**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): **July 28, 2020**

# Osmotica Pharmaceuticals plc

(Exact name of registrant as specified in its charter)

| **Ireland** | **001-38709** | **Not Applicable** |
|---|---|---|
| (State or other jurisdiction of incorporation) | (Commission File Number) | (IRS Employer Identification No.) |

| **400 Crossing Boulevard**<br>**Bridgewater, NJ** | **08807** |
|---|---|
| (Address of principal executive offices) | (Zip Code) |

(Registrant's telephone number, including area code): **(908) 809-1300**

**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:

☐ 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 |
|---|---|---|
| Ordinary Shares | OSMT | Nasdaq Global Select Market |

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

Emerging growth company ☒

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

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

On July 28, 2020, RVL Pharmaceuticals, Inc. ("RVL"), a wholly-owned subsidiary of Osmotica Pharmaceuticals plc, entered into a License Agreement (the "License Agreement") with Santen Pharmaceutical Co. Ltd. ("Licensee"). Pursuant to the License Agreement, RVL granted Licensee exclusive development, registration, and commercialization rights to RVL-1201 for the treatment and alleviation of ptosis, or drooping of the eyelid, in Japan, China, and other Asian countries as well as EMEA countries (collectively, the "Territory").

Under the terms of the License Agreement, RVL will receive an upfront cash payment of $25 million and up to an additional $64 million in cash milestone payments based on regulatory and sales achievements in the Territory. Licensee will pay RVL royalties on Net Sales (as defined in the License Agreement) of products covered by the License Agreement in the Territory during the Royalty Term, which is defined in the License Agreement generally to mean, with respect to each country in the Territory, the later of (i) the tenth anniversary of the first commercial sale of a licensed product in such country and (ii) (a) the expiration of the latest to expire of RVL's patents covering the exploitation of licensed products or (b) the expiration of any applicable regulatory exclusivity period in such country. Royalty rates vary from mid-single digit royalties to a mid-teens royalty depending upon aggregate Net Sales in the Territory.

The foregoing description of the License Agreement does not purport to be complete and is subject to and qualified in its entirety by reference to the full text of the License Agreement, a copy of which is filed as Exhibit 99.1 hereto and is incorporated herein by reference.

**Item 9.01. Financial Statements and Exhibits**

**(d) Exhibits**

| Exhibit No. | Description |
|---|---|
| 99.1 | License Agreement, dated as of July 28, 2020, by and between RVL Pharmaceuticals, Inc. and Santen Pharmaceutical Co. Ltd. |

**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.

**OSMOTICA PHARMACEUTICALS PLC**

Dated: July 31, 2020

By: /s/ Andrew Einhorn
Andrew Einhorn
Chief Financial Officer

**Exhibit 99.1**

***Execution Version***

CERTAIN CONFIDENTIAL PORTIONS OF THIS EXHIBIT HAVE BEEN OMITTED AND REPLACED WITH "[***]". SUCH IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE IT IS (I) NOT MATERIAL AND (II) WOULD LIKELY CAUSE COMPETITIVE HARM TO THE COMPANY IF DISCLOSED.

# LICENSE AGREEMENT

**between**

**RVL PHARMACEUTICALS, INC.**

**and**

**SANTEN PHARMACEUTICAL CO. LTD.**

**Dated as of July 28, 2020**

**TABLE OF CONTENTS**


| | | |
|---|---|---|
| ARTICLE 1 | DEFINITIONS | 1 |
| ARTICLE 2 | GRANT OF RIGHTS | 14 |
| 2.1 | Grants to Licensee | 14 |
| 2.2 | Grants to RVL | 14 |
| 2.3 | Sublicenses | 15 |
| 2.4 | Assignment of RVL Trademark | 15 |
| 2.5 | Retention of Rights; Limitations Applicable to License Grants | 15 |
| 2.6 | Non-Compete | 17 |
| 2.7 | Right of First Refusal regarding Field Expansion | 18 |
| ARTICLE 3 | DEVELOPMENT, REGULATORY AND COMMERCIALIZATION ACTIVITIES | 19 |
| 3.1 | Development | 19 |
| 3.2 | Regulatory Activities | 20 |
| 3.3 | Commercialization | 22 |
| 3.4 | Compliance with Applicable Law | 23 |
| 3.5 | Supply of Licensed Products | 23 |
| 3.6 | Preservation of Territory Exclusivities | 23 |
| ARTICLE 4 | STEERING COMMITTEE | 24 |
| 4.1 | Joint Steering Committee | 24 |
| 4.2 | General Provisions Applicable to the JSC | 24 |
| ARTICLE 5 | PAYMENTS AND RECORDS | 26 |
| 5.1 | Upfront Payment | 26 |
| 5.2 | Milestones | 26 |
| 5.3 | Royalties | 28 |

| | | |
|---|---|---|
| 5.4 | Royalty Payments and Reports | 30 |
| 5.5 | Mode of Payment; Offsets | 30 |
| 5.6 | Taxes | 30 |
| 5.7 | Interest on Late Payments | 31 |
| 5.8 | Financial Records | 32 |
| 5.9 | Audit | 32 |
| 5.10 | Audit Dispute | 32 |
| ARTICLE 6 | INTELLECTUAL PROPERTY | 33 |
| 6.1 | Ownership of Intellectual Property | 33 |
| 6.2 | Maintenance and Prosecution of Patents | 34 |
| 6.3 | Enforcement of Patents | 36 |
| 6.4 | Infringement Claims by Third Parties | 38 |
| 6.5 | Invalidity or Unenforceability Defenses or Actions | 38 |
| 6.6 | Third Party Rights | 39 |
| 6.7 | Product Trademarks | 39 |
| ARTICLE 7 | CONFIDENTIALITY AND NON-DISCLOSURE | 40 |
| 7.1 | Confidentiality Obligations | 40 |
| 7.2 | Permitted Disclosures | 41 |
| 7.3 | Use of Name | 42 |
| 7.4 | Public Announcements | 43 |
| 7.5 | Publications | 43 |
| 7.6 | Return of Confidential Information | 43 |
| 7.7 | Privileged Communications | 44 |
| ARTICLE 8 | REPRESENTATIONS AND WARRANTIES | 44 |
| 8.1 | Mutual Representations and Warranties | 44 |

| | | |
|---|---|---|
| 8.2 | Additional Representations and Warranties of RVL | 45 |
| 8.3 | Additional Representations and Warranties of Licensee | 46 |
| 8.4 | DISCLAIMER OF WARRANTIES | 47 |
| 8.5 | ADDITIONAL WAIVER | 47 |
| 8.6 | Anti-Bribery and Anti-Corruption Compliance | 47 |
| ARTICLE 9 | INDEMNITY | 49 |
| 9.1 | Indemnification of RVL | 49 |
| 9.2 | Indemnification of Licensee | 49 |
| 9.3 | Indemnification Procedures | 50 |
| 9.4 | Special, Indirect and Other Losses | 52 |
| ARTICLE 10 | TERM AND TERMINATION | 52 |
| 10.1 | Term and Expiration | 52 |
| 10.2 | Termination | 52 |
| 10.3 | Rights in Bankruptcy | 54 |
| 10.4 | Consequences of Termination | 54 |
| 10.5 | Remedies | 57 |
| 10.6 | Accrued Rights; Surviving Obligations | 57 |
| ARTICLE 11 | MISCELLANEOUS | 57 |
| 11.1 | Force Majeure | 57 |
| 11.2 | Export Control | 58 |
| 11.3 | Assignment | 58 |
| 11.4 | Severability | 59 |
| 11.5 | Dispute Resolution | 59 |
| 11.6 | Governing Law | 61 |
| 11.7 | Notices | 61 |

| | | |
|---|---|---|
| 11.8 | Entire Agreement; Amendments | 62 |
| 11.9 | English Language | 62 |
| 11.10 | Equitable Relief | 62 |
| 11.11 | Waiver and Non-Exclusion of Remedies | 63 |
| 11.12 | No Benefit to Third Parties | 63 |
| 11.13 | Further Assurance | 63 |
| 11.14 | Relationship of the Parties | 63 |
| 11.15 | References | 63 |
| 11.16 | Construction | 64 |
| 11.17 | Counterparts | 64 |


**SCHEDULES**


| | |
|---|---|
| Schedule 1.24 | Corporate Names |
| Schedule 1.35 | Existing Patents |
| Schedule 1.57 | In-License Agreement |
| Schedule 1.66 | Licensed Product |
| Schedule 1.101 | RVL Trademark |
| Schedule 1.108 | Territory |
| Schedule 3.1.2 | Development Plan |
| Schedule 3.6 | Protection of Territorial Integrity |
| Schedule 5.2.1 | Approval Letter and Invoice |
| Schedule 7.4 | Press Release |
| Schedule 8.2.9 | Credit Agreement |

**LICENSE AGREEMENT**

This License Agreement (this "**Agreement**") is made and entered into effective as of July 28, 2020 (the "**Effective Date**") by and between RVL Pharmaceuticals, Inc., a Delaware corporation ("**RVL**") and Santen Pharmaceutical Co. Ltd., a Japanese corporation ("**Licensee**"). RVL and Licensee are sometimes referred to herein individually as a "**Party**" and collectively as the "**Parties**."

