UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934
Date of Report (Date of earliest event reported): November 6, 2022

OCUPHIRE PHARMA, INC.

(Exact name of Registrant as Specified in Its Charter)

Delaware	**001-34079**	**11-3516358**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)
37000 Grand River Avenue, Suite 120 **Farmington Hills, MI**		**48335**
(Address of Principal Executive Offices)		(Zip Code)

Registrant's Telephone Number, Including Area Code: **(248) 681-9815**
Not Applicable
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (*see* General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c)) Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, $0.0001 par value	**OCUP**	**The Nasdaq Stock Market LLC**

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

Emerging growth company ☐

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

Item 1.01. Entry into a Material Definitive Agreement

License Agreement

On November 6, 2022, Ocuphire Pharma, Inc. ("***Ocuphire***") entered into a License and Collaboration Agreement (the "***License Agreement***") with FamyGen Life Sciences, Inc. ("***Famy***"), pursuant to which Ocuphire granted Famy an exclusive, perpetual, sub-licensable license to develop, manufacture, import, export and commercialize (i) Nyxol for treating (a) reversal of mydriasis, (b) night vision disturbances or dim light vision, and (c) presbyopia, and (ii) Nyxol and low dose pilocarpine for treating presbyopia (together, the "***Products***") worldwide except for certain countries and jurisdictions in Asia (the "***Territory***"). Ocuphire retains the exclusive right to develop, manufacture, have manufactured, import, export and commercialize the Product outside of the Territory.

Under the terms of the License Agreement, Ocuphire will be responsible for developing the Products in the United States, and Famy will be responsible for developing the Products in countries and jurisdictions in the Territory outside of the United States. Famy will reimburse Ocuphire for budgeted costs related to the development of the Products through U.S. Food and Drug Administration ("***FDA***") approval. The parties have agreed to establish a joint steering committee, which will oversee and make decisions regarding the development of the Products. The committee shall be composed of an equal number of representatives of Famy and Ocuphire.

Famy has agreed to procure that Viatris Inc. or its affiliates will commercialize the Products in the Territory for each indication that receives regulatory approval.

Pursuant to the License Agreement, Famy will make to Ocuphire an upfront cash payment of $35 million. In addition, with respect to each Product, Ocuphire will be eligible to receive potential additional payments of up to $130 million in the aggregate upon achieving certain specified regulatory or net sales milestones, with the first potential payment of $10 million to be made following approval by the FDA of Nyxol for reversal of mydriasis. Ocuphire will also receive tiered royalties, starting at low double digit royalties up to low twenty percent royalties, based on the aggregate annual net sales of all Products in the United States, and will receive low double digit royalties based on all annual net sales in the Territory outside of the United States. The royalty payments will continue on a country-by-country basis from the date of the first commercial sale of the first Product in a country of the Territory until December 31, 2040.

Either party may terminate the License Agreement upon written notice in the case of the other party's material breach (subject to applicable cure periods) or if the other party becomes subject to an insolvency event. In addition, Ocuphire may terminate the agreement in its entirety if Famy, Viatris or their affiliates commence an action challenging the validity, enforceability or scope of any of Ocuphire's patents that are exclusively licensed to Famy. Additionally, if Famy determines not to pursue development or commercialization of a Product in a country or jurisdiction in the Territory, Famy may terminate the license with respect to such Product in such country or jurisdiction.

Each of Ocuphire and Famy has agreed to indemnify the other party against certain losses and expenses relating to any breach of the indemnifying party's obligations, representations, warranties or covenants under the License Agreement.

The foregoing description of the License Agreement is not complete and is qualified in its entirety by reference to the License Agreement, which is attached hereto as Exhibit 10.1 and incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

See the Exhibit Index below, which is incorporated by reference herein.

EXHIBIT INDEX

Exhibit Number	Description
10.1*	License and Collaboration Agreement dated as of November 6, 2022 by and between Ocuphire Pharma, Inc. and Famy
99.1	Press Release dated November 7, 2022 issued by Ocuphire
104	Cover Page Interactive Data File (embedded within Inline XBRL document).

* Certain schedules and exhibits have been omitted pursuant to Item 601(a)(5) of Regulation S-K. A copy of any omitted schedule and/or exhibit will be furnished to the SEC upon request. Certain portions of the License Agreement have been redacted pursuant to Item 601(b)(10)(iv) of Regulation S-K because the Company customarily and actually treats the redacted information as private or confidential and the omitted information is not material. A copy of the unredacted License Agreement will be furnished to the SEC upon request.

SIGNATURES

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

Ocuphire Pharma, Inc.

Date: November 7, 2022

By: /s/ Mina Sooch

Mina Sooch
Chief Executive Officer

Certain identified information has been excluded from the exhibit because it is both not material and is of the type that the Company treats as private or confidential. Double asterisks denote omissions.

THIS LICENSE AND COLLABORATION AGREEMENT (this "**Agreement**") is made on November 6, 2022 ("**Effective Date**"):

BETWEEN:

Ocuphire Pharma Inc., having its corporate offices at 37000 Grand River Avenue, Suite 120, Farmington Hills, Michigan, USA ("**Licensor**"); and

FamyGen Life Sciences, Inc having its offices at 701 S Carson STE 200, Carson City, NV 89701, USA and correspondence office at 550 Cochituate Road, East Wing, 4th Floor, Suite 25, Framingham, MA 01701, USA ("**Licensee**").

Each of Licensor and Licensee are referred to individually herein as a "**Party**" or collectively as "**Parties**". In this Agreement, capitalized terms have the meaning set forth in "Defined Terms".

WHEREAS

A. Licensor is a clinical-stage ophthalmic biopharmaceutical company focused on developing and commercializing therapies for the treatment of refractive and retinal eye disorders.

B. Licensee develops novel pharmaceutical drugs, new chemical entities, proprietary formulation products and complex generic products for the global markets and is also engaged in providing services relating to the development of pharmaceutical products.

C. Licensor has been developing and has conducted: (a) Phase I Clinical Trial and Phase II Clinical Trial of each Product; and (b) Phase III Clinical Trial for Product 1A and Product 1B, in each case, in a manner sufficient to be submitted in an NDA for Regulatory Approval in the United States of America in accordance with FDA guidance.

D. Licensor has agreed to grant to Licensee a License in respect of the Licensed Intellectual Property (*as defined below*) including for the purposes of Development (*as defined below*), Manufacturing (*as defined below*) and Commercialization (*as defined below*) of the Products in the Field (*as defined below*) for the Territory (*as defined below*), in accordance with the terms and conditions set forth in this Agreement.

NOW, **THEREFORE**, in consideration of the premises and the respective promises, conditions, terms, and agreements contained herein, and other good and valuable consideration, the receipt and adequacy of which are hereby acknowledged, the Parties do hereby agree as follows:

1. DEFINITIONS AND INTERPRETATION

1.1 Defined Terms

For purposes of this Agreement, including the foregoing recitals, unless specifically set forth to the contrary herein, the following terms, whether used in the singular or plural, shall have the respective meanings set forth below:

1.1.1 "**Accounting Standards**" means IFRS, as consistently applied by the applicable Party (including for the purposes of Commercialization, members of the Viatris Group) and its Affiliates, and any other internationally recognized accounting standards that may be adopted by such Party from time to time

1.1.2 "**Additional Royalty**" has the meaning ascribed to the term in Schedule 3.

1.1.3 "**Affiliate**" means, with respect to a Party, any Person that directly or indirectly controls, is controlled by, or is under common control with that Party. "control" for the purposes of this definition means: (a) direct or indirect ownership of more than fifty percent (50%) of the shares of stock entitled to vote for the election of directors, in the case of a corporation; (b) more than fifty percent (50%) of the equity interest in the case of any other type of legal entity or status as a general partner in any partnership; (c) any other arrangement whereby the entity or Person controls or has the right to control the board of directors or equivalent governing body of a corporation or other entity; (d) if a Party has rights to variable returns from its involvement with an entity or Person and has the ability to affect its returns and cause the direction of the management or policies of such entity or Person through its power over such entity or Person; or (e) the ability to cause the direction of the management or policies of a corporation or other entity. In the case of entities organized under the Laws of certain countries, the maximum percentage ownership permitted by Law for a foreign investor may be less than fifty percent (50%), and in such case such lower percentage shall be substituted in the preceding sentence, *provided that* such foreign investor has the power to direct the management and policies of such entity.

1.1.4 "**Aggregate Amount**" has the meaning ascribed to the term in Section 4.2.1.

1.1.5 "**Agreement**" has the meaning ascribed to the term in the Preamble.

1.1.6 "**Auditor**" has the meaning ascribed to the term in Section 5.7.6(b).

1.1.7 "**Authorized Generic**" means, with respect to a particular Product being sold in a particular country, any authorized generic version of such Product. For clarity, an "Authorized Generic" is a Product only for the purposes of the provisions of Section 2 and calculating Sales Milestones, Royalties and Royalty Payments in Schedule 3.

1.1.8 "**Business Day**" means any day other than: (a) a Saturday or a Sunday; and (b) a bank or other public holiday in New York, US or Mumbai, India.

1.1.9 "**Calendar Quarter**" means the respective periods of three (3) consecutive calendar months ending on March 31, June 30, September 30, and December 31.

1.1.10 "**Calendar Year**" means each successive period of twelve (12) months commencing on January 1 and ending on December 31, provided that, for the purposes of determining the budget for the first (1st) year, the Development Costs and any other cost / item usually accounted for in the budget / financials on the basis of the Calendar Year shall be reduced proportionately such that only the number of months remaining from the Effective Date till December 31 shall be used for such calculation.

1.1.11 "**Chemistry, Manufacturing and Controls**" and "**CMC**" are used interchangeably herein and mean any act(s) within Development that are directed to: (a) the pharmaceutical development and manufacture of Products and/or a Compound; and (b) the specifications and other parameters and controls that define or set forth: (i) a finished Compound or finished Product, (ii) consistent and controlled manufacturing process(es) for the Compound or Product(s) including storage conditions for raw materials, intermediates, current good manufacturing practices, intermediate(s), purity requirements, excipients, permitted impurities, packaging and labelling, and Product shelf-life, each as it relates to the Compound or any Product; as specified by the FDA or other applicable Regulatory Authority in the chemistry, manufacturing and controls section of an IND or NDA or any other Regulatory Submissions in the US, or the equivalent section of regulatory filings made outside of the US.

1.1.12 "**Clinical Trial(s)**" means Phase I Clinical Trial, Phase II Clinical Trial, Phase III Clinical Trial and/or post-Regulatory Approval clinical trial, as the context dictates.

1.1.13 "**Commercially Reasonable Efforts**" means, [**]

1.1.14 "**Commercialize**" means any and all activities undertaken before and after Regulatory Approval related to the commercialization of any Product, including pre-launch, launch and post-launch marketing, promoting, detailing, distributing (including as applicable, importing, exporting, transporting, customs clearance, warehousing, invoicing, handling and delivering Products to customers), selling or offering to sell any Product, including any and all Manufacturing activities, pharmacovigilance and scientific and medical affairs in support of the foregoing. "Commercialization" and "Commercializing" shall have a corresponding meaning.

1.1.15 "**Compound**" means phentolamine or a salt thereof (including phentolamine mesylate) and in any combination with Pilocarpine.

1.1.16 "**Control**" or "**Controlled**" means, with respect to any proprietary, trade secret or other data or information, the legal authority or right (whether by ownership, license or otherwise) of a Party or its Affiliates to grant a license or a sublicense of data to the other Party or its Affiliates or provide such data or other information to such other Party or its Affiliates without breaching the terms of any agreement with a Third Party, or misappropriating the proprietary or trade secret information of a Third Party or without giving rise to any financial or other obligation to any Third Party.

1.1.17 "**Develop**" or "**Development**" means, with respect to the Compound or any Product, all drug research and development activities, including, without limitation, test method development and stability testing, assay development and audit development, toxicology, formulation, pharmaceutical development, quality assurance/quality control development, statistical analysis, pre-clinical and other non-clinical testing, clinical studies, process development, packaging development, manufacturing scale-up, product validation activities, regulatory affairs, and the preparation, filing and prosecution of Regulatory Submissions with Regulatory Authority, including, without limitation, the FDA, in order to obtain the Regulatory Approval for any such Product, and "**Developing**" shall have its corresponding meaning.

1.1.18 "**Development Budget**" has the meaning ascribed to the term in Section 4.2.1.

1.1.19 "**Development Costs**" means, the reasonable Out-Of-Pocket Costs and Development FTE Costs incurred by Licensor or its Affiliates, or subcontractors after the Effective Date in the performance of Development activities and pre-commercialization activities that are directly attributable and reasonably allocable to the Development and/or pre-commercialization activities of a Compound or a Product, to the extent incurred in accordance with the Development Budget [**]

1.1.20 "**Development Data**" means all data (including raw data) and results generated under Development of the Product or Compound by the Licensor, including reports and related documentation set out in Section 5.7.

1.1.21 "**Development Excess Costs**" has the meaning ascribed to the term in Section [**]

1.1.22 "**Development FTE Costs**" means, as applicable with respect to any period, the aggregate of all FTE Contributions for such period.

1.1.23 "**Development Plan**" means the detailed plan for Development activities designed to obtain Regulatory Approval of each of the four (4) Products, as approved by the Steering Committee together with the detailed timeline and budget for such activities (as updated or amended in accordance with Section 5.5.1). An outline of the Development Plan which sets out and describes material Development activities required for obtaining the aforesaid Regulatory Approvals is attached hereto as Schedule 2.

1.1.24 "**Dollars**" or "**$**" means US dollars.

1.1.25 "**Effective Date**" has the meaning ascribed to the term in the Preamble.

1.1.26 "**EMA**" means European Medicines Evaluation Agency or any successor entity thereto.

1.1.27 "**Encumbrance**" means any mortgage, pledge, assessment, security interest, option, deed of trust, lease, lien, levy, license or other grant of rights, restriction on transferability, charge, or other encumbrance of any kind, whether voluntarily incurred by Licensor or arising by operation of Law applicable to Licensor (or any of its assets) or any conditional sale or title retention agreement or other agreement entered into by Licensor to give any of the foregoing in the future.

