publication, general knowledge or the like through no breach of this Agreement by, or other wrongful act of, the Receiving Party;

**6.1.2.** can be demonstrated by documentation or other competent proof to have been in the Receiving Party’s possession prior to disclosure by or on behalf of the

Disclosing Party, directly or indirectly, without any obligation of confidentiality or restriction on use with respect to such information;

**6.1.3.** was received by the Receiving Party from a Third Party who was, at the time of receipt, not bound by any obligation of confidentiality with respect to such information;

**6.1.4.** has been published by a Third Party or otherwise enters the public domain through no fault of the Receiving Party in breach of this Agreement; or

**6.1.5.** can be demonstrated by documentation or other competent evidence to have been independently developed by or for the Receiving Party without reference to the Disclosing Party's Confidential Information.

Specific aspects or details of Confidential Information shall not be deemed to be within the public domain or in the possession of the Receiving Party merely because the Confidential Information is embraced by more general information in the public domain or in the possession of the Receiving Party. Further, any combination of Confidential Information shall not be considered in the public domain or in the possession of the Receiving Party merely because individual elements of such Confidential Information are in the public domain or in the possession of the Receiving Party unless the combination and its principles are in the public domain or in the possession of the Receiving Party.

**6.2. Permitted Disclosures.** Each Party may disclose Confidential Information of the other Party to the extent that such disclosure is:

**6.2.1.** made in response to a valid order of a court of competent jurisdiction or other Governmental Authority of competent jurisdiction or, if in the reasonable opinion of the Receiving Party's legal counsel, such disclosure is otherwise required by Applicable Law, including by reason of filing with securities regulators or the rules of a stock exchange on which the securities of the Receiving Party are listed (or to which an application for listing has been submitted); *provided, however*, that before any such disclosure, the Receiving Party shall first notify the Disclosing Party and provide the Disclosing Party a reasonable opportunity (i) to narrow the scope of disclosure, or (ii) to quash such order or to obtain a protective order or confidential treatment requiring that the Confidential Information and documents that are the subject of such order be held in confidence by such court or agency or, if disclosed, be used only for the purposes for which the order was issued or such disclosure was required by Applicable Law; and *provided, further*, that the Confidential Information disclosed in response to such Governmental Authority order or Applicable Law shall be limited to that information which is legally required to be disclosed in response to such Governmental Authority order or by such Applicable Law;

**6.2.2.** made by or on behalf of the Receiving Party to the Regulatory Authorities as required in connection with any filing, application or request for Regulatory Approval; *provided, however*, that reasonable measures shall be taken to assure confidential treatment of such information to the extent practicable and consistent with Applicable Law;

**6.2.3.** made by or on behalf of the Receiving Party to a patent authority as may be reasonably necessary or useful for purposes of obtaining or enforcing a Patent; *provided, however*, that reasonable measures shall be taken to assure confidential treatment of such information, to the extent such protection is available;

**6.2.4.** made by or on behalf of the Receiving Party, in connection with its performance of its obligations or exercise of its rights under this Agreement; or

**6.2.5.** made by or on behalf of the Receiving Party to potential or actual investors, collaboration partners or acquirers as may be necessary in connection with their evaluation of such potential or actual investment, collaboration or acquisition; *provided, however*, that such persons shall be subject to obligations of confidentiality and non-use with respect to such Confidential Information substantially similar to the obligations of confidentiality and non-use of the Receiving Party pursuant to this Article 6 (with a duration of confidentiality and non-use obligations as appropriate that is no less than [\*\*\*] from the date of disclosure).

**6.3. Use of Name.** Except as expressly provided herein, neither Party shall mention or otherwise use the name, logo or Trademark of the other Party or any of its Affiliates or any of its or their (sub)licensees (or Sublicensees) (or any abbreviation or adaptation thereof) in any publication, press release, marketing and promotional material or other form of publicity without the prior written approval of such other Party in each instance. The restrictions imposed by this Section 6.3 shall not prohibit (a) either Party from making any disclosure identifying the other Party to the extent required in connection with its exercise of its rights or obligations under this Agreement or its financing, investments or other corporate endeavors, and (b) either Party from making any disclosure identifying the other Party that is required by Applicable Law or the rules of a stock exchange on which the securities of the disclosing Party are listed (or to which an application for listing has been submitted).

**6.4. Public Announcements.** The Parties shall agree upon the content of one or more press releases, the release of which the Parties shall coordinate in order to accomplish such release promptly after execution of this Agreement. Except as set forth in the foregoing sentence, neither Party shall issue any public announcement, statement, press release, marketing materials or other public disclosure regarding this Agreement or its subject matter without the other Party's prior written consent, except for any such disclosure that is, in the reasonable opinion of the issuing Party's counsel, required by Applicable Law or the rules of a stock exchange on which the securities of the issuing Party are listed (or to which an application for listing has been submitted). If a Party is, in the reasonable opinion of its counsel, required by Applicable Law or the rules of a stock exchange on which its securities are listed (or to which an application for listing has been submitted) to make such a public disclosure, such Party shall submit the proposed disclosure in writing to the other Party as far in advance as reasonably practicable so as to provide a reasonable opportunity to comment thereon. Neither Party shall be required to seek the permission of the other Party to repeat any information regarding the terms of this Agreement or any amendment hereto that has already been publicly disclosed by such Party or by the other Party, in accordance with this Section 6.4; *provided* that such information remains accurate as of such time.

**6.5. Publications.** AstraZeneca shall have no right to, and shall ensure its employees and contractors do not, publish or present any data or results regarding Licensed Compounds or Licensed Products generated by or on behalf of Licensee, its Affiliates or Sublicensees. AstraZeneca shall not and shall ensure its employees and contractors do not publicly disclose the results of, or information regarding, its or any of its Affiliate's activities regarding Licensed Compounds or Licensed Products conducted prior to the Effective Date of this Agreement; *provided* that for the period commencing on the Effective Date and continuing for [\*\*\*] thereafter, notwithstanding the foregoing, AstraZeneca's employees and contractors may publicly disclose the results of, or information regarding, its or any of its Affiliate's activities regarding Licensed Compounds or Licensed Products conducted prior to the Effective Date of this Agreement, subject in each instance to the prior review and written consent of Licensee, in a manner consistent with Applicable Law and industry practices, as provided in this Section 6.5. Licensee shall be free to publicly disclose the results of, and information regarding, activities under this Agreement, subject to prior review by AstraZeneca of any disclosure of AstraZeneca's Confidential Information solely for issues of patentability and protection of such Confidential Information, in a manner consistent with Applicable Law and industry practices, as provided in this Section 6.5; *provided* that, notwithstanding the foregoing, upon the expiration of the First Negotiation Period (or, if AstraZeneca exercises its right of first negotiation, the Negotiation Period) and continuing thereafter for the remainder of the Term, Licensee shall be free to publicly disclose the results of, and information regarding, activities under this Agreement without any prior review by AstraZeneca. Accordingly, as required by this Section 6.5, prior to publishing or disclosing any Confidential Information regarding Licensed Compounds or Licensed Products, (i) the Party seeking to publish shall provide the other Party with drafts of proposed abstracts, manuscripts or summaries of presentations that cover such Confidential Information; (ii) the non-publishing Party shall respond promptly through its designated representative and in any event no later than [\*\*\*] after receipt of such proposed publication or presentation or such shorter period as may be required by the publication or presentation; (iii) the publishing Party agrees to allow a reasonable period (not to exceed [\*\*\*]) to permit filings for patent protection and to otherwise address issues of Confidential Information or related competitive harm to the reasonable satisfaction of the other Party; and (iv) the publishing Party shall consider such comments furnished by the non-publishing Party in good faith.