**Recitals**

**WHEREAS**, RVL owns and controls certain intellectual property rights with respect to the Licensed Compound (as defined herein) and Licensed Product (as defined herein) in the Territory (as defined herein); and

**WHEREAS**, RVL wishes to grant a license to Licensee and Licensee wishes to take, a license under such intellectual property rights to Develop and Commercialize Licensed Product in the Territory, in each case in accordance with the terms and conditions set forth below.

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

**ARTICLE 1**
**DEFINITIONS**

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

**1.1.** "**Acquiring Party**" has the meaning set forth in Section 2.6.3.

**1.2.** "**Acquisition Closing Notice**" has the meaning set forth in Section 2.6.3.

**1.3.** "**Acquisition Termination Notice**" has the meaning set forth in Section 2.6.3.

**1.4.** "**Acquisition Termination Period**" has the meaning set forth in Section 2.6.3.

**1.5.** "**Affiliate**" means, with respect to a Party, any Person that, directly or indirectly, through one or more intermediaries, controls, is controlled by or is under common control with such Party. For purposes of this definition, "control" and, with correlative meanings, the terms "controlled by" and "under common control with" means: (i) the possession, directly or indirectly, of the power to direct the management or policies of a business entity, whether through the ownership of voting securities, by contract relating to voting rights or corporate governance or otherwise; or (ii) the ownership, directly or indirectly, of fifty percent (50%) of the voting securities or other ownership interest of a business entity (or, with respect to a limited partnership or other similar entity, its general partner or controlling entity). Notwithstanding the foregoing, the following companies shall not be considered Affiliates of RVL: ACP Holdco (Offshore), L.P., a Bermuda exempted limited partnership, ACP III AIV, L.P., a Bermuda exempted limited partnership and Altchem Limited.

**1.6.** "**Agreement**" has the meaning set forth in the preamble hereto.

**1.7.** "**Alliance Managers**" has the meaning set forth in Section 4.2.5.

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

**1.9.** "**Applicable Law**" means applicable laws, rules and regulations, including any rules, regulations, guidelines or other requirements of the Regulatory Authorities, that may be in effect from time to time.

**1.10.** "**Arbitrators**" has the meaning set forth in Section 11.5.3.

**1.11.** "**Audit**" has the meaning set forth in Section 8.6.3.

**1.12.** "**Auditor**" has the meaning set forth in Section 5.10.

**1.13.** "**Board of Directors**" has the meaning set forth in the definition of Change of Control.

**1.14.** "**Breaching Party**" has the meaning set forth in Section 10.2.1.

**1.15.** "**Business Day**" means a day other than a Saturday or Sunday or a day on which banking institutions in New York, New York and Tokyo, Japan are permitted or required to be closed.

**1.16.** "**Calendar Quarter**" means each successive period of three (3) calendar months commencing on January 1, April 1, July 1 and October 1, except that the first Calendar Quarter of the Term shall commence on the Effective Date and end on the day immediately prior to the first to occur of January 1, April 1, July 1 or October 1 after the Effective Date and the last Calendar Quarter shall end on the last day of the Term.

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

**1.18.** "**Change of Control**" with respect to a Party, shall be deemed to have occurred if any of the following occurs after the Effective Date:

**1.18.1.** any “person” or “group” (as such terms are defined below) (i) is or becomes the “beneficial owner” (as defined below, except that a “person” or “group” shall be deemed to have “beneficial ownership” of all shares of capital stock or other equity interests if such person or group has the right to acquire, whether such right is exercisable immediately or only after the passage of time), directly or indirectly, of shares of capital stock or other interests (including partnership interests) of such Party then outstanding and normally entitled (without regard to the occurrence of any contingency) to vote in the election of the directors, managers or similar supervisory positions (“**Voting Stock**”) of such Party representing fifty percent (50%) or more of the total voting power of all outstanding classes of Voting Stock of such Party or (ii) has the power, directly or indirectly, to elect a majority of the members of the Party’s board of directors or similar governing body (“**Board of Directors**”);

**1.18.2.** such Party enters into a merger, consolidation or similar transaction with another Person (whether or not such Party is the surviving entity) and as a result of such merger, consolidation or similar transaction (i) the members of the Board of Directors of such Party immediately prior to such transaction constitute less than a majority of the members of the Board of Directors of such Party or such surviving Person immediately following such transaction or (ii) the Persons that beneficially owned, directly or indirectly, the shares of Voting Stock of such Party immediately prior to such transaction cease to beneficially own, directly or indirectly, shares of Voting Stock of such Party representing at least a majority of the total voting power of all outstanding classes of Voting Stock of the surviving Person in substantially the same proportions as their ownership of Voting Stock of such Party immediately prior to such transaction;

**1.18.3.** such Party sells or transfers to any Third Party, in one or more related transactions, properties or assets representing all or substantially all of such Party’s consolidated total assets;

**1.18.4.** during any period of twenty-four (24) consecutive months, a majority of the members of the Board of Directors of such Party cease to be composed of individuals (i) who were members of that board or similar governing body on the first day of such period, (ii) whose election or nomination to that board or similar governing body was approved by individuals referred to in clause (i) above constituting at the time of such election or nomination at least a majority of that board or similar governing body or (iii) whose election or nomination to that board or other similar governing body was approved by individuals referred to in clauses (i) and (ii) above constituting at the time of such election or nomination at least a majority of that board or similar governing body (excluding, in the case of both clause (ii) and clause (iii), any individual whose initial nomination for, or assumption of office as, a member of that board or similar governing body occurs as a result of an actual or threatened solicitation of proxies or consents for the election or removal of one or more directors by any person or group other than a solicitation for the election of one or more directors by or on behalf of the board of directors); or

**1.18.5.** the holders of capital stock of such Party approve a plan or proposal for the liquidation or dissolution of such Party.

For the purpose of this definition of Change of Control: (i) "person" and "group" have the meanings given such terms under Section 13(d) and 14(d) of the United States Securities Exchange Act of 1934 and the term "group" includes any group acting for the purpose of acquiring, holding or disposing of securities within the meaning of Rule 13d-5(b)(1) under the aforesaid Act; (ii) a "beneficial owner" shall be determined in accordance with Rule 13d-3 under the aforesaid Act; and (iii) the terms "beneficially owned" and "beneficially own" shall have meanings correlative to that of "beneficial owner."

**1.19.** "**Commercialization**" means any and all activities directed to the preparation for sale of, offering for sale of or sale of a Licensed Product, including activities related to marketing, promoting, distributing and importing such Licensed Product and interacting with Regulatory Authorities regarding any of the foregoing. When used as a verb, "**to Commercialize**" and "**Commercializing**" means to engage in Commercialization and "**Commercialized**" has a corresponding meaning.

**1.20.** "**Commercialization Plan**" has the meaning set forth in Section 3.3.2.

**1.21.** "**Commercially Reasonable Efforts**" means, with respect to the performance of Development, Commercialization or Manufacturing activities with respect to the Licensed Compound or a Licensed Product by Licensee, the carrying out of such activities in a sustained and diligent manner and using efforts and resources comparable to the efforts and resources used by Licensee for compounds or products of similar market potential at a similar stage in development or product life in a similar market under similar conditions. "Commercially Reasonable Efforts," when used in the context of evaluating such activities in specific countries or regions, shall be determined on a country-by-country (or region-by-region, where applicable) and indication-by-indication basis, without regard to any payments owed by Licensee to RVL under this Agreement, based on Licensee's launch sequence strategy for the Territory and given the country's (or region's) priority level in the Licensee's overall scheme or plan for Development, Commercialization or Manufacturing activities; *provided* that such manner, efforts and resources shall not be diminished based upon other portfolio compounds or products of similar value Controlled by Licensee or any of its Affiliates.

**1.22.** "**Confidential Information**" has the meaning set forth in Section 7.1.

**1.23.** "**Control**" means, with respect to any item of Information, Regulatory Documentation, material, Patent or other intellectual property right, and subject to Section 11.3.2, possession of the right, whether directly or indirectly and whether by ownership, license or otherwise (other than by operation of the license and other grants in Section 2.1 or 2.2), to grant a license, sublicense or other right (including the right to reference Regulatory Documentation) to or under such Information, Regulatory Documentation, material, Patent or other intellectual property right as provided for herein without violating the terms of any agreement with any Third Party.

**1.24.** "**Corporate Names**" means the Trademarks and logos identified on Schedule 1.24 and such other names and logos as RVL may designate in writing from time to time.

**1.25.** "**Development**" means any activity related to research, pre-clinical and other non-clinical testing, test method development and stability testing, toxicology, formulation, process development, manufacturing scale-up, qualification and validation, quality assurance/quality control, clinical studies, including Manufacturing in support thereof, statistical analysis and report writing, the preparation and submission of Drug Approval Applications, regulatory affairs with respect to the foregoing and all other activities, to the extent that such activity is necessary or reasonably useful or otherwise requested or required by a Regulatory Authority as a condition or in support of obtaining or maintaining a Regulatory Approval. When used as a verb, "**Develop**" means to engage in Development.