1.1.28 "**Excluded Territory**" means all countries and jurisdictions in Asia (except China and its territories of Hong Kong, Taiwan, and Macau, Japan, Thailand, Vietnam and India) and such other territories as may be classified as Excluded Territory in accordance with Section 11 (*Term and Termination*) of this Agreement. [**]

1.1.29 **"Excluded Territory Commercialization"** has the meaning ascribed to the term in Section 6.3.

1.1.30 **"Excluded Territory Development"** has the meaning ascribed to the term in Section 5.4.

1.1.31 "**Export Control Laws**" means all applicable U.S. laws and regulations relating to: (a) sanctions and embargoes imposed by the Office of Foreign Assets Control of the U.S. Department of Treasury, or (b) the export or re-export of commodities, technologies, or services, including the Export Administration Act of 1979, 24 U.S.C. §§ 2401-2420, the International Emergency Economic Powers Act, 50 U.S.C. §§ 1701-1706, the Trading with the Enemy Act, 50 U.S.C. §§ 1 et. seq., the Arms Export Control Act, 22 U.S.C. §§ 2778 and 2779, and the International Boycott Provisions of Section 999 of the U.S. Internal Revenue Code of 1986, in each case, as amended.

1.1.32 "**FCPA**" means the U.S. Foreign Corrupt Practices Act (15 U.S.C. Section 78dd-1, et. seq.), as amended.

1.1.33 "**FDA**" means the United States Food and Drug Administration or any successor entity thereto.

1.1.34 "**FDA Approval**" has the meaning ascribed to the term in Section 4.1.1(a).

1.1.35 "**FDA Submissions**" has the meaning ascribed to the term in Section 4.3.2.

1.1.36 "**Field(s)**" means the area of ophthalmology.

1.1.37 "**First Commercial Sale**" means, with respect to a Product in a country in the Territory, the first sale or commercial transfer or disposition in an arms-length transaction for value of such Product in such country to a Third Party by Licensee, its Affiliates or their sublicensees, after receipt of Regulatory Approval for such Product in such country.

1.1.38 "**Force Majeure**" means any unavoidable and unforeseeable event which is beyond the reasonable control of the Party affected, including but not limited to the following events: acts of God, earthquake, storm, flood, fire or other acts of nature, acts of aggression, civil disorders or commotions, war (whether or not declared), riot, public disturbance, non-performance due to policies of a Governmental Authority, a national emergency or appropriations of property, strike or lockouts, government actions, terrorist attack or the like and epidemic, provided that the COVID-19 pandemic and/or any measures taken by any Governmental Authority in connection with such pandemic shall in no case qualify as Force Majeure event.

1.1.39 "**FTE Contribution**" means [**] multiplied by [**]

1.1.40 "**GCP**" means the current Good Clinical Practices officially published by EMA, FDA, and the International Council for Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) that may be in effect from time to time, and further including analogous set of regulations, guidelines or standards as defined, from time-to-time, that are applicable to the Compound and Product.

1.1.41 "**Generic Competition**" means, when on a country or other jurisdiction and Product basis, volume of unit sales of a Generic Product(s) sold in such country or other jurisdiction by one (1) or more Third Party(ies) in a Calendar Quarter is at least [**] of the aggregate volume of unit sales of such Product sold by the Licensee or its Affiliates or sublicensees. Unless otherwise agreed by the Parties, the sales of each Generic Product sold during a Calendar Quarter shall be as reported by IQVIA, Inc. or any successor to IQVIA, Inc. or any other independent sales auditing firm reasonably agreed upon by the Parties.

1.1.42 **"Generic Product(s)"** means, with respect to a Product that has received Regulatory Approval granted by a Governmental Authority in a country in the Territory, a pharmaceutical product which contains any phentolamine salt which is highly similar, or similar enough to the one contained in a reference Product, notwithstanding minor differences in clinically inactive components, to permit an applicant for Governmental Authority to refer to and rely on clinical and other scientific information regarding the safety, purity, potency and/or efficacy of the reference Product in order to allow such pharmaceutical product to receive Regulatory Approval in any jurisdiction within the Territory through an abbreviated, expedited, or other similar regulatory pathway, that is marketed for sale in such country by a Third Party other than pursuant to any rights granted by Licensee or their Affiliates.

1.1.43 "**GLP**" means the current Good Laboratory Practices officially published by the EMA and / or FDA, as may be in effect or amended from time to time, and further including analogous set of regulations, guidelines or standards as defined, from time-to-time, by any relevant Governmental Authority, that are applicable to the Development, use, Manufacture and/or Commercialization of the Compound or Product.

1.1.44 "**GMP**" means the current Good Manufacturing Practices officially published by the EMA, FDA, or ICH, as may be amended from time to time, and further including an analogous set of regulations, guidelines or standards as defined, from time-to-time, by any relevant Governmental Authority, that are applicable to the Development, use, Manufacture and/or Commercialization of the Compound or Product.

1.1.45 "**Governmental Authority**" means any court, agency, authority, department, legislative or regulatory body or other instrumentality of any government, country, or national, federal, state, provincial, regional, county, city, ethical committee, or other political subdivision of any such government or country, a supra- national organization of which any such government or country is a member, or quasi-governmental authority or self-regulatory organization of competent authority.

1.1.46 "**HIPAA**" means the Health Insurance Portability and Accountability Act of 1996 as it may be amended from time to time, and any regulations issued thereunder.

1.1.47 **"IFRS"** means the International Financial Reporting Standards as adopted by the United Kingdom, applied on a consistent basis.

1.1.48 "**IND**" means an Investigational New Drug Application to the FDA as required under 21 CFR §312 or an equivalent application required in a foreign jurisdiction.

1.1.49 "**Indemnity Claim**" means any and all Third Party demands, claims, actions, proceedings, and liability (whether criminal or civil, in contract, tort or otherwise) for losses, damages, costs, (including reasonable attorneys' fees and expenses) and other expenses of any nature whatsoever.

1.1.50 "**Indemnified Party**" has the meaning ascribed to the term in Section 10.4.1.

1.1.51 "**Indemnifying Party**" has the meaning ascribed to the term in Section 10.4.1.

1.1.52 "**Information**" means all proprietary information and data of a financial, commercial, clinical or technical nature, including Know-How, owned or Controlled by a Party, which has been supplied or otherwise made available to the other Party or its Affiliates, under this Agreement and whether made available orally (if and to the extent a written summary of such oral information is made available within thirty (30) days after the oral information is made available), in writing or in electronic form, including information comprising of or relating to concepts, discoveries, inventions, (whether or not patentable), data, designs or formulae.

1.1.53 "**Infringement**" has the meaning ascribed to the term in Section 8.5.1.

1.1.54 "**Insolvency Event**" means, in relation to a Party, any one of the following: (a) such Party is the subject of voluntary or involuntary bankruptcy proceedings instituted on behalf of or against such Party (except for involuntary bankruptcy proceedings which are dismissed within sixty (60) days); (b) an administrative receiver, receiver and manager, interim receiver, custodian, sequestrator or similar officer is appointed for substantially all of the assets of such Party; (c) a resolution to wind up such Party shall have been passed, other than a resolution for the solvent reconstruction or reorganization of such Party; or (d) a resolution shall have been passed by such Party's board of directors to make an application for an administration order or to appoint an administrator for substantially all of the assets of such Party.

1.1.55 "**Intellectual Property**" means all rights in Patents, rights to inventions, copyrights and related rights, rights in trademarks, trade names, trade dress, and domain names, rights in designs, rights in computer software, database rights, rights in Information, Know-How and any other intellectual property rights, in each case whether registered or unregistered and whether arising under statute or common law, including all applications (or rights to apply) for, and renewals or extensions (for their full term) of, such rights and all similar or equivalent rights or forms of protection which subsist now or will subsist at any time during the Term in any part of the world.

1.1.56 "**Key Issue**" has the meaning ascribed to the term in Section 4.4.1.

1.1.57 "**Know-How**" means all existing and available technical information, know-how and data, including inventions (whether patentable or not), discoveries, trade secrets, package specifications, chemical specifications, analytical test methods, stability data, testing data, product specifications, instructions, processes, formulation information, validation documents, materials (including all biological and chemical materials), drawings, formulae, reports, and other technology and techniques including all biological, chemical, pharmacological, toxicological, pharmaceutical, physical and analytical, clinical safety, safety data, preclinical and clinical data, and expertise and other technology applicable to compounds, molecules, cell lines, formulations, compositions, products or to their manufacture, development, registration, use or commercialization or methods of assaying or testing them or process for their manufacture, formulations containing them, compositions incorporating or com- prising them, expertise and information, regulatory filings and copies thereof, relevant to the development, manufacture, use or commercialization of and/or which may be useful in studying, testing, development, production or formulation of products, or intermediates for the synthesis thereof.

1.1.58 "**Law**" means any statute, law, regulation, rule, code, order, ordinance, judgment, or requirement of a Governmental Authority, including for clarity GCP, GLP and GMP.

1.1.59 "**Legal Proceeding**" means any notice, action, suit, litigation, arbitration, proceeding (including any civil, criminal, administrative, investigative or appellate proceeding), hearing, inquiry, audit, examination or investigation commenced, brought, conducted or heard by or before, or otherwise involving, any court or other Governmental Authority or any arbitrator or arbitration panel.

1.1.60 "**License**" has the meaning ascribed to the term in Section 2.1.

1.1.61 "**Licensee Improvements**" has the meaning ascribed to the term in Section 8.2.1.

1.1.62 "**Licensor Improvements**" has the meaning ascribed to the term in Section 8.3.1.

1.1.63 "**Licensed Intellectual Property**" means the Licensed Patents, Licensed Know-How, and Licensed Marks.

1.1.64 "**Licensed Know-How**" means all Know-How relating to the Compound and/or the Product(s) (including Know-How used or relevant for the Development, Manufacturing and/or Commercialization thereof in the Field) owned, created and/or Controlled by Licensor prior to or as of the Effective Date or at any time during the Term, including the Product-Related Document and Data, and Know-How identified in Schedule 1.

1.1.65 "**Licensee Terminated Product(s) in Terminated Country(ies)**" has the meaning ascribed to the term in Section 11.3.2.

1.1.66 "**Licensed Marks**" means the 'Marks' that are identified in Schedule 1.

1.1.67 "**Licensed Patents**" means any and all Patents that are owned, created or Controlled by Licensor or any of its Affiliates prior to or as of the Effective Date or at any time during the Term, that: (a) claim a Product and/or the Compound, or a process used in the manufacture of a Product and/or Compound; or (b) are necessary or useful for the Development, Manufacture and/or Commercialization of the Product, including the Patents set out in Schedule 1.

1.1.68 "**Licensee**" has the meaning ascribed to the term in the Preamble.

1.1.69 "**Licensee Indemnitees**" has the meaning ascribed to the term in Section 10.1.1.

1.1.70 "**Licensor**" has the meaning ascribed to the term in the Preamble.

1.1.71 "**Licensor Indemnitees**" has the meaning ascribed to the term in Section 10.2.1.

1.1.72 **"Manufacture**" or "**Manufacturing**" means any and all activities directed to the manufacture, storage and handling of the Compound and/or Product, and the manufacture, processing, formulation, fill, finish, packaging, labelling, warehousing, quality control testing (including in-process, release and stability testing), supplying, shipping, and release thereof, including manufacturing process development, scale-up, yield and other improvements, and validation and other testing, as well as recordkeeping, data and database development, management, storage and retention activities relating to any of the foregoing in this definition.

1.1.73 "**Monthly Payments**" has the meaning ascribed to the term in Section [**]

1.1.74 "**NDA**" means an application submitted for Regulatory Approval to market any Product in any country, including a New Drug Application (as defined in 21 CFR § 314) submitted to the FDA, any successor or supplemental applications or procedures, and/or any supplements and amendments that may be filed with respect to the foregoing.

1.1.75 **"Net Sales"** means, with respect to a Product, the gross amounts invoiced by Licensee, its Affiliates, and permitted sublicensees for any Product to a Third Party in accordance with the Accounting Standards, less customary and documented deductions to the extent allocated to such Product (and consistently applied as set forth below), including:

[**]

1.1.76 "**Out-of-Pocket Costs**" means the actual amounts paid by a Party or its Affiliate to a Third Party for specific external activities conducted for the Compound or Products.

1.1.77 "**Party**" or "**Parties**" has the meaning ascribed to the term in the Preamble.

1.1.78 "**Patent**" means any and all: (a) granted patents; (b) pending patent applications, including all provisional applications, divisionals, continuations, substitutions, continuations-in-part and renewals, and all patents granted thereon; (c) patents-of-addition, re-examinations, reissues and extensions or restorations by existing or future extension or restoration mechanisms, including patent term adjustments, patent term extensions, supplementary protection certificates or the equivalent thereof; (d) inventor's certificates; and (e) other forms of government-issued rights substantially similar to any of the foregoing.

1.1.79 "**Patent Challenge**" has the meaning ascribed to the term in Section 11.2.1(c).

1.1.80 "**Person**" means any individual, partnership, limited liability company, firm, corporation, association, trust, unincorporated organization, or other entity.

1.1.81 "**Phase I Clinical Trial**" means a study of an investigational new or existing drug in humans for the purpose of preliminary determination of safety in healthy individuals or patients consistent with the meaning of U.S. 21 C.F.R. §312.21(a) or its foreign equivalents.

1.1.82 "**Phase II Clinical Trial**" means a study of an investigational new or existing drug in humans for thepurposes of preliminary determination of efficacy and/or preliminary establishment of appropriate dosage ranges for efficacy and safety in patients, consistent with the meaning of U.S. 21 C.F.R. §312.21(b) or its foreign equivalents.

1.1.83 "**Phase III Clinical Trial**" means a study of an investigational new or existing drug in humans for the demonstration of the efficacy and safety of a product, which is designed to demonstrate statistically whether such product is effective and safe for use in a particular indication in a manner sufficient to be submitted in an application for Regulatory Approval, consistent with the meaning of U.S. 21 C.F.R. §312.21(c) or its foreign equivalents.

1.1.84 "**Product(s)**" means:

(a) 0.75% phentolamine ophthalmic solution (or 1% phentolamine mesylate ophthalmic solution) used for treating: (a) reversal of mydriasis ("**Product 1A**"); (b) night vision disturbances or dim light vision ("**Product 1B**"); and (c) presbyopia ("**Product 1C**") (collectively "**Product 1**").