**6.6. Return of Confidential Information.** Upon the effective date of the expiration or termination of this Agreement for any reason, the Disclosing Party may request in writing and the Receiving Party shall either, with respect to Confidential Information of the Disclosing Party to which such Receiving Party does not retain rights under the surviving provisions of this Agreement, at the Disclosing Party's election, (a) promptly destroy all copies of such Confidential Information in the possession or control of the Receiving Party and confirm such destruction in writing to the Disclosing Party or (b) promptly deliver to the Disclosing Party, at the Receiving Party's sole cost and expense, all copies of such Confidential Information in the possession or control of the Receiving Party. Notwithstanding the foregoing, the Receiving Party shall be permitted to retain such Confidential Information (i) to the extent necessary or useful for purposes of performing any continuing obligations, exercising any ongoing rights hereunder, or complying with Applicable Law, and, in any event, a single copy of such Confidential Information for archival purposes and (ii) any computer records or files containing such Confidential Information that have been created solely by such Receiving Party's automatic archiving and back-

up procedures, to the extent created and retained in a manner consistent with such Receiving Party's standard archiving and back-up procedures, but not for any other uses or purposes. All Confidential Information shall continue to be subject to the terms of this Agreement for the period set forth in Section 6.1.

## **ARTICLE 7 REPRESENTATIONS AND WARRANTIES**

**7.1. Mutual Representations and Warranties.** Each Party represents and warrants to the other Party, as of the Effective Date, and covenants, that:

**7.1.1.** It is a corporation duly organized, validly existing and in good standing under the laws of the jurisdiction of its organization and has all requisite power and authority, corporate or otherwise, to execute, deliver and perform this Agreement;

**7.1.2.** The execution and delivery of this Agreement and the performance by it of the transactions contemplated hereby have been duly authorized by all necessary corporate action and do not violate: (a) such Party's charter documents, bylaws or other organizational documents; (b) in any material respect, any agreement, instrument or contractual obligation to which such Party is bound; (c) any requirement of any Applicable Law; or (d) any order, writ, judgment, injunction, decree, determination or award of any court or governmental agency presently in effect applicable to such Party;

**7.1.3.** This Agreement is a legal, valid and binding obligation of such Party enforceable against it in accordance with its terms and conditions, subject to the effects of bankruptcy, insolvency or other laws of general application affecting the enforcement of creditor rights, judicial principles affecting the availability of specific performance and general principles of equity (whether enforceability is considered a proceeding at law or equity);

**7.1.4.** It is not under any obligation, contractual or otherwise, to any Person that conflicts with or is inconsistent in any material respect with the terms of this Agreement or that would impede the diligent and complete fulfillment of its obligations hereunder;

**7.1.5.** Neither it nor any of its Affiliates has been debarred by any Regulatory Authority, or is subject to such debarment and neither it nor any of its Affiliates will use in any capacity, in connection with the services to be performed under this Agreement, any Person who has been debarred pursuant to Section 306 of the FFDCFA or who is the subject of a conviction described in such section. It will inform the other Party in writing promptly if it or any such Person who is performing services hereunder is debarred or is the subject of a conviction described in Section 306 of the FFDCFA, or if any action, suit, claim, investigation or legal or administrative proceeding is pending or, to the best of its or its Affiliates' knowledge, is threatened, relating to such a debarment or conviction of it or any such Person performing services hereunder; and

**7.1.6.** It shall perform this Agreement in material compliance with Applicable Law.

**7.2. Additional Representation and Warranty of AstraZeneca.** AstraZeneca further represents and warrants to Licensee, as of the Effective Date, that:

**7.2.1. Schedule 1.9** sets forth a complete and accurate list of all AstraZeneca Patents in existence as of the Effective Date, indicating the owner or co-owners thereof (including Affiliates of AstraZeneca), if such AstraZeneca Patent is not solely owned by AstraZeneca;

**7.2.2. Schedule 7.2.2** sets forth a complete and accurate list of all Third Party IP In-Licenses in existence as of Effective Date; true, complete, and correct copies of all Third Party IP In-Licenses have been provided to Licensee on or prior to the Effective Date;

**7.2.3.** The Patents identified on Schedule 7.2.1 are all the Patents owned or otherwise Controlled by AstraZeneca or any of its Affiliates that are necessary or, to the Knowledge of AstraZeneca, useful, for Licensee to Exploit the Licensed Compounds and Licensed Products in the Territory;

**7.2.4.** Neither AstraZeneca nor any of its Affiliates has any Knowledge of any Patents, inventions, or discoveries owned or otherwise Controlled by a Third Party, other than as set forth on **Schedule 7.2.2**, that is necessary to Exploit the Licensed Compounds and Licensed Products in the Territory;

**7.2.5.** AstraZeneca is the sole and exclusive owner of, or otherwise Controls, all the AstraZeneca Patents and AstraZeneca Know-How free from Encumbrances and, with respect to the AstraZeneca Patents, is listed in the records of the appropriate Governmental Authorities as the sole and exclusive owner of record for each registration, grant and application included in the AstraZeneca Patents;

**7.2.6.** All of AstraZeneca's and its Affiliates' employees and contractors who participated in any respect in the invention or authorship of any AstraZeneca Patents or AstraZeneca Know-How (i) have perpetually and irrevocably assigned to AstraZeneca or its Affiliates, as applicable, all inventions made during the course and as the result of such employment or engagement, as applicable, by AstraZeneca, and (ii) are under existing written obligations restricting disclosure and use by such employee or contractor, as applicable, of any non-public, confidential or proprietary information which such employee or contractor, as applicable, received to support AstraZeneca's Exploitation of Licensed Compounds or Licensed Products;

**7.2.7.** none of the AstraZeneca Patents or AstraZeneca Know-How were created or developed with funding of any Governmental Authority or any other funding that would reasonably be expected to affect ownership or rights or the rights granted hereunder to the AstraZeneca Patents or AstraZeneca Know-How;

**7.2.8.** it has the lawful right to grant the licenses granted to Licensee hereunder, and it has not granted, and is not under any obligation to grant, to any Third Party or Affiliate any license, lien, option, encumbrance, or other contingent or non-contingent right, title,

or interest in or to the AstraZeneca Patents or the AstraZeneca Know-How that conflicts with the rights and licenses granted to Licensee hereunder;

**7.2.9.** there is no settled, pending, or to AstraZeneca's Knowledge, threatened litigation, claim, or proceeding alleging that any AstraZeneca Patent is invalid or unenforceable (including any interference, nullity, opposition, inter partes, or post-grant review or similar invalidity or patentability proceedings before the United States Patent and Trademark Office or any foreign patent office) and to AstraZeneca's Knowledge there is no factual, legal, or other reasonable basis for any such litigation, claim, or proceeding;

**7.2.10.** all animal studies and other non-clinical tests conducted by AstraZeneca or its Affiliates relating to any Licensed Compounds were conducted by or on behalf of AstraZeneca or its Affiliates in all material respects in accordance with its or their standard operating procedures for the conduct of animal or non-clinical studies at the time such tests were conducted and, to the actual knowledge of the employees for AstraZeneca and its Affiliates having responsibility for the KCC2 program as of the Effective Date ("**KCC2 Scientists**"), all results of such studies and tests have been disclosed to Licensee.

### **7.3. Covenants by AstraZeneca.**

**7.3.1. Covenant Not to Sue.** AstraZeneca covenants that at no time will it, its Affiliates, or its successors or assigns, directly or indirectly, alone or by, with, or through others, cause, induce, or authorize, or voluntarily assist, participate, or cooperate in the commencement, maintenance, or prosecution of any action or proceeding in, of, or before any courts or Governmental Authority against Licensee, any of its Affiliates or its or their Sublicensees, past or present directors, officers, employees, successors, assigns, customers, manufacturers, distributors, licensees, or other transferees based upon assertion of direct or indirect patent infringement of any claim of any Patent Covering composition of matter or method of use of a compound in the Neurology Field arising after the Effective Date owned or otherwise Controlled by AstraZeneca or its Affiliates that are necessary to Exploit the Licensed Compounds and Licensed Products in the Neurology Field.