**1.26.** "**Development Plan**" has the meaning set forth in Section 3.1.2.

**1.27.** "**Direct Net Sales Report**" has the meaning set forth in Section 5.4.

**1.28.** "**Dispute**" has the meaning set forth in Section 11.5.1.

**1.29.** "**Distributor**" means any Person(s) appointed by Licensee or any of its Affiliates or its or their Sublicensees to distribute, market and sell Licensed Product(s), with or without packaging rights, in one or more countries in the Territory, in circumstances where the Person purchases its requirements of Licensed Product(s) from Licensee or its Affiliates or its or their Sublicensees but does not otherwise make any royalty or other payment to Licensee or its Affiliates or its or their Sublicensees with respect to its intellectual property rights with respect to such Licensed Product(s).

**1.30.** "**Dollars**" or "**$**" means United States Dollars.

**1.31.** "**Drug Approval Application**" means a New Drug Application as defined in the FFDCA or any corresponding foreign application in the Territory, including, with respect to the European Union, a Marketing Authorization Application filed with the EMA pursuant to the centralized approval procedure or with the applicable Regulatory Authority of a country in Europe with respect to the mutual recognition or any other national approval.

**1.32.** "**Effective Date**" has the meaning set forth in the preamble hereto.

**1.33.** "**EMA**" means the European Medicines Agency and any successor agency thereto.

**1.34.** "**European Union**" means (i) the economic, scientific and political organization of member states as constituted from time to time, which as of the Effective Date consists of Austria, Belgium, Bulgaria, Croatia, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, The Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden and that certain portion of Cyprus included in such organization, (ii) the member states of the European Free Trade Association as constituted from time to time during the Term which participate in the European Economic Area with respect to trade relating to pharmaceutical products, (iii) the United Kingdom of Great Britain and Northern Ireland and (iv) Switzerland.

**1.35.** "**Existing Patents**" means the Patents listed on Schedule 1.35.

**1.36.** "**Exploit**" means to make, have made, import, use, sell or offer for sale, including to research, Develop, Commercialize, register, Manufacture, have Manufactured, hold or keep (whether for disposal or otherwise), have used, export, transport, distribute, promote, market or have sold or otherwise dispose of. "**Exploitation**" means the act of Exploiting a compound, product or process.

**1.37.** "**FDA**" means the United States Food and Drug Administration and any successor agency thereto.

**1.38.** "**FFDCA**" means the United States Food, Drug and Cosmetic Act, as amended from time to time, together with any rules, regulations and requirements promulgated thereunder (including all additions, supplements, extensions and modifications thereto).

**1.39.** "**Field**" means all human diagnostic, prophylactic and therapeutic uses for the treatment and alleviation of ptosis of the eyelid and drooping of the eyelid, including the symptoms associated therewith and arising from ptosis, including but not limited to blurred vision, eye fatigue, discomfort and diminished field of vision, headaches, shoulder pain, and any other known or subsequently discovered symptoms of ptosis, subject to expansion pursuant to Section 2.7.

**1.40.** "**Field Expansion Negotiation Period**" has the meaning set forth in Section 2.7.

**1.41.** "**First Commercial Sale**" means, with respect to a Licensed Product and a country, the first sale for monetary value for use or consumption by the end user of such Licensed Product in such country after Regulatory Approval for such Licensed Product has been obtained in such country. Sales prior to receipt of Regulatory Approval for such Licensed Product, such as so-called "treatment IND sales," "named patient sales," and "compassionate use sales," shall not be construed as a First Commercial Sale.

**1.42.** "**Force Majeure Termination Event**" has the meaning set forth in Section 11.1.

**1.43.** "**GAAP**" means, with respect to a Party or its Affiliates or its or their sublicensees, United States generally accepted accounting principles, International Financial Reporting Standards or such other similar national standards as such Party, Affiliates or its or their sublicensee adopts, in each case, consistently applied.

**1.44.** "**Generic Product**" has the meaning set forth in Section 5.3.3.

**1.45.** "**Government Official**" means (i) any Person employed by or acting on behalf of a government, government-controlled agency or entity or public international organization, (ii) any political party, party official or candidate, (iii) any Person who holds or performs the duties of an appointment, office or position created by custom or convention or (iv) any Person who holds himself out to be the authorized intermediary of any of the foregoing.

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

**1.47.** "**ICC**" has the meaning set forth in Section 11.5.3.

**1.48.** "**ICC Rules**" has the meaning set forth in Section 11.5.3.

**1.49.** "**Improvements**" means any invention, discovery, development or modification with respect to the Licensed Compound or a Licensed Product or relating to the Exploitation thereof, whether or not patented or patentable, including any enhancement in the efficiency, operation, Manufacture, ingredients, preparation, presentation, formulation, means of delivery or dosage of such Licensed Compound or Licensed Product, any discovery or development of any new or expanded indications for such Licensed Compound or Licensed Product, or any discovery or development that improves the stability, safety or efficacy of such Licensed Compound or Licensed Product.

**1.50.** "**IND**" means (i) an investigational new drug application filed with the FDA for authorization to commence clinical studies and its equivalent in other countries or regulatory jurisdictions and (ii) all supplements and amendments that may be filed with respect to the foregoing.

**1.51.** "**Indemnification Claim Notice**" has the meaning set forth in Section 9.3.1.

**1.52.** "**Indemnified Party**" has the meaning set forth in Section 9.3.1.

**1.53.** "**Indirect Net Sales Report**" has the meaning set forth in Section 5.4.

**1.54.** "**Indirect Taxes**" has the meaning set forth in Section 5.6.3.

**1.55.** "**Information**" means all technical, scientific and other know-how and information, trade secrets, knowledge, technology, means, methods, processes, practices, formulae, instructions, skills, techniques, procedures, experiences, ideas, technical assistance, designs, drawings, assembly procedures, computer programs, apparatuses, specifications, data, results and other material, including: biological, chemical, pharmacological, toxicological, pharmaceutical, physical and analytical, pre-clinical, clinical, safety, manufacturing and quality control data and information, including study designs and protocols, assays and biological methodology, in each case (whether or not confidential, proprietary, patented or patentable) in written, electronic or any other form now known or hereafter developed.

**1.56.** "**Infringement**" has the meaning set forth in Section 6.3.1.

**1.57.** "**In-License Agreement**" means that certain license agreement listed in Schedule 1.57.

**1.58.** "**Investor**" means any purchaser or lender, as applicable, of any assets, debt, equity, or other securities convertible into debt or equity of a Party.

**1.59.** "**Invoiced Sales**" has the meaning set forth in the definition of "Net Sales."

**1.60.** "**Joint Intellectual Property Rights**" has the meaning set forth in Section 6.1.2.

**1.61.** "**Joint Know-How**" has the meaning set forth in Section 6.1.2.

**1.62.** "**Joint Patents**" has the meaning set forth in Section 6.1.2.

**1.63.** "**Joint Steering Committee**" or "**JSC**" has the meaning set forth in Section 4.1.

**1.64.** "**JSC Dispute**" has the meaning set forth in Section 11.5.1.

**1.65.** "**Licensed Compound**" means the pharmaceutical compound oxymetazoline hydrochloride.

**1.66.** "**Licensed Product**" means the pharmaceutical product that is comprised of the Licensed Compound as the sole active ingredient, in a 0.1% formulation, as described in further detail on Schedule 1.66, and such additional pharmaceutical products that contain the Licensed Compound as may be agreed pursuant to Section 2.7.

**1.67.** "**Licensed Product Agreement**" means, with respect to a Licensed Product, any agreement entered into by and between Licensee or any of its Affiliates or its or their Sublicensees, on the one hand and one or more Third Parties, on the other hand, that is necessary or reasonably useful for the Exploitation of such Licensed Product in the Field in the Territory, including (i) any agreement pursuant to which Licensee, its Affiliates or its or their Sublicensees receives any license or other rights to Exploit such Licensed Product, (ii) supply agreements pursuant to which Licensee, its Affiliates or its or their Sublicensees obtain or will obtain quantities of such Licensed Product, (iii) clinical trial agreements, (iv) contract research organization agreements and (v) service agreements.

**1.68.** "**Licensee**" has the meaning set forth in the preamble hereto.

**1.69.** "**Licensee Know-How**" means all Information Controlled by Licensee or any of its Affiliates or its or their Sublicensees as of the Effective Date or at any time during the Term that is (i) not generally known and (ii) necessary for the Licensed Product, but excluding any Information to the extent covered or claimed by published Licensee Patents or Joint Patents or any Joint Know-How.

**1.70.** "**Licensee Patents**" means all of the Patents Controlled by Licensee or any of its Affiliates or its or their Sublicensees as of the Effective Date or at any time during the Term that claim or cover the Exploitation of the Licensed Product, but excluding any Joint Patents.

**1.71.** "**Licensee Regulatory Documentation**" has the meaning set forth in Section 3.2.1(ii).

**1.72.** "**Licensee Representatives**" has the meaning set forth in Section 8.6.1.

**1.73.** "**Losses**" has the meaning set forth in Section 9.1.

**1.74.** "**Major Market**" means each of France, Germany, Italy, Japan, People's Republic of China (excluding Hong Kong, Macau and Taiwan), South Korea, Spain, and the United Kingdom.