(b) 0.75% phentolamine ophthalmic solution (or 1% phentolamine mesylate ophthalmic solution) in combination with 0.4% Low Dose Pilocarpine ("**LDP**") ophthalmic solution ("**Product 2**") used for treating presbyopia.

1.1.85 "**Product Marks**" has the meaning ascribed to the term in Section 8.6.

1.1.86 "**Product-Related Document and Data**" means any and all information, documents, materials and results of any type related to the Compound or the Products which is held or in Control of Licensor, whether or not proprietary, including research, Development, pre-clinical data, pharmacology data, chemistry data (including analytical, product characterization, toxicology data), clinical data (including original patient report forms, investigator reports (both preliminary and final reports), clinical protocols, statistical analyses, expert opinions and reports, safety and other electronic databases), Manufacturing data (including analytical and quality control data and stability data, other chemistry and medical CMC data), correspondence to and from any Regulatory Authority, minutes from teleconferences with any Regulatory Authority, Regulatory Submissions and Regulatory Approvals, adverse drug reaction / experience files and complaint files, reports from contract research organizations, investigators' brochures.

1.1.87 "**Regulatory Approval**" means, with respect to any Product, any approval (notwithstanding the indication), registration, license, or authorization from a Regulatory Authority to market and sell such Product in the Field in one or more countries in the Territory.

1.1.88 "**Regulatory Authority**" means any national or supranational Governmental Authority, including the FDA in the US, the European Medicines Agency (and any successor entity thereto) in the EU, or any health regulatory authority in any country or other jurisdiction that is a counterpart to the foregoing agencies, in each case, that holds responsibility for the Development and Commercialization of, and the granting of marketing approval for, pharmaceutical products in such country or jurisdiction.

1.1.89 "**Regulatory Correspondence**" has the meaning ascribed to the term in Section 4.3.1.

1.1.90 **"Regulatory Milestone"** has the meaning ascribed to the term in Schedule 3.

1.1.91 "**Regulatory Submission**" means, with respect to any Product, any submission to a Regulatory Authority for any appropriate Regulatory Approval.

1.1.92 "**ROW**" has the meaning ascribed to the term in Section 5.1.

1.1.93 "**Royalty**" has the meaning ascribed to the term in Schedule 3.

1.1.94 "**Royalty Payments**" has the meaning ascribed to the term in Schedule 3.

1.1.95 "**Royalty Term**" has the meaning ascribed to the term in Schedule 3.

1.1.96 "**Sales Milestone**" has the meaning ascribed to the term in Schedule 3.

1.1.97 "**Secretary**" means a representative of the Licensee on the Steering Committee designated as the secretary of the Steering Committee by the Licensee.

1.1.98 "**Steering Committee**" means the committee incorporated in accordance with Section 5.5.1.

1.1.99 "**Term**" has the meaning ascribed to the term in Section 11.1.

1.1.100 "**Territory**" means worldwide, except for Excluded Territory.

1.1.101 "**Third Party**" means any Person other than a Party or an Affiliate of a Party.

1.1.102 "**Transition Plan**" has the meaning ascribed to the term in Section 4.5.1.

1.1.103 "**United States of America**", or "**US**" means United States, its territories, commonwealths, and possessions, including, but not limited to, the District of Columbia, Commonwealth of Puerto Rico, the U.S. Virgin Islands, the Marshall Islands and Guam.

1.1.104 "**US GAAP**" means US Generally Accepted Accounting Principles as consistently applied by the Licensor, and any other internationally recognized accounting standards that may be adopted by the Licensor from time to time.

1.1.105 "**Viatris Group**" means Viatris Inc. and any entity in which, or who has, directly or indirectly a right to: (a) exercise [**] or more of voting rights of or by Viatris, or (b) appoint more than [**] of the members of board of directors by, or in, Viatris, which includes its subsidiaries, Affiliates, or shareholders.

1.2 **Interpretation**

In this Agreement (unless the context otherwise requires):

1.2.1 "includes" and "including" shall mean respectively includes and including without limitation;

1.2.2 words denoting the singular shall include the plural and vice versa and words denoting any gender shall include all genders;

1.2.3 the Schedules and other attachments form part of the operative provision of this Agreement and references to this Agreement shall, unless the context otherwise requires, include references to the Schedules and attachments;

1.2.4 references to Sections are to Sections of this Agreement unless otherwise specified;

1.2.5 a reference to an enactment or statutory provision is a reference to it as it may from time to time be amended, modified, consolidated, repealed, or re-enacted and shall include any orders, regulations, instruments, or other subordinate legislation made under the relevant statute;

1.2.6 the headings in this Agreement are for information only and shall not be considered in the interpretation of this Agreement;

1.2.7 the expression "agreed form" in relation to any document shall mean the document in such form and substance as agreed between Licensee and Licensor, and initialled for the purpose of identification, by each of them;

1.2.8 any reference to "writing" or "written" includes faxes and any legible reproduction of words delivered in permanent and tangible form (but does not include email);

1.2.9 the words "hereof", "herein" and "hereunder" and words of like import used in this Agreement shall refer to this Agreement as a whole and not to any particular provision of this Agreement;

1.2.10 the word "or" includes "and/or"; and

1.2.11 the Parties agree that the terms and conditions of this Agreement are the result of negotiations between the Parties and that this Agreement shall not be construed in favour of or against any Party by reason of the extent to which any Party participated in its preparation.

1.3 The Parties acknowledge and agree that the terms of this Agreement and their respective rights and obligations under this Agreement shall come into force on the Effective Date.

2. GRANT OF LICENSE

2.1 **License**. Subject to the terms and conditions of this Agreement, Licensor hereby grants to Licensee:

2.1.1 an exclusive (even as to Licensor, except for limited rights retained by Licensor under Section 2.2), perpetual, sub-licensable (subject to the terms of Section 2.3), license to use the Licensed Intellectual Property to Develop the Compound and/or the Products in the Field and in the Territory; and

2.1.2 an exclusive (even as to Licensor), perpetual, sub-licensable (subject to the terms of Section 2.3), license to use the Licensed Intellectual Property to Manufacture, have Manufactured, import, export and Commercialize the Compound and/or the Products in the Field and in the Territory in each case subject to the termination rights in Section 11 (*Term and Termination*) of this Agreement

(collectively the "**License"**).

2.2 **Retained Rights**.

2.2.1 To the extent of the Territory, Licensor retains a limited, non-exclusive right for itself and its Affiliates under the Licensed Intellectual Property solely to conduct the Development of the Products and/or the Compound on behalf of Licensee in the Territory and in compliance with the terms of this Agreement.

2.2.2 Licensor retains the exclusive right to Develop, Manufacture, have Manufactured, import, export and Commercialize the Product in the Excluded Territory.

2.3 **Sublicense**. The Licensee may sub-license its rights under the License, in whole or part [**]

2.3.1 Each sublicense entered into by Licensee shall refer to this Agreement and, except to the extent the Parties otherwise agree in writing, any such sublicense must be consistent in all material respects with the applicable terms and conditions of this Agreement. Licensee shall secure all appropriate covenants, obligations and rights from any such sublicensee, including, but not limited to, protection of intellectual property rights and confidentiality obligations, to ensure that such sublicensee is subject to, and Licensee can comply with, all of Licensee's covenants and obligations to the Licensor under this Agreement. Without limiting the generality of the foregoing, Licensee shall not grant any sublicensee under this Agreement rights outside the Field or Territory. Licensee shall not be relieved of its obligations under this Agreement as a result of granting any sublicense for any of its activities except to the extent such obligations are satisfactorily performed by the applicable sublicensee in a manner consistent with Licensee's obligations under this Agreement. In the case of breach of any of Licensee's material obligations hereunder by any sublicensee, Licensor may elect to require Licensee to enforce its agreement against such sublicensee and/or Licensor may give written notice of material breach.

3. KNOW-HOW TRANSFER

3.1 Within [**] from the payment of the Upfront Payment as set out in Section 1(a) of Schedule 3, Licensor shall deliver and transfer to Licensee a data package containing [**]. To the extent that the Licensed Intellectual Property is not fully embodied in the delivered documents and electronic records, Licensor shall disclose the same to Licensee and its employees and designated representatives, orally, including by training and by demonstration by Licensor's employees and experts, at no additional cost to Licensee.

3.2 Licensor shall introduce Licensee to all external consultants (including consultants providing regulatory, clinical, CMC and/or intellectual property related services) that Licensor had previously contracted for the Development, Manufacture and/or Commercialization of the Products.

4. DEVELOPMENT

4.1 **Licensor Conduct of Development**

4.1.1 Licensor shall:

(a) use [**] to undertake the Development of the Products in the US to obtain Regulatory Approval from the FDA for each of the Products (**"FDA Approval**").

(b) use [**] to ensure all such Development is performed in accordance with this Agreement, the Development Plan (including the timelines and budgets indicated therein), and directions of the Steering Committee.

(c) ensure all Development is performed in accordance with applicable Law (including by complying with GLP, GMP, GCP and obtaining relevant Regulatory Approvals) and in a good scientific manner.

(d) act as the sponsor of the study(ies) in relation to the Development under the existing INDs for the Compound and Products obtained by Licensor in its name. Except as outlined in this Agreement, Licensor shall be responsible for all operational aspects of such studies pursuant to Development.

4.1.2 Licensee shall have the right to participate in any development meetings (in person or virtual) or events held by the Licensor in connection with the Development of the Products that the Licensee becomes aware of (including consequent to any discussions in the Steering Committee) and if so requested by the Licensee, the Licensor shall invite representative(s) of the Licensee to such development meetings or events.

4.2 **Development Costs**

4.2.1 Licensor shall undertake and complete all Development, for and up to FDA Approval for each of the four (4) Products, in accordance with Section 4.1, within the timelines and line item based budget set out in the Development Plan (the "**Development Budget**"), which Licensor agrees and acknowledges can reasonably be completed in aggregate for no more than [**] ("**Aggregate Amount**").

4.2.2 Payments. Within [**] from the completion of each [**] Licensor shall issue to the Licensee an invoice reflecting and enclosing Third Party invoices actually received and paid in such [**] (which invoices may be for Development prior [**] but in no event related to periods prior to the Effective Date), along with details of all Development FTE Costs for such [**]. Within [**] from receipt of such invoice, Licensee shall pay Licensor the amount set forth in the invoice [**]

4.2.3 [**]

4.2.4 **Overruns.** [**]

4.2.5 [**]

4.2.6 [**]

4.3 **Regulatory Matters**

4.3.1 Up to completion of the Clinical Trials Licensor shall have the responsibility for preparing and submitting all filings and correspondence ("**Regulatory Correspondence**") with Regulatory Authorities up to the successful completion of Clinical Trials.

4.3.2 Applying for FDA Approval and post application. Subject to the terms of this Agreement, Licensor shall have the responsibility for preparing all submissions and correspondence post the completion of the Clinical Trials as set out in Section 4.3.1, for obtaining the FDA Approvals (collectively, " **FDA Submissions**"). All such FDA Submissions will be presented before the Steering Committee on a regular basis, and material FDA Submissions (including Type A, Type B, and Type C meetings with the FDA and all NDA submissions, except for the NDA submission for Product 1A (if such NDA submission is filed within 30 (thirty) days of the Effective Date, failing which, approval of the Licensee designee would be sought prior to such NDA submission) will require approval of a designee of the Licensee prior to submission.

4.3.3 A designee of Licensee shall collaborate with Licensor for all FDA Submissions and Regulatory Correspondence. A designee of the Licensee shall be involved in all weekly progress meetings relating to the Development of the Product(s) (including regulatory discussions).

4.3.4 Any and all FDA Approval shall be filed for with the Licensor as the named applicant. Following transfer of any FDA Approval, Licensee shall maintain the FDA Approvals with the assistance, as may be required by the Licensee from the Licensor from time to time. [**] Each Party shall promptly submit any and all notices and authorizations to the Regulatory Authorities that are necessary to affect the transfer and acceptance of such NDA submission, FDA Submissions and the FDA Approval.

4.3.5 All communications by the Licensor with the FDA in relation to the Product or the Compound shallbe presented before the Steering Committee on a regular basis. Licensee shall have representative(s) attend any meetings / interactions that Licensor has with the FDA in relation to the Product or Compound.

4.3.6 If any Regulatory Authority conducts, or gives notice to Licensor of its intent to conduct an inspection or audit at any investigational site or any Licensor office or facility or to take any other regulatory action, or otherwise makes an inquiry, in each case with respect to or involving the Development activities or any clinical trial related thereto, Licensor shall, unless prohibited from doing so by applicable Law, notify Licensee within three (3) Business Days after Licensor first learns of such governmental inspection or audit and notify Licensee in advance of any proposed plan of action for responding to or complying with any associated demand or request of such Regulatory Authority. To the extent permitted under applicable Law, Licensor shall provide Licensee with the opportunity: (a) to have a representative present at any regulatory inspection or audit, and (b) to review in advance and comment on any communications or submissions proposed to be made by the Licensor to any Regulatory Authority in relation to any inquiry, inspection, or audit.

4.4 **Key Issues**

4.4.1 In the event, during Development in relation to any of the Products, the Licensor becomes aware of any reason to believe [**] the Licensor shall report such event (a, "**Key Issue**") promptly to the Steering Committee [**]

4.5 **Transition**

4.5.1 The Steering Committee in its sole discretion may decide to transition any Development (including any ongoing trials) from Licensor (including its sub-contractors) to Licensee or other Third Party identified by the Steering Committee. The Steering Committee would put together a reasonable plan to factor in such transition, with such transition to be completed within 90 days ("**Transition Plan**"). For avoidance of doubt, the obligations of Licensee to make payments in accordance with Schedule 3 are separate from Development and shall subsist notwithstanding any transition under this Section 4.5.