**7.3.2. No Encumbrances.** AstraZeneca covenants and agrees that from the Effective Date until the expiration of the Term, (i) it shall retain, the lawful right to grant the license granted to Licensee hereunder; and (ii) neither it nor its Affiliates shall assign, transfer, license, convey its right, title or interest in or to or grant any other Encumbrance to or under, any AstraZeneca Patents or AstraZeneca Know-How, whether by written agreement or otherwise, that (x) conflicts with the rights and licenses granted to Licensee hereunder; or (y) could reasonably be expected to diminish Licensee's rights hereunder. If during the Term AstraZeneca or its Affiliates enter into any written agreement with any Third Party with respect to any AstraZeneca Patents or AstraZeneca Know-How, then, upon execution of such agreement, AstraZeneca shall promptly (but no later than [\*\*\*] after such execution) provide notice and a copy thereof to Licensee.

**7.3.3.** During the Term, AstraZeneca shall comply with and maintain in full force the research, license, assignment or other agreements between AstraZeneca and any Third Party under which it is or has been granted a license or other rights relating to any

AstraZeneca Patents or AstraZeneca Know-How (the “**Third Party IP In-Licenses**”) and shall not amend or modify such Third Party IP In-Licenses in a manner which would diminish Licensee’s rights hereunder without the prior written consent of Licensee. AstraZeneca shall promptly provide written notice to Licensee describing any breach, alleged breach or potential breach of a Third Party IP In-License of which it becomes aware and provide Licensee with copies of any correspondence related thereto. Licensee shall be entitled to cure any such breach, including through negotiating an amendment of the relevant Third Party IP In-License or a new agreement with the other party(ies) thereto, and set off any Losses incurred in doing so against any payment due to AstraZeneca under this Agreement. For the avoidance of doubt, if any Third Party IP In-License is assigned by AstraZeneca or any of its Affiliates to Licensee, then, solely with respect to such Third Party IP In-License, AstraZeneca’s obligations under this Section 7.3.3 shall no longer apply as of the effective date of such assignment.

**7.4. DISCLAIMER OF WARRANTIES.** EXCEPT FOR THE EXPRESS WARRANTIES SET FORTH HEREIN, **LICENSEE AGREES THAT THE ASTRAZENECA PATENTS ARE LICENSED “AS IS” AND NEITHER PARTY MAKES ANY REPRESENTATIONS OR GRANTS ANY WARRANTIES, EXPRESS OR IMPLIED, EITHER IN FACT OR BY OPERATION OF LAW, BY STATUTE OR OTHERWISE AND EACH PARTY SPECIFICALLY DISCLAIMS ANY OTHER WARRANTIES, WHETHER WRITTEN OR ORAL OR EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF QUALITY, MERCHANTABILITY OR FITNESS FOR A PARTICULAR USE OR PURPOSE OR ANY WARRANTY AS TO THE VALIDITY OF ANY PATENTS OR THE NON-INFRINGEMENT OF ANY INTELLECTUAL PROPERTY RIGHTS OF THIRD PARTIES.**

**7.5. Anti-Bribery and Anti-Corruption Compliance.** Each Party agrees, on behalf of itself, its officers, directors and employees and on behalf of its Affiliates, agents, representatives, consultants and subcontractors hired in connection with the subject matter of this Agreement (“**Representatives**”) that for the performance of its obligations hereunder:

**7.5.1.** It and its Representatives shall comply with the Anti-Corruption Laws and shall not take any action that will, or would reasonably be expected to, cause the other Party or its Affiliates to be in violation of any Anti-Corruption Laws; and

**7.5.2.** Each Party shall promptly provide the other Party with written notice of the following events: (a) upon becoming aware of any breach or violation by the Party or its Representative of any representation, warranty or undertaking set forth in Section 7.5.1, or (b) upon receiving a formal notification that it is the target of a formal investigation by a Governmental Authority for a Material Anti-Corruption Law Violation or upon receipt of information from any of its Representatives connected with this Agreement that any of them is the target of a formal investigation by a Governmental Authority for a Material Anti-Corruption Law Violation.

**ARTICLE 8**  
**INDEMNITY**

**8.1. Indemnification of AstraZeneca.** Licensee shall indemnify AstraZeneca, its Affiliates, and its and their respective directors, officers, employees and agents (the “**AstraZeneca Indemnitees**”) and defend and save each of them harmless, from and against any and all losses, damages, liabilities, costs and expenses (including reasonable attorneys’ fees and expenses) (collectively, “**Losses**”) in connection with any and all suits, investigations, proceedings, claims or demands of Third Parties (collectively, “**Third Party Claims**”) arising from or occurring as a result of: (a) the breach by Licensee of any representation, warranty, covenant, or obligation under this Agreement, including the enforcement of AstraZeneca’s rights under this Section 8.1; (b) the gross negligence or willful misconduct on the part of Licensee or its Affiliates or its or their Sublicensees or its or their respective directors, officers, employees or agents in performing its obligations under this Agreement; or (c) the Exploitation by or on behalf of Licensee by any of its Affiliates or its or their Sublicensees of the Licensed Compounds or the Licensed Products in or for the Territory, except in each case ((a), (b) and (c)), for those Losses for which AstraZeneca has an obligation to indemnify Licensee pursuant to Section 8.2, as to which Losses each Party shall indemnify the other to the extent of their respective liability.

**8.2. Indemnification of Licensee.** AstraZeneca shall indemnify Licensee, its Affiliates and their respective directors, officers, employees and agents (the “**Licensee Indemnitees**”) and defend and save each of them harmless, from and against any and all Losses in connection with any and all Third Party Claims arising from or occurring as a result of: (a) the breach by AstraZeneca of any representation, warranty, covenant, or obligation under this Agreement, including the enforcement of Licensee’s rights under this Section 8.2; or (b) the gross negligence or willful misconduct on the part of AstraZeneca or its Affiliates or its or their respective directors, officers, employees or agents in performing its obligations under this Agreement, except, in each case ((a) and (b)), for those Losses for which Licensee has an obligation to indemnify AstraZeneca pursuant to Section 8.1, as to which Losses each Party shall indemnify the other to the extent of their respective liability for the Losses.

**8.3. Indemnification Procedures.** All indemnification claims in respect of an AstraZeneca Indemnatee or Licensee Indemnatee shall be made solely by AstraZeneca or Licensee, as applicable (each of AstraZeneca or Licensee in such capacity, the “**Indemnified Party**”). The Indemnified Party shall give the indemnifying Party prompt written notice (an “**Indemnification Claim Notice**”) of any Losses or discovery of fact upon which such Indemnified Party intends to base a request for indemnification under this Article 8, but in no event shall the indemnifying Party be liable for any Losses that result from any delay in providing such notice. Each Indemnification Claim Notice must contain a description of the claim and the nature and amount of such Loss (to the extent that the nature and amount of such Loss is known at such time). The Indemnified Party shall furnish promptly to the indemnifying Party copies of all papers and official documents received in respect of any Losses and Third Party Claims. The indemnifying Party shall have the right to assume and control the defense of any such Third Party Claim, including the right to select counsel of its choosing and the right to compromise or settle any Third Party Claim, by giving written notice to the Indemnified Party within 30 days after the indemnifying Party’s receipt of an Indemnification Claim Notice; *provided, however*, that the indemnifying Party shall not make any

compromise or settlement admitting fault, subjecting the Indemnified Party to injunctive or other relief, adversely affecting the rights of the Indemnified Party or any AstraZeneca Indemnitee or Licensee Indemnitee, as applicable, or incurring any liability on the part of the Indemnified Party or any AstraZeneca Indemnitee or Licensee Indemnitee, as applicable, without the Indemnified Party's prior written consent, such consent not to be unreasonably withheld or delayed. The Indemnified Party shall be entitled to retain counsel of its choice (at its own expense) to participate in, but not control, the defense of any Third Party Claim. If the indemnifying Party is required to defend any Third Party Claim, the Indemnified Party shall, and shall cause its employees and agents to, cooperate in the defense or prosecution thereof and shall furnish such records, information and testimony, provide such witnesses and attend such conferences, discovery proceedings, hearings, trials and appeals as may be reasonably requested in connection therewith.

