Exhibit 10.1  
Execution Version  
Certain confidential portions of this Exhibit were omitted by means of marking such portions with brackets (“[\*\*\*]”) because the identified confidential portions (i) are not material and (ii) contain the type of information that the registrant treats as private or confidential.  
LICENSE AGREEMENT  
dated  
August 15, 2023  
by and between  
FORMOSA PHARMACEUTICALS, INC.  
and  
EYENOVIA, INC.  
Table of Contents  
1.  
DEFINITIONS  
6  
2.  
GRANT OF LICENSE; SUBLICENSING  
14  
2.1  
Grant  
14  
2.2  
Sublicensee  
14  
2.3  
Reservation of Rights  
15  
2.4  
No Impairment  
15  
3.  
PAYMENTS  
15  
3.1  
Upfront Payment  
15  
3.2  
Milestone Payments  
15  
3.3  
Reporting; Transfer Pricing and Invoicing  
16  
3.4  
Payments; Payment Method  
17  
3.5  
Interest on Late Payments  
17  
3.6  
Taxes  
17  
3.7  
Records  
17  
3.8  
Audits  
17  
4.  
DEVELOPMENT AND REGULATORY OBLIGATIONS  
18  
4.1  
Development  
18  
4.2  
Regulatory  
18  
4.3  
Pharmacovigilance and Post Marketing Surveillance  
21  
5.  
COMMERCIALIZATION  
22  
5.1  
Commercialization in Territory  
22  
5.2  
Licensee Diligence  
22  
5.3  
Licensed Product Branding  
22  
5.4  
Reporting by Licensee  
23  
2  
6.  
JOINT STEERING COMMITTEE  
23  
6.1  
General Provisions  
23  
6.2  
Meetings and Minutes  
24  
6.3  
Procedural Rules  
24  
6.4  
Limitations on Authority  
24  
6.5  
Decision Making within JSC  
25  
6.6  
Disbanding  
25  
6.7  
Alliance Managers  
25  
7.  
SUPPLY  
25  
7.1  
Supply Agreement  
26  
7.2  
Product Warranty  
26  
7.3  
Delivery  
26  
7.4  
Transfer Pricing and Invoicing  
26  
7.5  
Minimum Supply Price  
26  
8.  
INTELLECTUAL PROPERTY  
27  
8.1  
Ownership of Intellectual Property  
27  
8.2  
Prosecution and Maintenance of Patents  
27  
8.3  
Third Party Infringement  
27  
8.4  
Patent Invalidity Claim  
28  
8.5  
Claimed Infringement  
28  
8.6  
Procedure and Settlement  
29  
8.7  
Licensor Marks  
29  
8.8  
Licensor Marks  
29  
9.  
TERM AND TERMINATION  
29  
9.1  
Term  
30  
3  
9.2  
Termination by Either Party  
30  
9.3  
Termination by Licensor  
30  
9.4  
Termination by Licensee  
30  
9.5  
Effect of Termination or Expiration  
31  
9.6  
Survival  
32  
10.  
REPRESENTATIONS, WARRANTIES AND COVENANTS  
32  
10.1  
Mutual Representations, Warranties and Covenants  
32  
10.2  
Representations and Warranties of Licensor  
33  
10.3  
Representations and Warranties of Licensee  
35  
11.  
INDEMNIFICATION; LIMITATION OF LIABILITY  
35  
11.1  
Indemnification by Licensee  
35  
11.2  
Indemnification by Licensor  
36  
11.3  
Indemnification Procedures  
36  
11.4  
Insurance Recovery  
38  
11.5  
LIMITATION OF LIABILITY  
38  
12.  
CONFIDENTIALITY  
39  
12.1  
Duty of Confidence  
39  
12.2  
Exclusions  
39  
12.3  
Permitted Disclosures  
40  
12.4  
Press Releases and Other Announcements  
40  
12.5  
Publications  
40  
12.6  
Duration  
40  
13.  
FORCE MAJEURE  
41  
13.1  
Force Majeure Event  
41  
14.  
MISCELLANEOUS  
41  
4  
14.1  
Assignment  
41  
14.2  
Rights in Bankruptcy  
42  
14.3  
Governing Law and Venue  
42  
14.4  
Dispute Resolution  
42  
14.5  
Waiver; Amendments; Non-Exclusion of Remedies  
43  
14.6  
Severability  
44  
14.7  
Relationship of the Parties  
44  
14.8  
Notices  
44  
14.9  
Further Assurance  
45  
14.10  
Counterparts  
45  
14.11  
Change of Control  
45  
14.12  
Language  
46  
14.13  
Third Parties  
46  
14.14  
Subscription Agreement  
46  
14.15  
Entire Agreement  
46  
14.16  
Interpretation  
46  
14.17  
Costs  
46  
Schedules and Exhibits  
Schedule 7.1  
Supply Agreement Key Terms  
Schedule 10.2(a)  
Existing Patents  
Schedule 10.2(h)  
Existing Agreements  
Schedule 12.4  
Press Releases  
Exhibit A  
Form of Subscription Agreement  
5  
License Agreement  
This License Agreement (“Agreement”) is entered into on August 15, 2023 (“Effective Date”)  
BY AND BETWEEN  
Formosa Pharmaceuticals Inc., a Taiwanese corporation with primary business office at 0X-0 Xxxxxx Xxxxx Xxxx, Xxxxxxxx Xxxxxxxx, Xxxxxx Xxxx, Xxxxxx 000000 (“Licensor”);  
AND  
Eyenovia, Inc, a Delaware corporation with primary business office at 000 Xxxxxxx Xxx., Xxxxx 0000, Xxx Xxxx, Xxx Xxxx 00000, X.X. (“Licensee”);  
Licensor and Licensee each is referred to as a “Party” and collectively referred to as the “Parties”.  
INTRODUCTION  
A.  
Licensor is a preclinical and clinical stage biopharmaceutical company with a focus in therapeutic areas of ophthalmology, oncology, and is engaged in the business of developing, manufacturing and supplying related products and services.  
B.  
Licensor is Developing the Licensed Product and owns or controls an evolving intellectual property portfolio related to the Licensed Product and is willing to grant a license to such intellectual property to Licensee.  
C.  
Licensee is interested in Commercializing the Licensed Product and wishes to receive such a license.  
D.  
The Parties intend to negotiate and enter into a separate supply agreement as well as quality and pharmacovigilance agreements following signature of this Agreement.  
NOW THEREFORE, in consideration of the foregoing premises and the following mutual covenants and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Parties agree as follows:  
1.  
DEFINITIONS  
Unless otherwise specifically provided herein, the following terms shall have the meanings set forth in this Article 1.  
1.1  
“AAA Rules” has the meaning set forth in Section 14.4(b)(i).  
1.2  
“Acquiring Affiliate” means (a) [\*\*\*] and (b) [\*\*\*], in each case ((a) and (b)), other than [\*\*\*].  
6  
1.3  
“Affiliate” means any company, partnership, joint venture or other entity, which directly or indirectly controls, is controlled by or is under common control with a respective named Party. Control shall mean the possession of more than fifty percent (50%) of the voting stock or the power to control the management and policies of the controlled entity, whether through the ownership of voting securities, by contract, or otherwise. Licensor’s Affiliate includes [\*\*\*]. For purposes of this Agreement, [\*\*\*].  
1.4  
“Agreement” has the meaning set forth in the preamble hereto.  
1.5  
“Alliance Manager” has the meaning set forth in Section 6.7.  
1.6  
“Arbitrators” has the meaning set forth in Section 14.4(b)(i).  
1.7  
“Auditor” has the meaning set forth in Section 3.8.  
1.8  
“Business Day” means a day other than a Saturday, Sunday, or other day on which commercial banks, in Taipei, Taiwan, or the United States, are authorized or required to be closed for business.  
1.9  
“Calendar Quarter” means the respective periods of three (3) consecutive calendar months ending on March 31, June 30, September 30, and December 31.  
1.10  
“Calendar Year” means the respective periods of twelve (12) consecutive calendar months ending on December 31, except that (a) the first Calendar Year under this Agreement shall commence on the Effective Date and end on the first December 31 to occur after the Effective Date and (b) the last Calendar Year under this Agreement shall commence on the last January 1 to occur prior to the end of the Term and end on the last day of the Term.  
1.11  
“Change of Control” means, with respect to a Party, any of the following events: (a) the sale or other disposition of all or substantially all of Licensee’s assets or business to any Third Party, (b) the sale or other disposition of more than fifty percent (50%) of the securities having ordinary voting power for the election of directors or other governing body of Licensee to any Third Party, or (c) the merger or consolidation of Licensee with or into a Third Party with the effect that a Third Party other than the existing shareholders of Licensee prior to such transaction own or control, directly or indirectly, more than fifty percent (50%) of the securities having ordinary voting power for the election of directors or other governing body of Licensee surviving such merger, or the entity surviving or resulting from such consolidation.  
1.12  
“Commercialization” or “Commercialize” means any and all activities directed to marketing, promoting, distributing, importing, exporting, offering for sale or selling a Licensed Product.  
1.13  
“Commercially Reasonable Efforts” means, with respect to a Party’s obligations under this Agreement, including to Develop or Commercialize the Licensed  
7  
Product, those efforts and resources (including expenditures) consistent with the usual practices of such Party in pursuing the Development, Commercialization of its own biologic or pharmaceutical products that are of similar status, such as commercial potential, the proprietary position of the product, the regulatory structure involved, the probable profitability of the applicable product, and other relevant factors including technical, legal, scientific or medical factors. Without limiting the foregoing, Commercially Reasonable Efforts requires, with respect to such obligations, that the Party: (a) [\*\*\*]; (b) [\*\*\*]; and (c) [\*\*\*].  
1.14  
“Common Stock” has the meaning set forth in Section 3.1.  
1.15  
“Competing Program” means [\*\*\*].  
1.16  
“Development” or “Develop” means all activities related to obtaining Regulatory Approval of a Licensed Product and all non-clinical and clinical research, delivery system development, quality assurance and quality control development, statistical analysis, clinical pharmacology, clinical studies (including pre- and post-approval studies and investigator sponsored clinical studies), regulatory affairs, and Regulatory Approval and clinical study regulatory activities (excluding regulatory activities directed to obtaining pricing and reimbursement approvals).  
1.17  
“Dollars” or “$” means United States Dollars.  
1.18  
“Effective Date” has the meaning set forth at the beginning of this Agreement.  
1.19  
“Existing Agreements” has the meaning set forth in Section 10.2(h).  
1.20  
“Existing Patents” has the meaning set forth in Section 10.2(a).  
1.21  
“FDA” means the United States Food and Drug Administration or any successor entity thereto.  
1.22  
“FDA Approval” has the meaning set forth in Section 4.2(a).  
1.23  
“FFDCA” means the United States Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq., as amended from time to time, together with any rules, regulations, and requirements promulgated thereunder (including all additions, supplements, extensions, and modifications thereto).  
1.24  
“Field” means for ophthalmic use for inflammation and pain after ocular surgery and supplemental ophthalmic disease indications (i.e., uveitis or dry eye disease), if any, associated with NDA No. [\*\*\*].  
1.25  
“First Commercial Sale” means the first arm’s length commercial sale for monetary value by Licensee or its Affiliates or Sublicensee to a Third Party of a Licensed Product in the Field in the Territory following the receipt of Regulatory Approval for such Licensed Product. For clarity, any first arm’s length commercial  
8  
sale of a Licensed Product by Licensee or its Affiliate or its Sublicensee to a distributor or wholesaler would be a First Commercial Sale.  
1.26  
“Force Majeure” has the meaning set forth in Section 13.1.  
1.27  
“Generic Product” means, with respect to a Licensed Product, any pharmaceutical or biological product that (a) is distributed by a Third Party under a Regulatory Filing approved by a Regulatory Authority in reliance, in whole or in part, on the prior approval (or on safety or efficacy data submitted in support of the prior approval) of such Licensed Product, including any product authorized for sale in the U.S. pursuant to Section 505(j) of the Act (21 U.S.C. 355(j)) or (b) is otherwise substitutable under applicable law for such Licensed Product when dispensed without the intervention of a physician or other health care provider with prescribing authority.  
1.28  
“IND” means an Investigational New Drug Application as defined in the FFDCA.  
1.29  
“Indemnification Claim Notice” has the meaning set forth in Section 11.3(a).  
1.30  
“Indemnified Party” has the meaning set forth in Section 11.3(a).  
1.31  
“Infringement Claim” has the meaning set forth in Section 8.3(a).  