4.5.2 Licensor will make available and transfer to Licensee or Third Party identified by the Steering Committee, with reimbursement by Licensee of reasonable costs incurred, originals or copies of currently available records, data and documentation which exist and are Controlled by Licensor its sub-contractors or their respective Affiliates and are necessary for Licensee or Third Party to continue Developing the applicable Product and ensure that Licensee obtains the benefits of any or all Third Party agreements and with respect to any activities that involve human clinical trials, transfer control to Licensee or its designee of such clinical trials. Licensor will give effect to the assignment or other transfer by Licensor, its sub-contractors, or its Affiliate, to Licensee or the Third Party identified by the Steering Committee of all existing documentation filed by Licensor with the FDA.

4.5.3 After Licensee assumes any Development activities, Licensee shall no longer have any obligation to pay Licensor any Development Costs in respect of such Products after the date of such assumption. Each Party shall perform the transition activities specified for each Party in the Transition Plan and to otherwise reasonably cooperate with Licensee to enable the continued, efficient, uninterrupted Development of the applicable Product.

5. LICENSEE DEVELOPMENT AND GOVERNANCE

5.1 **Licensee Development and Regulatory Obligations.** Subject to Licensor successfully completing Development of a Product and successfully obtaining Regulatory Approval for such Product, Licensee shall use [**] to undertake the Development of such Product in the Territory outside of the US (the "**ROW**") to obtain and maintain Regulatory Approval from the applicable Governmental Authority, doing so at the sole cost and expense of Licensee. Without limiting the generality of the foregoing, Licensee shall use [**] to begin development of a Product within [**] years after Regulatory Approval of a Product is received in the United States.

5.2 **Sub-Contracting**

5.2.1 Permitted Licensee Subcontracting. Licensee may engage one or more Third Parties as contract service providers to perform its obligations under this Agreement for or on behalf of Licensee without the prior consent of Licensor.

5.2.2 Permitted Licensor Subcontracting. Licensor may engage one or more Third Parties as contract service providers to perform its obligations under this Agreement for or on behalf of Licensor without the prior consent of Licensee, provided that, prior to engaging any sub-contractor for any material Development activity (CROs or CMOs) (other than any such sub-contractor engaged as of the Effective Date), Licensor shall seek approval for such sub-contracting from the Steering Committee.

5.3 **Compliance.** Each of Licensee and Licensor shall, and cause its Affiliates to, cause its sub-contractors to, comply with all requirements under this Agreement and under applicable Law in carrying out their respective duties and obligations under this Agreement. Any act or omission by such sub-contractors which if carried out by the Licensee or Licensor, as applicable, would be a material breach of this Agreement shall be deemed a material breach of this Agreement by Licensee or Licensor, as applicable.

5.4 **Development in the Excluded Territory.** Licensor may conduct Development of the Compounds and to use the Compounds for Regulatory Approval of the Products and/or other products in the Excluded Territory ("**Excluded Territory Development**"); provided that all Excluded Territory Development is conducted in compliance with applicable Law and that such Development does not have an adverse impact on Development activities, Regulatory Submissions and Regulatory Approvals for the Compound and/or Products in the Territory. Licensor shall promptly inform the Licensee upon becoming aware of any breach of applicable Law by the Licensor (or its Affiliates or sub-contractors) in the course of the Excluded Territory Development or upon occurrence of any event that is likely to have a risk of an adverse impact on Development activities, Regulatory Submissions and Regulatory Approvals for the Compound and/or Products in the Territory. If the Licensee determines, in its reasonable sole discretion [**] then the Parties shall engage in good faith productive discussion intended to determine an alternative course of development that would not give rise to such adverse risks, or sufficient to mitigate against any such adverse risk, if any. Provided that in the event Parties are unable to reach a consensus on a sufficient method to mitigate the adverse risk within [**] of commencing such discussions, then at the direction of the Licensee (acting in good faith and reasonably), the Licensor shall cease such Excluded Territory Development.

5.5 **Steering Committee Formation, Role, and Decision Making**

5.5.1 Within [**] from the Effective Date, the Parties shall establish a committee formed by equal members of both Parties (of at least three (3) members from each Party) which shall oversee and make decisions with respect to Licensor's Development of the Products, including in respect to discussing and agreeing on all updates and amendments to the Development Plan, including the timeline and budget included therein (the "**Steering Committee**"). From time to time, each Party may substitute one or more of its representatives on the Steering Committee with written notice to the other Party.

5.5.2 The Secretary of the Steering Committee shall call a meeting [**] The Secretary of the Steering Committee shall create the agenda items for each meeting, with each Party having the right to make proposals for agenda items and provide appropriate information with respect to such proposed items prior to the Steering Committee meeting. The Secretary shall prepare and circulate the minutes of each meeting of the Steering Committee and shall use efforts to complete this within [**] after such Steering Committee meeting. Representatives of the Parties on the Steering Committee may attend a meeting either in person or by telephone or tele video conference, or similar means in which each participant can hear what is said by and be heard by, the other participants. Representation by proxy shall be allowed. Each Party shall have a single vote irrespective of the number of representatives of such Party in attendance.

5.5.3 A quorum of the Steering Committee shall exist whenever there is present at a meeting at least one representative appointed by each Party. Each Party shall make reasonable efforts to procure that their representatives are present for all meetings of the Steering Committee.

5.5.4 In the event of any dispute or disagreement in relation to any oversight to be provided, or decisions to be made, by the Steering Committee, the senior executives of each Party shall attempt to resolve any such dispute within [**] of submission from the Steering Committee. If the senior executives cannot resolve such dispute within such [**] period, then, Licensee shall have the right to make the final decision on all matters.

5.6 Upon receipt of FDA Approval for all Products, or the Licensor ceasing to Develop in terms of this Agreement, or termination of this Agreement, the Steering Committee shall be dissolved, and its activities and authority shall be automatically terminated.

5.7 **Reporting; Records; Audits**.

5.7.1 Reporting.

(a) At each regularly scheduled Steering Committee meeting, Licensor shall provide Licensee with a written report summarizing the significant Development activities conducted (either itself or through its Affiliates and sub-contractors) with respect to the Products and the safety and efficacy results generated from such activities, if any, since the last Steering Committee meeting. Such reports must be at a level of detail requested by the Steering Committee and sufficient to enable the Steering Committee to determine Licensor's Development progress and compliance with its obligations under Section 4.1.

(b) Licensor shall promptly provide Licensee with: (i) copies of all written or electronic communications received by it or its Affiliates or any sub-contractor from, or forwarded by it or its Affiliates to, any Regulatory Authority related to the Compound or the Products (including, the Development activities and related clinical trials), including copies of all minutes and summaries of all meetings and discussions scheduled with any Regulatory Authority concerning the Development activities (and related clinical trials); (ii) written notice of all meetings and discussions scheduled with any Regulatory Authority concerning the Development activities (and related clinical trials) in sufficient time to give Licensee a reasonable opportunity to attend such meetings and discussions; and (iii) responses to Licensee or Steering Committee's questions or requests for additional information relating to such Development activities.

(c) Licensee shall promptly provide Licensor with copies of all written or electronic communications sent or received in relation to the Licensed Patents and otherwise inform Licensor in writing of all major developments in relation to the Licensed Patents and any external reports relating to the Product.

5.7.2 Development Data. Licensor shall provide to Licensee copies of all Development Data in electronic form or other mutually agreeable alternate form as and when such Development Data arises. Licensor shall ensure that study investigators conducting Development obtain all patient authorizations and consents required under HIPAA, the EU Data Protection Directive, or any other similar applicable Law in connection with such Development to permit such sharing of Development Data with Licensee and exploitation of such Development Data for any and all uses under this Agreement.

5.7.3 Records. Licensor shall maintain, in good scientific manner, complete and accurate books and records pertaining to the Development activities, in sufficient detail to verify compliance with its obligations under this Agreement and which shall be appropriate for patent and/or regulatory purposes, in compliance with applicable Law and properly reflect all work done and results achieved in the performance of the Development activities, which books and records shall record only the Development activities and shall not include or be commingled with records of activities outside the scope of this Agreement. Such books and records shall be retained by Licensor for at least three (3) years after the expiration or termination of this Agreement or for such longer period as may be required by applicable Law.

5.7.4 Licensee Audits. No more than once per Calendar Year, Licensor shall permit Licensee to physically inspect the Licensor's premises or audit the facilities, systems and equipment at or through which the Development activities are conducted (including Third Party facilities), and personnel, procedures, programming, and records used in the performance of such Development activities, upon not less than ten (10) Business Days' prior written notice; provided, that any Licensee auditor is bound by written obligations to maintain the secrecy of Licensor's confidential information or Third Party confidential information if such audit is conducted at Third Party facilities. Any audit permitted under this Section 5.7.4 shall be: (a) conducted during normal business hours; and (b) restricted to such facilities, systems, equipment, to verify that the Development activities are being conducted in accordance with the terms of this Agreement, that the facilities are adequate for such Development activities and that Licensor has otherwise complied with its obligations hereunder. Licensor shall, and shall cause its employees, sub-contractors and agents to, cooperate with any reasonable requests of Licensee under this Section 5.7.4.

5.7.5 Financial Records. Each Party shall, and shall cause its Affiliates and permitted sublicensees to, keep complete and accurate financial books and records to the extent required to calculate and verify all amounts payable under this Agreement. Each Party shall, and shall cause its Affiliates and permitted sublicensees to, retain such books and records for a period of three (3) years following the earlier of the termination or expiration of this Agreement.

5.7.6 Financial Audit.

(a) Procedures. At the request of a Party, the other Party shall, and shall cause its Affiliates to, permit an independent auditor designated by the requesting Party, during normal business hours and upon at least fifteen (15) days' prior notice, to audit the books and records maintained pursuant to Section 5.7.5 to ensure the accuracy of all reports and payments made hereunder. The requesting Party shall ensure that the independent auditor execute a customary confidentiality agreement prior to such audit. Such examinations may not: (i) be conducted more than once in any twelve (12)-month period (unless a previous audit during such twelve (12)-month period revealed an underpayment (or with respect to any reimbursement, an overpayment) with respect to such period); or (ii) be repeated for any Calendar Quarter. Except as provided below, the cost of this audit shall be borne by the requesting Party, unless the audit reveals a variance of more than five percent (5%) from the reported amounts, in which case the other Party shall bear the cost of the audit. Unless disputed pursuant to Section 5.7.6(b), if such audit concludes that (X) additional amounts were owed by a Party, such Party shall pay the additional amounts, or (Y) excess payments were made by a Party, the other Party shall reimburse such excess payments, in either case ((X) or (Y)), within sixty (60) days after the date on which such audit is completed by the Party.

(b) Financial Audit Dispute. In the event of a dispute with respect to any audit under Section 5.7.6(a), Licensor and Licensee shall work in good faith to resolve the dispute. If the Parties are unable to reach a mutually acceptable resolution of any such dispute within thirty (30) days, the dispute shall be submitted for resolution to an independent accounting firm jointly selected by the Parties (the "**Auditor**"). The decision of the Auditor shall be final and the costs of such adjudication as well as the initial audit shall be borne between the Parties in such manner as the Auditor shall determine. Not later than ten (10) days after such decision and in accordance with such decision, the Party as directed by the Auditor shall pay the additional amounts, or reimburse the excess payments, as applicable.

5.7.7 Taxes. All payments under this Agreement would be made subject to withholding of taxes under applicable Law. Each Party agrees to reasonably assist the other Party in lawfully claiming exemptions from and/or minimizing such withholdings under double taxation Laws, treaties, or similar circumstances.

6. COMMERCIALIZATION AND COMMERCIAL MANUFACTURING

6.1 Subject to Licensor meeting its obligation for Development pursuant to Section 4 (*Development*) (i.e., each Product being submitted for FDA Approval) for each of the Products, Licensee shall procure that the Viatris Group shall:

6.1.1 (a) use [**] to Commercialize such Products in the US after receipt of the relevant Regulatory Approvals for such Products in the relevant Territory, and bear all commercial Manufacturing costs including compliance costs in relation to the foregoing; and (b) maintain FDA Approvals and bear all costs in relation to such approvals.

6.1.2 use [**] to: (a) Commercialize such Products in the ROW after receipt of the relevant Regulatory Approvals for such Products in the relevant Territory, and bear all commercial Manufacturing costs including compliance costs in relation to the foregoing; and (b) maintain Regulatory Approvals and bear all costs in relation to such approvals.

6.1.3 Without limiting the generality of the foregoing, Viatris shall [**] to launch the Products [**] after receiving applicable Regulatory Approval of a Product in any region. Thereafter, Viatris shall [**] in the ongoing support for the Product in each region in the Territory, unless such region becomes part of the Excluded Territory in accordance with Section [**].

6.2 **Commercialization**. [**] Notwithstanding anything contained in this Agreement, Viatris shall have full control and authority with respect to the day-to-day Commercialization of the Products and implementation of Commercialization.

6.3 Licensor may Manufacture and Commercialize the Compounds and/or Products or other products in the Excluded Territory (the "**Excluded Territory Commercialization**"); provided that all such Excluded Territory Commercialization activities are conducted in compliance with applicable Law and that such activities do not have a material impact on Licensee's Manufacturing and Commercialization of the Compound and/or Products in the Territory and Licensor shall promptly inform the Licensee upon becoming aware of any breach of applicable Law by the Licensor (or its Affiliates or sub-contractors) in the course of the Excluded Territory Commercialization or upon occurrence of an event that is reasonably likely to have a risk of an adverse impact on the Manufacturing and Commercialization of the Compound and/or Products in the Territory. If Licensee determines, in its reasonable sole discretion, that the Excluded Territory Commercialization is [**] the Parties shall engage in good faith productive discussion intended to determine an alternative course of commercialization that would not give rise to such adverse risks, or sufficiently mitigate against any such adverse risk, if any. Provided that in the event Parties are unable to reach a consensus on a sufficient method to mitigate the adverse risk within [**] of commencing such discussions, at the direction of the Licensee (acting in good faith and reasonably), the Licensor shall cease such Excluded Territory Development.

7. PAYMENT TERMS

In consideration for the rights and licenses granted to Licensee under this Agreement, Licensee shall pay to Licensor, as and when they become due, such payments provided for in Schedule 3.

8. INTELLECTUAL PROPERTY

8.1 **Background Intellectual Property**.

Other than as specifically provided under this Agreement, each Party shall retain all right, title, and interest in and to any Intellectual Property that is owned, licensed or sub-licensed by such Party prior to or independent of this Agreement.