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

**1.76.** "**Material Anti-Corruption Law Violation**" means a violation of an Anti-Corruption Law relating to the subject matter of this Agreement that would, if it were publicly known, in the reasonable view of RVL, have a material adverse effect on RVL or on the reputation of RVL because of its relationship with Licensee.

**1.77.** **"MHLW"** means the Japanese Ministry of Health, Labor and Welfare, and any successor agency thereto.

**1.78.** "**Net Sales**" means, with respect to a Licensed Product for any period, the gross amount billed or invoiced by Licensee, its Affiliates or its or their Sublicensees to Third Parties, including Distributors, for the sale of a Licensed Product (the "**Invoiced Sales**"), less the following deductions to the extent reasonable, customary, and actually allowed and taken with respect to such sales:

**1.78.1.** trade, cash, prompt pay or quantity discounts not already reflected in the amount invoiced, to the extent related to the gross amount billed or invoiced;

**1.78.2.** price reductions, rebates, clawbacks and administrative fees (including those paid or credited to pharmacy benefit managers, governmental authorities or otherwise;

**1.78.3.** freight, postage, shipping and insurance expenses to the extent that such items are included in the gross amount invoiced, in each case to the extent not reimbursed from any Third Party;

**1.78.4.** sales, use, excise, value-added tax or similar taxes, customs duties and other governmental fees, charges and surcharges imposed on the sale, transportation or delivery of the Licensed Product, including pharmaceutical excise taxes, to the extent that such items are included in the gross amount invoiced and paid by the selling party, but excluding any taxes assessed on income derived from sales;

**1.78.5.** amounts repaid or credited by reason of rejections, defects, recalls, returns or wastage replacement;

**1.78.6.** amounts paid or credited for wholesaler chargebacks; and

**1.78.7.** any receivables that have been included in gross sales and are deemed to be uncollectible according to GAAP (any such bad debt deductions shall be applied to Net Sales in the period in which such receivables are written off); *provided* that any amounts actually collected shall be added back to Net Sales in the period in which such amounts are actually collected.

Any of the deductions listed above that involves a payment by Licensee, its Affiliates or its or their Sublicensees shall be taken as a deduction in the Calendar Quarter in which the payment is accrued in accordance with GAAP by such entity. For purposes of determining Net Sales, a Licensed Product shall be deemed to be sold when invoiced and a "sale" shall not include transfers or dispositions of such Licensed Product for pre-clinical or clinical purposes or as samples, in each case, without charge. Licensee's, its Affiliates' or its or their Sublicensees' transfer of any Licensed Product to an Affiliate or Sublicensee shall not result in any Net Sales, unless such Licensed Product is consumed by such Affiliate or Sublicensee in the course of its commercial activities.

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

Subject to the above, Net Sales shall be calculated and paid in accordance with GAAP for Licensee, its Affiliates or its or their Sublicensees.

**1.79.** "**Net Sales Reports**" means the Direct Net Sales Report and the Indirect Net Sales Report.

**1.80.** **"NMPA"** means the National Medical Products Administration of the People's Republic of China, and any successor agency thereto.

**1.81.** "**Non-Acquiring Party**" has the meaning set forth in Section 2.6.3.

**1.82.** "**Non-Breaching Party**" has the meaning set forth in Section 10.2.1.

**1.83.** "**Notice Period**" has the meaning set forth in Section 10.2.1.

**1.84.** "**Party**" and "**Parties**" have the meaning set forth in the preamble hereto.

**1.85.** "**Patents**" means: (i) all national, regional and international patents and patent applications, including provisional patent applications; (ii) all patent applications filed either from such patents, patent applications or provisional applications or from an application claiming priority from either of these, including divisionals, continuations, continuations-in-part, provisionals, converted provisionals and continued prosecution applications; (iii) any and all patents that have issued or in the future issue from the foregoing patent applications (clauses (i) and (ii)), including utility models, petty patents, innovation patents and design patents and certificates of invention; (iv) any and all extensions or restorations by existing or future extension or restoration mechanisms, including revalidations, reissues, re-examinations and extensions (including any supplementary protection certificates and the like) of the foregoing patents or patent applications (clauses (i), (ii) and (iii)); and (v) any similar rights, including so-called pipeline protection or any importation, revalidation, confirmation or introduction patent or registration patent or patent of additions to any of such foregoing patent applications and patents.

**1.86.** "**Payment**" has the meaning set forth in Section 5.6.2.

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

**1.88.** "**Phase III Placebo Controlled Efficacy Study**" means a Phase III study [***].

**1.89.** "**PMDA**" means the Japanese Pharmaceuticals and Medical Devices Agency, or any successor entity thereto.

**1.90.** "**Product Trademarks**" means the Trademark(s) used or to be used by Licensee or its Affiliates or its or their Sublicensees for the Commercialization of Licensed Products in the Territory and any registrations thereof or any pending applications relating thereto in the Territory (excluding, in any event, any trademarks, service marks, names or logos that include any corporate name or logo of the Parties or their Affiliates or its or their (sub)licensees).

**1.91.** "**Provisions**" has the meaning set forth in Section 8.6.4.

**1.92.** "**Regulatory Approval**" means, with respect to a country in the Territory (or outside the Territory where the context requires), any and all approvals (including Drug Approval Applications), licenses, registrations or authorizations of any Regulatory Authority necessary to commercially distribute, sell or market a Licensed Product in such country, including, where applicable, (i) pricing or reimbursement approval in such country, (ii) pre- and post-approval marketing authorizations (including any prerequisite Manufacturing approval or authorization related thereto) and (iii) labeling approval.

**1.93.** "**Regulatory Authority**" means any applicable supra-national, federal, national, regional, state, provincial or local regulatory agencies, departments, bureaus, commissions, councils or other government entities regulating or otherwise exercising authority with respect to the Exploitation of the Licensed Compound or Licensed Products in the Territory (or outside the Territory where the context requires), including the FDA in the United States and the EMA in the European Union.

**1.94.** "**Regulatory Documentation**" means: all (i) applications (including all INDs and Drug Approval Applications), registrations, licenses, authorizations and approvals (including Regulatory Approvals); (ii) correspondence and reports submitted to or received from Regulatory Authorities (including minutes and official contact reports relating to any communications with any Regulatory Authority) and all supporting documents with respect thereto, including all adverse event files and complaint files; and (iii) clinical and other data contained or relied upon in any of the foregoing; in each case (clauses (i), (ii) and (iii)) relating to the Licensed Compound or a Licensed Product.

**1.95.** "**Regulatory Exclusivity Period**" means, with respect to the Licensed Product in any country in the Territory, a period of exclusivity (other than Patent exclusivity) granted or afforded by Applicable Law or by a Regulatory Authority in such country that confers exclusive marketing rights with respect to such Licensed Product in such country or prevents another party from using or otherwise relying on any data supporting the approval of the NDA or supporting the MAA for such Licensed Product without the prior written consent of the NDA-holder or MAA-holder, as applicable, such as new chemical entity exclusivity, new use or indication exclusivity, new formulation exclusivity, orphan drug exclusivity, non-patent related pediatric exclusivity or any other applicable marketing or data exclusivity, including any such periods listed in the FDA's Orange Book or any such periods under national implementations in the EU of Article 10 of Directive 2001/83/ED, Article 14(11) of Parliament and Council Regulation (EC) No. 726/2004, Parliament and Council Regulation (ED) No. 141/2000 on orphan medicines, Parliament and Council Regulation (ED) No. 1901/2006 on medicinal products for pediatric use and all international equivalents of any of the foregoing.

**1.96.** "**Royalty Term**" means, with respect of the Licensed Product and each country in the Territory, the later of (i) the tenth (10th) anniversary of the First Commercial Sale of the Licensed Product in such country and (ii) (a) the expiration of the last to expire of RVL Patents that contains a Valid Claim or (b) the expiration of the Regulatory Exclusivity Period.

**1.97.** "**RVL**" has the meaning set forth in the preamble hereto.

**1.98.** "**RVL Know-How**" means all Information Controlled by RVL or any of its Affiliates or its or their sublicensees as of the Effective Date or at any time during the Term that is (i) not generally known and (ii) necessary for the Licensed Product, but excluding any Information to the extent covered or claimed by published RVL Patents or Joint Patents or any Joint Know-How.

**1.99.** "**RVL Patents**" means all of the Patents Controlled by RVL or any of its Affiliates or its or their sublicensees as of the Effective Date or at any time during the Term that claim or cover the Exploitation of the Licensed Product, but excluding any Joint Patents.

**1.100.** "**RVL Regulatory Documentation**" means Regulatory Documentation other than the Licensee Regulatory Documentation.

**1.101.** **"RVL Trademark"** means those Trademarks set forth on Schedule 1.101.

**1.102.** "**Senior Officer**" means, with respect to RVL, its chief executive officer and with respect to Licensee, its chief executive officer.

**1.103.** "**Sublicensee**" means a Person, other than an Affiliate, that is granted a sublicense by Licensee or its Affiliate under the grants in Section 2.1, as provided in Section 2.3.