1.32  
“Information” means all Know-How and other proprietary information and data of a financial, commercial, regulatory, research and development or technical nature which the disclosing Party or any of its Affiliates has supplied or otherwise made available to the other Party or its Affiliates, whether made available orally, in writing or in electronic form, including information comprising or relating to concepts, discoveries, inventions, data, designs, formulae or strategy in relation to this Agreement.  
1.33  
“Initial Presentation” has the meaning set forth in the definition of “Licensed Product.”  
1.34  
“Insolvency Event” means with respect to a Party, the occurrence of any of the following: (a) the Party is deemed to be or is declared to be unable to pay its debts as they fall due or admits inability to pay its debts; (b) a petition is filed or a notice is given by a Party, or a resolution is passed, or an order is made, for or in connection with the winding-up of the Party; (c) an application is made to court, or an order is made, for the appointment of an administrator, or if an administrator is appointed over the Party; (d) a person becomes entitled to appoint a receiver over the assets of the Party or a receiver is appointed over the assets of the Party; (e) the holder of a qualifying floating charge over the assets of a Party has become entitled to appoint or has appointed an administrative receiver; (f) a creditor or encumbrancer of the Party attaches or takes possession of, or a distress, execution, sequestration or other such process is levied or enforced on or sued against, the whole or a material portion of its assets and such attachment or process is not discharged within [\*\*\*]; (g) if the other Party shall make an assignment for the  
9  
benefit of its creditors, file a petition in bankruptcy, petition or apply to any tribunal for the appointment of a custodian, receiver or trustee for it or a substantial part of its assets, or shall commence any proceeding under any bankruptcy, reorganization, readjustment of debt, dissolution or liquidation law or statute of any jurisdiction, whether now or hereafter in effect; (h) that the sum of such Party’s debts is greater than all of such Party’s property, at a fair valuation; or (i) any event occurs, or proceeding is taken, with respect to the Party in any jurisdiction in which it has assets and to which it is subject, that has an effect equivalent or similar to any of the events mentioned in (a) to (h) above.  
1.35  
“Joint Steering Committee” or “JSC” has the meaning set forth in Section 6.1.  
1.36  
“JSC Deadlock” has the meaning set forth in Section 6.5.  
1.37  
“Know-How” means all technical information, know-how and data, including inventions (whether patentable or not), discoveries, trade secrets, specifications, instructions, processes, formulae, materials, expertise and other technology applicable to compounds, formulations, compositions, products or to their manufacture, development, registration, use or commercialization or methods of assaying or testing them or processes for their manufacture, formulations containing them, compositions incorporating or comprising them and including all biological, chemical, pharmacological, biochemical, toxicological, pharmaceutical, physical and analytical, safety, quality control, manufacturing, preclinical and clinical data, instructions, processes, formulae, regulatory strategy, expertise and information, Regulatory Filings and copies thereof, relevant to the development, manufacture, use or commercialization of or which may be useful in studying, testing, development, production or formulation of products, or intermediates for the synthesis thereof.  
1.38  
“Late Payment Notice” has the meaning set forth in Section 3.5.  
1.39  
“Licensed Product” means any product sold, offered for sale or distributed pursuant to NDA No. [\*\*\*], including APP13007, a novel formulation of Clobetasol Propionate (Clobetasol Propionate Ophthalmic Nanosuspension, 0.05%) as 3.5 mL of a preserved eye drop in a 5 mL multidose eyedropper bottle (the “Initial Presentation”).  
1.40  
“Licensee” has the meaning set forth in the preamble hereto.  
1.41  
“Licensee Regulatory Data” has the meaning set forth in Section 4.2(d).  
1.42  
“Licensor” has the meaning set forth in the preamble hereto.  
1.43  
“Licensor Know-How” means all information, data and other Know-How owned or controlled by Licensor or any of its Affiliates prior to or on the Effective Date or at any time during the Term that is necessary or reasonably useful for the Commercialization of the Licensed Product in the Field in the Territory.  
10  
1.44  
“Licensee Marks” means trademarks owned or controlled by Licensee or its Affiliates or Sublicensee and any associated logos, graphic designs or trade dress to be used with the Licensed Product, excluding any trademarks of Licensee’s corporate name, other than Licensor Marks.  
1.45  
“Licensor Marks” means trademarks owned or controlled by Licensor or its Affiliates and any associated logos, graphic designs or trade dress, [\*\*\*].  
1.46  
“Licensor Patents” means all Patents owned or controlled by Licensor or any of its Affiliates prior to or on the Effective Date or at any time during the Term that are necessary or reasonably useful for the Commercialization of the Licensed Product in the Field in the Territory, including any Patents owned or controlled by Licensor or any of its Affiliates prior to or on the Effective Date or at any time during the Term that claim the Licensed Product or a component thereof.  
1.47  
“Licensor Regulatory Data” has the meaning set forth in Section 4.2(d).  
1.48  
“Licensor Technology” means all Licensor Know-How and Licensor Patents.  
1.49  
“Losses” has the meaning set forth in Section 11.1.  
1.50  
“Manufacture” or “Manufacturing” means all activities related to producing, making, having made, manufacturing, processing, filling, finishing, packaging, labeling, quality assurance testing and release, shipping or storage of a Licensed Product, or any intermediate thereof, including process development, process improvement, process qualification and validation, scale-up, non-clinical, clinical and commercial manufacturing and analytic development, product characterization, stability testing, quality assurance and quality control.  
1.51  
“Milestone Event” has the meaning set for in Section 3.2.  
1.52  
“Milestone Payment” has the meaning set for in Section 3.2.  
1.53  
“Minimum Supply Price” means, (a) with respect to the Initial Presentation, a price equal to [\*\*\*] per unit (provided, however, if a Generic Product is available, the price shall be the lower of the then-current Minimum Supply Price or [\*\*\*] or (b) with respect to any other presentation of Licensed Product, the price per unit negotiated by the Parties pursuant to Section 7.5, and in the case of both (a) and (b) as may be adjusted in accordance with Section 7.5(a).  
1.54  
“NDA” means a New Drug Application as defined in the FFDCA.  
1.55  
“Net Sales” means, with respect to each Licensed Product for any period, the gross amounts received by Licensee or its Affiliates or its Sublicensee for sales of such Licensed Product in such period, less the following deductions:  
(a)  
normal and customary trade, quantity and cash discounts and sales returns and allowances;  
11  
(b)  
sales and other taxes directly related to the sale or delivery of Licensed Product;  
(c)  
amounts repaid or credits taken by reason of damaged goods, rejections, defects, expired dating, recalls, returns or because of retroactive price changes;  
(d)  
charge back payments and rebates granted to (i) managed healthcare organizations, (ii) federal, state and/or provincial and/or local governments or other agencies, (iii) purchasers and reimbursors, or (iv) trade customers, including wholesalers and chain and pharmacy buying groups, to the extent permitted by applicable law and regulations; and  
(e)  
distribution costs and expenses;  
(f)  
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) and reasonably allocable to sales of the Licensed Product as agreed by the Parties;  
(g)  
any other customary deductions that are consistent with GAAP, but which may not be duplicative of the deductions specified in (a)-(f).  
  
In no event will any particular amount identified above be deducted more than once in calculating Net Sales (i.e., no “double counting” of the reductions). For purposes of determining Net Sales, a Licensed Product shall be deemed to be sold when invoiced and a “sale” shall not include transfers or dispositions of such Licensed Product for pre-clinical or clinical purposes or as samples, in each case, without charge. Licensee’s or its Affiliate’s transfer of any Licensed Product to an Affiliate shall not result in any Net Sales, unless such Licensed Product is consumed or administered by such Affiliate in the course of commercial activities.  
1.56  
“Net Sales Price” means for a given Calendar Quarter, total Net Sales in the Territory in such Calendar Quarter divided by total units of the Licensed Product sold in the Territory in that Calendar Quarter.  
1.57  
“Net Sales Price Reconciliation Payment” means, with respect to a Calendar Quarter, (a) [\*\*\*] multiplied by (b) [\*\*\*]. For clarity, the Net Sales Price Reconciliation Payment may be positive or negative.  
1.58  
“Net Sales Report” has the meaning set forth in Section 3.3.  
1.59  
“Party” and “Parties” have the meanings set forth in the preamble hereto.  
1.60  
“Patents” means (a) all national, regional and international patents and patent applications, including provisional patent applications; (b) all patent applications filed either from such patents, patent applications or provisional applications or  
12  
from an application claiming priority from either of these, 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, xxxxx 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 and extensions (including any supplementary protection certificates and the like) of the foregoing patents or patent applications ((a), (b) and (c)).  
1.61  
“Regulatory Approval” means, with respect to the Licensed Product in any country or jurisdiction, any and all approvals, licenses, registrations, or authorizations from a Regulatory Authority required to Commercialize the Licensed Product in such country or region.  
1.62  
“Regulatory Authority” means any governmental agency or authority responsible for granting Regulatory Approvals for the Licensed Product, including the FDA, with responsibility for granting licenses or approvals necessary for the marketing and sale of the Licensed Product.  
1.63  
“Regulatory Filings” means, with respect to the Licensed Product, all (a) applications (including all INDs and NDAs), registrations, licenses, authorizations and approvals (including Regulatory Approvals), (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 regulatory drug lists, advertising and promotion documents, adverse event files, and complaint files and (c) clinical and other data, datasets, and databases contained, referenced or relied upon in any of the foregoing, in each case ((a), (b) and (c)), relating to the Licensed Product in the Field.  
1.64  
“Regulatory Maintenance” means all interactions with Regulatory Authorities with respect to the Licensed Product in the Territory, including communications and filings with the Regulatory Authorities and preparations of such communications and filings.  
1.65  
“Remedial Action” has the meaning set forth in Section 4.3(c).  
1.66  
“Senior Officers” means, with respect to Licensor, Chairman of the Board of Directors or Chief Executive Officer of Licensor, or either of their designee, and, with respect to Licensee, [\*\*\*].  
1.67  
“Subscription Agreement” has the meaning set forth in Section 14.14.  
1.68  
“Sublicensee” has the meaning set forth in Section 2.2.  
1.69  
“Sublicenses” has the meaning set forth in Section 2.2.  
13  
1.70  
“Supply Agreement” has the meaning set forth in Section 7.1.  
1.71  
“Term” has the meaning set forth in Section 9.1.  
1.72  
“Territory” means the United States and its territories and possessions (including the District of Columbia and Puerto Rico).  
1.73  
“Third Party” means any individual or entity other than the Parties and their respective Affiliates.  
1.74  
“Third Party Claims” has the meaning set forth in Section 11.1.  
1.75  
“United States” or “U.S.” means the United States of America and its territories and possessions (including the District of Columbia and Puerto Rico).  
2.  
GRANT OF LICENSE; SUBLICENSING  
2.1  
Grant. Licensor (on behalf of itself and its Affiliates) hereby grants to Licensee (a) an exclusive (including with regard to Licensor and its Affiliates) license, with the right to grant sublicenses through multiple tiers, under the Licensor Technology to Commercialize the Licensed Product in the Field and in the Territory, (b) a non-exclusive license, with the right to grant sublicenses through multiple tiers, to use the Licensor Marks solely to Commercialize the Licensed Product in the Field and in the Territory, (c) an exclusive (including with regard to Licensor and its Affiliates) license and right of reference and use, with the right to grant sublicenses through multiple tiers, under the Regulatory Filings owned or controlled by Licensor or its Affiliates to Commercialize the Licensed Product in the Field in the Territory and (d) only as expressly provided in this Agreement or the Supply Agreement, a non-exclusive license to Manufacture the Licensed Product for Commercialization in the Field and in the Territory. For avoidance of doubt, this Agreement does not grant Licensee Development rights to the Licensed Product either stand-alone or in combination with any device (including but not limited to Optejet® or any other current or future Licensee owned or developed device).  
2.2  
Sublicensee. Licensee shall have the right to grant sublicenses under the licenses and rights of reference granted to Licensee in Section 2.1 to Third Parties (such Third Parties, the “Sublicensees”) or its Affiliates to Commercialize the Licensed Product within the Field and Territory; provided that (a) any such sublicense or further rights of reference (each “Sublicense”) shall be consistent with the terms and conditions of this Agreement, (b) Licensee shall remain responsible for the Sublicensees’ compliance with the applicable terms and conditions of this Agreement, (c) Licensee shall notify Licensor of each Sublicense no later than [\*\*\*] before the execution of such Sublicense and (d) copies of Sublicense agreement (which may be redacted to prevent disclosure of competitively sensitive information) will be provided to Licensor within [\*\*\*] of signing by any Sublicensee and Licensee.  