8.2 **Licensee Intellectual Property**.

8.2.1 Licensee shall be the sole owner of any Intellectual Property, including Patents and Know-How, Development Data, discovered, developed, invented, conceived, or reduced to practice, solely, by or on behalf of Licensee in connection with this Agreement, including in respect of any improvements to the Licensed Intellectual Property arising from such activities, including the Development undertaken by Licensor in the Territory ("**Licensee Improvements**"). Licensor shall not at any time, claim ownership or attempt to acquire any rights in relation to any Licensee Improvements. All right, title and interest to such Licensee Improvements shall be, and hereby is, assigned to Licensee. Licensee hereby grants (and agrees to grant) to Licensor a non-exclusive, sublicensable license to the Licensee Improvements for the purpose of Licensor conducting Development of the Products and the Compound in the Territory in accordance with this Agreement and to Develop, Manufacture, have Manufactured, import, export and Commercialize the Compound and Product in the Excluded Territory.

8.2.2 As of the Effective Date, Licensee shall be solely entitled and responsible for the preparation, filing, prosecution and maintenance of all Licensee Improvements, and Licensor shall provide Licensee with all assistance as may be reasonably requested in relation to the same. Till such time as the Licensor is carrying out Development under this Agreement, Licensor shall propose outside patent counsel to conduct the preparation, filing, prosecution and maintenance of each of the Licensor Improvements, subject to Licensee's consent, not to be unreasonably withheld. All costs and expenses incurred by it relating to such filing, prosecution, and maintenance in the United States, including outside patent counsel fees and internal costs incurred in connection therewith shall be treated as a part of the Development Cost. Licensee shall keep Licensor informed of all material developments and communications with the applicable patent authorities in the Territory in relation to Patents to Licensee Improvements.

8.2.3 As reasonably requested by Licensee in writing, Licensor will cooperate, in assisting and facilitating Licensee's efforts to prosecute, revive and maintain the Patents to Licensee Improvements pursuant to Section 8.2.2.

8.3 **Licensor Intellectual Property.**

8.3.1 Licensor shall be the sole owner of any Intellectual Property, including Patents and Know-How, discovered, developed, invented, conceived, or reduced to practice solely by or on behalf of the Licensor (other than the activities undertaken pursuant to this Agreement) in connection with its activities in and which arise or get created after the Effective Date ("**Licensor Improvements**"). Any Licensor Improvement will automatically be treated as "Licensed Intellectual Property" hereunder for all purposes.

8.3.2 Licensor shall have the first right, but not the obligation, for the filing, prosecution and maintenance of all Licensor Improvements. Licensor shall be responsible for all costs and expenses incurred by it relating to such filing, prosecution, and maintenance, including outside patent counsel fees and internal costs incurred in connection therewith. At Licensee's written request, Licensor shall keep Licensee informed of all material developments and communications with the applicable patent authorities in the Excluded Territory in relation to Patents to Licensor Improvements. Licensor will give reasonable notice to Licensee, but in any event at least ninety (90) days advance written notice, before deciding to abandon the prosecution, maintenance or defence of any Licensor Improvement in the Excluded Territory, and Licensee shall, upon receipt of such notice, be entitled to assume and thereafter direct such prosecution and maintenance at Licensee's sole cost and expense. Upon provision of written notice by Licensee to Licensor of its desire to assume control of such activities, the Licensor shall, and shall cause any patent counsel engaged by Licensor to, promptly transfer all relevant documents and records, and provide all such other reasonably necessary support to Licensee in order to promptly and fully transfer such activities to Licensee.

8.4 Prosecution of Licensed Patents.

8.4.1 As long as the Licensor continues to undertake Development for and on behalf of the Licensee under this Agreement, the Licensor shall have the first right, but not the obligation, for the filing, prosecution and maintenance of all Licensed Patents. All costs and expenses incurred by it relating to such filing, prosecution, and maintenance, including outside patent counsel fees and internal costs incurred in connection therewith shall be treated as a part of the Development Cost. At Licensee's written request, Licensor shall keep Licensee informed of all material steps to be taken in the preparation and prosecution of all Licensed Patents in the Territory and shall furnish and provide Licensee with copies of correspondence to and from patent offices, and, to the extent reasonably practicable, permit Licensee an opportunity to offer its comments thereon before making a submission to a patent office and Licensor shall consider in good faith Licensee's comments. Licensor will give reasonable notice to Licensee, but in any event at least ninety (90) days advance written notice, before deciding to abandon the prosecution, maintenance or defence of any Licensed Patent in the Territory, and Licensee shall, upon receipt of such notice, be entitled to assume and thereafter direct such prosecution and maintenance, cost of which shall be borne as part of the Development Cost. Upon provision of written notice by Licensee to Licensor of its desire to assume control of such activities, the Licensor shall, and shall cause any patent counsel engaged by Licensor to, promptly transfer all relevant documents and records, and provide all such other reasonably necessary support to Licensee in order to promptly and fully transfer such activities to Licensee. Licensee has the right but not the obligation to engage any patent counsel engaged by the Licensor for assuming any of the filing, prosecution or maintenance going forward.

8.4.2 Once Development has ceased by the Licensor under this Agreement, Licensee shall be solely entitled and responsible for the preparation, filing, prosecution and maintenance of all Licensed Patents and Licensor shall provide Licensee with all assistance as may be reasonably requested in relation to the same.

8.5 **Third Party Infringement**.

8.5.1 During the Term, each Party shall promptly notify the other Party of (a) any known or suspected infringement, or (b) unauthorized use of, or any challenge to the validity, scope or enforceability of any Licensed Intellectual Property in the Territory, or (c) any other Legal Proceedings threatened or initiated against Licensor and/or its Affiliates that may adversely impact or diminish the rights granted to Licensee under this Agreement, or (d) any declaratory judgment action against any Licensed Patent(s) right in the Territory, in connection with any infringement, (each, an "**Infringement**") of which such Party becomes aware, promptly in writing, and provide information and documents relating to, any Infringement and, upon request, shall provide the other Party with all evidence within its possession or control supporting such known or suspected infringement or unauthorized use. Licensee shall have the first right, but not the obligation, at its sole cost and expense, to enforce such Licensed Intellectual Property against any Third Party in the Territory. Licensor shall have the first right, but not the obligation, at its sole cost and expense, to enforce Licensed Intellectual Property against any Third Party in the Excluded Territory.

8.5.2 In the event that either Party does not initiate an enforcement action within ninety (90) calendar days of the Infringement or notifies the other Party in writing that it does not intend to take such action, the other Party shall be entitled to bring such enforcement action at its own cost and expense. If a Party is authorized to bring an enforcement action under this Section 8 (*Intellectual Property*), but the Party is not recognized by the applicable court or authority as having the requisite standing to pursue such action, then the other Party shall, at the enforcing Party's request and expense, join as a party-plaintiff. Any damages, awards, settlement payments or other recoveries resulting from an enforcement action brought by a Party pursuant to this Section 8 (*Intellectual Property*) shall be to the account of the Party bringing such action.

8.5.3 Licensor shall not enter into any settlement agreement regarding any Infringement of any Licensed Intellectual Property without the Licensee's prior written consent which shall not be unreasonably withheld.

8.6 **Trademarks**.

Licensee shall have the right to brand Products in the Field using Licensee related trademarks and any other marks and trade names it determines appropriate for such Products, which may vary by country or within a country ("**Product Marks**"). Licensee shall own all rights in the Product Marks (other than the Licensed Marks)and register and maintain the Product Marks in the countries and regions it determines reasonably necessary.

9. REPRESENTATIONS AND WARRANTIES

9.1 Each Party represents and warrants that:

9.1.1 it is a legal entity duly organized, validly existing, and in good standing under the Laws of its jurisdiction of incorporation or organization;

9.1.2 it has full power and authority to execute, deliver and perform the Agreement, and has taken all corporate action required by Law and its organizational documents to authorize the execution and delivery of this Agreement and the consummation of the transaction contemplated by this Agreement;

9.1.3 the execution and delivery of this Agreement does not and shall not: (a) conflict with or result in a breach of any provision of its organization documents; (b) result in a breach of any agreement to which it is a party that would impair the performance of its obligations hereunder; or (c) violate any applicable Law; and

9.1.4 this Agreement constitutes legal, valid, and binding obligations, enforceable against it in accordance with its terms.

9.2 In addition to the representation and warranties under Section 9.1, Licensor also represents and warrants to Licensee that as on the Effective Date:

9.2.1 all rights in the Intellectual Property set out in Schedule 1 (or which relate to the items set out in Schedule 1) are either exclusively owned or otherwise exclusively vest with the Licensor, and the Licensor requires no consent of any Person for the use, exploitation, assignment, or licensing / sub-licensing of such Intellectual Property;

9.2.2 the Licensed Intellectual Property includes all intellectual property owned, created or Controlled by or on behalf of Licensor which relates to the Products and/or the Compound, and the Licensor is the sole owner of such Licensed Intellectual Property, with good and marketable title, free and clear of all liens and Encumbrances, and has the complete right and authority to grant licenses in relation thereto to Licensee to the fullest extent as contemplated under this Agreement and no licenses, options or rights in relation thereto have been granted by Licensor (or otherwise) in favour of, or lie with, any Third Party (and no costs are due to any such Third Party, including for clarity, any liability whatsoever to make any payments by way of royalties, license or other fees to any owner or licensee of, or other claimant to, any Products or Licensed Intellectual Property);

9.2.3 other than the Patents listed in Schedule 1, there are no Patent rights associated with the Licensed Intellectual Property and no other applications have been filed or registrations or statutory protection obtained in respect of any of the Licensed Intellectual Property. None of the Licensed Patents have ever been found to be invalid, unpatentable, or unenforceable for any reason in any judicial, administrative and/or quasi-judicial proceeding. To the extent required by applicable Law, all inventors of the Licensed Patents have been named as inventors on the patent applications comprised in the Licensed Patents. All inventors of the Licensed Patents have executed written assignment agreements duly assigning all their rights in the Licensed Patents and inventions covered thereunder, in favour of Licensor and have received all remuneration due to them under any applicable agreement and/or applicable Law. All actions required to maintain each of the Licensed Patents have been timely taken and the maintenance fees and annuities, due or payable on each of the Licensed Patents have been timely paid. No act has been done or, omitted to be done and no event has occurred or, to the knowledge of Licensor, is likely to occur which may render any of the Licensed Patents subject to revocation, compulsory license, cancellation, or amendment or may prevent the grant or registration of a patent pursuant to a pending patent application comprised in the Licensed Patents. Licensor has not acquiesced to the unauthorised use of the Licensed Intellectual Property by any Third Party;

9.2.4 (a) there are no Legal Proceedings pending or, to the knowledge of Licensor, threatened relating in any way to the Licensed Intellectual Property (or any part thereof), in relation to the Development of any Product, or with respect to the Products, Compound or Regulatory Approvals; and (b) Licensor has not received: (i) notice of (and is not aware of any facts or circumstances which could reasonably be expected to give rise to) any other Legal Proceedings in relation thereto; or (ii) any written communication (and is not aware of any facts or circumstances which could reasonably be expected to give rise to) alleging that Licensor's activities with respect to any of the Products, the Compound and/or use of Licensed Intellectual Property have infringed or misappropriated any of the Intellectual Property rights of any Third Party;

9.2.5 Licensor has taken all reasonable steps in accordance with normal industry practice to maintain the confidentiality of all confidential information including within the Licensed Intellectual Property, the Know-How and Product-Related Document and Data, and has not disclosed such confidential information to any Third Party;

9.2.6 (a) the Development of the Products by Licensor has been in accordance with applicable Law. Licensor has not received any written communication from any Governmental Authority alleging any violation of any applicable Law in the Development of the Products by Licensor; (b) neither Licensor nor any of its Affiliates is the subject of any pending or, to the knowledge of Licensor, threatened investigation by any Governmental Authority with respect to any of the Products, the Compound or the Regulatory Approvals obtained by Licensor; and (c) Licensor has sufficient in-house experience and expertise (including appropriate personnel) to complete the Development of the Products in accordance with the timelines and budgets set out in the Development Plan;

9.2.7 all information provided to Licensee in relation to the Products and Licensed Intellectual Property is true, correct, complete and accurate;

9.2.8 Licensor has duly undertaken: (a) Phase I Clinical Trial and Phase II Clinical Trial of each Product, and (b) Phase III Clinical Trial for Product 1A and Product 1B, in each case, in a manner sufficient to be included in an NDA for Regulatory Approval, consistent with the requirements of U.S. 21 C.F.R. §312.21(a) and U.S. 21 C.F.R. §312.21(b) respectively;

9.2.1 Product 1A is ready for NDA submission, Product 1B is ready for the second pivotal Phase III Clinical Trial (if required), and Products 1C and 2 are ready for Phase III Clinical Trial in a manner sufficient to be submitted in an NDA for Regulatory Approval, each in accordance with FDA guidance; and

9.2.2 No Third Party has been licensed, authorised, or permitted by the Licensor to use a name incorporating all or part of the Licensed Marks or trademarks constituting Licensed Intellectual Property.

9.3 The Licensor covenants that:

9.3.1 it shall not, and shall ensure that its Affiliates do not, during the Term, undertake or agree to undertake the following actions:

(a) use any of the Licensed Intellectual Property other than as expressly provided in this Agreement or carry out Development of the Product other than as provided in this Agreement;

(b) not to do any act or thing that would adversely affect Licensee's full enjoyment and exploitation of the rights granted under this Agreement including by availing of any financial indebtedness; and

(c) settle any Legal Proceeding by or against Licensor in connection with any of the Licensed Intellectual Property in the Territory;

9.3.2 each of Licensor and its Affiliates, and their respective employees and contractors, in connection with the performance of their respective obligations under this Agreement, shall not violate or cause the violation of the FCPA, Export Control Laws, or any other analogous Laws;

9.3.3 if any employees or contractors of the Licensee are debarred, suspended, excluded or otherwise disqualified under the Federal Food, Drug and Cosmetic Act, as amended, or excluded from a federal health care program, including Medicare and Medicaid, it will promptly notify the other Parties after learning that any such employees or contractors are and terminate such employee or contractor; and

9.3.4 shall immediately notify Licensee of any breach, or any reasonably foreseeable breach, of any of Licensor's representations, warranties, covenants, or obligations under this Agreement.