**1.104.** "**Subsequent Indication**" has the meaning set forth in Section 2.7.

**1.105.** "**Term**" has the meaning set forth in Section 10.1.

**1.106.** "**Terminated Territory**" means each country with respect to which this Agreement is terminated pursuant to Section 10.2.1, 10.2.4, 10.2.5 or 10.2.6 or, if this Agreement is terminated in its entirety, the entire Territory.

**1.107.** "**Termination Notice**" has the meaning set forth in Section 10.2.1.

**1.108.** "**Territory**" means the countries listed on Schedule 1.108.

**1.109.** "**Third Party**" means any Person other than RVL, Licensee and their respective Affiliates.

**1.110.** "**Third Party Claims**" has the meaning set forth in Section 9.1.

**1.111.** "**Third Party Infringement Claim**" has the meaning set forth in Section 6.4.

**1.112.** "**Trademark**" means any word, name, symbol, color, shape, designation or any combination thereof, including any trademark, service mark, trade name, brand name, sub-brand name, trade dress, product configuration, program name, delivery form name, certification mark, collective mark, logo, tagline, slogan, design or business symbol, that functions as an identifier of source or origin, whether or not registered and all statutory and common law rights therein and all registrations and applications therefor, together with all goodwill associated with, or symbolized by, any of the foregoing.

**1.113.** "**Tribunal**" has the meaning set forth in Section 11.5.3.

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

**1.115.** "**Valid Claim**" means (i) a claim of any issued and unexpired Patent whose validity, enforceability or patentability has not been affected by (a) an irretrievable lapse, abandonment, revocation, dedication to the public or disclaimer or (b) a holding, finding or decision of invalidity, unenforceability or non-patentability by a court, governmental agency, national or regional patent office or other appropriate body that has competent jurisdiction, such holding, finding or decision being final and unappealable or unappealed within the time allowed for appeal or (ii) a claim of a pending Patent application that is being prosecuted in good faith and has not been abandoned or finally disallowed without the possibility of appeal or re-filing of the application, except where the Patent has not been issued for the Patent application as of the First Commercial Sale.

**1.116.** "**Voting Stock**" has the meaning set forth in the definition of "Change of Control."

## ARTICLE 2
## GRANT OF RIGHTS

**2.1.** **Grants to Licensee.** Subject to Sections 2.2, 2.5 and the other terms and conditions of this Agreement, RVL hereby grants to Licensee:

**2.1.1.** an exclusive (including with regard to RVL and its Affiliates) license (or sublicense), with the right to grant sublicenses in accordance with Section 2.3, under the RVL Patents, the RVL Know-How and RVL's interests in the Joint Patents and the Joint Know-How, to Exploit the Licensed Products in the Field in the Territory;

**2.1.2.** an exclusive (including with regard to RVL and its Affiliates) license and right of reference, with the right to grant sublicenses and further rights of reference in accordance with Section 2.3, under the RVL Regulatory Documentation that RVL or its Affiliates Control during the Term as necessary for purposes of Exploiting the Licensed Products in the Field in the Territory; and

**2.1.3.** a non-exclusive license, with the right to grant sublicenses in accordance with Section 2.3, to use RVL's Corporate Names solely as required to Exploit the Licensed Products in the Field in the Territory.

**2.2.** **Grants to RVL.** Subject to Sections 2.1, 2.5 and the other terms and conditions of this Agreement, Licensee hereby grants to RVL:

**2.2.1.** an exclusive (including with regard to Licensee and its Affiliates) license, with the right to grant sublicenses in accordance with Section 2.3, under the Licensee Patents, the Licensee Know-How and Licensee's interests in the Joint Patents and the Joint Know-How, to Exploit the Licensed Products in the Field outside the Territory; and

**2.2.2.** an exclusive (including with regard to Licensee and its Affiliates) license and right of reference, with the right to grant sublicenses and further rights of reference in accordance with Section 2.3, under the Licensee Regulatory Documentation that Licensee or its Affiliates Control during the Term as necessary for purposes of Exploiting the Licensed Products in the Field outside the Territory.

**2.3. Sublicenses.** Each Party shall have the right to grant sublicenses (or further rights of reference), through multiple tiers of sublicensees or Sublicensees, under the licenses and rights of reference granted in Section 2.1 or Section 2.2 (as the case may be), to its Affiliates and other Persons; *provided* that any such sublicenses shall be consistent with, and expressly made subject to, the terms and conditions of this Agreement. Each Party shall cause each sublicensee or Sublicensee to comply with the applicable terms and conditions of this Agreement. A copy of any sublicense agreement executed by Licensee shall be provided to RVL within fifteen (15) Business Days after its execution; *provided* that the financial terms of any such sublicense agreement to the extent not pertinent to an understanding of a Party's obligations or benefits under this Agreement may be redacted.

**2.4. Assignment of RVL Trademark.** RVL hereby grants to Licensee an exclusive and irrevocable option to purchase all right, title and interest in and to the RVL Trademarks in the Territory for the duration of the Term, exercisable at no additional cost or consideration. At any time during the Term, but no later than the date of the First Commercial Sale of Licensed Product in any country in the Territory, Licensee may exercise this option by sending RVL a written notice of Licensee's intention to exercise the option. Upon such notice, RVL shall irrevocably sell, assign, transfer, and convey to Licensee for no additional consideration, and Licensee shall accept, all right, title, and interest in and to the RVL Trademarks in the Territory for all goods and services, including all registrations, applications for registration, and renewals of the RVL Trademarks in the Territory. The RVL Trademarks in the Territory shall thereafter be regarded as a Product Trademark for purposes of this Agreement to the extent the RVL Trademarks are used by Licensee or its Affiliates or its or their Sublicensees for the Commercialization of Licensed Products in the Territory. For the avoidance of doubt, all rights granted under this Section 2.4 shall automatically terminate upon the expiration or termination of this Agreement.

**2.5. Retention of Rights; Limitations Applicable to License Grants.**

**2.5.1. Retained Rights.** Notwithstanding anything to the contrary in this Agreement, each Party hereby expressly retains, for itself and its Affiliates (and on behalf of its licensors, (sub)licensees and contractors):

(i) rights in and to the Patents, know-how (whether Licensee Know-How, RVL Know-How or Joint Know-How, as the case may be), and Regulatory Documentation licensed by such Party hereunder, in each case, to perform its obligations under this Agreement; and

(ii) rights in and to the Patents, know-how (whether Licensee Know-How, RVL Know-How or Joint Know-How, as the case may be), and Regulatory Documentation licensed by such Party hereunder, (i) in the case of RVL, to Develop and Manufacture Licensed Products in the Territory solely for purposes of (a) Commercializing Licensed Product outside the Field in the Territory, and (b) Commercializing Licensed Products outside the Territory, and (ii) in the case of Licensee, to Develop and Manufacture Licensed Products outside the Territory solely for purposes of Commercializing Licensed Product in the Field in the Territory.

**2.5.2. In-License Agreements.** The licenses granted by RVL in Section 2.1 include sublicenses under the applicable license rights granted to RVL by Third Parties under the In-License Agreements. Any sublicense with respect to Information or intellectual property rights of a Third Party hereunder and any right of Licensee (if any) to grant a further sublicense thereunder, shall be subject and subordinate to the terms and conditions of the In-License Agreement under which such sublicense is granted and shall be effective solely to the extent permitted under the terms of such agreement. Without limitation of the foregoing, in the event and to the extent that any In-License Agreement requires that particular terms or conditions of such In-License Agreement be contained or incorporated in any agreement granting a sublicense thereunder, such terms and conditions are hereby deemed to be incorporated herein by reference and made applicable to the sublicense granted herein under such In-License Agreement. RVL shall promptly provide Licensee with a true and complete copy of any amendment to the In-License Agreement entered into after the Effective Date. RVL shall not, without Licensee's prior written consent not to be unreasonably withheld, conditioned or delayed (i) amend, restate, delete, substitute, or waive any material terms or conditions of the In-License Agreement; or (ii) exercise any right to terminate or consent to any termination, in whole or in part, of the In-License Agreement, in both clauses (i) and (ii) in a manner that would materially and adversely affect Licensee's rights hereunder. RVL shall notify Licensee in writing promptly (and in any event within five (5) Business Days) after receipt of any notice from the other party to the In-License Agreement of its termination or intent to exercise any right of termination of the In-License Agreement or of any alleged breach by RVL under the In-License Agreement. RVL covenants that it shall not materially breach its obligations under the In-License Agreement, and will not exercise any of its rights under or in connection with the In-License Agreement to terminate the In-License Agreement without prior written consent of Licensee. Licensee has the right, but not the obligation, to cure any alleged breach by RVL of any of its obligations under the In-License Agreement that would materially and adversely affect Licensee's rights hereunder, on RVL's behalf. RVL shall reimburse Licensee for its costs and expenses incurred in connection with such cure, and, without prejudice to any other rights or remedies of Licensee, Licensee may offset such costs and expenses against any milestone payments under Section 5.2 or any royalty payments under Section 5.3.