14  
2.3  
Reservation of Rights. All worldwide rights of Licensor in and to the Licensor Technology that are not expressly granted to Licensee by this Agreement are reserved to Licensor. No rights are granted under this Agreement by implication, estoppel or statute. By way of example and without limitation, Licensor retains the rights to Develop, use, Manufacture, make, have made the Licensed Product anywhere in the world inside or outside the Field (but not Commercialize in the Territory), and sell, offer for sale, export and import Licensed Product anywhere outside of the Field or outside the Territory. This Agreement does not prevent or restrict in any respect Licensor’s ability to, or to grant a license to any third party to, Develop, use, Manufacture, make, have made, sell, offer for sale, export, or import any product other than the Licensed Product.  
2.4  
No Impairment. Parties shall not, and shall cause their respective Affiliates not to, grant to any Third Party any (sub)licenses or other rights that conflict with any of the (sub)licenses or other rights granted to Licensee under this Article 2.  
3.  
PAYMENTS  
3.1  
Upfront Payment. In partial consideration for the licenses and rights granted to Licensee hereunder, no later than forty-five (45) days following the Effective Date, Licensee shall pay to Licensor a non-refundable, non-creditable payment in the amount of Two Million Dollars ($2,000,000), payable as One Million Dollars ($1,000,000) in cash and One Million Dollars ($1,000,000) in EYENOVIA common stock, $0.0001 par value per share (the “Common Stock”) (NASDAQ: EYEN), with EYEN share value calculated using [\*\*\*]. If EYENOVIA Common Stock (NASDAQ: EYEN) cannot be issued to Licensor within forty-five (45) days after the Effective Date, Licensee shall pay to Licensor One Million Dollars ($1,000,000) in cash in lieu of such Common Stock.  
3.2  
Milestone Payments. In partial consideration for the licenses and rights granted to Licensee hereunder, and on the terms and subject to the conditions set forth herein, Licensee shall pay to Licensor the non-refundable, non-creditable one-time milestone payments set out below (each, a “Milestone Payment”) following the first achievement of the corresponding milestone events by Licensee, its Affiliates or Sublicensees (each, a “Milestone Event”).  
(a)  
Development Milestone Payments. Milestone Payments set forth in this Section 3.2(a) will be paid no later than [\*\*\*] following achievement of each corresponding Milestone Event.  
Milestone Event  
Milestone Payment  
Upon (a) the FDA Approval of the Licensed Product in the Territory and (b) the effective date of the acceptance by Licensee of the transfer and assignment of the FDA Approval from Licensor to Licensee  
[\*\*\*]  
15  
The date that is the earlier of (a) [\*\*\*] after the FDA Approval of the Licensed Product in the Territory and (b) [\*\*\*] following the First Commercial Sale of the Licensed Product in the Territory  
[\*\*\*]  
Maximum Potential  
Milestone Payments  
Four Million Dollars ($4,000,000)  
(b)  
Sales Milestone Payments. Commencing from the First Commercial Sale, Licensee will pay to Licensor a one-time sales milestone payment based on the first achievement by in total the Licensee or its Affiliates or Sublicensee of the corresponding Milestone Event. Milestone Payments set forth in this Section 3.2(b) shall be paid [\*\*\*]. If multiple sales Milestone Events are achieved in the same Calendar Year, Licensee will pay the Milestone Payment with respect to the first such Milestone Event [\*\*\*] and may elect to pay any additional Milestone Payment(s) with respect to such additional Milestone Event(s) [\*\*\*].  
Milestone Event  
Milestone Payment  
[\*\*\*]  
[\*\*\*]  
[\*\*\*]  
[\*\*\*]  
[\*\*\*]  
[\*\*\*]  
[\*\*\*]  
[\*\*\*]  
[\*\*\*]  
[\*\*\*]  
[\*\*\*]  
[\*\*\*]  
Maximum Potential Sales Milestones  
Eighty Million Dollars ($80,000,000)  
Each Milestone Payment under this Section 3.2 shall be payable only once, upon the first achievement of the applicable Milestone Event in a given Calendar Year by the first Licensed Product, and no amounts shall be due for subsequent or repeated achievements of such milestone event in any subsequent Calendar Years or for achievements of such milestone event by other Licensed Product, unless otherwise agreed by the Parties in writing for future products.  
3.3  
Reporting; Transfer Pricing and Invoicing. Licensee shall submit to Licensor within [\*\*\*] in which Licensee, its Affiliates or its Sublicensee books sales of Licensed Product, an accurate, complete, itemized report (the “Net Sales Report”) setting forth for such Calendar Quarter or cumulative year to date the following information:  
(a)  
the quantity of Net Sales for the applicable Calendar Quarter for the Territory; and  
16  
(b)  
the amount of sales Milestone Payment, Net Sales Price and Net Sales Price Reconciliation Payment due thereon, or, if no Sales Milestone Payment or Net Sales Price Reconciliation Payment are due to Licensor for such reporting period, a statement that no Sales Milestone Payment or Net Sales Price Reconciliation Payment is due.  
Pricing and invoicing for the sale of Licensed Product under the Supply Agreement, including invoicing of the Net Sales Price Reconciliation Payment, if applicable, are set forth in Section 7.4.  
3.4  
Payments; Payment Method. All payments due to Licensor hereunder will be made in Dollars and shall be remitted to the following bank account:  
[\*\*\*]  
Licensee shall have the right to offset any payment that is owed by Licensor to Licensee or its Affiliates against any payments owed by Licensee, if any, under this Agreement.  
3.5  
Interest on Late Payments. If Licensee fails to make a timely payment pursuant to the terms of this Agreement, Licensor shall provide a written notice of such failure to Licensee (a “Late Payment Notice”), and interest shall accrue on the past due amount starting on the date of the Late Payment Notice at [\*\*\*].  
3.6  
Taxes. Each Party will pay any and all taxes levied on account of any payments made to it under this Agreement. If any taxes are required to be withheld by the Party who makes the payment, the paying Party will: (a) deduct such taxes from the payment made to the other Party; (b) timely pay the taxes to the relevant tax authority; (c) send proof of payment to the other Party within [\*\*\*]; and (d) reasonably assist the other Party in its efforts to obtain a credit for such tax payment. Each Party agrees to reasonably assist the other Party in lawfully claiming exemptions from or minimizing such deductions or withholdings under double taxation laws, treaties or similar circumstances. The Parties acknowledge and agree that it is their mutual objective and intent to minimize, to the extent feasible, taxes payable with respect to their collaborative efforts under this Agreement and that they shall use their reasonable efforts to cooperate and coordinate with each other to achieve such objective.  
3.7  
Records. Licensee shall keep, and require its Affiliates and Sublicensees to keep, complete, true and accurate books of accounts and records for the purpose of determining the amounts payable to Licensor pursuant to this Agreement. Such books and records shall be kept for such period of time required by applicable laws, but no less than [\*\*\*]. Such records shall be subject to inspection in accordance with Section 3.8.  
3.8  
Audits. Upon not less than [\*\*\*] prior written notice, Licensee shall, and cause its Affiliates to, permit an independent, certified public accountant selected by Licensor and reasonably acceptable to Licensee (for the purposes of this Section  
17  
3.8, the “Auditor”), to audit or inspect such books or records of Licensee and its Affiliates that relate to Net Sales for the sole purpose of verifying the: (a) Milestone Payments payable hereunder in respect of Net Sales; (b) Net Sales Price; (c) Net Sales Report; (d) Net Sales Price Reconciliation Payment and (e) withholding taxes, if any, required by applicable laws to be deducted as a payment by Licensee in respect of such Net Sales. The Auditor will send a copy of the report to Licensor at the same time it is sent to Licensee; provided that the Auditor shall disclose only whether the reports are correct or not and the specific details concerning any discrepancies. No other information (including pricing information) shall be shared. Such inspections may be made no more than once each Calendar Year and during normal business hours. The Auditor shall be obligated to execute a reasonable confidentiality agreement prior to commencing any such inspection. With respect to Licensee’s Sublicensees, upon not less than [\*\*\*] prior written notice, Licensee shall, or shall request an auditor agreed upon by the Sublicensee to, conduct such audit and inspection of books or records of its Sublicensees that relate to such purpose. Should such inspection lead to the discovery of a discrepancy to Licensor’s detriment, Licensee shall pay to Licensor such discrepancy within [\*\*\*] after its receipt from the Auditor of the report. Any overpayment by Licensee revealed by an audit shall, at Licensee’s election, be reimbursed to Licensee within [\*\*\*] after its receipt from the Auditor of the report or fully credited against future payments to be made to Licensor hereunder. Inspections conducted under this Section 3.8 shall be at the expense of [\*\*\*].  
4.  
DEVELOPMENT AND REGULATORY OBLIGATIONS  
4.1  
Development  
(a)  
Development Activities for FDA Approval. After the Effective Date, Licensor will continue to use Commercially Reasonable Efforts at its own cost to carry out the Development needed to obtain Regulatory Approval of the Licensed Product in the Field and in the Territory.  
4.2  
Regulatory  
(a)  
Regulatory Approval. Licensor will be responsible for applying for the Regulatory Approval from FDA for the application under NDA No. [\*\*\*] (the “FDA Approval”) with respect to Commercialization of the Initial Presentation of the Licensed Product, and Licensor shall use Commercially Reasonable Efforts to obtain such FDA Approval by [\*\*\*].  
(b)  
Transfer and Assignment of FDA Approval. To the extent permitted by applicable laws, after the Initial Presentation of the Licensed Product receives FDA Approval, Licensor shall, at its own cost, convey, assign, transfer and deliver to Licensee, and Licensee shall accept, all of Licensor’s right, title and interest in and to the FDA Approval for the Licensed Product as well as any associated post-approval regulatory obligations received from FDA related to the Licensed Product under NDA No. [\*\*\*]. The  
18  
Parties shall take all actions necessary to accomplish the foregoing as soon as reasonably practical, including promptly notifying the FDA of such transfer and assignment of the FDA Approval in accordance with the provision of 21 C.F.R. 314.72.  
(c)  
Regulatory Fees. Licensor will bear all regulatory fees charged by the Regulatory Authorities for submission of the Regulatory Filing for FDA Approval of the NDA for the Initial Presentation of the Licensed Product in the Field in the Territory and any cost associated with the transfer and assignment of FDA Approval to Licensee pursuant to Section 4.2(b).  
(d)  
Regulatory Data. To the extent required by Licensee to Commercialize or maintain Regulatory Approval of the Licensed Product in the Field in the Territory or to the extent necessary for Licensee (i) to have FDA Approval transferred and assigned from Licensor in accordance with Section 4.2(b) and (ii) thereafter to maintain the FDA Approval and to conduct all communications and interactions with the FDA in accordance with Section 4.2(e), Licensor shall, to the extent permitted by applicable law, provide to Licensee copy of or access to all non-clinical data and clinical data, NDA packages and other information, results and analyses that are available or generated at any time within a reasonable time (the “Licensor Regulatory Data”). Licensee shall, upon request by Licensor and to the extent permitted by applicable law, provide to Licensor copies of or access to all non-clinical data and clinical data, regulatory packages and other information, results and analyses that are generated at any time with respect to the Licensed Product within a reasonable time (a “Licensee Regulatory Data”).  
(e)  
Disclosure of Licensor Know-How. At any time upon the reasonable request of Licensee, Licensor shall promptly disclose to Licensee any Licensor Know-How in its or its Affiliates possession, to the extent (i) not previously disclosed or transferred to Licensee in connection with the transfer of Licensor Regulatory Data pursuant to Section 4.2(d) and (ii) reasonably necessary for Licensee to exercise its rights or perform its obligations under this Agreement.  
(f)  
Maintenance of Regulatory Approvals. Licensee will at its own cost and effort be responsible for Regulatory Maintenance in the Territory, including providing all relevant information and documentation needed as well as payment of any required fees, including for avoidance of doubt the annual fee on prescription drug manufacturers imposed by the Patient Protection and Affordable Care Act, Pub. L. No. 111-148 (as amended), and any other like fees as a result of the sale of Licensed Product in the Territory. Licensor will provide reasonable support as required in a timely manner.  