9.4 Licensee covenants as follows:

9.4.1 Each of Licensee and its Affiliates, and their respective employees and contractors, in connection with the performance of their respective obligations under this Agreement, shall not violate or cause the violation of the FCPA, Export Control Laws, or any other analogous Laws.

9.4.2 [**]

9.4.3 [**]

9.4.4 [**]

9.4.5 If any employees or contractors of the Licensee are debarred, suspended, excluded or otherwise disqualified under the Federal Food, Drug and Cosmetic Act, as amended, or excluded from a federal health care program, including Medicare and Medicaid, it will promptly notify the other Parties after learning that any such employees or contractors are and terminate such employee or contractor.

9.5 **Disclaimer**. Except as expressly set forth in this Agreement (including the representations and warranties set out in Section 9 (*Representations and Warranties*)), THE INTELLECTUAL PROPERTY RIGHTS PROVIDED BY EACH PARTY HEREUNDER ARE PROVIDED "AS IS" AND EACH PARTY EXPRESSLY DISCLAIMS ANY AND ALL WARRANTIES OF ANY KIND, EXPRESS OR IMPLIED, INCLUDING THE WARRANTIES OF DESIGN, MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, OR ARISING FROM A COURSE OF DEALING, USAGE OR TRADE PRACTICES, IN ALL CASES WITH RESPECT THERETO. Without limiting the foregoing: (a) neither Party represents or warrants that any data obtained from conducting Clinical Trials in one country or region will comply with the laws and regulations of any other country or region, and (b) neither Party represents or warrants the success of any study or test conducted pursuant to this Agreement.

10. INDEMNIFICATION

10.1 **Indemnification by Licensor.**

10.1.1 Subject to the terms of Section 10.3, Licensor hereby agrees to defend, hold harmless and indemnify, to the extent permitted by applicable Law, Licensee and its Affiliates and their respective directors, owners, officers, employees, and agents (the "**Licensee Indemnitees**") from and against any and all Indemnity Claims against any Licensee Indemnitee to the extent arising or resulting from: (a) any breach of Licensor's obligations, representations, warranties or covenants under this Agreement or negligence, recklessness or wrongful intentional acts or omissions from Licensor Indemnitees; or (b) the Licensor undergoing an Insolvency Event; provided, however, except in each case to the extent such Indemnity Claims are directly attributable to any matter for which Licensee is obligated to indemnify a Licensor Indemnitee pursuant to Section 10.2.

10.2 **Indemnification by Licensee.**

10.2.1 Subject to the terms of Section 10.3, Licensee hereby agrees to hold harmless and indemnify, to the extent permitted by applicable Law, Licensor and their Affiliates and their respective agents, directors, officers and employees (the "**Licensor Indemnitees**") from and against any and all Indemnity Claims against any Licensor Indemnitee to the extent arising or resulting from: (a) any breach of Licensee's obligations, representations, warranties or covenants under this Agreement or negligence, recklessness or wrongful intentional acts or omissions from Licensee Indemnitees, or (b) the Licensee undergoing an Insolvency Event; provided, however, except in each case to the extent such Indemnity Claims are directly attributable to any matter for which Licensor is obligated to indemnify a Licensee Indemnitee pursuant to Section 10.1.

10.3 **Limitations of Liability.**

10.3.1 No Double Recovery. Licensor Indemnitees and/or Licensee Indemnitees shall not be entitled to recover more than once in respect of the same loss.

10.3.2 Contingent Liability. If any claim arises out of, or in connection with, or relating to this Agreement (or breach thereof) by reason or in respect of a liability that is future, contingent and/or unquantifiable, the Parties shall not be liable for such claim until such time as that liability becomes an actual liability or is capable of being quantified.

10.3.3 EXCLUDED LOSSES. IN NO EVENT SHALL ANY PARTY (INCLUDING ANY LICENSOR INDEMNITEES AND/OR LICENSEE INDEMNITEES) BE LIABLE TO THE OTHER PARTY (INCLUDING ANY LICENSOR INDEMNITEES AND/OR LICENSEE INDEMNITEES) FOR ANY PUNITIVE, INCIDENTAL, CONSEQUENTIAL, SPECIAL OR INDIRECT LOSS OR DAMAGES, INCLUDING LOSS OF FUTURE REVENUE, OR INCOME, LOSS OF GOODWILL, LOSS OF PROFIT, LOSS OF BUSINESS (WHETHER ACTUAL OR PROSPECTIVE), LOSS OF REPUTATION OR OPPORTUNITY, OR DIMINUTION OF VALUE OR ANY DAMAGES BASED ON ANY TYPE OF MULTIPLE, WHETHER BASED ON A CONTRACT, TORT, OR ANY OTHER LEGAL THEORY, ARISING OUT OF, RELATING TO, AND/OR IN CONNECTION WITH THIS AGREEMENT (OR BREACH THEREOF), WHETHER SUCH DAMAGES WERE FORESEEABLE, OR OTHERWISE (WHETHER ACTUAL OR PROSPECTIVE OR WHETHER DIRECT OR INDIRECT), EXCEPT TO THE EXTENT ANY SUCH DAMAGES ARE: (A) REQUIRED TO BE PAID TO A THIRD PARTY AS PART OF AN INDEMNITY CLAIM FOR WHICH A PARTY PROVIDES INDEMNIFICATION UNDER THIS SECTION 10 (*INDEMNIFICATION*), OR (B) ARISING FROM THE FRAUDULENT ACTIONS OR OMISSIONS OF THE INDEMNIFYING PARTY (*AS DEFINED BELOW*) OR ITS GROSS NEGLIGENCE OR WILFUL MISCONDUCT.

10.3.4 No Projections. Licensor and Licensee acknowledge and agree that nothing in this Agreement shall be construed as representing an estimate or projection of the commercial success of any Compound or Product, and that the payments set forth in this Agreement or that have otherwise been discussed by the Parties are merely intended to define the payments in the event such payments are achieved. NEITHER LICENSOR NOR LICENSEE MAKES ANY REPRESENTATION OR WARRANTY, EITHER EXPRESS OR IMPLIED, THAT ANY PARTICULAR SALES LEVEL OF ANY PRODUCT WILL BE ACHIEVED.

10.3.5 Nothing contained in this Agreement (including without limitation Section 10.1, Section 10.2, Section 13.3, Section 14 (*Governing Law and Jurisdiction*), Section 23 (*Injunctive Relief*) and Section 24 (*Cumulative Remedies*) shall be construed as to supersede or amend the limitations of liability set out in this Section 10.3.

10.4 **Indemnification Process.**

10.4.1 Indemnification Procedure. In connection with any Indemnity Claim for which a Party (the "**Indemnified Party**") seeks indemnification from the other Party (the "**Indemnifying Party**") pursuant to this Agreement, the Indemnified Party shall: (a) give the Indemnifying Party prompt written notice of the Indemnity Claim; provided, however, that failure to provide such notice shall not relieve the Indemnifying Party from its liability or obligation hereunder, except to the extent of any material prejudice as a direct result of such failure; (b) cooperate with the Indemnifying Party, at the Indemnifying Party's expense, in connection with the defense and settlement of the Indemnity Claim; and (c) permit the Indemnifying Party to control the defense and settlement of the Indemnity Claim only if the Indemnifying Party confirms in writing that it is liable to indemnify Licensor Indemnitees or Licensee Indemnitees, as applicable, in connection with the relevant matter and provides reasonable substantiation that the Indemnifying Party has the financial resources to pay for the defense and settlement of the Indemnity Claim (including any settlement thereof or judgment thereon); provided, however, that the Indemnifying Party may not settle the Indemnity Claim without the Indemnified Party's prior written consent, which shall not be unreasonably withheld or delayed, in the event such settlement materially adversely impacts the Indemnified Party's rights or obligations. Further, the Indemnified Party shall have the right to participate (but not control) and be represented in any suit or action by advisory counsel of its selection and at its own expense.

11. TERM AND TERMINATION

11.1 **Term.**

The term of this Agreement (the "**Term**") shall commence as of the Effective Date and the Agreement shall continue to remain in force until terminated in accordance with the terms of this Agreement.

11.2 **Termination by Licensor.**

11.2.1 Upon written notice to the Licensee, Licensor may immediately terminate this Agreement:

(a) if the Licensee materially breaches its obligations under this Agreement (except for its obligations under Section 5.1, Section 6.1 or Section 6.2) and fails to cure such breach within a period of [**] from the date the Licensor provides written notice to the Licensee of such material breach;

(b) an Insolvency Event of the Licensee;

(c) except to the extent that this Section 11.2.1(c) is unenforceable under the Law of the applicable jurisdiction where the applicable Patent is pending or issued, if Viatris, Licensee or either of their respective Affiliates directly asserts in its own respective name, or directs a Third Party to assert, an action challenging the validity, scope, or enforceability of any Patent within the scope of the Licensed Patents that are then exclusively licensed to Licensee under this Agreement (each, a "**Patent Challenge**") and the Licensee or its Affiliates fails to withdraw, or cause to be withdrawn, such Patent Challenge within [**] following the date the Licensor issues written notice to the Licensee of such Patent Challenge. Further, this Section 11.2.1(c) shall not apply to any Affiliates of Licensee that first become Affiliates of Licensee after the Effective Date in connection with a merger or acquisition event, where such Affiliates of Licensee were already engaged in a Patent Challenge prior to such merger or acquisition event, so long as Licensee causes such Patent Challenge to terminate within sixty (60) days after such merger or acquisition event.

11.2.2 Upon written notice to the Licensee, Licensor may immediately terminate the License granted over a particular Product in the Territory if the Licensee materially breaches its obligations under Section 6.1.1 in respect of such Product(s) in the US and fails to cure such breach within a period of [**] from the date the Licensor notifies the Licensee of such material breach.

11.2.3 Upon written notice to the Licensee, Licensor may immediately terminate the License granted over a particular Product in a particular country in the Territory if the Licensee materially breaches its obligations under Section 5.1, Section 6.1.2 or Section 6.1.3 or Section 6.2 in respect of such Product(s) in such country in the Territory and fails to cure such breach within a period of [**] from the date the Licensor notifies the Licensee of such material breach.

11.3 **Termination by Licensee.**

11.3.1 Upon written notice to the Licensor, Licensee may immediately terminate this Agreement:

(a) If the Licensor materially breaches its obligations under this Agreement and fails to cure such breach within a period of [**] from the date the Licensee provides written notice to the Licensor of such material breach; or

(b) an Insolvency Event of the Licensor.

11.3.2 Licensee has the right from time to time throughout the Term, in its sole discretion, to terminate this Agreement in its entirety, or as to one (1) or more of the Products, each with respect to any one (1) or more countries in the Territory, (such terminated Products in terminated countries applicable to each, "**Licensee Terminated Product(s) in Terminated Country(ies)**"), without cause for any reason at any time after the Effective Date on [**] prior written notice, and for clarity, any such Licensee Terminated Product(s) in Terminated Country(ies) shall be: (a) included as of the date of the relevant termination in the Excluded Territory but solely with respect to the applicable terminated Product; and (b) shall be excluded as of the date of the relevant termination from the definition of Products but solely with respect to the applicable terminated country. For example, a particular Product could be terminated with respect to two (2) countries, and another Product could be terminated with respect to another set of countries.

11.4 **Consequences of Termination.**

11.4.1 In the event of termination of this Agreement by Licensor pursuant to Section 11.2.1, all the Licenses and rights granted to Licensee under this Agreement will cease and revert to Licensor as of the date of such termination and Licensee shall cease all use thereof of the Licensed Intellectual Property, and the Licensee shall grant to Licensor a perpetual, worldwide, fully-paid up, royalty-free, non-sublicensable, right and license under the Licensee Improvements for the sole purpose of Licensor's Development, Manufacture or Commercialization of Products in the Field.

11.4.2 In the event of termination by Licensor pursuant to Section 11.2.2: (a) the licenses granted to Licensee under Section 2.1 and any sublicenses granted under this Agreement shall automatically terminate with respect to such Product(s) in the Territory, but shall remain in full force and effect for all remaining Products in the Territory; and (b) Licensee shall grant to Licensor a perpetual, fully-paid up, royalty-free, non-sublicensable, right and license under the Licensee Improvements for the sole purpose of Licensor's Development, Manufacture or Commercialization of such terminated Product(s) in the Field in the Territory.

11.4.3 In the event of termination by Licensor pursuant to Section 11.2.3: (a) the licenses granted to Licensee under Section 2.1 and any sublicenses granted under this Agreement shall automatically terminate with respect to such Product(s) in such country(ies) to which such material breach pertains to, but shall remain in full force and effect for all remaining Products in all countries and for such Product in all remaining countries; and (b) Licensee shall grant to Licensor a perpetual, fully-paid up, royalty-free, non-sublicensable, right and license under the Licensee Improvements for the sole purpose of Licensor's Development, Manufacture or Commercialization of such terminated Product(s) in the Field in such country(ies).

11.4.4 In the event of termination of this Agreement by Licensee pursuant to Section 11.3.1: (a) the licenses granted to Licensee under Section 2.1 shall survive in perpetuity and all Licensee's obligations (including any obligation to make payments) that have not yet accrued shall fall away; and (b) Licensor shall promptly return to Licensee, or, at Licensee's request, destroy, all material, and documents related to the Compound or the Product, provided that, Licensor shall retain a copy of such Information if required by applicable Law; and the license granted to Licensor under Licensee Improvements in Section 8.2.1 and Section 11 will cease.

11.4.5

(a) In the event of termination of this Agreement in its entirety by Licensee pursuant to Section 11.3.2, all the Licenses and rights granted to Licensee under this Agreement will cease and revert to Licensor as of the date of such termination and Licensee shall cease all use thereof of the Licensed Intellectual Property, and the Licensee shall grant to Licensor a perpetual, worldwide, fully-paid up, royalty-free, non-sublicensable, right and license under the Licensee Improvements for the sole purpose of Licensor's Development, Manufacture or Commercialization of Products in the Field.