**8.4. Special, Indirect and Other Losses.** EXCEPT (a) IN THE EVENT OF THE GROSS NEGLIGENCE, WILLFUL MISCONDUCT OR FRAUD OF A PARTY OR OF A PARTY'S BREACH OF ITS OBLIGATIONS UNDER ARTICLE 6, (b) AS PROVIDED UNDER SECTION 10.10, OR (c) TO THE EXTENT ANY DAMAGES ARE REQUIRED TO BE PAID TO A THIRD PARTY AS PART OF A THIRD PARTY CLAIM FOR WHICH A PARTY PROVIDES INDEMNIFICATION UNDER THIS ARTICLE 8, NEITHER PARTY NOR ANY OF ITS AFFILIATES SHALL BE LIABLE TO THE OTHER PARTY FOR ANY INCIDENTAL, INDIRECT, EXEMPLARY, SPECIAL, PUNITIVE, ENHANCED OR CONSEQUENTIAL DAMAGES OF ANY KIND, WHETHER ARISING OUT OF BREACH OF CONTRACT, TORT, NEGLIGENCE, BREACH OF STATUTORY DUTY, STRICT LIABILITY, PRODUCT LIABILITY, OR OTHERWISE (INCLUDING THE ENTRY INTO, PERFORMANCE, OR BREACH OF THIS AGREEMENT), INCLUDING BASED ON ECONOMIC DAMAGES OR LOST PROFITS, REGARDLESS OF WHETHER SUCH LOSS OR DAMAGE WAS FORESEEABLE OR SUCH PARTY SHALL BE ADVISED, SHALL HAVE OTHER REASON TO KNOW, OR IN FACT SHALL KNOW THE POSSIBILITY OF THE FOREGOING.

**8.5. Insurance.** Licensee shall have and maintain such types and amounts of insurance covering its Exploitation of the Licensed Compounds and Licensed Products as is (a) normal and customary in the pharmaceutical industry generally for parties similarly situated and (b) otherwise required by Applicable Law. Upon request by AstraZeneca, Licensee shall provide to AstraZeneca evidence of its insurance coverage, including copies of applicable insurance policies. The insurance policies shall be under an occurrence form or a claims-made form, and for a claims-made form of insurance policies, Licensee shall continue to maintain such insurance after the expiration or termination of this Agreement in its entirety for a period of [\*\*\*].

## **ARTICLE 9 TERM AND TERMINATION**

**9.1. Term and Expiration.** This Agreement shall commence on the Effective Date and, unless earlier terminated in accordance herewith, shall continue in force and effect until the date of expiration of the last Royalty Term for the last Licensed Product (such period, the "**Term**"). Following the expiration (but not earlier termination) of the Royalty Term for any Licensed Product in any country, all rights and licenses hereunder (including the grants in Section

2.1) with respect to such Licensed Product in such country shall become perpetual, irrevocable, exclusive, fully paid-up, and royalty-free, and Licensee's development and commercialization obligations to AstraZeneca under this Agreement shall cease with respect to such Licensed Product in such country. For clarity, upon the expiration of the Term of this Agreement in its entirety, Licensee shall have a perpetual, irrevocable, fully paid-up, royalty-free right and license under the AstraZeneca Patents and AstraZeneca Know-How to subsequently Exploit in the Field any and all Licensed Products throughout the Territory, and shall have no further obligations to AstraZeneca with respect to any Licensed Products, AstraZeneca Patents, or AstraZeneca Know-How, except as set forth in Section 9.6.

## 9.2. Termination.

**9.2.1. Material Breach.** If either Party materially breaches any of its obligations under this Agreement (such Party, the "**Breaching Party**"), in addition to any other right and remedy the other Party (the "**Non-Breaching Party**") may have, the Non-Breaching Party may terminate this Agreement by providing [\*\*\*] (the "**Notice Period**") prior written notice (the "**Termination Notice**") to the Breaching Party and specifying the breach and its claim of right to terminate; *provided* that the termination shall not become effective at the end of the Notice Period if the Breaching Party cures the breach specified in the Termination Notice during the Notice Period and *provided, further*, that if the cure is not capable of cure during the Notice Period, the Breaching Party commences actions to cure such breach within the Notice Period and thereafter diligently continues such actions, then the termination shall not become effective unless and until the Breaching Party fails to diligently continue such actions.

(a) **Disputes Regarding Material Breach.** Notwithstanding the foregoing in this Section 9.2.1, if the Breaching Party disputes in good faith the existence, materiality, failure to cure or failure to commence and commit to undertaking continuing diligent efforts to cure any alleged uncured material breach, and provides notice to the Non-Breaching Party of such dispute within the relevant Notice Period, then the Non-Breaching Party will not have the right to terminate this Agreement in accordance with Section 9.2.1, unless and until (i) it has been determined in accordance with Section 10.5 or Section 10.6 that this Agreement was materially breached by the Breaching Party and (ii) the Breaching Party fails to cure such material breach within [\*\*\*] after such determination. It is understood and acknowledged that during the pendency of such dispute, all the terms and conditions of this Agreement will remain in effect and the Parties will continue to perform all of their respective obligations hereunder, including satisfying any undisputed payment obligations.

### 9.2.2. Termination by AstraZeneca.

(a) If Licensee or any of its Affiliates or Sublicensees, anywhere in the Territory, institutes, prosecutes or otherwise actively participates as an adverse party in, at law or in equity or before any administrative or regulatory body, including the U.S. Patent and Trademark Office or its foreign counterparts, any action, suit, or other proceeding, to invalidate or limit the scope of any AstraZeneca Patent claim or to obtain a ruling that any AstraZeneca Patent claim is unenforceable or not patentable, AstraZeneca shall have the right to immediately terminate this Agreement in its entirety upon written notice to Licensee.

(b) If Licensee acknowledges that it has permanently ceased development of all Licensed Products and a Licensed Product is not being commercialized in any Territory by or on behalf of Licensee, AstraZeneca shall have the right to terminate this Agreement in its entirety by providing [\*\*\*] prior written notice to Licensee; *provided* that the normal pauses or gaps between or following clinical studies or other studies for the analysis of data, preparation of reports and design of future clinical studies or preparation of regulatory filings and other customary development functions not constituting clinical studies do not constitute a cessation of development.

**9.2.3. Termination for Insolvency.** If either Party (a) files for protection under bankruptcy or insolvency laws, (b) makes an assignment for the benefit of creditors, (c) appoints or suffers appointment of a receiver or trustee over substantially all of its property that is not discharged within [\*\*\*] after such filing, (d) proposes a written agreement of composition or extension of its debts, (e) is dissolved or liquidated or takes any corporate action for such purpose, or (f) files a petition under any bankruptcy or insolvency act or has any such petition filed against that is not discharged within [\*\*\*] of the filing thereof, then the other Party may terminate this Agreement in its entirety effective immediately upon written notice to such Party.

**9.2.4. Termination for Convenience.** Licensee shall have the right to terminate this Agreement in its entirety without any cause at any time by giving at least [\*\*\*] advance written notice to AstraZeneca of such termination; *provided* that, Licensee shall remain obligated to meet its obligations hereunder and under Applicable Law, including with respect to conducting or funding any development and commercialization activities, during such [\*\*\*] period, or such longer period as may be required under Applicable Law.