(g)  
Communications and Filings with Regulatory Authorities. To the extent permitted under applicable law, for obtaining Regulatory Approvals of the  
19  
Licensed Product in the Territory, each Party shall provide the other Party with copies of material submissions to or communications with a Regulatory Authority (in the original language) relating to the Licensed Product in a reasonable amount of time prior to the anticipated date for the submission or communication to allow the other Party a reasonable opportunity to review and comment on submission or communication, and in such event each Party shall consider all comments and proposed revisions from the other Party in good faith in connection with effecting such submission or communication. In the event that an exigent action prevents a Party from allowing the other Party the time set forth above, such first Party shall make all efforts to provide the other Party with as much time as possible to review and comment as the timeline permits. Each Party shall consult with the other Party regarding, and keep the other Party informed of, the status of the preparation of all material submissions and communications it has with the applicable Regulatory Authority relating to each Licensed Product in the Territory.  
(h)  
Post FDA Approval of Licensed Product in the Field and in the Territory Changes; Variations.  
Licensor will bear all actual related costs resulting from:  
(i)  
Changes requested by Licensor (on its own or on behalf of any approved subcontractor);  
(ii)  
Changes required under applicable laws or regulations or requested or required by a Regulatory Authority relating to Manufacturing of the Licensed Product or any component of the Licensed Product; and  
(iii)  
Changes in the materials or suppliers of the Licensed Product or components of the Licensed Product.  
Licensee will bear all actual and related costs resulting from:  
(i)  
Changes requested by Licensee, which are approved by Licensor in writing, which approval shall not be unreasonably withheld, conditioned or delayed; and  
(ii)  
Changes required under applicable laws or regulations or changes requested or required by FDA relating to the Development or Commercialization, or marketing of the Licensed Product in the Field in the Territory; and  
(iii)  
Changes in the text of prescribing information (package insert), labeling and trade dress.  
20  
(i)  
Right of Reference. Licensee hereby grants Licensor and its Affiliates and Licensors’ sublicensees a right of full access, a right of reference and the right to use and incorporate by reference all of its and its Affiliates’ and its Sublicensees’ Regulatory Approvals and Licensee Regulatory Data contained therein for use outside the Territory. Upon request from Licensor for right of reference, the Licensee shall without delay request, or require its Sublicensee or Affiliate or Acquiring Affiliate to request without delay from Regulatory Authority any required documents or provide any signed documentations or statements as required by Licensor as to meet the requirements of the relevant Regulatory Authority.  
4.3  
Pharmacovigilance and Post Marketing Surveillance  
(a)  
Pharmacovigilance Agreement. Following the Effective Date and no later than [\*\*\*] prior to the First Commercial Sale of the Licensed Product by Licensee or any of its Affiliates in the Field and in the Territory, the Parties shall enter into a separate written pharmacovigilance agreement providing details related to managing and reporting adverse events, adverse drug experiences and similar events or experiences in respect of the Licensed Product (including those of such events or experiences as occur during clinical studies worldwide) and other safety and reporting practices and procedures in respect to the Licensed Product in compliance with all applicable law.  
(b)  
Global Safety Database. Licensor shall establish, hold and maintain the global safety database for the Licensed Product. Each Party shall provide the other Party with information in such Party’s possession or control as necessary for such other Party to comply with its pharmacovigilance or other post-marketing regulatory responsibilities and reporting in respect to the Licensed Product, including, as applicable, any adverse events, adverse drug experiences or similar events or experiences (including those events or experiences that are required to be reported to the FDA under 21 C.F.R. 312.32 or 314.80 or to foreign Regulatory Authorities under corresponding applicable law outside the United States) from pre-clinical or clinical laboratory, animal toxicology and pharmacology studies, clinical studies and commercial experiences with the Licensed Product, in each case, in the form reasonably requested by such other Party.  
(c)  
Remedial Actions. Each Party shall notify the other immediately, and promptly confirm such notice in writing, if it obtains information indicating that any Licensed Product may be subject to any recall, corrective action or other regulatory action by any Regulatory Authority (a “Remedial Action”). The Parties shall assist each other in gathering and evaluating such information as is necessary to determine the necessity of conducting a Remedial Action. Licensee shall have sole discretion, except as required by applicable law, with respect to any matters relating to any Remedial Action in or for the Territory, including the decision to commence such  
21  
Remedial Action and the control over such Remedial Action, and Licensor shall, and shall cause its Affiliates to, cooperate fully with Licensee’s reasonable requests in respect of such matters. Unless otherwise provided in any applicable supply agreement between the Parties or their Affiliates, the costs and expenses of any Remedial Action in or for the Territory shall be borne solely by Licensee, and the costs and expenses of any Remedial Action outside the Territory shall be borne solely by Licensor. Each Party shall maintain, and shall ensure that its Affiliates shall maintain, adequate records to permit the Parties to trace the manufacture, distribution and use of the Licensed Product in their respective territories.  
5.  
COMMERCIALIZATION  
5.1  
Commercialization in Territory. Subject to the terms and conditions of this Agreement, Licensor hereby appoints Licensee as Licensor’s exclusive distributor of the Licensed Product in the Territory during the Term, and Licensee hereby accept such appointment. Licensee will have the sole right and responsibility, at its sole cost and expense, for all aspects of Commercialization of the Licensed Product in the Field in the Territory, including planning and implementation, distribution, marketing, salesbooking of sales, pricing and reimbursement and including import and export unless otherwise agreed in the Supply Agreement. Licensee shall have the right, in its sole discretion, to appoint its Affiliates, and Licensee and its Affiliates shall have the right, in their sole discretion, to appoint any other distributors, in the Territory, to distribute, market, and sell the Licensed Product.  
5.2  
Licensee Diligence. At all times during the Term, Licensee shall, directly or through its Affiliates, use Commercially Reasonable Efforts to Commercialize the Licensed Product in the Territory. Licensee will use Commercially Reasonable Efforts to launch the Licensed Product in the United States within [\*\*\*] of FDA Approval. Without further limiting any other obligations set forth in this Agreement, at all times during the Term, Licensee shall keep Licensor through the JSC reasonably and timely informed as to the Commercialization efforts and results thereof relating to the Licensed Product in the Territory.  
5.3  
Licensed Product Branding.  
(a)  
Licensee shall have the sole right to determine the trademarks to be used with respect to the Commercialization of the Licensed Product for its Initial Presentation in the Field in the Territory, including whether to use any Licensor Mark or Licensee Mark used or held for use with the Licensed Product. Licensor shall not, and shall not permit its Affiliates to, (i) use in their respective businesses, any trademark that is confusingly similar to, misleading or deceptive with respect to or that dilutes any (or any part) of the Licensed Product trademarks or (ii) do any act which endangers, destroys or similarly affects, in any material respect, the value of the goodwill pertaining to the Licensed Product trademarks. Licensor shall not, and shall not permit its Affiliates to, attack, dispute or contest the validity  
22  
of or ownership of such Licensed Product trademark anywhere in the Territory or any registrations issued or issuing with respect thereto.  
(b)  
Licensee acknowledges the standards and reputation for quality symbolized by the Licensor Marks as of the Effective Date and, if applicable, Licensee shall use the Licensor Marks in a manner consistent with such quality standards and reputation. Licensor shall have the right to inspect and audit, from time to time, any Licensed Product Commercialized by Licensee using a Licensor Mark, and all packaging, product inserts and marketing materials therefor, in order to monitor and ensure the quality of all products and services being marketed with or bearing any Licensor Mark.  
(c)  
Upon Licensor’s request to use Licensee Marks for the Licensed Product in the Field outside the Territory, the Parties shall promptly notify JSC and JSC shall determine whether such Licensee Xxxx xxx be licensed to Licensor for such use with the Licensed Product in the Field outside the Territory.  
5.4  
Reporting by Licensee. Prior to Licensee or its Affiliates achieving aggregate Net Sales of [\*\*\*] in the Territory, Licensee shall update Licensor via the JSC no less than [\*\*\*] during the Term regarding its Commercialization activities (including to the extent material, pre-marketing activities, market research, health economic and outcome research, plans and publications) and Commercialization strategy (including to the extent material, launch plans, pricing and reimbursement strategy and twelve (12)-month sales forecasts). From and after achievement of aggregate Net Sales of [\*\*\*] in the Territory, Licensee shall provide such updates no less than [\*\*\*].  
6.  
JOINT STEERING COMMITTEE  
6.1  
General Provisions. Within [\*\*\*] after the Effective Date, the Parties shall establish a Joint Steering Committee (the “Joint Steering Committee” or “JSC”), which shall consist of two (2) representatives from each of the Parties, each with the requisite experience and seniority to enable such individuals to make decisions on behalf of the Parties with respect to the issues falling within the jurisdiction of the JSC. From time to time, each Party may substitute one or more of its representatives to the JSC on written notice to the other Party. Each Party shall designate one of its representatives to serve as co-chairpersons. The JSC shall: (a) provide a forum to update on Licensor Development, Manufacture and regulatory activity and Licensee Commercialization progress; (b) discuss any Licensee sponsored Development activity for the Licensed Product in the Territory; (c) upon Licensor’s request, determine whether Licensee Marks of the Licensed Product may be licensed to Licensor for use with the Licensed Product outside the Territory; (d) in the event that Licensee decides to abandon a Licensee Mark of the Licensed Product, determine whether Licensor may have the right to request assignment of such Licensee Xxxx; (e) attempt to resolve any dispute with respect to matters  
23  
within the JSC’s jurisdiction; and (f) perform such other functions as expressly set forth in this Agreement or allocated to it by the Parties’ written agreement.  
6.2  
Meetings and Minutes. The JSC shall meet [\*\*\*]; provided that from and after Licensee or its Affiliates achieves aggregate Net Sales of [\*\*\*] in the Territory, Licensee shall have the option to reduce the frequency of such meetings to [\*\*\*]. The co-chairpersons of the JSC shall be responsible for calling meetings on no less than [\*\*\*] notice unless exigent circumstances require shorter notice. Each Party shall make all proposals for agenda items at least [\*\*\*] in advance of the applicable meeting and shall provide all appropriate information with respect to such proposed items at least [\*\*\*] in advance of the applicable meeting; provided that under exigent circumstances requiring input by the JSC, a Party may provide its agenda items to the other Party within a shorter period of time in advance of the meeting or may propose that there not be a specific agenda for a particular meeting, so long as the other Party consents to such later addition of such agenda items or the absence of a specific agenda for such meeting (which consent shall not be unreasonably withheld, conditioned or delayed). The JSC shall prepare and circulate for review and approval of the Parties minutes of each meeting within [\*\*\*] after the meeting. The Parties shall alternate the responsibility for keeping such meeting minutes. The Parties shall agree on the minutes of each meeting promptly, but in no event later than the next meeting of the JSC.  
6.3  
Procedural Rules. The JSC shall have the right to adopt such standing rules as shall be necessary for its work, to the extent that such rules are not inconsistent with this Agreement. A quorum of the JSC shall exist whenever there is present at a meeting at least one (1) representative appointed by each Party. Representatives of the Parties on the JSC may attend a meeting either in person or by telephone, video conference or similar means in which each participant can hear what is said by, and be heard by, the other participants; provided that if one Party designated a location for an in-person meeting, the location for the next in-person meeting shall be designated by the other Party. The location for the first in-person meeting shall be designated by Licensor. Other employees or consultants of a Party who are not representatives of the Parties on the JSC may attend meetings of the JSC; provided, however, that such attendees (a) shall not vote or otherwise participate in the decision-making process of the JSC and (b) are bound by obligations of confidentiality and non-disclosure at least as protective of the other Party as those set forth in Article 12.  
6.4  
Limitations on Authority. Without limitation to the foregoing, the Parties hereby agree that matters explicitly reserved to the consent, approval or other decision-making authority of one or both Parties, as expressly provided in this Agreement, are outside the jurisdiction and authority of the JSC, including (a) amendment, modification or waiver of compliance with this Agreement; (b) such other matters as are reserved to the consent, approval, agreement or other decision-making authority of either or both Parties in this Agreement that are not required by this Agreement to be considered by the JSC prior to the exercise of such consent,  
24  
approval or other decision-making authority; and (c) any determination as to whether a Party is in breach of this Agreement.  
6.5  
Decision Making within JSC. Decisions of the JSC shall be made by consensus of the representatives present at a meeting at which a quorum exists, with each Party having one (1) vote; in order to make any decision, the JSC must have present (in person or via telephone or videoconference) and voting at least one representative of each Party, unless the meeting has been reconvened on not less than [\*\*\*] notice because the prior meeting was not quorate. If the JSC cannot resolve a material matter within its responsibilities by consensus (a “JSC Deadlock”), then either Party may escalate such JSC Deadlock to the Senior Officers for further consideration. Either Party shall have the right to select a Third Party who has experience of issues that are relevant to the disputed issue to present their views to the Senior Officer of the other Party who shall in good faith listen and consider such views. If the Senior Officers are unable to resolve a JSC Deadlock related to [\*\*\*] (a) [\*\*\*] shall have final decision-making authority with regard to [\*\*\*], and (b) [\*\*\*] shall have final decision-making authority for [\*\*\*]. Neither Party shall exercise its final decision-making authority to (i) require acts or omissions by or on behalf of the other Party in violation of applicable law, (ii) expand the non-decision-making Party’s obligations or reduce the non-decision-making Party’s rights under this Agreement or (iii) expand the decision-making Party’s rights or reduce the decision-making Party’s obligations under this Agreement.  