(b) In the event of termination by Licensee with respect to Licensee Terminated Product(s) in Terminated Country(ies) pursuant to Section 11.3.2, (a) the licenses granted to Licensee under Section 2.1 and any sublicenses granted under this Agreement shall automatically terminate with respect to the Licensee Terminated Product(s) in Terminated Country(ies) (and the applicable terminated country(ies) shall automatically form a part of the Excluded Territory but solely with respect to the applicable terminated Product(s)), but shall remain in full force and effect for all Products and countries in the Territory that are not Licensee Terminated Product(s) in Terminated Country(ies); and (b) Licensee shall grant to Licensor a perpetual, fully-paid up, royalty-free, non-sublicensable, right and license under the Licensee Improvements for the sole purpose of Licensor's Development, Manufacture or Commercialization of the Licensee Terminated Product(s) in Terminated Country(ies) in the Field.

12. CONFIDENTIALITY

12.1 **Duty of Confidence.**

12.1.1 Subject to the other provisions of this Section 12 (*Confidentiality*), each Party shall maintain all Information of the other Party in confidence. It is clarified that on and from the Effective Date, the Licensed Intellectual Property shall be deemed to be Licensee's Information and obligations of confidentiality relating to the Licensed Intellectual Property, including regarding the Licensed Patents, Product-Related Document and Data and Know-How shall lie on Licensor.

12.1.2 Each Party may use the other Party's and other Party's Affiliates' Information solely for the purposes of this Agreement and pursuant to the rights and obligations of such Party under this Agreement. Subject to the other provisions of this Section 12 (*Confidentiality*), each Party shall hold as confidential such Information of the other Party or such Party's Affiliates in the same manner and with the same protection as such recipient Party maintains its own confidential information, but in no event less than a reasonable degree of care.

12.1.3 Each Party shall not disclose Information of the other Party to any Third Party, other than to its shareholders, Affiliates and in each case each of their respective employees, agents, contractors, consultants, representatives, and advisers (including attorneys, accountants, consultants, bankers, financial advisors and members of advisory boards) who are bound by customary obligations of confidentiality, and for the Licensee, sub-licensee of the Licensee (appointed in accordance with Section 2.3) of such Party without the prior consent of the other Party.

12.2 **Exceptions and Authorized Disclosures.**

12.2.1 Exceptions. The obligations under this Section 12 (*Confidentiality*) shall not apply to any Information to the extent the recipient Party can demonstrate by competent evidence that such Information:

(a) is (at the time of disclosure) or becomes (after the time of disclosure) known to the public or part of the public domain through no breach of this Agreement by the recipient Party or its Affiliates;

(b) was known to, or was otherwise in the possession of, the recipient Party or its Affiliates prior to the time of disclosure by the disclosing Party or any of its Affiliates;

(c) is disclosed to the recipient Party or an Affiliate on a non-confidential basis by a Third Party who is entitled to disclose it without breaching any confidentiality obligation to the disclosing Party or any of its Affiliates;

(d) is independently developed by or on behalf of the recipient Party or its Affiliates, as evidenced by its written records, without reference to the Information disclosed by the disclosing Party or its Affiliates under this Agreement; or

(e) by Licensee to publish or have published information about Clinical Trials related to Products in the Field, including the results of such Clinical Trials, or to existing or potential sub-licensees.

12.2.2 Authorized Disclosures. In addition to the disclosure allowed in Section 12.2.1, either Party may disclose Information belonging to the other Party to the extent such disclosure is:

(a) necessary to prosecute or defend litigation as permitted by this Agreement;

(b) necessary to comply with Law, including governmental regulations or any securities regulatory organization's disclosure requirements;

(c) necessary for the purposes of any filings with any Regulatory Authority (including a Regulatory Submissions);

(d) required to be disclosed pursuant to an order of court or a Governmental Authority,*provided that* the recipient Party: (a) informs the disclosing Party as soon as reasonably practicable of the required disclosure; (b) limits the disclosure to the required purpose; and (c) at the disclosing Party's request and expense, assists in an attempt to object to or limit the required disclosure;

(e) to existing or potential acquirers or merger candidates, investment bankers, existing or potential investors, venture capital firms or other financial institutions or investors or commercial partners for purposes of obtaining financing, each of whom prior to disclosure must be bound by customary confidentiality obligations; or

(f) in the case of the Licensee, to a member of the Viatris Group, provided that prior to such disclosure, such member of the Viatris Group is bound by customary confidentiality obligations.

12.3 **Press Releases and Publications.**

Neither Party shall issue any press release, trade announcement or make any other public announcement or statement with regard to the transactions contemplated by this Agreement without the other Party's prior written consent (such approval not to be unreasonably withheld, conditioned or delayed), except that a Party may once a press release, public statement or other public statement has been made as permitted under the terms of this Agreement ("**Authorised Press Release**"), make subsequent public disclosure of the information contained in such Authorised Press Release so long as such information remains true, correct and current. Where consent is forthcoming, the Parties agree to consult with each other regarding the content of any such press release or other announcement. The aforementioned restriction shall not apply to announcements: (a) required by any Regulatory Authority, security exchanges or Governmental Authority under applicable Law, provided, that in such event the Parties shall coordinate the wording, and the Licensee shall take into consideration any requests of the Licensor; and (b) that are known to the public or part of the public domain as of the Effective Date. Each Party hereto acknowledges that Licensor and Licensee shall have the right to disclose a brief summary of the transaction, including the amounts payable by Licensee under this Agreement, in its official financial reports. Notwithstanding anything to the contrary in this Agreement, any Person who is part of or authorised by the Viatris Group shall be free to make any such announcements contemplated under this Section 12.3 without any restrictions or requirement to seek consent from either Party.

13. SURVIVING PROVISIONS

13.1 Except as otherwise specifically provided herein, expiration or termination of this Agreement shall not relieve the Parties of any liability or obligation that accrued prior to the expiration or such termination, nor preclude either Party from pursuing all rights and remedies it may have under this Agreement or at Law or in equity with respect to any breach of this Agreement nor prejudice either Party's right to obtain performance of any obligation. In addition, termination of this Agreement shall not terminate provisions that provide by their respective terms for obligations or undertakings following the expiration of the Term.

13.2 The rights and obligations of the Parties set forth in Section 8 (*Intellectual Property*), Section 9 (*Representations and Warranties*), Section 10 (*Indemnification*), Section 11 (*Term & Termination*), Section 12 (*Confidentiality*), this Section 13 (*Surviving Provisions*), and Section 14 (*Governing Law and Jurisdiction*) shall survive the termination of this Agreement.

13.3 Termination of this Agreement shall be in addition to, and shall not prejudice, either Party's remedies at Law or in equity, including either Party's ability to receive damages and/or equitable relief with respect to any breach of this Agreement, regardless of whether or not any such breach was the reason for the termination.

14. GOVERNING LAW AND JURISDICTION

14.1 **GOVERNING LAW**

This Agreement and all matters relating to this Agreement (including any dispute, claim, controversy, and cause of action arising out of or relating to this Agreement), whether in contract, statute, tort (including, without limitation, negligence) or otherwise, shall be governed by, and construed and enforced in accordance with, the Laws of the State of New York, United States of America, without giving effect to any conflict of laws principles thereof or other rule that would result in the application of the Laws of any jurisdiction other than those of the State of New York. The United Nations Convention of Contracts for the International Sale of Goods does not apply to this Agreement.

14.2 **EXCLUSIVE JURISDICTION**

The Parties irrevocably agree that the courts of New York, New York shall have exclusive jurisdiction to hear and decide any suit, action or proceedings, and/or to settle any disputes, which may arise out of or in any way relate to this Agreement or its formation and, for these purposes, each Party irrevocably submits to the exclusive jurisdiction of the courts of New York. Each Party further irrevocably and unconditionally waives and agrees not to plead or claim in such court that any such action, suit or proceeding brought in any such court has been brought in an inconvenient forum.

15. ASSIGNMENT

15.1 Neither Party shall assign this Agreement without prior written consent of the other Party, which consent shall not be unreasonably withheld, conditioned or delayed. Notwithstanding the foregoing: (a) a Party may assign its rights and delegate its obligations under this Agreement, in whole or in part, without any consent of the other Party, to: (i) an Affiliate, or (ii) a Third Party that acquires all or substantially all of the assets of such Party to which the subject matter of this Agreement pertains (whether by merger, reorganization, acquisition, or sale of assets); and (b) the Licensee may assign its rights and delegate its obligations, in whole or in part, to any Person in the Viatris Group, without the consent of the Licensor, provided that such Party assigning its rights shall give the other Party notice of the same within a reasonable time of doing so.

15.2 Any attempted assignment by any Party in breach of this provision shall be null and void and have no force or effect whatsoever.

15.3 The terms of this Agreement shall be binding upon and shall inure to the benefit of the successors-in-interest and permitted assigns of the Parties. In the event of any assignment by a Party of its rights and obligations under this Agreement in accordance with this Section 15 (*Assignment*), the assignee shall assume all obligations of its assignor under this Agreement.

16. EXPENSES

Except as otherwise expressly provided in this Agreement, each Party shall bear its own costs incurred in the performance of its obligations hereunder without charge or expense to the other (including the fees and expenses of its respective lawyers and other experts) and all other expenses and costs incurred by such Party incidental to the negotiation, preparation, execution, and delivery of this Agreement. Neither Party will have any responsibility for the hiring, termination, or compensation of the other Party's employees or for any employee compensation or benefits of the other Party's employees. No employee or representative of a Party will have any authority to bind or obligate the other Party for any sum or in any manner whatsoever, or to create or impose any contractual or other liability on the other Party without such other Party's approval.

17. NOTICES

17.1 All notices, consents, waivers, and other communications under this Agreement must be in writing and will be deemed to have been duly given when: (a) delivered by hand or by express courier service (in both instances with written confirmation of receipt); or (b) received by the addressee if sent by an internationally recognized overnight delivery service (receipt requested); or (c) in case of email the same to be sent confirming that a delivery receipt is required, upon receipt of the delivery confirmation to the sender, that it has been received by the addressee, in each case, to the appropriate addresses set forth below (or to such other addresses as a Party may designate by written notice):

In the case of notices to Licensor:

Address: 37000 Grand River Avenue, Suite 120,
Farmington Hills, MI 48335

Attention: Mina Sooch

Email: [**]

With a required copy to (which would not construe as a notice):

Address: 300 Ottawa Ave. NW, Suite 400,
Grand Rapid, MI 49503

Attention: Emily Johns

Email: [**]

In the case of notices to Licensee:

Address: **FamyGen Life Sciences, Inc**
550 Cochituate Road,
East Wing, 4th Floor,
Suite 25, Framingham,
MA 01701,
USA

Attention: Shiladitya Sengupta

E-mail: [**]

With a required copy to (which would not construe as a notice):

Address: **Khaitan & Co**
One World Centre
13th Floor, Tower 1
841 Senapati Bapat Marg
Mumbai – 400 013
India

Attention: Kapish Mandhyan
Kartick Maheshwari

E-mail: [**]
[**]

17.2 Each Party may change its address for purposes of this Agreement by written notice to the other Party.

18. WAIVER AND AMENDMENT

The failure of a Party to assert a right hereunder or to insist upon compliance with any term or condition of this Agreement shall 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 shall be effective unless it has been given in writing and signed by the Party giving such waiver. No provision of this Agreement may be amended or modified other than by a written document signed by authorized representatives of each Party.

19. SEVERABILITY

Without prejudice to any other rights that a Party may have pursuant to this Agreement, every provision of this Agreement is intended to be severable. If any provision of this Agreement shall be invalid or unenforceable, such invalidity or unenforceability shall not affect the other provisions of this Agreement, which shall remain in full force and effect. The Parties hereto agree to consult each other and to agree upon a new stipulation which is permissible under the Law and which comes as close as possible to the original purpose and intent of the invalid, void, or unenforceable provision.

20. ENTIRE AGREEMENT

This Agreement constitutes the entire agreement and supersedes all prior agreements and understandings, both written and oral, between the Parties with respect to the subject matter hereof.

21. RELATIONSHIP OF THE PARTIES

Nothing contained in this Agreement shall be deemed to constitute, create, give effect to, or otherwise recognize a partnership, association, joint venture, or legal entity of any type between Licensor and Licensee, or to constitute one as the agent of the other. Moreover, each Party agrees not to construe this Agreement, or any of the transactions contemplated hereby, as a partnership for any tax purposes. Each Party shall act solely as an independent contractor, and nothing in this Agreement shall be construed to give any Party the power or authority to act for, bind, or commit the other.

22. COUNTERPARTS

This Agreement may be executed in two (2) or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one (1) and the same instrument. This Agreement and any amendments hereto, to the extent signed and delivered by means of electronic reproduction (e.g., portable document format (.pdf), shall be treated in all manner and respects as an original and shall be considered to have the same binding legal effects as if it were the original signed version thereof delivered in person.

23. INJUNCTIVE RELIEF

The Parties understand and agree that monetary damages may not be a sufficient remedy for breach of this Agreement and that each Party will be entitled to seek equitable relief, including injunction and specific performance for any such breach.

24. CUMULATIVE REMEDIES

No remedy referred to in this Agreement is intended to be exclusive, but each shall be cumulative and in addition to any other remedy referred to in this Agreement or otherwise available under Law.

25. FORCE MAJEURE

If and to the extent that either Party is prevented or delayed by Force Majeure from performing any of its obligations under this Agreement and promptly so notifies the other Party in writing, specifying the matters constituting Force Majeure together with such evidence in verification thereof as it can reasonably give and specifying the period for which it is estimated that the prevention or delay will continue, then the Party so affected shall be relieved of liability to the other for failure to perform or for delay in performing such obligations (as the case may be), but shall nevertheless use all efforts to resume full performance thereof.

26. FURTHER ASSURANCES

Licensee and Licensor hereby covenant and agree without the necessity of any further consideration, to execute, acknowledge and deliver any and all such other documents and take any such other action as may be reasonably necessary to carry out the intent and purposes of this Agreement.

[*Following this page are the signature pages*]

IN WITNESS WHEREOF, THE PARTIES HERETO HAVE CAUSED THIS AGREEMENT TO BE DULY EXECUTED AND DELIVERED BY THEIR DULY AUTHORISED REPRESENTATIVES AS OF THE DAY AND YEAR FIRST HEREINABOVE WRITTEN

Signed and delivered for and on behalf of

Ocuphire Pharma Inc.