**2.5.3. No Other Rights Granted by RVL.** Except as expressly provided herein and without limiting the foregoing, RVL grants no other right or license, including any rights or licenses to the RVL Patents, the RVL Know-How, RVL's interest in the Joint Patents and the Joint Know-How, the RVL Regulatory Documentation, the RVL Corporate Names or any other Patent or intellectual property rights not otherwise expressly granted herein.

**2.5.4. No Other Rights Granted by Licensee.** Except as expressly provided herein, Licensee grants no other right or license, including any rights or licenses to the Licensee Patents, the Licensee Know-How, Licensee's interest in the Joint Patents and the Joint Know-How, the Licensee Regulatory Documentation or any other Patent or intellectual property rights not otherwise expressly granted herein.

**2.6. Non-Compete.**

**2.6.1. By RVL.** During the Term, RVL shall not, and shall cause its Affiliates not to, (i) directly or indirectly, Commercialize or (ii) license, authorize, appoint or otherwise enable any Third Party to directly or indirectly Commercialize, in either case clause (i) or (ii) any human pharmaceutical product containing the Licensed Compound as the sole active pharmaceutical ingredient for use in the Field in any country in the Territory.

**2.6.2. By Licensee.** During the Term, Licensee shall not, and shall cause its Affiliates not to, (i) directly or indirectly, Commercialize or (ii) license, authorize, appoint or otherwise enable any Third Party to directly or indirectly Commercialize, in either case clause (i) or (ii) [***] in any country outside the Territory. For the avoidance of doubt, Licensee may carry out its own Development, and Exploit its own technology, in relation to products that do not contain the Licensed Compound and would not utilize the rights granted pursuant to Section 2.1.

**2.6.3. Exception.** The restrictions set forth in this Section 2.6 shall not apply to an Affiliate of a Party ("**Acquiring Party**") that becomes an Affiliate of such Acquiring Party after the Effective Date as a result of a Change of Control; *provided* that such Affiliate was Commercializing the applicable product prior to the date on which the agreements effecting such Change of Control were first executed; and *provided, further*, that the applicable product and activities conducted with respect thereto are not covered by or otherwise related to and do not incorporate or reference the Patents or know-how (whether Licensee Know-How, RVL Know-How or Joint Know-How, as the case may be) that are licensed hereunder. If the Affiliate was Commercializing the applicable product, the Acquiring Party shall notify the other Party ("**Non-Acquiring Party**") (i) within three (3) Business Days of the execution of the agreements effecting such Change of Control and (ii) within three (3) Business Days of the occurrence of such Change of Control (clause (ii), the "**Acquisition Closing Notice**"). The Non-Acquiring Party shall have the right to terminate this Agreement by providing the Acquiring Party a termination notice (the "**Acquisition Termination Notice**") pursuant to Section 10.2.7 within five (5) Business Days of receiving the Acquisition Closing Notice (the "**Acquisition Termination Period**"). For the avoidance of doubt, if the Acquisition Termination Notice is not provided to the Acquiring Party during the Acquisition Termination Period, the Non-Acquiring Party shall have irrevocably waived its right to terminate this Agreement under Section 10.2.7 in respect of the particular instance of Change of Control notified in the Acquisition Closing Notice that initiates such Acquisition Termination Period, but shall not be deemed to have waived the right to terminate this Agreement under Section 10.2.7 in respect of any subsequent instances of Change of Control even if such subsequent instances of Change of Control involve the same Affiliate or its successor. Without limitation of Section 11.3.2, upon such Change of Control, the Acquiring Party shall ensure that: (a) no such Affiliate obtains any rights or access to, employs or is permitted to benefit from the services of any Person who has access to, the Confidential Information of the other Party or any other Information generated under or in connection with this Agreement; and (b) all such Affiliates' research, development and commercialization activities related to the applicable competing product(s) are kept separate from the research, Development and Commercialization activities for Licensed Products under this Agreement. Each Party acknowledges and agrees that (1) this Section 2.6 has been negotiated by the Parties, (2) the geographical and time limitations on activities set forth in this Section 2.6 are reasonable, valid and necessary in light of the Parties' circumstances and necessary for the adequate protection of the business of the Licensed Products and (3) neither Party would have entered into this Agreement without the protection afforded it by this Section 2.6. If, notwithstanding the foregoing, a court of competent jurisdiction determines that the restrictions set forth in this Section 2.6 are too broad or otherwise unreasonable under Applicable Law, including with respect to duration, geographic scope or space, the court is hereby requested and authorized by the Parties to revise this Section 2.6 to include the maximum restrictions allowable under Applicable Law.

**2.7. Right of First Refusal regarding Field Expansion.** In the event that RVL or any of its Affiliates intends to submit a Drug Approval Application in the United States, or in the European Union (including submission to EMA) for a pharmaceutical product containing the Licensed Compound (including in combination with another active ingredient) for any human ophthalmic indication outside the Field (each, a "**Subsequent Indication**"), RVL shall notify Licensee as soon as practicable after completion of the pivotal trial for such Subsequent Indication. To aid Licensee's evaluation of Field expansion, RVL shall comply with Licensee's reasonable requests of information on such Subsequent Indication and Drug Approval Application. RVL shall notify Licensee within thirty (30) days of the submission of a Drug Approval Application in the United States, or in the European Union (including submission to EMA) for a Subsequent Indication, and shall make a copy of such Drug Approval Application available to Licensee. If Licensee notifies RVL within thirty (30) days of receipt of such notice from RVL that it desires to expand the Field to include such Subsequent Indication, RVL shall negotiate exclusively with Licensee in good faith to establish mutually agreeable terms for such expansion of the Field until ninety (90) days after Licensee provides such notification to RVL, or such later time as the Parties may mutually agree in writing (each, a "**Field Expansion Negotiation Period**"). The Parties intend that any such agreement would provide for (i) a payment by Licensee to RVL, on the condition that the Drug Approval Application is subsequently approved, in the amount of [***], which shall be paid to and held in an escrow account until the Drug Approval Application is approved, and shall be refunded to Licensee if (a) a Drug Approval Application does not result in a complete approval but consists of other types of responses such as a Complete Response Letter, or a limited approval approving indications that are only a portion of the Subsequent Indication applied for in the Drug Approval Application, (b) the Drug Approval Application is amended or resubmitted, or (c) a Drug Approval Application is granted with a substantial safety warning, where the proportions of such refund shall be stipulated in such agreement, and (ii) mutually agreeable milestone payments for Regulatory Approval, where such payments shall not exceed the amounts set forth herein for the Licensed Product in the Field, except that, such financial terms shall be renegotiated downward, and such agreement shall be terminable or cancellable if (a) the response from the relevant authority on the Drug Approval Application does not consist of a complete approval but consists of other types of responses such as a Complete Response Letter, a limited approval approving indications that are only a portion of the Subsequent Indication applied for in the Drug Approval Application, or a Drug Approval Application is granted with a substantial safety warning, or (b) the Drug Approval Application is amended or resubmitted. In the event the Parties mutually agree, each in their sole discretion and without obligation to reach agreement, upon appropriate financial and other terms for such Subsequent Indication, the Parties shall memorialize their agreement in accordance with Section 11.8 and thereafter the Field shall be deemed to include such Subsequent Indication. If Licensee does not notify RVL that it desires to expand the Field to include a Subsequent Indication or the Parties do not memorialize an agreement in accordance with Section 11.8 for such Subsequent Indication within the Field Expansion Negotiation Period, RVL shall have no further obligation to Licensee with respect to the Licensed Product for such Subsequent Indication.

## ARTICLE 3
## DEVELOPMENT, REGULATORY AND COMMERCIALIZATION ACTIVITIES

**3.1. Development.**

**3.1.1. Diligence.** Licensee shall be solely responsible for all aspects of the Development of the Licensed Products in the Field in the Territory. Licensee shall use Commercially Reasonable Efforts to Develop, obtain and maintain Regulatory Approvals for, the Licensed Products for use throughout the Territory in the Field.

**3.1.2. Development Plan**. Attached hereto as Schedule 3.1.2 is the initial plan for the Development of the Licensed Product in the Field in the Major Markets (the "**Development Plan**"). For each country in the Major Markets in which the Regulatory Approval for the initial indication has not yet been granted, Licensee shall deliver to RVL an updated Development Plan, in reasonable detail, each Calendar Year during the Term, no later than March 31 of each Calendar Year. The JSC shall promptly review and discuss each Development Plan submitted by Licensee.

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

**3.1.4. Development Records.** Licensee shall, and shall cause its Affiliates and its and their Sublicensees to, maintain, in good scientific manner, books and records of clinical trials and experiments conducted during the course of Development of Licensed Products hereunder and included or referred to in the New Drug Applications or IND for Licensed Products, in sufficient detail to verify compliance with its obligations under this Agreement. Such books and records shall (i) be appropriate for Patent and regulatory purposes, (ii) be in compliance with Applicable Law, (iii) properly reflect work done and results achieved in the performance of its Development activities hereunder**,** and (iv) be retained by Licensee for at least three (3) years after the expiration or termination of this Agreement in its entirety or for such longer period as may be required by Applicable Law. RVL shall have the right, during normal business hours and upon reasonable notice, to inspect and copy such books and records; *provided* that RVL has a justifiable reason and makes the request at reasonable timings and frequency, not exceeding once every Calendar Year during the term of this Agreement; *provided, further,* that RVL shall maintain such records and information disclosed therein in confidence in accordance with Article 7.