6.6  
Disbanding. The JSC shall continue to exist until the Parties mutually agree to disband the JSC. If the JSC is disbanded, the JSC shall be terminated and shall have no further rights or obligations under this Agreement, and thereafter any requirement of either Party to provide information or other materials to the JSC shall be deemed a requirement to provide such information or other materials to the other Party upon such other Party’s reasonable request in order to facilitate the carrying out of such other Party’s obligations under this Agreement.  
6.7  
Alliance Managers. Promptly following the Effective Date, each Party shall designate an individual to act as the primary business contact for such Party for matters related to this Agreement (such Party’s “Alliance Manager”), unless another contact is expressly specified in the Agreement or designated by the Parties for a particular purpose. The Alliance Managers shall facilitate communication and collaboration between the Parties and assist in the resolution of potential and pending issues and potential non-technical disputes in a timely manner to enable the Parties to reach consensus and avert escalation of such issues or potential disputes. The Alliance Managers may attend all meetings of the JSC contemplated herein as non-voting participants and will be responsible for assisting such committees and teams in performing their informational and review responsibilities. Either Party may replace its Alliance Manager at any time by notifying the other Party’s Alliance Manager in writing (which may be by email).  
7.  
SUPPLY  
25  
7.1  
Supply Agreement. Licensor will be the sole supplier of Licensed Product to the Licensee or its Affiliates or its Sublicensee in the Territory. The Parties will negotiate in good faith and in no later than [\*\*\*] prior to the First Commercial Sale of the Licensed Product by Licensee or any of its Affiliates in the Field and in the Territory to enter into a Supply Agreement (a “Supply Agreement”), which Supply Agreement shall be consistent with this Article 7 and shall contain the material terms set forth in Schedule 7.1 and a Quality Agreement (“Quality Agreement”). If the Parties are unable to agree on the terms and conditions of the Supply Agreement by such time, either Party may submit such dispute for arbitration in accordance with Section 14.4(b) to establish a commercially reasonable Supply Agreement that incorporates all the material terms set forth in Schedule 7.1. The Parties acknowledge that Licensee will be unable to Commercialize the Licensed Product without an executed Supply Agreement between the Parties.  
7.2  
Product Warranty. With respect to Licensed Product Manufactured and supplied by or on behalf of Licensor, (a) the Licensed Product shall be in conformity with the specifications for the Licensed Product, (b) the Licensed Product shall, at the time of delivery, have a remaining shelf life [\*\*\*], (c) the Licensed Product shall have been Manufactured in conformance in all material respects with all applicable law, this Agreement and any quality agreement, if applicable, (d) the Licensed Product shall have been Manufactured in facilities that are in compliance with applicable law at the time of such Manufacture (including applicable inspection requirements of FDA and other Regulatory Authorities), (e) the Licensed Product shall not be adulterated or misbranded under the FFDCA or similar provisions of any other applicable law and (f) the Licensed Product may be introduced into interstate commerce pursuant to the FFDCA.  
7.3  
Delivery. Licensor shall deliver all quantities of Licensed Product ordered by Licensee CIP (Incoterms 2020) Licensee’s warehouse in [\*\*\*].  
7.4  
Transfer Pricing and Invoicing.  
(a)  
Invoicing for Product on Delivery. Licensor shall invoice Licensee for each unit of Licensed Product ordered by and delivered to Licensee at the Minimum Supply Price. Licensee shall pay the undisputed portion of such invoices within [\*\*\*] of receipt of such invoice by Licensee.  
(b)  
Net Sales Price Reconciliation. After the end of each Calendar Quarter, within [\*\*\*] after Licensor’s receipt of the Net Sales Report, if the Net Sales Price Reconciliation Payment is positive, Licensor shall issue to Licensee an invoice for the amount of the Net Sales Price Reconciliation Payment. Licensee shall pay the undisputed portion of any such invoice within [\*\*\*] of receipt of such invoice by Licensee. For clarity, if the Net Sales Price Reconciliation Payment is negative, Licensor shall not invoice Licensee for, and Licensee shall have no obligation to pay Licensor, such amount.  
7.5  
Minimum Supply Price.  
26  
(a)  
Adjustment. If with respect to any Calendar Year there is no Net Sales Price Reconciliation Payment, the Minimum Supply Price of the Licensed Product will increase by [\*\*\*] from the then-current Minimum Supply Price for the following Calendar Year; provided, however, that in no event shall the Minimum Supply Price of the Licensed Product exceed [\*\*\*]. If the Minimum Supply Price of the Licensed Product has exceeded [\*\*\*], the Minimum Supply Price will remain at the last set Minimum Supply Price.  
(b)  
Additional Presentations. If during the Term Licensor Develops and seeks Regulatory Approval for a presentation of the Licensed Product in the Field in the Territory other than the Initial Presentation, the Parties will negotiate in good faith a Minimum Supply Price with respect to such Licensed Product.  
8.  
INTELLECTUAL PROPERTY  
8.1  
Ownership of Intellectual Property.  
(a)  
Licensor Know How, Licensor Patents. Licensor has and shall retain, all right, title and interest in and to, the Licensor Know How and Licensor Patents.  
8.2  
Prosecution and Maintenance of Patents.  
(a)  
Prosecution of Licensor Patents. Licensor shall have sole right to obtain, prosecute and maintain at its own cost the Licensor Patents in and outside the Territory. Licensor shall also have the exclusive right to seek patent term extensions or supplemental patent protection under the Licensor Patents, if available, including supplementary protection certificates, in the Field and in the Territory in relation to the Licensed Product.  
8.3  
Third Party Infringement.  
(a)  
Notice. Each Party shall promptly report in writing to the other Party during the Term any known or suspected (i) infringement of any of the Licensor Patents, or (ii) unauthorized use or misappropriation of any of the Licensor Know-How, in the case of either clause (i) or clause (ii), that could reasonably be expected to impact the (A) Commercialization of any Licensed Product in the Field in the Territory by or on behalf of Licensee or its Affiliates, or (B) scope of the rights licensed to Licensee under Section 2.1 (an “Infringement Claim”), of which such Party becomes aware, and shall provide the other Party with all available evidence supporting such Infringement Claim.  
(b)  
Enforcement Rights. Licensee shall have the right, but not the obligation, after consultation with Licensor, to initiate a suit, or take other appropriate action that it believes is reasonably required to protect (i.e., prevent or xxxxx actual or threatened infringement or misappropriation of) or otherwise  
27  
enforce the Licensor Patents, Licensor Know-How, with respect to an Infringement Claim in the Territory and shall consider in good faith the reasonable interests of Licensor in so doing. For this purpose, Licensor shall execute such legal papers and cooperate in the prosecution of such suit as may be reasonably required for Licensee to take such action; provided that Licensee shall promptly reimburse all out-of-pocket expenses (including reasonable counsel fees and expenses) actually incurred by Licensor in connection with such cooperation.  
(c)  
Conduct of Certain Actions; Costs. Licensee shall have the sole and exclusive right to select counsel for, and otherwise control, any suit initiated by it pursuant to Section 8.3(b) and will pay its own costs and expenses in connection with such suit.  
(d)  
Recoveries. Any damages, settlements, accounts of profits, or other financial compensation recovered from a Third Party by the Licensee over enforcing any Infringement Claim in the Territory shall be allocated first to reimburse each Party’s out-of-pocket costs and expenses in connection with such enforcement and then shared equally between the Parties.  
8.4  
Patent Invalidity Claim. Each of the Parties shall promptly notify the other in the event of any legal or administrative action by any Third Party against a Licensor Patent in the Field or in the Territory of which it becomes aware, including any nullity, revocation, reexamination or compulsory license proceeding. To the extent permitted by applicable law, Licensee shall have the first right, but not the obligation, to defend against any such action involving a Licensor Patent in its own name, and the costs of any such defense shall be at Licensee’s expense. Licensor, upon request of Licensee, agrees to join in any such action and to cooperate reasonably with Licensee at its own cost. If Licensee does not defend against any such action involving a Licensor Patent, then Licensor shall have the right, but not the obligation, to defend such action and any such defense shall be at Licensor’s expense.  
8.5  
Claimed Infringement. Each of the Parties shall promptly notify the other in the event a Party becomes aware that the Commercialization of any Licensed Product in the Field in the Territory infringes or misappropriates the intellectual property rights of any Third Party, and shall promptly provide the other Party with any notice it receives or has received from a Third Party related to such suspected infringement or misappropriation. Licensee shall have in the Territory the first right, but not the obligation, to defend and control the defense of any such claim, suit, or proceeding at its own expense, using counsel of its own choice. Licensor may participate in any such claim, suit, or proceeding with counsel of its choice at its own expense if Licensee give up the first right. Without limitation of the foregoing, if each Party finds it necessary or desirable to join the other Party as a party to any such action, such other Party shall execute all papers and perform such acts as shall be reasonably required. Each Party shall keep the other Party reasonably informed of all material developments in connection with any such claim, suit, or proceeding.  
28  
8.6  
Procedure and Settlement. To the extent Licensee takes a lead role to enforce or defend a Licensor Patent or the Licensor Know-How in a suit, legal or administrative proceeding or action in pursuance with this Article 8, Licensee shall keep Licensor reasonably informed of the status of the suit, proceeding or action. Licensee (a) shall consult with Licensor, provide relevant documents to Licensor with a reasonable amount of time prior to each deadline set by a court or other venue or authority of competent jurisdiction and consider Licensor’s comments in good faith and (b) without Licensor’s prior written consent, shall not offer or enter into any settlement or compromise, admit or concede that any aspect of any such Patents or Know-How is invalid or unenforceable or may adversely affect the scope of the Licensor Patents or the Licensor Know-How, or admit any wrongdoing or misconduct on the part of Licensor. Licensor shall have the right, but not the obligation, to join Licensee in such proceedings to the extent permissible under applicable law at Licensor’s sole cost and expense. Licensee will take the lead in the control and conduct of any such suit or action under this Article 8 in close coordination with Licensor.  
8.7  
Licensor Marks. Licensor shall own the Licensor Marks and will be primarily responsible for registering, defending and maintaining the same in the Territory to the extent necessary for Commercialization of Licensed Product at its sole cost and expense, using counsel of its choice. Licensee shall have the sole right, but not the obligation to register, defend and maintain all trademarks used for Commercialization of the Licensed Product other than the Licensor Marks, using counsel of its choice. In the event that Xxxxxxxx decides to abandon a Licensor Xxxx being used in connection with the Commercialization of the Licensed Product in the Territory, it shall promptly notify Licensee of such intention and Licensee shall have the right to request assignment of the applicable Licensor Mark. Upon receipt of the notice requesting assignment, Licensor shall, at Licensee’s costs, take all reasonable steps to assign the applicable Licensor Mark to Licensee before abandonment of the applicable Licensor Mark, and shall provide applicable correspondence with the relevant trademark office and other documents reasonably related to such Licensor Xxxx to assist in transition of prosecution and maintenance of the applicable Licensor Mark.  
8.8  
Licensee Marks. Licensee shall own the Licensee Marks and will be primarily responsible for registering, defending and maintaining the same in the Territory to the extent necessary for Commercialization of Licensed Product at its sole cost and expense, using counsel of its choice. Licensee shall have the sole right, but not the obligation to register, defend and maintain all trademarks used for Commercialization of the Licensed Product, using counsel of its choice. In the event that Licensee decides to abandon a Licensee Xxxx being used in connection with the Commercialization of the Licensed Product in the Territory, it shall promptly notify JSC and based on the determination by JSC Licensor may have the right to request assignment of the applicable Licensee Mark.  
9.  
TERM AND TERMINATION  
29  
9.1  
Term. The term of this Agreement shall commence on the Effective Date and, unless sooner terminated by a Party pursuant to this Article 9, shall continue in full force for ten (10) years from the First Commercial Sale (the “Term”). The Agreement may be renewed subject to the Parties’ mutual agreement and other terms to be agreed by the Parties.  