**9.3. Rights in Bankruptcy.** All rights and licenses granted under or pursuant to this Agreement by Licensee or AstraZeneca 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. The Parties agree that the Parties, as licensees of such rights under this Agreement, shall retain and may fully exercise all of their rights and elections under the U.S. Bankruptcy Code or any analogous provisions in any other country or jurisdiction. The Parties further agree that, in the event of the commencement of a bankruptcy proceeding by or against either Party under the U.S. Bankruptcy Code or any analogous provisions in any other country or jurisdiction, the Party that is not a party to such proceeding shall be entitled to a complete duplicate of (or complete access to, as appropriate) any such intellectual property and all embodiments of such intellectual property, which, if not already in the non-subject Party’s possession, shall be promptly delivered to it (a) upon any such commencement of a bankruptcy proceeding upon the non-subject Party’s written request therefor, unless the Party subject to such proceeding elects to continue to perform all of its obligations under this Agreement or (b) if not delivered under clause (a) above, following the rejection of this Agreement by or on behalf of the Party subject to such proceeding upon written request therefor by the non-subject Party.

#### 9.4. Consequences of Termination.

9.4.1. In the event of a termination of this Agreement by Licensee pursuant to Section 9.2.1 or 9.2.3:

(a) all rights and licenses granted by AstraZeneca hereunder shall immediately terminate, *provided, however*, that any sublicense granted by Licensee to a Sublicensee shall survive if such Sublicensee is not then in default such that Licensee would have a termination right thereof;

(b) AstraZeneca may, upon request to Licensee, at Licensee's sole discretion, have the exclusive option for a period of [\*\*\*] after such termination to negotiate for the assignment of all Regulatory Documentation (including any Regulatory Approvals), and an exclusive license for all Licensee Know-How, Licensee Patents and Product Trademarks applicable to Licensed Compounds or Licensed Products, in each case, to the extent (i) existing as of the effective date of such termination and (ii) necessary for AstraZeneca to continue to Exploit Licensed Compounds and Licensed Products; and

(c) unless expressly prohibited by any Regulatory Authority or Applicable Law, at AstraZeneca's written request, Licensee shall, and shall cause its Affiliates to, transfer control to AstraZeneca of all clinical studies involving Licensed Products being conducted by Licensee as of the effective date of termination and reasonably cooperate to effectuate such transfer without material interruption of any such clinical study.

**9.4.2. Additional Remedy of Licensee in Lieu of Termination of this Agreement.** If Licensee has the right to terminate this Agreement pursuant to Section 9.2.1 after giving effect to the applicable Notice Period to afford AstraZeneca the opportunity to cure the breach specified in the Termination Notice, then in lieu of Licensee terminating pursuant to Section 9.2.1, Licensee shall have the right, as its sole and exclusive remedy for the events giving rise to Licensee's termination right, to elect, by providing written notice to AstraZeneca, to have this Agreement continue in full force and effect [\*\*\*].

9.4.3. In the event of a termination of this Agreement by Licensee pursuant to Section 9.2.4 or by AstraZeneca pursuant to Section 9.2.1, 9.2.2 or 9.2.3:

(a) all rights and licenses granted by AstraZeneca hereunder shall immediately terminate, *provided, however*, that any sublicense granted by Licensee to a Sublicensee shall survive if such Sublicensee is not then in default such that Licensee would have a termination right thereof;

(b) Licensee shall, and shall cause its Affiliates to, when and as requested by AstraZeneca, assign or license to AstraZeneca all of its right, title and interest in and to all Regulatory Documentation (including any Regulatory Approvals) applicable to any Licensed Compound or Licensed Product relating to the Licensed Products affected by such termination then owned or Controlled by Licensee or any of its Affiliates; *provided* that if any such Regulatory Documentation or Regulatory Approval is not immediately transferable in a country, Licensee shall provide AstraZeneca assistance and cooperation as reasonably requested by

AstraZeneca to timely transfer such Regulatory Documentation or Regulatory Approval, as applicable, to AstraZeneca or its designee, and Licensee shall use commercially reasonable efforts to continue to maintain such Regulatory Documentation (including any Regulatory Approvals) at AstraZeneca's cost unless and until AstraZeneca notifies Licensee that such maintenance is no longer required;

(c) Licensee shall notify the applicable Regulatory Authorities and, to the extent reasonably practicable, take any other action reasonably necessary to effect the transfer set forth in 9.4.3(b) above;

(d) Licensee shall provide AstraZeneca with copies of all material reports and data generated or obtained by Licensee or any of its Affiliates that relate to any Licensed Compound or Licensed Product that have not previously been provided to AstraZeneca;

(e) unless expressly prohibited by any Regulatory Authority or Applicable Law, at AstraZeneca's written request, Licensee shall, and shall cause its Affiliates to, to the extent reasonably practicable, transfer control to AstraZeneca of any or all clinical studies involving Licensed Products being conducted by or on behalf of Licensee or an Affiliate as of the effective date of termination and reasonably cooperate to effectuate such transfer without material interruption of any such clinical study; *provided* that AstraZeneca shall not have any obligation to continue any clinical study unless required by Applicable Law;

(f) at AstraZeneca's written request, and to the extent permitted by Applicable Law, Licensee shall, and shall cause its Affiliates, assign to AstraZeneca all Licensed Product Agreements, unless, with respect to any such Licensed Product Agreement, such Licensed Product Agreement (a) expressly prohibits such assignment, in which case Licensee (or such Affiliate) shall cooperate with AstraZeneca in all reasonable respects to secure the consent of the applicable Third Party to such assignment, or (b) relates both to Licensed Products and products other than Licensed Products, in which case, at AstraZeneca's request, Licensee (or such Affiliate) shall cooperate with AstraZeneca in all reasonable respects to secure the written agreement of the applicable Third Party to a partial assignment of the applicable Licensed Product Agreement relating to the Licensed Products;

(g) Licensee shall transfer to AstraZeneca such quantities of Licensee's, and its Affiliates' existing and unsold inventory of Licensed Compound or Licensed Products, "as is" and without warranties, as AstraZeneca may request. ASTRAZENECA AGREES THAT ALL SUCH INVENTORY WOULD BE PROVIDED "AS IS" AND WITHOUT ANY WARRANTIES, EXPRESS OR IMPLIED. The cost to AstraZeneca for such transfer shall be Licensee's actual cost (excluding costs for general overhead or communications) to acquire or Manufacture, as applicable, such Licensed Compounds and Licensed Products;

(h) at AstraZeneca's written request, the Parties shall discuss in good faith Licensee supplying to AstraZeneca such quantities of the Licensed Compounds and Licensed Products as AstraZeneca may indicate in written forecasts and orders therefor from time to time at Licensee's actual cost (excluding costs for general overhead or communications) to

Manufacture such Licensed Compound and Licensed Products for a period of time to be mutually agreed to by the Parties; and

(i) Subject to Section 9.4.4, AstraZeneca shall have the exclusive option for a period of [\*\*\*] after such termination to negotiate for a license, solely to continue to Exploit Licensed Compounds and Licensed Products, for all Licensee Know-How, Licensee Patents and Product Trademarks, applicable to Licensed Compounds or Licensed Products, in each case, to the extent (i) existing as of the effective date of such termination and (ii) necessary for AstraZeneca to continue to Exploit Licensed Compounds and Licensed Products (the “**Reversion License**”); *provided* that, unless otherwise agreed by the Parties, the Reversion License would be (A) an exclusive license to that portion of such Licensee Know-How, Licensee Patents and Product Trademarks set forth in the foregoing clauses (i) and (ii) which is exclusively related to Licensed Compounds or Licensed Products and (B) a non-exclusive license to that portion of such Licensee Know-How, Licensee Patents and Product Trademarks set forth in the foregoing clauses (i) and (ii) which is not exclusively related to Licensed Compounds or Licensed Products.

**9.4.4.** [\*\*\*].

**9.4.5.** Without limiting AstraZeneca’s rights under other provisions of this Sections 9.4.3 and 9.4.4, at the request and expense of AstraZeneca, the Parties shall negotiate in good faith a transfer plan to provide AstraZeneca with such assistance as is reasonably necessary to effectuate a smooth and orderly transition of any development, Manufacture and commercialization activities with respect to the Licensed Compounds and the Licensed Products to AstraZeneca or its designee so as to minimize any disruption of such activities, including technical assistance as may reasonably be requested to transfer all Manufacturing technology that is or had been used by or on behalf of Licensee and its Affiliates in connection with the Manufacture of any Licensed Compound or Licensed Product.