**3.1.5. Development Reports.** At the end of June and December of each Calendar Year and while Licensee is conducting Development activities hereunder, Licensee shall provide to RVL a written report, in reasonable detail for each of the Major Markets, of such Development activities it has performed, or caused to be performed, since the preceding report, and its Development activities in process, together with a high level report of its Development efforts outside of the Major Markets relating to the Licensed Products.

**3.2. Regulatory Activities.**

**3.2.1. Regulatory Approvals.**

(i) As between the Parties and except as otherwise set forth in this Section 3.2, Licensee shall have the sole right and responsibility to prepare, obtain and maintain Drug Approval Applications (including the setting of the overall regulatory strategy therefor), marketing authorizations, other Regulatory Approvals and other submissions and to conduct communications with the Regulatory Authorities, for Licensed Products in the Field in the Territory (which shall include filings of or with respect to INDs and other filings or communications with the Regulatory Authorities). RVL shall use reasonable efforts to cooperate in respect of this Section 3.2.1(i), which shall include providing to Licensee upon request by Licensee documentation including the Regulatory Documentation (including RVL Regulatory Documentation), and any letter of access, certificate of pharmaceutical product, or other letter, document, or certification that is reasonably necessary for Licensee to prepare, obtain, or maintain Drug Approval Applications or otherwise exercise the license and right granted under this Agreement. In addition, RVL shall provide to Licensee true and complete copies of the Regulatory Documentation submitted by RVL to Regulatory Authorities.

(ii) All Regulatory Documentation (including all Regulatory Approvals) relating to the Licensed Products in the Field in the Territory developed or granted after the Effective Date shall be owned by and shall be the sole property and held in the name of, Licensee or its designated Affiliate or Sublicensee (the "**Licensee Regulatory Documentation**").

**3.2.2. Communications with Regulatory Authorities.** Licensee shall provide RVL with reasonable advance notice of all meetings, conferences or discussions (whether face-to-face or teleconference and including any meeting of experts convened by a Regulatory Authority concerning any topic relevant to a Licensed Product) scheduled with a Regulatory Authority concerning any material regulatory matters relating to a Licensed Product in the Field in the Major Markets within two (2) Business Days after the scheduling of such meeting and shall provide RVL copies of all related documents and other relevant information relating to such meetings or other contacts in advance to permit RVL a reasonable amount of time to review and comment prior to Licensee submitting such documents and information to the Regulatory Authority. In addition, with respect to the Licensed Product in the Field in the Major Markets, Licensee shall promptly provide RVL with: (i) copies of all pre-clinical and clinical data compiled in support of regulatory filings; (ii) copies of material regulatory correspondence to or from the Regulatory Authorities, including minutes of meetings whether in person or by telephone; (iii) advance copies of material, non-recurring submissions matters (*e.g.*, filings related to new indications and proposed labeling, etc.) to the Regulatory Authorities and a reasonable opportunity to comment in advance on such submissions (and to have its comments reasonably taken into account); (iv) notices of any revocations of Regulatory Approvals with respect to any such Licensed Product and any Licensed Product recalls or withdrawals; and (v) reasonable responses to inquiries by RVL regarding the Regulatory Approval and Commercialization processes for any Licensed Product. Notwithstanding Section 11.9, Licensee may deliver the regulatory materials under this Section 3.2.2 in the language that such regulatory materials are submitted to the Regulatory Authorities.

**3.2.3. Regulatory Filings.** Licensee shall provide RVL with copies of INDs, and Module 1.5 and Module 2 of Drug Approval Applications for the Licensed Product in the Field in the Major Markets after completion of such filings. Notwithstanding Section 11.9, Licensee may deliver the regulatory materials under this Section 3.2.3 in the language that such regulatory materials are submitted to the Regulatory Authorities.

**3.2.4. Recalls, Suspensions or Withdrawals.** Each Party shall notify the other Party promptly (but in no event later than forty-eight (48) hours) following its determination that any event, incident or circumstance has occurred that may result in the need for a recall, market suspension or market withdrawal of a Licensed Product and shall include in such notice the reasoning behind such determination and any supporting facts. As between the Parties, Licensee shall have the right to make the final determination whether to voluntarily implement any such recall, market suspension or market withdrawal in the Territory and RVL shall have the right to make the final determination whether to voluntarily implement any such recall, market suspension or market withdrawal outside the Territory; *provided* that prior to any implementation of such a recall, market suspension or market withdrawal, the Party making such determination shall, when circumstances permit, make an attempt to consult with the other Party, and the other Party shall respond on an expedited basis to such request for consultation, and if requested, the other Party shall provide reasonable cooperation and assistance to the determining Party in the Party's initiation or implementation of such a recall, market suspension or market withdrawal. If a recall, market suspension or market withdrawal is mandated by a Regulatory Authority, as between the Parties, Licensee shall initiate such a recall, market suspension or market withdrawal in compliance with Applicable Law in the Territory and RVL shall initiate such a recall, market suspension or market withdrawal in compliance with Applicable Law outside the Territory. For all recalls, market suspensions or market withdrawals undertaken pursuant to this Section 3.2.4, as between the Parties, Licensee shall be solely responsible for the execution and all costs thereof in the Territory, and RVL shall be solely responsible for the execution and all costs thereof outside the Territory, except where such recall, market suspension or market withdrawal arises from (i) the failure to comply with RVL's obligation under Section 3.2.1(i) to provide Licensee true and complete copies of the Regulatory Documentation submitted by RVL to Regulatory Authorities, (ii) RVL's breach of its representation and warranty set forth in Section 8.2.10, (iii) defects in the products, materials, or components supplied by the non-initiating Party (in which cases such costs shall be borne solely by the non-initiating Party) or (iv) where the Parties have a separate agreement covering the situation leading to such recall, market suspension or market withdrawal (in which case such separate agreement shall be followed).

**3.2.5. Safety Data Exchange Agreement.** Within one hundred eighty (180) days of the Effective Date, the Parties shall enter into an agreement providing for the exchange of adverse event safety data (including post-marketing spontaneous reports received by Licensee and its Affiliates) in a mutually agreed format in order to monitor the safety of the Licensed Product and to meet reporting requirements with any applicable Regulatory Authority.

**3.3. Commercialization.**

**3.3.1. Diligence.** Licensee (itself or through its Affiliates or Sublicensees) shall be solely responsible for Commercialization of the Licensed Products in the Field throughout the Territory at Licensee's own cost and expense. Licensee shall use Commercially Reasonable Efforts to Commercialize the Licensed Products in the Field throughout the Territory.

**3.3.2. Commercialization Plan.** At least sixty (60) days prior to the anticipated date of the First Commercial Sale of a Licensed Product, Licensee shall deliver to RVL a reasonably detailed, multi-year plan for Commercialization of the Licensed Product throughout the Major Markets (the "**Commercialization Plan**"). The Commercialization Plan shall include a high-level overview of: (i) general strategies for promoting, pricing, marketing and distributing the Licensed Products, including expected investment and promotional efforts and sales force allocation; (ii) pre-launch Commercialization activities and the expected date of launch; (iii) the nature of promotional activities anticipated; and (iv) plans regarding distribution and supply chain management. Thereafter, Licensee shall deliver to RVL an updated Commercialization Plan each Calendar Year during the Term, no later than March 31 of each Calendar Year. The JSC shall promptly review and discuss each Commercialization Plan submitted by Licensee.

**3.3.3. Commercialization Costs.** Licensee shall be responsible for all of its costs and expenses in connection with the Commercialization of the Licensed Products.

**3.3.4. Commercialization Records.** Licensee shall, and shall cause its Affiliates and its and their Sublicensees to, maintain books and records pertaining to Commercialization of Licensed Products hereunder, in sufficient detail to verify compliance with its obligations under this Agreement. Such records shall be retained by Licensee for at least three (3) years after the expiration or termination of this Agreement in its entirety or for such longer period as may be required by Applicable Law. RVL shall have the right, during normal business hours and upon reasonable notice, to inspect and copy all such books and records maintained pursuant to this Section 3.3.4; *provided* that RVL has a justifiable reason and makes the request at reasonable timings and frequency, not exceeding once every Calendar Year during the term of this Agreement; *provided, further,* that RVL shall maintain such records and information disclosed therein in confidence in accordance with Article 7.

**3.3.5. Commercialization Reports.** Within thirty (30) days following the end of each Calendar Year during which Licensee is conducting Commercialization activities hereunder**,** Licensee shall provide to RVL a written report, in reasonable detail for each of the Major Markets, of such Commercialization activities it has performed, or caused to be performed, since the preceding report, and of its on-going Commercialization activities, together with a high-level report of its Commercialization efforts outside of the Major Markets relating to the Licensed Products. Such reports shall include, for each of the Major Markets: (i) a description of the relevant incentive compensation plan and sales force size and allocation; (ii) the number and position of details in the applicable period; (iii) the nature of promotional activities and Licensed Product sampling activities; (iv) market and sales promotional programs; and (v) the conduct of advertising, public relations and other promotional programs, including professional symposia and speaker and peer-to-peer activity programs used in the Commercialization of such Licensed Product.