9.2  
Termination by Either Party. This Agreement may be terminated by either Party:  
(a)  
at any time with immediate effect if the other Party is in material breach of this Agreement and where such breach is capable of being cured but has not been cured within [\*\*\*]; provided that if the breaching Party disputes that it has materially breached one or more of its obligations under this Agreement, the non-breaching Party shall not be entitled to terminate the Agreement unless and until (i) a final and non-appealable judgment has been issued pursuant to which the breaching Party is determined to have been in material breach of one or more of its obligations under this Agreement and (ii) where such breach is capable of being cured, such breach has not been cured within [\*\*\*];  
(b)  
upon mutual agreement of the Parties; or  
(c)  
at any time with immediate effect if an Insolvency Event occurs with respect to the other Party.  
9.3  
Termination by Licensor. Licensor may terminate this Agreement on written notice to Licensee if:  
(a)  
during the Term, Licensee undergoes a Change of Control and the Acquiring Affiliate is then engaged in a Competing Program, with such termination to become effective one hundred and twenty (120) days after notice is given or at any time after the Change of Control has occurred and Commercialization has ceased on the Licensed Product;  
(b)  
during [\*\*\*] after the First Commercial Sale, Net Sales has not attained [\*\*\*] or annual unit sales of [\*\*\*], with such termination to become effective one hundred and twenty (120) days after notice is given;  
(c)  
at any time after [\*\*\*] following the First Commercial Sale, annual Net Sales is less than [\*\*\*], with such termination to become effective one hundred and twenty (120) days after notice is given; or  
(d)  
the Supply Agreement is terminated, with such termination to become effective on the date on which the Supply Agreement is terminated.  
9.4  
Termination by Licensee. Licensee may terminate this Agreement:  
(a)  
on written notice to Licensor if a material unexpected or new safety concern is reported in compliance with Section 4.3, and the JSC determines such  
30  
safety concern is not curable within [\*\*\*], or if such safety concern remains uncured after [\*\*\*]; or  
(b)  
on written notice to Licensor if the FDA Approval is rejected or revoked after issuance, and the JSC determines that such FDA Approval would not be reasonably expected to issue or re-issue, as applicable, following use of further Commercially Reasonable Efforts for [\*\*\*] by Licensee and Licensor.  
9.5  
Effect of Termination or Expiration.  
(a)  
Expiration of Agreement or Termination by Either Party. If this Agreement expires under Section 9.1 or is terminated by either Party under Section 9.2 to Section 9.4, then:  
(i)  
the effects of termination in this Section 9.5(a) are without prejudice to the rights of either Party accrued at the date of the termination and to any right and remedy of either Party in respect of the event(s) leading to the termination;  
(ii)  
all rights and licenses granted by either Party hereunder shall terminate;  
(iii)  
each Party shall promptly return to the other Party, or delete or destroy, all relevant records and materials in such Party’s possession or control containing Information of the other Party; provided that such Party may keep one (1) copy for archival purposes only subject to a continuing confidentiality obligations;  
(iv)  
to the extent permitted by applicable law, Licensee shall promptly assign and transfer to Licensor or such persons as Licensor may designate all of its right, title and interest in (and shall cause its Affiliates and Sublicensees to assign all of their right, title and interest in) the Regulatory Filings and Regulatory Approvals (including the FDA Approval) and Licensee Regulatory Data related to the Licensed Product in the Territory, Licensee Marks for the Licensed Product as of the effective date of the termination and shall take any actions reasonably requested by Licensor to give full effect of such assignment, including making any necessary filings with Regulatory Authorities and transferring to Licensor or its designee any copies of such items in the possession or under control of Licensee or its Affiliates or Sublicensees, provided that if any such Regulatory Filings, Regulatory Approval, or Licensee Regulatory Data is not immediately transferrable, Licensee will grant Licensor a non-exclusive and royalty-free right of reference under all other Regulatory Filings and Regulatory Approvals (including the FDA  
31  
Approval) or Licensee Regulatory Data, if any, that relate to the Licensed Product in the Territory; and  
(v)  
Licensee shall be permitted to sell off inventory of the Licensed Product to the extent permitted by applicable laws and the expiration date(s) of such inventory.  
9.6  
Survival. The rights and obligations set forth in this Agreement shall extend beyond the Term or termination of this Agreement only to the extent expressly provided for in this Agreement. Without limiting the generality of the foregoing, it is agreed that the provisions of this Section 9.6 and of Sections 3.4 (for final accounting), 3.5 (for final accounting), 3.6 (for final accounting), 7.2 (with respect to Licensed Product delivered prior to termination), 8.1, 8.2, 8.3 (with respect to Infringement Claims arising during the Term), 8.5 (with respect to claims of infringement or misappropriation occurring during the Term), 8.6 (for the duration of the survival of Sections 8.3 and 8.5) and 9.5, and of Article 1 and the Schedules (to the extent required to give effect to the provisions set forth in this Section 9.6), Article 11, Article 12 (for the period set forth therein), Article 13 and Article 14 shall survive expiration or termination of this Agreement.  
10.  
REPRESENTATIONS, WARRANTIES AND COVENANTS  
10.1  
Mutual Representations, Warranties and Covenants. Licensor and Licensee each represents and warrants to the other, as of the Effective Date, that:  
(a)  
Good Standing. It is validly existing and in good standing under the applicable laws of the jurisdiction of its incorporation and has the full right, power and authority to enter into this Agreement.  
(b)  
No Conflicts. It is not a party to or otherwise bound by any oral or written contract or agreement that will result in any individual or entity obtaining any interest in, or that would give to any individual or entity any right to assert any claim in or with respect to, any of such Party’s rights granted under this Agreement.  
(c)  
Authorization. It has the corporate power and authority to execute and deliver this Agreement and to perform its obligations hereunder. The execution, delivery and performance of this Agreement has been duly and validly authorized and approved by all necessary corporate action on the part of such Party. Assuming due authorization, execution and delivery on the part of the other Party, this Agreement constitutes a legal, valid and binding obligation of such Party, enforceable against such Party in accordance with its terms.  
(d)  
Debarment. Neither it nor any of its Affiliates has been debarred or is subject to debarment and neither it nor any of its Affiliates will use in any capacity in connection with the activities to be performed under this Agreement, any individual or entity who has been debarred pursuant to  
32  
section 306 of the FFDCA 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 individual or entity who is performing activities hereunder is debarred or is the subject of a conviction described in section 306 or if any action, suit, claims, investigation or legal or administrative proceeding is pending or, to its knowledge, is threatened, relating to the debarment or conviction of it or any such individual or entity performing activities hereunder.  
10.2  
Representations and Warranties of Licensor. Licensor represents and warrants to Licensee the following as of the Effective Date:  
(a)  
All Licensor Patents existing as of the Effective Date (the “Existing Patents”) are set forth on Schedule 10.2(a) and are solely and exclusively owned by Licensor. All Existing Patents are subsisting and are not invalid or unenforceable, in whole or in part;  
(b)  
Licensor is entitled to grant to Licensee the licenses herein and for the purposes set forth in this Agreement herein and to the best of Licensor’s knowledge the Licensor Patents and the Licensor Know-How are valid and enforceable, and are not known to be infringed by any Third Party;  
(c)  
To Licensor’s knowledge, the exercise of the licenses and rights granted hereunder to Licensee does not infringe on any intellectual property rights of any Third Party;  
(d)  
Licensor has not received any written claim or demand alleging that (i) the Existing Patents, the Licensor Know-How, the Licensor Marks or any intellectual property right granted by the Third Party under an Existing Agreement that is reasonably necessary or useful for the Licensed Product in the Field in the Territory are invalid or unenforceable in the Territory or (ii) the Development or Commercialization of the Licensed Product as contemplated herein infringes any Patent owned by any Third Party;.  
(e)  
Licensor and its Affiliates have generated, prepared, maintained and retained all Regulatory Filings that is required to be maintained or retained pursuant to and in accordance with applicable law;  
(f)  
Licensor, its Affiliates, and its and their respective contractors and consultants have conducted, and with respect to Development occurring after the Effective Date, will conduct, all Development of the Licensed Product in accordance with good laboratory and clinical practice as applicable and applicable laws, including compliance with 21 C.F.R. 50, 54, 56, 58, 812 and similar regulatory or legal obligations outside the United States;  
(g)  
True, complete and correct (as of the Effective Date) copies of all material adverse information with respect to the safety and efficacy of the Licensed  
33  
Product known to Licensor have been provided to Licensee prior to the Effective Date;  
(h)  
True, complete and correct copies (as of the Effective Date) of (i) the file wrappers and other documents and materials relating to the prosecution, defense, maintenance, validity and enforceability of the Existing Patents and (ii) all license and other agreements regarding any intellectual property rights licensed in the Field hereunder, including the Existing Patents, as amended to the date hereof (the “Existing Agreements”), in each case ((i) and (ii)) have been provided to Licensee prior to the Effective Date. All of the Existing Agreements are listed on Schedule 10.2(h);  
(i)  
The Existing Patents represent all Patents that Licensor or its Affiliates own, Control or otherwise have rights to relating to the Licensed Product or the Commercialization thereof, as of the Effective Date. There is no Information owned by or otherwise in the possession or control of Licensor or any of its Affiliates as of the Effective Date that relates to the Licensed Product in the Field that is not within the Licensor Know-How. All intellectual property rights relating to the Licensed Product or the Commercialization in the Field thereof licensed to Licensor or its Affiliates pursuant to the Existing Agreements are Controlled by Licensor and the rights and obligations of the Parties hereunder are fully consistent with and are not limited by the Existing Agreements, including such that the rights granted to Licensee hereunder to intellectual property licensed pursuant to an Existing Agreement are no more restricted than the analogous rights granted to Licensee hereunder with respect to intellectual property rights wholly owned by Licensor or its Affiliates. No rights or licenses are required under the Existing Patents or Licensor Know-How for Licensee to Commercialize the Licensed Product as contemplated herein other than those granted under Section 2.1;  
(j)  
Neither Licensor nor any of its Affiliates has previously entered into any agreement, whether written or oral, with respect to or otherwise assigned, transferred, licensed, conveyed or otherwise encumbered its right, title or interest in or to the Existing Patents, Licensor Know-How, Regulatory Filings, or the Licensed Product in the Field (including by granting any covenant not to sue with respect thereto) or any Patent or other intellectual property or proprietary right or Information that would be Existing Patents, Licensor Know-How or Regulatory Filings but for such assignment, transfer, license, conveyance or encumbrance and it will not enter into any such agreements, grant any such right, title or interest to any person during the Term that is inconsistent with or otherwise diminish the rights and licenses granted to Licensee under this Agreement. Without limiting the foregoing, during the Term, Licensor will not (i) commit any acts or permit the occurrence of any omissions that would cause breach or termination of any Existing Agreement or (ii) amend or otherwise modify or permit to be amended or modified, any Existing Agreement; and  
34  
(k)  
The Commercialization of the Licensed Product as contemplated herein will not be subject to any other license or agreement to which Licensor or any of its Affiliates is a party, other than the Existing Agreements.  
10.3  
Representations and Warranties of Licensee. Licensee represents and warrants to Licensor the following as of the Effective Date (except for any representations and warranties that are expressly stated to have been made as of a specified date, which shall have been true and correct as of such specified date):  
(a)  
Licensee has the financial resources, and Licensee has itself or through its Affiliates the capabilities and expertise, to (i) Commercialize the Licensed Product and (ii) perform such other obligations assigned to Licensee under this Agreement in compliance with all applicable laws, and Licensee further covenants that it shall continue to maintain such capabilities during the Term; and  
(b)  
During the Term, Licensee shall continue to use Commercially Reasonable Efforts following receipt of the FDA Approval for the Licensed Product, to Commercialize and launch in the Territory. Licensee shall keep Licensor reasonably and timely informed as to the foregoing efforts and results thereof relating to the Licensed Product in the Territory.  
11.  
INDEMNIFICATION; LIMITATION OF LIABILITY  
11.1  
Indemnification by Licensee. Licensee agrees to defend, indemnify and hold Licensor, its Affiliates and their respective officers, directors, employees, consultants, agents, successors and assigns harmless from and against any and all claims, demands, actions, causes of action, judgments, losses, damages, costs and expenses (including attorneys’ and expert witness fees and expenses) (collectively “Losses”) to the extent resulting from any claim, action, suit, proceeding, liability or obligation asserted by a Third Party (collectively, “Third Party Claims”) arising out of, relating to or resulting from:  
(a)  
any breach of any representation, warranty, covenant or agreement made by Licensee in this Agreement;  
(b)  
the gross negligence or willful misconduct of Licensee in connection with Licensee’s performance of this Agreement; or  
(c)  
the post-approval Development activities (to the extent agreed by the Parties) or Commercialization of Licensed Product by or on behalf of Licensee, its Affiliates or Sublicensees in or for the Territory,  
except, in each case ((a)-(c)) for those Losses for which Licensor has an obligation to indemnify Licensee pursuant to Section 11.2, as to which Losses each Party shall indemnify the other to the extent of their respective liability.  