**9.4.6. Additional Remedy of AstraZeneca in Lieu of Termination of this Agreement.** [\*\*\*].

**9.5. Remedies.** Except as otherwise expressly provided herein, termination of this Agreement in accordance with the provisions hereof shall not limit remedies that may otherwise be available in law or equity.

**9.6. Accrued Rights; Surviving Obligations.** Termination or expiration of this Agreement for any reason shall be without prejudice to any rights that shall have accrued to the benefit of a Party prior to such termination or expiration. Such termination or expiration shall not relieve a Party from obligations that are expressly indicated to survive the termination or expiration of this Agreement. Without limiting the foregoing, Article 1, Sections 2.2 (final sentence), 3.2.3(e), 3.6.4 (final sentence), 4.9, 4.10, 4.11, 5.1.1, 5.1.2, 5.1.4, Article 6, Sections 7.1, 7.3.1 and 7.3.2 (each of 7.1, 7.3.1 and 7.3.2 solely on expiration of this Agreement and not upon termination), Article 8, Sections 9.1, 9.2.1(a), 9.3, 9.4.1, 9.4.3, 9.4.4, 9.4.5, 9.5, this Section 9.6, Section 10.1 and Sections 10.3 through 10.17 shall survive the termination or expiration of this Agreement for any reason.

**ARTICLE 10  
MISCELLANEOUS**

**10.1. Force Majeure.** Neither Party shall be held liable or responsible to the other Party or be deemed to have defaulted under or breached this Agreement for failure or delay in fulfilling or performing any term of this Agreement (other than an obligation to make payments) to the extent such failure or delay is caused by or results from events beyond the reasonable control of the non-performing Party, including fires, floods, earthquakes, hurricanes, embargoes, shortages, epidemics, pandemics, quarantines, war, acts of war (whether war be declared or not), terrorist acts, insurrections, riots, civil commotion, acts of God or any acts, omissions or delays in acting by any Governmental Authority (except to the extent such delay results from the breach by the non-performing Party or any of its Affiliates of any term or condition of this Agreement). The non-performing Party shall notify the other Party of such force majeure within 10 days after such occurrence by giving written notice to the other Party stating the nature of the event, its anticipated duration and any action being taken to avoid or minimize its effect. Such suspension of performance shall be of no greater scope and no longer duration than is reasonably necessary and the non-performing Party shall use commercially reasonable efforts to remedy its inability to perform.

**10.2. Export Control.** This Agreement is made subject to any restrictions concerning the export of products or technical information from the United States or other countries that may be imposed on the Parties from time to time. Each Party agrees that it will not export, directly or indirectly, any technical information acquired from the other Party under this Agreement or any products using such technical information to a location or in a manner that at the time of export requires an export license or other governmental approval, without first obtaining the written consent to do so from the appropriate agency or other governmental entity in accordance with Applicable Law.

**10.3. Assignment.** Neither Party may assign its rights or, except as provided in Section 3.9, delegate its obligations under this Agreement, whether by operation of law or otherwise, in whole or in part without the prior written consent of the other Party, which consent shall not be unreasonably withheld, conditioned or delayed, except that each Party shall have the right, without such consent, to (a) perform any or all of its obligations and exercise any or all of its rights under this Agreement through any of its Affiliates or its or their (sub)licensees or (Sub)licensees, as applicable, (b) assign any or all of its rights and delegate any or all of its obligations under this Agreement to any Person who acquires all or substantially all of the business to which this Agreement relates, and (c) assign any or all of its rights and delegate any or all of its obligations under this Agreement to (i) any of its Affiliates or its or their (sub)licensees or (Sub)licensees, as applicable, or (ii) to any successor in interest as a result of a Change of Control; *provided* that each Party shall provide written notice to the other Party within 30 days after such assignment or delegation set forth in the foregoing clauses (b) and (c)(ii). Any permitted successor of a Party or any permitted assignee of all of a Party's rights under this Agreement that has also assumed all of such Party's obligations hereunder in writing shall, upon any such succession or assignment and assumption, be deemed to be a party to this Agreement as though named herein in substitution for the assigning Party, whereupon the assigning Party shall cease to be a party to this Agreement and shall cease to have any rights or obligations under this Agreement. All validly

assigned rights of a Party shall inure to the benefit of and be enforceable by, and all validly delegated obligations of such Party shall be binding on and be enforceable against, the permitted successors and assigns of such Party. Any attempted assignment or delegation in violation of this Section 10.3 shall be void and of no effect.

**10.4. Severability.** If any provision of this Agreement is held to be illegal, invalid or unenforceable under any present or future law and if the rights or obligations of either Party under this Agreement will not be materially and adversely affected thereby, (a) such provision shall be fully severable, (b) this Agreement shall be construed and enforced as if such illegal, invalid or unenforceable provision had never comprised a part hereof, (c) the remaining provisions of this Agreement shall remain in full force and effect and shall not be affected by the illegal, invalid or unenforceable provision or by its severance herefrom and (d) in lieu of such illegal, invalid or unenforceable provision, the Parties shall negotiate in good faith a legal, valid and enforceable provision similar in terms to such illegal, invalid or unenforceable provision so as to effect the original intent of the Parties as closely as may be possible and reasonably acceptable to the Parties. To the fullest extent permitted by Applicable Law, each Party hereby waives any provision of law that would render any provision hereof illegal, invalid or unenforceable in any respect.

**10.5. Dispute Resolution.**

**10.5.1.** Except as provided in Section 4.11 or 10.10, if a dispute arises between the Parties in connection with or relating to this Agreement or any document or instrument delivered in connection herewith (a “**Dispute**”), then either Party shall have the right to refer such Dispute to the Senior Officers for attempted resolution by good faith negotiations during a period of [\*\*\*]. Any final decision mutually agreed to by the Senior Officers in writing shall be conclusive and binding on the Parties.

**10.5.2.** If such Senior Officers are unable to resolve any such Dispute within such [\*\*\*] period, either Party shall be free to institute litigation in accordance with Section 10.6 and seek such remedies as may be available.

**10.6. Governing Law, Jurisdiction and Service.**

**10.6.1. Governing Law.** This Agreement shall be governed by and construed in accordance with the laws of the State of New York, USA, excluding any conflicts or choice of law rule or principle that might otherwise refer construction or interpretation of this Agreement to the substantive law of another jurisdiction.

**10.6.2. Jurisdiction.** Subject to Section 10.10, the Parties hereby irrevocably and unconditionally consent to the exclusive jurisdiction of the federal and state courts of the State of New York, in each case located in the borough of Manhattan, city of New York and County of New York, for any action, suit or proceeding (other than appeals therefrom) arising out of or relating to this Agreement and agree not to commence any action, suit or proceeding (other than appeals therefrom) related thereto except in such courts. The Parties irrevocably and unconditionally waive their right to a jury trial.

**10.6.3. Venue.** The Parties further hereby irrevocably and unconditionally waive any objection to the laying of venue of any action, suit or proceeding (other than appeals therefrom) arising out of or relating to this Agreement in the federal and state courts of the State of New York and hereby further irrevocably and unconditionally waive and agree not to plead or claim in any such court that any such action, suit or proceeding brought in any such court has been brought in an inconvenient forum.

**10.6.4. Service.** Each Party further agrees that service of any process, summons, notice or document by registered mail to its address set forth in Section 10.7.2 shall be effective service of process for any action, suit or proceeding brought against it under this Agreement in any such court.