/s/ Mina Sooch

Name: Mina Sooch

Title: Chief Executive Officer

IN WITNESS WHEREOF, THE PARTIES HERETO HAVE CAUSED THIS AGREEMENT TO BE DULY EXECUTED AND DELIVERED BY THEIR DULY AUTHORISED REPRESENTATIVES AS OF THE DAY AND YEAR FIRST HEREINABOVE WRITTEN

Signed and delivered for and on behalf of

FamyGen Life Sciences, Inc.

/s/ Shiladitya Sengupta

Name: Shiladitya Sengupta

Title: Director

SCHEDULE 1 | INTELLECTUAL PROPERTY

SCHEDULE 2 | DEVELOPMENT PLAN OUTLINE AND DEVELOPMENT BUDGET

SCHEDULE 3 | PAYMENT TERMS

1. PAYMENT TERMS

In consideration of the licenses and other rights granted to Licensee herein, the Licensee shall make the payments set out and in accordance with this Schedule 3, subject to the terms of this Agreement.

(a) **Upfront Payment**. Within [**] following the Effective Date, Licensee shall pay to Licensor a one-time non-refundable payment in the amount of thirty-five million Dollars ($35,000,000).

(b) **Milestone Payments.** Subject to the terms and conditions of this Agreement, Licensee shall pay to Licensor the following non-refundable milestone payments, *provided that* such milestone payments shall only be paid once during the Term:

i. ***Regulatory Milestones***

(A) Ten million Dollars ($10,000,000) on achieving FDA Approval for Product 1A;

(B) [**] on achieving [**]

(C) [**] on achieving [**] and

(D) [**] on achieving [**]

each of the aforesaid hereinafter referred to as the "**Regulatory Milestone**".

Licensor shall immediately notify Licensee in writing on receiving each of the aforesaid FDA Approval. Licensor shall raise an invoice for the milestone payment linked to such Regulatory Milestone [**] Within [**] of receipt of such invoice, Licensee shall make payment for the relevant Regulatory Milestone.

ii. ***Sales Milestones***

Each of the following non-refundable amounts shall be payable only upon the first time each of the following Net Sales (in a single Calendar Year) is achieved during the entire Term:

(A) An amount of [**] on achieving [**]

(B) An amount of [**] on achieving [**]

(C) An amount of [**] on achieving [**]

(D) An amount of [**] on achieving [**]

(E) An amount of [**] on achieving [**]

(F) An amount of [**] on achieving [**]

each of the aforesaid hereinafter referred to as the "**Sales Milestone**".

Licensee shall notify Licensor in writing within [**] following the close of the Calendar Year in which the milestone set forth in this Section 1(b)(ii) (*Sales Milestones*) has been met and shall make the appropriate milestone payment within [**] after the achievement of such milestone.

For the purposes of clarification: (i) in the event that in a given Calendar Year more than one (1) of the Sales Milestone is achieved, Licensee shall pay Licensor a separate payment for each such Sales Milestone that is achieved in such Calendar Year without any Sales Milestone being paid more than once during the Term; and (ii) post achievement of a Sales Milestones, no additional amounts shall be due for subsequent or repeated achievements of aforesaid Sales Milestones in subsequent Calendar Years.

(c) **Royalty.**

(i) ***Royalty Payable by Licensee.*** Subject to the terms and conditions of this Agreement, Licensee shall pay Licensor Royalty for the aggregate annual Net Sales of all Products, as follows:

	Royalty Rate
From the date of the First Commercial Sale of the first Product, for the aggregate annual Net Sales of Products in the US	[**]
From the date of the First Commercial Sale of the first Product, for the aggregate annual Net Sales of Products in the ROW	[**]

(collectively, the "**Royalty Payments**")

(ii) ***Additional Royalty Payable by Licensee.*** Subject to the terms and conditions of this Agreement, Licensee shall pay Licensor additional royalty for the aggregate Net Sales of all Products in the US, as follows:

Annual Product Net Sales per Calendar Year	**Royalty Rate**
An additional royalty on the amount of aggregate annual Net Sales of Products in the US that is greater than [**]	Additional [**] on all annual Net Sales that exceeds [**] in a given year
An additional royalty on the amount of aggregate annual Net Sales of Products in the US that is greater than [**]	Additional [**] on all annual Net Sales that exceeds [**] in a given year

(collectively, the "**Additional Royalty**").

(A) Royalty Payments pursuant to Section 1(c)(i) (*Royalty Payable by Licensee*) shall be calculated based on the aggregate Net Sales of Products in the relevant Territory during a Calendar Quarter.

(B) Additional Royalty pursuant to Section 1(c)(ii) (*Additional Royalty Payable by Licensee*) shall be calculated based on the aggregate annual Net Sales of Products in the US during a Calendar Year.

Royalty Payments and Additional Royalty are herein after referred to collectively as "**Royalty**".

(C) Royalty on each Product at the rates set forth above shall continue on a country-by-country basis from the date of the First Commercial Sale of the first Product until December 31, 2040 (the "**Royalty Term**").

(D) All Royalty are subject to the following conditions:

I. no Royalty shall be due upon the sale or other transfer among Licensee or its Affiliates, but in such cases the Royalty shall be due and calculated upon Licensee's or its Affiliates' Net Sales to the first independent Third Party;

II. no Royalty shall accrue on the sale or other disposition of Product(s) by Licensee or its Affiliates for use in a Clinical Trial;

III. no Royalty shall accrue on the disposition of Product(s) by Licensee or its Affiliates as samples (promotion or otherwise); and

IV. no Royalty shall accrue on donations (for example, to non-profit institutions or government agencies for a non-commercial purpose).

(E) Generic Competition. In the event that in any country or other jurisdiction in the Territory during the Royalty Term for any Product there is Generic Competition in such country or other jurisdiction, then the Royalty set forth in Section 1(c) (*Royalty*) will be reduced by [**] for the remainder of the Royalty Term for all Products in such country or other jurisdiction.

(F) Payment of Royalty; Royalty Reports.

I. Royalty Payments. Royalty Payments payable under Section 1(c)(i) (*Royalty Payable by Licensee*) shall be payable on actual aggregate Net Sales and shall accrue at the time the invoice for the sale of a Product is delivered. Royalty Payment obligations that have accrued during a particular [**] shall be paid, on a [**] basis, within [**] after the end of [**] during which the royalty obligation accrued.

II. Additional Royalty. Additional Royalty payable under Section 1(c)(ii) (*Additional Royalty Payable by Licensee*) shall be payable on actual aggregate annual Net Sales and shall accrue at the end [**]. Additional Royalty obligations that have accrued during a particular [**] shall be paid no later than [**] after the [**]

III. Royalty Reports. Commencing with the [**] in which the First Commercial Sale of a Product in a country of the Territory is made by the Licensee or its Affiliate or sublicensee, the Licensee shall submit to the Licensor with each Royalty Payment a written report of its computation of Royalty due on the aggregate Net Sales in each country during each [**] within [**] after the end of each [**] (and the Licensee shall cause its sub-licensees to submit Royalty reports, which report shall indicate: (W) the amount of Net Sales of a Product sold by the Licensee, its Affiliates and sublicensees during the reporting period; (X) the Royalty due thereon; (Y) the exchange rates used in determining the amount of US Dollars; and (Z) the number of units and average selling price for the Product included in Net Sales for such [**]

(d) Conversion. All payments made under this Schedule 3 shall be made in Dollars except as otherwise agreed to in writing by the parties. With respect to amounts required to be converted into another currency for calculation of the payment amount, such amount shall be converted using a rate of exchange which corresponds to the average monthly rate used for conversion between the relative currencies that are maintained in accordance with Accounting Standards.

(e) Products**.** Notwithstanding the definition of "Products" in the Agreement, for the purpose of calculating Sales Milestones, Royalties and Royalty Payments in Schedule 3, the definition of "Products" shall also include [**]

Ocuphire Pharma Enters into a Global License Agreement for Development and Commercialization of Nyxol Eye Drops for Reversal of Mydriasis, Presbyopia and Night Vision Disturbances

Ocuphire to Receive $35 Million Upfront, Nyxol Development Funding and Additional Potential Milestone Payments plus Tiered Double-Digit Royalties

Strengthened Financial Position Supports Operations and APX3330 Program into 2025

Conference Call Tomorrow November 8, 2022 at 8:30 AM ET

FARMINGTON HILLS, Mich., November 7, 2022 - Ocuphire Pharma, Inc. (Nasdaq: OCUP) today announced it has concluded an exclusive license agreement with FamyGen Life Sciences, Inc. (Famy) for the development and commercialization of Nyxol across three indications in US, Europe, Japan, India, China and other global markets. In connection with its separately announced transaction with Famy, Viatris Inc. (Nasdaq: VTRS), a leading global healthcare company, has agreed to commercialize Nyxol following each regulatory approval.

“Famy and Ocuphire have been engaging for several months, in a collaborative spirit, to conclude this agreement. This partnership provides a clear pathway to completing development and regulatory activities and executing a successful US and global commercial launch of Nyxol through Viatris,” said Mina Sooch, MBA, founder and CEO of Ocuphire. With its strategic commitment to ophthalmics and its global commercial infrastructure, we believe Viatris provides a great opportunity for all of the Nyxol indications to realize their full commercial potential in their respective markets. In addition, the upfront payment and development funding provided by this transaction markedly improve our cash position into 2025, allowing us to expedite the registration trials for presbyopia and night vision disturbances and to execute our late-stage development strategy for the APX3330 retina program.”

Under the terms of the license agreement, Ocuphire will receive an upfront cash payment of $35 million. Famywill fund Nyxol development through FDA approvals that will be managed by Ocuphire, including clinical, manufacturing, and regulatory activities required for FDA approval of all three Nyxol indications, including Nyxol+Low-Dose Pilocarpine. With the upcoming NDA submission for the reversal of mydriasis indication this quarter, Ocuphire has the potential to receive a $10 million milestone payment upon FDA approval later in 2023 and thereafter to receive additional regulatory milestones for presbyopia and night vision disturbances indications. In addition to funding Ocuphire’s development of Nxyol in the US, Famy will undertake development in the non-US markets.

Upon commercialization, Ocuphire will receive tiered double-digit royalties on worldwide net sales through 2040 and is eligible to receive sales milestone payments upon achievement of certain annual sales thresholds.

Conference Call Details:

Date: November 8, 2022
Time: 8:30 AM ET

Dial-in information: 1-888-886-7786 (US); 1-416-764-8658 (International)
Passcode: 21367120

Webcast link

A link to the webcast can also be found on the "News and Media" section of Ocuphire's corporate website at https://www.ocuphire.com/news-media/events.

About Ocuphire Pharma

Ocuphire is a publicly traded (Nasdaq: OCUP), clinical-stage, ophthalmic biopharmaceutical company focused on developing and commercializing small-molecule therapies for the treatment of refractive and retinal eye disorders.

The Company has a collaboration with FamyGen Life Sciences and Viatristo develop and commercialize Nyxol® eye drops (0.75% phentolamine ophthalmic solution), as a once-daily, preservative-free eye drop formulation of phentolamine mesylate, a non-selective alpha-1 and alpha-2 adrenergic antagonist designed to reduce pupil size and is being developed for three indications, including reversal of pharmacologically-induced mydriasis (RM), presbyopia and dim light or night vision disturbances (NVD), pending regulatory approval. Nyxol is currently in Phase 3 for presbyopia and NVD, and ready for NDA submission for RM in Q4 2022.

The Company's product candidate APX3330 is an oral tablet designed to inhibit angiogenesis and inflammation pathways relevant to retinal and choroidal vascular diseases, such as diabetic retinopathy (DR) and diabetic macular edema (DME). APX3330 has been studied in 11 Phase 1 and 2 trials. The Company announced the completion of last patient last visit in late August with top-line results expected in early 2023 (NCT04692688).

For more information, visit www.ocuphire.com

About FamyGen Life Sciences

FamyGen Life Sciences (Famy) is a drug development focused company, engaged in identifying and in-licensing clinical-stage assets and providing development expertise & strategic funding to advance them towards regulatory approvals. Famy has built a strong ophthalmic portfolio, making significant investments dedicated to bringing innovative ophthalmic therapies to the market.

Forward Looking Statements

Statements contained in this press release regarding matters that are not historical facts are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Such statements include, but are not limited to, statements concerning Ocuphire's potential receipt of payments, including regulatory and sales milestone payments, Ocuphire's potential receipt of royalty payments, Ocuphire's partnerships with Famy and Viatris, initiation of clinical trials, receipt of data from clinical trials, submission and receipt of regulatory approvals, business strategy and potential growth, timelines, and scope for global commercialization of Nyxol. These forward-looking statements are based upon Ocuphire's current expectations and involve assumptions that may never materialize or may prove to be incorrect. Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of various risks and uncertainties, including, without limitation: (i) the success and timing of regulatory submissions and pre-clinical and clinical trials, including enrollment and data readouts; (ii) regulatory requirements or developments; (iii) changes to clinical trial designs and regulatory pathways; (iv) changes in capital resource requirements; (v) risks related to the inability of Ocuphire to obtain sufficient additional capital to continue to advance its product candidates and its preclinical programs; (vi) legislative, regulatory, political and economic developments, (vii) changes in market opportunities, (viii) the effects of COVID-19 on clinical programs and business operations, (ix) risks that the partnerships with Famy and Viatris may not facilitate the commercialization or market acceptance of Ocuphire's product candidates; (x) the success and timing of commercialization of any of Ocuphire's product candidates and (xi) the maintenance of Ocuphire's intellectual property rights. The foregoing review of important factors that could cause actual events to differ from expectations should not be construed as exhaustive and should be read in conjunction with statements that are included herein and elsewhere, including the risk factors detailed in documents that have been and may be filed by Ocuphire from time to time with the SEC. All forward-looking statements contained in this press release speak only as of the date on which they were made. Ocuphire undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

Contacts

Corporate	Investor Relations	
Mina Sooch, MBA CEO & Founder ir@ocuphire.com	Corey Davis, Ph.D. LifeSci Advisors cdavis@lifesciadvisors.com	Bret Shapiro CoreIR brets@coreir.com