35  
11.2  
Indemnification by Licensor. Licensor agrees to defend, indemnify and hold Licensee and its Affiliates and their respective officers, directors, employees, agents, successors and assigns harmless from and against any and all Losses to the extent resulting from any Third Party Claim arising out of or relating to or resulting from:  
(a)  
any breach of any representation, warranty, covenant or agreement made by Licensor in this Agreement;  
(b)  
the gross negligence or willful misconduct of Licensor in connection with Licensor’s performance of this Agreement; or  
(c)  
the Development or Manufacture of Licensed Product by or on behalf of Licensor, its Affiliates, or their respective sublicensees and collaborators or the Commercialization of Licensed Product by or on behalf of Licensor, its Affiliates, or their respective sublicensees and collaborators outside the Field or outside the Territory,  
except, in each case ((a)-(c)) for those Losses for which Licensee has an obligation to indemnify Licensor pursuant to Section 11.1, as to which Losses each Party shall indemnify the other to the extent of their respective liability.  
11.3  
Indemnification Procedures.  
(a)  
Notice of Claim. All indemnification claims in respect of a Party, its Affiliates, or its or their sublicensees or their respective directors, officers, employees and agents shall be made solely by such Party to this Agreement (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 11; provided that no failure or delay in providing such notice shall relieve the indemnifying Party of any liability it may have to the Indemnified Party, except to the extent that such failure or delay materially prejudices the indemnifying Party with respect to such claim. 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.  
(b)  
Control of Defense. The indemnifying Party shall have the right to assume the defense of any Third Party Claim by giving written notice to the Indemnified Party within [\*\*\*] after the indemnifying Party’s receipt of an Indemnification Claim Notice. The assumption of the defense of a Third Party Claim by the indemnifying Party shall not be construed as an  
36  
acknowledgment that the indemnifying Party is liable to indemnify the Indemnified Party in respect of the Third Party Claim, nor shall it constitute a waiver by the indemnifying Party of any defenses it may assert against the Indemnified Party’s claim for indemnification. Upon assuming the defense of a Third Party Claim, the indemnifying Party may appoint as lead counsel in the defense of the Third Party Claim any legal counsel selected by the indemnifying Party. In the event the indemnifying Party assumes the defense of a Third Party Claim, the Indemnified Party shall immediately deliver to the indemnifying Party all original notices and documents (including court papers) received by the Indemnified Party in connection with the Third Party Claim. Should the indemnifying Party assume the defense of a Third Party Claim, except as provided in Section 11.3(c), the indemnifying Party shall not be liable to the Indemnified Party for any legal expenses subsequently incurred by such Indemnified Party in connection with the analysis, defense or settlement of the Third Party Claim unless specifically requested in writing by the indemnifying Party. In the event that it is ultimately determined that the indemnifying Party is not obligated to indemnify the Indemnified Party from and against such Third Party Claim, the Indemnified Party shall reimburse the indemnifying Party for any and all reasonable and verifiable costs and expenses (including attorney’s fees and costs of suit) and any Losses incurred by the indemnifying Party in accordance with this Section 11.3(b) in its defense of the Third Party Claim.  
(c)  
Right to Participate in Defense. Any Indemnified Party shall be entitled to participate in the defense of such Third Party Claim and to employ counsel of its choice for such purpose; provided, however, that such employment shall be at the Indemnified Party’s sole cost and expense unless (i) the employment thereof has been specifically authorized by the indemnifying Party in writing (in which case, the defense shall be controlled as provided in Section 11.3(b)), (ii) the indemnifying Party has failed to assume the defense and employ counsel in accordance with Section 11.3(b) (in which case the Indemnified Party shall control the defense), or (iii) the interests of the indemnitee and the indemnifying Party with respect to such Third Party Claim are sufficiently adverse to prohibit the representation by the same counsel of both Parties under applicable law, ethical rules or equitable principles (in which case, the Indemnified Party shall control its defense).  
(d)  
Settlement. With respect to any Losses relating solely to the payment of money damages in connection with a Third Party Claim and that shall not result in the applicable indemnitee(s) becoming subject to injunctive or other relief or otherwise adversely affecting the business of the Indemnified Party in any manner, the indemnifying Party shall have the sole right to consent to the entry of any judgment, enter into any settlement or otherwise dispose of such Loss, on such terms as the indemnifying Party, in its sole discretion, shall deem appropriate. With respect to all other Losses in  
37  
connection with Third Party Claims, where the indemnifying Party has assumed the defense of the Third Party Claim in accordance with Section 11.3(b), the indemnifying Party shall have authority to consent to the entry of any judgment, enter into any settlement or otherwise dispose of such Loss; provided it obtains the prior written consent of the Indemnified Party (which consent shall not be unreasonably withheld, conditioned or delayed). If the indemnifying Party does not assume and conduct the defense of a Third Party Claim as provided above, the Indemnified Party may defend against such Third Party Claim; provided that the Indemnified Party shall not settle any Third Party Claim without the prior written consent of the indemnifying Party (which consent shall not be unreasonably withheld, conditioned or delayed).  
(e)  
Cooperation. Regardless of whether the indemnifying Party chooses to defend or prosecute any Third Party Claim, the Indemnified Party shall, and shall cause each indemnitee 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. Such cooperation shall include access during normal business hours afforded to the indemnifying Party to and reasonable retention by the Indemnified Party of, records and information that are reasonably relevant to such Third Party Claim and making Indemnified Parties and other employees and agents available on a mutually convenient basis to provide additional information and explanation of any material provided.  
(f)  
Expenses. Except as provided above, the costs and expenses, including fees and disbursements of counsel, incurred by the Indemnified Party in connection with any claim shall be reimbursed [\*\*\*] by the indemnifying Party, without prejudice to the indemnifying Party’s right to contest the Indemnified Party’s right to indemnification and subject to refund in the event the indemnifying Party is ultimately held not to be obligated to indemnify the Indemnified Party.  
11.4  
Insurance Recovery. Any indemnification hereunder shall be made net of any insurance proceeds actually recovered by the Indemnified Party from unaffiliated Third Parties; provided, however, that if, following the payment to the Indemnified Party of any amount under this Article 11, such Indemnified Party recovers any such insurance proceeds in respect of the claim for which such indemnification payment was made, the Indemnified Party shall promptly pay an amount equal to the amount of such proceeds (but not exceeding the amount of such net indemnification payment) to the indemnifying Party.  
11.5  
LIMITATION OF LIABILITY. EXCEPT AS EXPRESSLY SET OUT IN THIS AGREEMENT OR THE SUPPLY AGREEMENT, NEITHER PARTY NOR ANY OF ITS AFFILIATES WILL BE LIABLE IN CONTRACT, TORT, NEGLIGENCE BEACH OF STATUTORY DUTY OR OTHERWISE FOR ANY  
38  
SPECIAL, INDIRECT, INCIDENTAL, PUNITIVE OR CONSEQUENTIAL DAMAGES OR FOR ANY CURRENT OR FUTURE POTENTIAL ECONOMIC LOSS, OR LOSS OF PROFITS SUFFERED BY THE OTHER PARTY, EXCEPT (A) IN THE EVENT OF THE WILLFUL MISCONDUCT OR FRAUD OF A PARTY OR (B) TO THE EXTENT ANY SUCH DAMAGES ARE REQUIRED TO BE PAID TO A THIRD PARTY AS PART OF A CLAIM FOR WHICH A PARTY PROVIDES INDEMNIFICATION UNDER THIS ARTICLE 11.  
12.  
CONFIDENTIALITY  
12.1  
Duty of Confidence. Subject to the other provisions of this Article 12, all Information disclosed by a Party or its Affiliates under or in connection with this Agreement, whether prior to, on or after the Effective Date, shall be maintained in confidence and otherwise safeguarded by the recipient Party. The recipient Party may only use Information of the other Party for the purposes of this Agreement and pursuant to the rights granted to the recipient Party under this Agreement. Subject to the other provisions of this Article 12, each Party will hold as confidential such Information of the other Party or its Affiliates in the same manner and with the same protection as such recipient Party maintains its own confidential information. A recipient Party may disclose Information of the other Party to employees, agents, contractors, consultants and advisor of the Party, its Affiliates and sublicenses to the extent reasonably necessary for the purposes of this Agreement, provided that such persons are bound to maintain the confidentiality of the Information in a manner consistent with the confidentiality provisions of this Agreement. Notwithstanding the foregoing, (a) the terms of this Agreement and (b) Licensor Know-How related to the Licensed Product in the Field in the Territory that is exclusively licensed to Licensee hereunder shall in each case ((a) and (b)) be deemed to be the Information of both Parties (and both Parties shall be deemed to be the receiving Party and the disclosing Party with respect thereto); provided that in the case of clause (b), (i) Licensor shall have the right to use and disclose (subject to customary confidentiality obligations) such Information outside the Territory or outside the Field consistent with its customary practices, and (ii) Licensee shall have the right to use and disclose such Information solely to the extent required for Licensee’s exercise and performance of its rights and obligations under this Agreement or the Supply Agreement.  
12.2  
Exclusions. Information does not include information that (a) was known to the receiving Party prior to receipt from the disclosing Party as evidenced by the receiving Party’s records; (b) is or becomes (at time of disclosure) part of the public domain through no breach of this Agreement by the receiving Party; (c) is lawfully received by the receiving Party from a Third Party that is not bound by any obligations of confidentiality with respect to such information; or (d) comprises identical subject matter to that which had been originally and independently developed by or for the receiving Party without knowledge or use of any Information as evidenced by written records.  
39  
12.3  
Permitted Disclosures. Notwithstanding the foregoing, the receiving Party may disclose the Information of the disclosing Party (a) as and to the extent required by the order of any governmental authority of competent jurisdiction; provided that the receiving Party shall, to the extent permitted by applicable law, use reasonable efforts to notify the disclosing Party of such proposed disclosure in such a manner and on such a schedule as will afford the disclosing Party a reasonable opportunity to seek a protective order or similar restriction on disclosure of the disclosing Party’s Information proposed to be disclosed by the receiving Party, (b) as 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 a disclosure that describes or refers to the terms and conditions of this Agreement or any related agreements between the Parties, (c) to the extent that such disclosure is made to Regulatory Authorities as deemed reasonably necessary by the receiving Party in connection with any filing, application, or request for Regulatory Approval, response to any requests or inquiries from a Regulatory Authority, or other communication with a Regulatory Authority, and (d) to prospective acquirers, lenders, investors, collaboration partners, and sublicensees that agree to be bound by non-use and non-disclosure obligations no less onerous than those under this Agreement in respect of such Information.  
12.4  
Press Releases and Other Announcements. The Parties have agreed upon the content of press releases which shall be issued substantially in the form attached hereto as Schedule 12.4, the release of which the Parties shall coordinate in order to accomplish such release promptly upon execution of this Agreement. Neither Party shall issue any other press release or otherwise make a public announcement concerning the subject matter of this Agreement without the prior review and written approval of the text of any such press release or other public announcement by the other Party. The other Party shall not unreasonably withhold or delay such review and approval.  
12.5  
Publications. The Parties recognize the desirability of publishing and publicly disclosing the results of and information regarding, activities under this Agreement. Accordingly, Parties shall be free to publicly disclose the results of and information regarding, activities under this Agreement, subject to prior review and consent by the other Party of any disclosure of the other Party’s Information. Accordingly, prior to publishing or disclosing any of the other Party’s Information, Parties shall provide the other Party with drafts of proposed abstracts, manuscripts or summaries of presentations that cover such Information for the other Party’s approval. Parties shall respond promptly through its designated representative and in any event no later than [\*\*\*] after receipt of such proposed publication or presentation.  
12.6  
Duration. Except as otherwise provided herein, the restrictions and covenants set forth in this Article 12 shall survive until [\*\*\*]; provided, however, that with respect to Information that constitutes a trade secret under applicable law, the receiving Party’s obligations pursuant to this Article 12 shall survive so long as such Information remains a trade secret under applicable law.  
40  
13.  