**10.7. Notices.**

**10.7.1. Notice Requirements.** Any notice, request, demand, waiver, consent, approval or other communication permitted or required under this Agreement shall be in writing, shall refer specifically to this Agreement and shall be deemed given only if delivered by hand or sent by internationally recognized overnight delivery service that maintains records of delivery, addressed to the applicable Party at its respective addresses specified in Section 10.7.2 or to such other address as the Party to whom notice is to be given may have provided to the other Party in accordance with this Section 10.7.1. A copy of the communication shall also be e-mailed to the applicable Party at its respective e-mail address(es) specified in Section 10.7.2 (or to such other e-mail address as the Party to whom notice is to be given may have provided to the other Party in accordance with this Section 10.7.1). Such notice shall be deemed to have been given as of the date delivered by hand or on the second Business Day (at the place of delivery) after deposit with an internationally recognized overnight delivery service. This Section 10.7.1 is not intended to govern the day-to-day business communications necessary between the Parties in performing their obligations under the terms of this Agreement.

**10.7.2. Address for Notice.**

If to Licensee, to:

Ovid Therapeutics Inc.  
1460 Broadway  
New York, NY 10036  
USA  
Attention: Thomas Perone  
E-mail: [\*\*\*]

with a copy (which shall not constitute notice) to:

Proskauer  
Eleven Times Square  
New York, NY 10036  
USA  
Attention: Daryn Grossman  
E-mail: dgrossman@proskauer.com

If to AstraZeneca, to:

AstraZeneca AB  
SE-431 83 Mölndal  
Sweden  
Attention: Legal Department  
E-mail: [\*\*\*]

with a copy (which shall not constitute notice) to:

AstraZeneca AB  
SE-431 83 Mölndal  
Sweden  
Attention: Global Head of Business Development and Licensing for BioPharmaceuticals R&D  
E-mail: [\*\*\*]

**10.8. Entire Agreement; Amendments.** This Agreement, together with the Schedules attached hereto, sets forth and constitutes the entire agreement and understanding between the Parties with respect to the subject matter hereof and all prior agreements, understandings, promises and representations, whether written or oral, with respect thereto are superseded hereby. Each Party confirms that it is not relying on any representations or warranties of the other Party except as specifically set forth in this Agreement. No amendment, modification, release or discharge shall be binding on the Parties unless in writing and duly executed by authorized representatives of both Parties. In the event of any inconsistencies between this Agreement and any schedules or other attachments hereto, the terms of this Agreement shall control.

**10.9. English Language.** This Agreement shall be written and executed in and all other communications under or in connection with this Agreement shall be in, the English language. Any translation into any other language shall not be an official version thereof and in the event of any conflict in interpretation between the English version and such translation, the English version shall control.

**10.10. Equitable Relief.** Notwithstanding anything herein to the contrary, each Party acknowledges and agrees that any breach or threatened breach of any provision of this Agreement may result in irreparable injury to such other Party for which there will be no adequate remedy at law. In the event of a breach or threatened breach of any provision of this Agreement, the non-breaching Party shall be authorized and entitled to seek from any court of competent jurisdiction equitable relief, including in the form of a temporary restraining order, orders for injunctive relief, whether preliminary or permanent, specific performance, an equitable accounting of all earnings, profits and other benefits arising from such breach, and any other relief that may be available from any court of competent jurisdiction before or after the initiation of dispute resolution as otherwise set forth in Section 10.5, which rights shall be cumulative and in addition to any other rights or remedies to which such non-breaching Party may be entitled in law or equity. Each Party hereby waives any requirement that the other Party (a) post a bond or other security as a condition for obtaining any such relief or (b) show irreparable harm, balancing of harms, consideration of the public interest or inadequacy of monetary damages as a remedy. This Section 10.10 shall be specifically enforceable.

**10.11. Waiver and Non-Exclusion of Remedies.** Any term or condition of this Agreement may be waived at any time by the Party that is entitled to the benefit thereof, but no such waiver shall be effective unless set forth in a written instrument duly executed by or on behalf of the Party waiving such term or condition. The waiver by either Party of any right hereunder or of the failure to perform or of a breach by the other Party shall not be deemed a waiver of any other right hereunder or of any other breach or failure by such other Party whether of a similar nature or otherwise. The rights and remedies provided herein are cumulative and do not exclude any other right or remedy provided by Applicable Law or otherwise available except as expressly set forth herein.

**10.12. No Benefit to Third Parties.** Except as provided in Article 8, covenants and agreements set forth in this Agreement are for the sole benefit of the Parties and their successors and permitted assigns and they shall not be construed as conferring any rights on any other Persons.

**10.13. Further Assurance.** Each Party shall duly execute and deliver or cause to be duly executed and delivered, such further instruments and do and cause to be done such further acts and things, including the filing of such assignments, agreements, documents and instruments, as may be necessary or as the other Party may reasonably request in connection with this Agreement or to carry out more effectively the provisions and purposes hereof or to better assure and confirm unto such other Party its rights and remedies under this Agreement.

**10.14. Relationship of the Parties.** It is expressly agreed that AstraZeneca, on the one hand and Licensee, on the other hand, shall be independent contractors and that the relationship between the two Parties shall not constitute a partnership, joint venture or agency. Neither AstraZeneca, on the one hand, nor Licensee, on the other hand, shall have the authority to make any statements, representations or commitments of any kind or to take any action that will be binding on the other Party, without the prior written consent of the other Party to do so. All persons employed by a Party shall be employees of such Party and not of the other Party and all costs and

obligations incurred by reason of any such employment shall be for the account and expense of such first Party.

**10.15. References.** Unless otherwise specified, (a) references in this Agreement to any Article, Section or Schedule shall mean references to such Article, Section or Schedule of this Agreement, (b) references in any Section to any clause are references to such clause of such Section and (c) references to any agreement, instrument or other document in this Agreement refer to such agreement, instrument or other document as originally executed or, if subsequently amended, replaced or supplemented from time to time, as so amended, replaced or supplemented and in effect at the relevant time of reference thereto.

**10.16. Construction.** Except where the context otherwise requires, wherever used, the singular shall include the plural, the plural the singular, the use of any gender shall be applicable to all genders and the word “or” is used in the inclusive sense (and/or). Whenever this Agreement refers to a number of days, unless otherwise specified, such number refers to calendar days. The captions of this Agreement are for convenience of reference only and in no way define, describe, extend or limit the scope or intent of this Agreement or the intent of any provision contained in this Agreement. The term “including,” “include,” or “includes” as used herein shall mean including, without limiting the generality of any description preceding such term. The language of this Agreement shall be deemed to be the language mutually chosen by the Parties and no rule of strict construction shall be applied against either Party.

**10.17. Counterparts.** This Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. This Agreement may be executed by facsimile, PDF format via email or other electronically transmitted signatures and such signatures shall be deemed to bind each Party as if they were original signatures.

[SIGNATURE PAGE FOLLOWS.]

THIS AGREEMENT IS EXECUTED by an authorized representatives of each Party as of the date first written above.

**ASTRAZENECA AB (publ)**

**OVID THERAPEUTICS INC.**

By: /s/ Ulrika Lilja  
Name: Ulrika Lilja  
Title: Authorised Signatory

By: /s/ Jeffrey Rona  
Name: Jeffrey Rona  
Title: Chief Business and Financial Officer



## Ovid Therapeutics Expands Epilepsy Franchise with Novel KCC2 Activators

- Exclusive license from AstraZeneca adds a unique candidate and a broad library of compounds to Ovid's franchise of potential first-in-class anti-epileptic therapies
- Collaboration with Dr. Stephen Moss, founder of Tufts Laboratory for Basic and Translational Neuroscience Research, and expert team in neuropharmacology
- Transaction is the first business development activity that seeks to enhance Ovid's pipeline of small-molecule and genetic CNS medicines

**NEW YORK, January 3, 2022** -- Ovid Therapeutics Inc. (NASDAQ: OVID), a biopharmaceutical company committed to developing medicines that transform the lives of people with rare neurological diseases, today announced the company has entered into an exclusive license agreement with AstraZeneca for a library of early-stage small molecules targeting the KCC2 transporter, including lead candidate, OV350. The company seeks to optimize and accelerate development of these KCC2 transporter activators in epilepsies and potentially other neuropathic conditions.

"The KCC2 transporter is an exciting and novel target that we believe holds great promise in treating epilepsies," said Jeremy Levin, D.Phil, MB BChir, Chairman and CEO of Ovid. "The compounds are a natural fit for our franchise dedicated to small molecule epilepsy medicines, and they follow our track record of successful partnering with large pharmaceutical companies."

Under the terms of the agreement, AstraZeneca will receive an upfront payment of \$5 million in cash and \$7.5 million in shares of Ovid common stock. AstraZeneca is eligible to receive potential clinical development milestones of up to \$8 million and regulatory milestones of up to \$45 million. Total commercial milestones could reach \$150 million and tiered royalty payments range from the single digits up to 10 percent on net sales. At the time of proof of clinical efficacy, AstraZeneca will have the right of first negotiation to opt in on a strategic collaboration.

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“Ovid’s focus in neuroscience and experience in developing novel anti-epileptics make it an optimal choice to advance KCC2 activators, including OV350,” noted Iain Chessell, Global Head of Neuroscience, BioPharmaceuticals R&D, AstraZeneca. “This transaction continues to align development resources to our stated areas of strategic focus.”

OV350 is an early-stage compound that has shown encouraging in-vitro and in-vivo proof of concept in resistant forms of epilepsy. The compound is designed to directly target and activate KCC2, a potassium chloride co-transporter responsible for maintaining chloride homeostasis in neurons. By improving chloride homeostasis, OV350 is thought to inhibit neuronal hyperexcitability commonly associated with epilepsies. Research has shown that the presence of KCC2 mutations and dysfunction may contribute to the neuronal hyperexcitability commonly seen in epilepsies.<sup>1,2</sup>

The program was advanced in a collaboration between AstraZeneca and the Tufts Laboratory for Basic and Translational Neuroscience Research, which included Drs. Stephen Moss and Jamie Maguire. Ovid plans to continue a strategic collaboration with Drs. Moss and Maguire, who are leading authorities in GABA receptor research and neuropharmacology. Their associate, Dr. Aaron Goldman of Harvard Medical School, will also collaborate with Ovid and translate his expertise in drug resistance to the Company’s epilepsy and targeted neurotherapeutics candidates.

“Despite therapeutic advances in recent decades, approximately one-third to one-half of people who are treated for epilepsy continue to experience seizures.<sup>3,4,5</sup> Therapies that activate KCC2, such as OV350, could become a powerful weapon for clinicians seeking to treat a potential underlying cause of epilepsies,” according to Dr. Moss.

OV350 expands Ovid’s franchise of novel anti-epileptic medicines. The Company is also developing OV329, a next generation pregabalin for tuberous sclerosis and infantile spasms, which is expected to enter the clinic in 2022. Earlier this year, Ovid licensed soticlestat, a novel cholesterol 24-hydroxylase inhibitor to Takeda. Soticlestat is currently being studied in Phase 3 trials for Dravet and Lennox Gastaut syndromes.

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<sup>1</sup> Ellender, T. J., Raimondo, J. V., Irkle, A., Lamsa, K. P., and Akerman, C. J. (2014). excitatory effects of parvalbumin-expressing interneurons maintain hippocampal epileptiform activity via synchronous after discharges. *J. Neurosci.* 34, 15208–15222. doi: 10.1523/JNEUROSCI.1747-14.2014

<sup>2</sup> Magloire, V., Cornford, J., Lieb, A., Kullmann, D. M., and Pavlov, I. (2019). KCC2 overexpression prevents the paradoxical seizure-promoting action of somatic inhibition. *Nat. Commun.* 10:1225. doi: 10.1038/s41467-019-08933-4

<sup>3</sup> Kwan, P., and Brodie, M. J. (2000). Early identification of refractory epilepsy. *N. Engl. J. Med.* 342, 314–319. doi: 10.1056/NEJM200002033420503

<sup>4</sup> Shorvon, S., and Luciano, A. L. (2007). Prognosis of chronic and newly diagnosed epilepsy: revisiting temporal aspects. *Curr. Opin. Neurol.* 20, 208–212. doi: 10.1097/wco.0b013e3280555175

<sup>5</sup> Cascino, G. D. (2008). When drugs and surgery don’t work. *Epilepsia* 49, 79–84. doi: 10.1111/j.1528-1167.2008.01930.x

### **About OV350**

OV350 is a small molecule that directly activates the KCC2 transporter, which is important to seizure control. In vivo studies illustrated that KCC2 activity leads to reduced seizure sensitivity and seizure-induced mortality. Pre-clinical mechanistic studies have also demonstrated that OV350 was well tolerated and did not induce sedation. OV350 has the potential to be developed for multiple epilepsies and other CNS indications including neurodevelopmental and neurodegenerative diseases.

### **About Ovid Therapeutics**

Ovid Therapeutics Inc. is a New York-based biopharmaceutical company using its BoldMedicine® approach to develop medicines that transform the lives of patients with neurological disorders. Ovid seeks to couple deep CNS experience with emerging advances in genetics and the pathways of the brain to build a leading, next-generation neuroscience pipeline. Ovid's current pipeline programs include: OV329, a small molecule GABA aminotransferase inhibitor for seizures associated with tuberous sclerosis complex and infantile spasms; OV882, a short hairpin RNA therapy approach for Angelman syndrome; OV815, a genetic therapy approach for KIF1A-associated neurological disorders; and other research targets. Additionally, Ovid maintains a significant financial interest in the future regulatory development and potential commercialization of soticlestat, which Takeda is responsible for advancing globally. Two Phase 3 trials for soticlestat in Dravet syndrome and Lennox-Gastaut syndrome are actively enrolling patients. For more information on Ovid, please visit [www.ovidrx.com](http://www.ovidrx.com).

### **Forward-Looking Statements**

This press release includes certain disclosures that contain “forward-looking statements,” including, without limitation, statements regarding the development and acceleration of Ovid's product candidate pipeline, Ovid's strategic approach and business development intentions and opportunities and ability to realize the desired benefits thereof, Ovid's ability to identify acquisition targets, the potential therapeutic benefits of Ovid's current or future product candidates, the clinical and regulatory development and potential commercialization of soticlestat, OV329, OV350 or any of Ovid's other current or future product candidates, and Ovid's eligibility for potential milestone and royalty payments. You can identify forward-looking statements because they contain words such as “will,” “appears,” “believes” and “expects.” Forward-looking statements are based on Ovid's current expectations and assumptions. Because forward-looking statements relate to the future, they are subject to inherent uncertainties, risks and changes in circumstances that may differ materially from those contemplated by the forward-looking statements, which are neither statements of historical fact nor guarantees or assurances of future performance. Important factors that could cause actual results to differ materially from those in the forward-looking statements include, without limitation, uncertainties inherent

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in the preclinical and clinical development and regulatory approval processes, risks related to Ovid's ability to achieve its financial objectives, the risk that Ovid may not be able to realize the intended benefits of its technology, risks related to Ovid's ability to identify acquisition targets or strategic partners, to enter into strategic transactions on favorable terms, or to consummate and realize the benefits of any strategic transactions or acquisitions and risks to Ovid's or Takeda's abilities to meet anticipated deadlines and milestones presented by the ongoing COVID-19 pandemic. Additional risks that could cause actual results to differ materially from those in the forward-looking statements are set forth under the caption "Risk Factors" in Ovid's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission (SEC) on November 10, 2021, and in future filings Ovid makes with the SEC. Any forward-looking statements contained in this press release speak only as of the date hereof, and Ovid assumes no obligation to update any forward-looking statements contained herein, whether because of any new information, future events, changed circumstances or otherwise, except as otherwise required by law.

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