FORCE MAJEURE  
13.1  
Force Majeure Event. In the event that either Party is prevented from performing its obligations under this Agreement as a result of any contingency beyond its reasonable control and without fault or negligence of such Party (“Force Majeure”), including but not limited to, acts of God, natural disasters, energy shortages, fire, flood, severe storm, earthquake, pandemic, civil disturbance, lockout, riot, order of any court or administrative body, embargo, acts of government, war (whether or not declared), acts of terrorism, or other similar causes, the Party immediately affected thereby will give prompt written notice to the other Party specifying the Force Majeure event complained of, and such affected Party shall not be held liable or responsible to the other Party or be deemed to have defaulted under or breached this Agreement to the extent caused by an even of Force Majeure, provided that such Party will use reasonable efforts to resume performance of its obligations. Under no circumstance will an event of Force Majeure excuse a Party’s obligations to make payments when due under this Agreement, unless such Force Majeure event results in a failure of the banking system that deprives a Party’s access to available funds. The Parties shall use their reasonable endeavors to:  
(a)  
overcome the effects of the Force Majeure;  
(b)  
mitigate the effect of any delay occasioned by any Force Majeure, including by recourse to alternative mutually acceptable (which acceptance shall not be unreasonably withheld by either Party) sources of services, equipment and materials; and  
(c)  
ensure resumption of normal performance of this Agreement as soon as reasonably practicable and shall perform their obligations to the maximum extent practicable, provided that neither Party shall be obliged to settle any strike, lock out, work stoppage, labor dispute or such other industrial action by its employees.  
14.  
MISCELLANEOUS  
14.1  
Assignment. Neither Party shall assign any of its rights or delegate any of its obligations hereunder without the prior written consent of the other Party; provided, however, that either Party may assign its rights or delegate its obligations, in whole or in part, without such consent (but with written notice to the other Party), to one (1) or more of its Affiliates or to any successor in interest (whether by merger, acquisition, asset purchase or otherwise) to or acquisition of all or substantially all of the business to which the Agreement relates; provided that such successor in interest does not have a Competing Program. The assigning Party will remain responsible for the performance by its assignee of any obligation hereunder so assigned. Any purported assignment or transfer in violation of this Section 14.1 will be void and of no force and effect.  
41  
14.2  
Rights in Bankruptcy. All rights and licenses granted under or pursuant to this Agreement are, and shall otherwise be deemed to be, for purposes of any applicable bankruptcy or insolvency law in the Territory or where a Party is situated (collectively, the “Bankruptcy Laws”), licenses of rights to “Intellectual Property” as defined under the Bankruptcy Laws. If a case is commenced during the Term by or against a Party under Bankruptcy Laws then, unless and until this Agreement is rejected as provided in such Bankruptcy Laws, such Party (in any capacity, including debtor-in-possession) and its successors and assigns (including a trustee) shall perform all of the obligations provided in this Agreement to be performed by such Party. If a case is commenced during the Term by or against a Party under the Bankruptcy Laws, this Agreement is rejected as provided in the Bankruptcy Laws and the other Party elects to retain its rights hereunder as provided in the Bankruptcy Laws, then the Party subject to such case under the Bankruptcy Laws (in any capacity, including debtor-in-possession) and its successors and assigns (including a trustee), shall provide to the other Party copies of all Information necessary for such other Party to prosecute, maintain and enjoy its rights under the terms of this Agreement promptly upon such other Party’s written request therefor. All rights, powers and remedies of the non-bankrupt or non-insolvent Party as provided herein are in addition to and not in substitution for any and all other rights, powers and remedies now or hereafter existing at law or in equity (including the Bankruptcy Laws) in the event of the commencement of a case by or against a Party under the Bankruptcy Laws.  
14.3  
Governing Law and Venue. This Agreement will be governed by and construed under the laws of State of Delaware without regard to conflicts or choice of law rules or principles that might otherwise refer construction or interpretation of this Agreement to the substantive law of another jurisdiction. The Parties agree to exclude the application to this Agreement of the United Nations Convention on Contracts for the International Sale of Goods.  
14.4  
Dispute Resolution.  
(a)  
Dispute Resolution. Except for disputes to be resolved by the procedures set forth in Section 6.5, in the event of a dispute arising out of or relating to this Agreement, either Party may provide written notice of the dispute to the other, in which event the dispute shall be referred to the Senior Officers of each Party for attempted resolution by good faith negotiations within [\*\*\*] after such notice is received. In the event the Senior Officers do not resolve such dispute within the allotted [\*\*\*], either Party may, after the expiration of the [\*\*\*] period, seek to resolve the dispute through arbitration in accordance with Section 14.4(b).  
(b)  
Claims.  
(i)  
Arbitration. Any unresolved disputes between the Parties relating to, arising out of or in any way connected with this Agreement or any term or condition hereof, or the performance by either Party of  
42  
its obligation hereunder, whether before or after termination of this Agreement, will be resolved by final and binding arbitration. Disputes shall be resolved by final and binding arbitration by a panel of experts with relevant industry experience (the “Arbitrators”). The arbitration process will be conducted expeditiously in accordance with the Commercial Arbitration Rules then in force (the “AAA Rules”) of the American Arbitration Association or any successor entity (the AAA). Arbitration will take place in New York City.  
(ii)  
Arbitrators’ Award. The Arbitrators shall endeavor, within [\*\*\*] after the conclusion of the arbitration hearing, to issue a written award and statement of decision describing the essential findings and conclusions on which the award is based, including the calculation of any damages awarded. The decision or award rendered by the Arbitrators shall be final and binding, and judgment may be entered upon it in accordance with applicable law in any court of competent jurisdiction. The Arbitrators shall be authorized to award compensatory damages, but shall not be authorized to reform, modify or materially change this Agreement or any other agreements contemplated hereunder.  
(iii)  
Compliance with this Agreement. Unless the Parties otherwise agree in writing, during the period of time that any arbitration proceeding is pending under this Agreement, the Parties shall continue to comply with all those terms and provisions of this Agreement that are not the subject of the pending arbitration proceeding.  
(iv)  
Injunctive or Other Equity Relief. Nothing contained in this Agreement shall deny any Party the right to seek injunctive or other equitable relief from a court of competent jurisdiction in the context of a bona fide emergency or prospective irreparable harm, and such an action may be filed and maintained notwithstanding any ongoing arbitration proceeding.  
(v)  
Confidentiality. All arbitration proceedings and decisions of the Arbitrators under this Section 14.4(b) shall be deemed the Information of both Parties.  
14.5  
Waiver; Amendments; Non-Exclusion of Remedies. The failure of any Party to assert a right hereunder or to insist upon compliance with any term or condition of this Agreement will not constitute a waiver of that right or excuse a similar subsequent failure to perform any such term or condition by the other Party. No waiver will be effective unless it has been given in writing and signed by the Party giving such waiver. This Agreement may not be modified or amended except in a writing signed by a duly authorized officer or representative of each Party. The  
43  
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.  
14.6  
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, there shall be added automatically as a part of this Agreement a legal, valid and enforceable provision as similar in terms to such illegal, invalid or unenforceable provision as may be possible and reasonably acceptable to the Parties. 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.  
14.7  
Relationship of the Parties. It is expressly agreed that Licensor, on the one hand, and Licensee, on the other hand, shall be independent contractors and that the relationship between the Parties shall not constitute or give rise to an employer-employee, partnership, joint venture or agency relationship. Neither Licensor, 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 and each Party’s performance hereunder is that of a separate, independent entity.  
14.8  
Notices. All notices which are required or permitted hereunder shall be in writing and sufficient if delivered personally, sent by internationally-recognized overnight courier or sent by registered or certified mail, postage prepaid, return receipt requested, or sent by email, addressed as follows:  
(a)  
if to Licensor, addressed to:  
Attention: [\*\*\*]  
Address: 0X-0, Xx. 00, Xxxxxx X. Xx., Xxxxxxxx Xxxx., Xxxxxx Xxxx 000, Xxxxxx  
Email: [\*\*\*]  
with copy to: Tsar & Tsai Law Firm  
Address: 00X., Xx. 000, Xxxxxxx Xx., XxxxxXxxx., Xxxxxx Xxxx 00000, Xxxxxx (R.O.C.)  
44  
Attention: Xxxx Xxx  
Email: [\*\*\*]  
(b)  
if to Licensee, addressed to:  
Attention: [\*\*\*]  
Address: 000 Xxxxxxx Xxx., Xxxxx 0000, Xxx Xxxx, XX 00000  
Email: [\*\*\*]  
With copy to: Xxxxxxxxx & Xxxxxxx LLP  
Address: The Xxx Xxxxxxxxxxxxx Xxxxx, Xxxxx 0000, Xxxxxx, XX 00000-0000  
Attention: Xxxxx Xxxxx  
Email:[\*\*\*]  
Or to such other address(es) as the Party to whom notice is to be given may have furnished to the other Party in writing in accordance herewith. Any such notice shall be deemed to have been given: (i) on the date of delivery if delivered in person, (ii) on the Business Day after dispatch if sent by nationally-recognized overnight courier, (iii) on the [\*\*\*] following the date of mailing, if sent by mail, or (iv) [\*\*\*] after the time sent (as recorded on the device from which the sender sent the email), unless the sender receives an automated message that the email has not been delivered.  
14.9  
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.  
14.10  
Counterparts. This Agreement may be executed in any number of counterparts, by original or electronic (including “pdf”) signature, each of which shall be deemed an original but all of which together shall constitute one and the same instrument.  
14.11  
Change of Control. Licensee may not undertake a Change of Control without the prior written consent of Licensor. Licensor shall have the right to request adjustment to terms and conditions under this Agreement including terms of Article 3 and Article 7 as a condition to give consent to the proposed Change of Control of Licensee. Licensee shall enter into good-faith negotiations with Licensor without undue delay on Licensor’s proposed adjustments upon Licensor’s request. In the  
45  
case of a permitted Change of Control, Licensee shall ensure continued performance of its obligations under this Agreement in accordance with its terms and conditions (as adjusted if requested by Licensor hereunder) by the applicable purchaser or surviving entity after the Change of Control.  
14.12  
Language. The language of this Agreement and all activities to be pursued under this Agreement is English. Any and all documents proffered by one Party to the other in fulfillment of any provision of this Agreement shall only be in compliance if in English. Any translation of this Agreement in another language shall be deemed for convenience only and shall never prevail over the original English version. This Agreement is established in the English language.  
14.13  
Third Parties. None of the provisions of this Agreement shall be for the benefit of or enforceable by any Third Party which shall be a Third Party beneficiary to this Agreement.  
14.14  
Subscription Agreement. As a condition to the issuance of the Common Stock pursuant to Article 3 hereof, Licensee and Licensor shall enter into the subscription agreement attached hereto as Exhibit A (the “Subscription Agreement”).  
14.15  
Entire Agreement. This Agreement, the Supply Agreement, Quality Agreement and Pharmacovigilance Agreement and the Subscription Agreement, together with their Schedules, sets forth the entire agreement and understanding of the Parties as to the subject matter hereof and supersedes all proposals, oral or written, and all other prior communications between the Parties with respect to such subject matter, including [\*\*\*]. In the event of any conflict between a substantive provision of this Agreement and any Schedule hereto, the substantive provisions of this Agreement will prevail.  
14.16  
Interpretation. The captions to the several Articles and Sections of this Agreement are not a part of this Agreement but are included for convenience of reference and shall not affect its meaning or interpretation. In this Agreement: (a) the word “including” shall be deemed to be followed by the phrase “without limitation” or like expression; (b) the word “or” means “and/or” unless the context dictates otherwise because the subject of the conjunction are mutually exclusive; (c) the words “herein,” “hereof” and “hereunder” and other words of similar import refer to this Agreement as a whole and not to any particular Article or Section or other subdivision; (d) references in this Agreement to “days” shall mean calendar days; (e) the singular shall include the plural and vice versa; and (f) masculine, feminine and neuter pronouns and expressions shall be interchangeable. Each accounting term used herein that is not specifically defined herein shall have the meaning given to it under GAAP consistently applied, but only to the extent consistent with its usage and the other definitions in this Agreement.  
14.17  
Costs. Except as is otherwise expressly set forth herein, each Party shall bear its own expenses in connection with the activities contemplated and performed hereunder.  
46  
[Signature Page Follows]  
47  
IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed as of the Effective Date.  
Formosa Pharmaceuticals Inc.  
By:  
/s/ Xxxxx Co  
Name:  
Xxxxx Xx  
Title:  
President and Chief Executive Officer  
Eyenovia, Inc.  
By:  
/s/ Xxxxxxx Xxxx  
Name:  
Xxxxxxx Xxxx  
Title:  
Chief Executive Officer  
SIGNATURE PAGE TO LICENSE AGREEMENT