**3.4. Compliance with Applicable Law.** Licensee shall and shall cause its Affiliates to, comply with Applicable Law with respect to the Exploitation of Licensed Products.

**3.5. Supply of Licensed Products.** After the Effective Date, upon Licensee's request, the Parties shall promptly engage in good faith negotiations for entrance into a clinical supply agreement and/or a technology transfer agreement on terms mutually agreeable to the Parties.

**3.6. Preservation of Territory Exclusivities**. [***].

## ARTICLE 4
## STEERING COMMITTEE

**4.1. Joint Steering Committee.** Within one month after the Effective Date, the Parties shall establish a joint steering committee (the "**Joint Steering Committee**" or "**JSC**"), which shall consist of three (3) representatives from each of the Parties, each with the requisite experience and seniority to enable such person to make decisions on behalf of the Parties with respect to the issues falling within the jurisdiction of the JSC. From time to time, each Party may substitute one or more of its representatives to the JSC on written notice to the other Party. Licensee shall select from its representatives the chairperson for the JSC. The JSC shall:

**4.1.1.** periodically serve as a forum for discussing Development of the Licensed Products, including by reviewing Development Plans as provided in Section 3.1.2 and reviewing Development reports delivered pursuant to Section 3.1.5;

**4.1.2.** periodically serve as a forum for discussing the Commercialization of Licensed Products as provided in Section 3.3.2, including by reviewing the Commercialization Plans and reviewing Commercialization reports as provided in Section 3.3.5;

**4.1.3.** periodically serve as a forum for each Party to update the other Party on any Development activities involving the Licensed Compound either as a sole active ingredient or in combination with other active ingredients;

**4.1.4.** review the manner in which the markings are to be presented on promotional materials, packaging and product labeling for the Licensed Products in the Territory;

**4.1.5.** coordinate the Parties' activities under this Agreement; and

**4.1.6.** perform such other functions as are set forth herein or as the Parties may mutually agree in writing, except where in conflict with any provision of this Agreement.

**4.2. General Provisions Applicable to the JSC.**

**4.2.1. Meetings and Minutes.** The JSC shall meet at the location of such meetings alternating between locations designated by Licensee and locations designated by RVL; *provided* that each Party, in its sole discretion, may attend any meeting telephonically or via web conferencing. The JSC shall meet quarterly until a New Drug Application is submitted in all Major Markets, and shall meet semi-annually thereafter. The chairperson of the JSC shall be responsible for calling meetings on no less than twenty (20) Business Days' notice unless exigent circumstances require shorter notice. Each Party shall make all proposals for agenda items at least ten (10) Business Days in advance of the applicable meeting and shall provide all appropriate information with respect to such proposed items at least five (5) Business Days in advance of the applicable meeting; *provided* that under exigent circumstances requiring input by the JSC, a Party may provide its agenda items to the other Party within a shorter period of time in advance of the meeting or may propose that there not be a specific agenda for a particular meeting, so long as the other Party consents to such later addition of such agenda items or the absence of a specific agenda for such meeting (which consent shall not be unreasonably withheld, conditioned or delayed). The chairperson of the JSC shall prepare and circulate for review and approval of the Parties minutes of each meeting within thirty (30) days after the meeting. The Parties shall agree on the minutes of each meeting promptly, but in no event later than the next meeting of the JSC.

**4.2.2. Procedural Rules.** The JSC shall have the right to adopt such standing rules as shall be necessary for its work, to the extent that such rules are not inconsistent with this Agreement. A quorum of the JSC shall exist whenever there is present at a meeting at least one representative appointed by each Party. Representatives of the Parties on the JSC may attend a meeting either in person or by telephone, video conference or similar means in which each participant can hear what is said by and be heard by, the other participants. Representation by proxy shall be allowed. Subject to Section 4.2.3, the JSC shall take action by consensus of the representatives present at a meeting at which a quorum exists, with each Party having a single vote irrespective of the number of representatives of such Party in attendance or by a written resolution signed by at least one representative appointed by each Party. The Alliance Managers or other employees or consultants of a Party who are not representatives of the Parties on the JSC may attend meetings of the JSC; *provided, however*, that such attendees (i) shall not vote or otherwise participate in the decision-making process of the JSC and (ii) are bound by obligations of confidentiality and non-disclosure at least as protective of the other Party as those set forth in Article 7.

**4.2.3. Decision-Making.** Except for matters outside the jurisdiction and authority of the JSC (including as set forth in Section 4.2.4), if the JSC cannot, or does not, reach consensus on an issue, then such issue shall be resolved pursuant to Section 11.5.

**4.2.4. Limitations on Authority.** Without limitation to the foregoing, the Parties hereby agree that matters explicitly reserved to the consent, approval or other decision-making authority of one or both Parties, as expressly provided in this Agreement, are outside the jurisdiction and authority of the JSC, including (i) amendment, modification or waiver of compliance with this Agreement, (which may only be amended or modified as provided in Section 11.8 or compliance with which may only be waived as provided in Section 11.11) and (ii) such other matters as are reserved to the consent, approval, agreement or other decision-making authority of either or both Parties in this Agreement that are not required by this Agreement to be considered by the JSC prior to the exercise of such consent, approval or other decision-making authority.

**4.2.5. Alliance Managers.** Each Party shall appoint a person(s) who shall oversee contact between the Parties for all matters between meetings of the JSC and shall have such other responsibilities as the Parties may agree in writing after the Effective Date, which person(s) may be replaced at any time by notice in writing to the other Party (the "**Alliance Managers**"). The Alliance Managers shall work together to manage and facilitate the communication between the Parties under this Agreement, including the resolution (in accordance with the terms of this Agreement) of issues between the Parties that arise in connection with this Agreement. The Alliance Managers shall not have final decision-making authority with respect to any matter under this Agreement.

**4.2.6. Discontinuation; Disbandment; Annual Reports.** The JSC shall continue to exist until the first to occur of: (i) the Parties mutually agreeing to disband the JSC; (ii) RVL providing to Licensee written notice of its intention to disband the JSC; or (iii) Licensee providing to RVL written notice of its intention to disband the JSC after receiving Regulatory Approval for the initial indication in all Major Markets. Upon the occurrence of any of the foregoing, (a) the JSC shall disband, have no further responsibilities or authority under this Agreement and will be considered dissolved by the Parties and (b) any requirement of a Party to provide Information or other materials to the JSC shall be deemed a requirement to provide such Information or other materials to the other Party and Licensee shall have the right to decide, after consultation with RVL and taking RVL's comments, if any, into consideration in good faith, all matters that are subject to the review or approval by the JSC hereunder.

## ARTICLE 5
## PAYMENTS AND RECORDS

**5.1. Upfront Payment.** In partial consideration of the rights granted by RVL to Licensee hereunder, within five (5) Business Days from the Effective Date, Licensee shall pay RVL a nonrefundable and noncreditable upfront amount equal to five million Dollars ($5,000,000).

**5.2. Milestones.**

**5.2.1. Development and Regulatory Milestones.** In partial consideration of the rights granted by RVL to Licensee hereunder, Licensee shall notify RVL within two (2) Business Days of the achievement of each of the following milestones for the Licensed Product (except for clause (i) below, as to which RVL is providing notice on the Effective Date pursuant to Schedule 5.2.1) and shall pay to RVL a milestone payment for the achievement of each such milestone within thirty (30) days after receiving an invoice from RVL for such milestone payment, calculated as follows:

(i) following receipt of the first Regulatory Approval by the FDA for a Licensed Product in the United States, twenty million Dollars ($20,000,000);

(ii) following the PMDA's acceptance and agreement with a Phase III Placebo Controlled Efficacy Study for a Licensed Product, [***] Dollars ($[***]);

(iii) following receipt of the first Regulatory Approval for a Licensed Product by any of (a) the EMA, (b) a Regulatory Authority of a member of the European Union, or (c) a Regulatory Authority of any country identified as "Other European Countries" on Schedule 1.108, [***] Dollars ($[***]);

(iv) following receipt of the first Regulatory Approval by the MHLW for a Licensed Product in Japan, [***] Dollars ($[***]); and

(v) following receipt of the first Regulatory Approval by the NMPA for a Licensed Product in the People's Republic of China, [***] Dollars ($[***]).

Each milestone payment in this Section 5.2.1 shall be payable only upon the first achievement of such milestone and no amounts shall be due for subsequent or repeated achievements of such milestone, whether for the same or a different Licensed Product.

**5.2.2. Commercial Milestones.** In partial consideration of the rights granted by RVL to Licensee hereunder, Licensee shall pay to RVL as follows:

(i) in the event that the aggregate of all Net Sales of the Licensed Product made by Licensee or any of its Affiliates or its or their Sublicensees during the Royalty Term exceeds [***] Dollars ($[***]), Licensee shall pay to RVL [***] Dollars ($[***]);

(ii) in the event that the aggregate of all Net Sales of the Licensed Product made by Licensee or any of its Affiliates or its or their Sublicensees during the Royalty Term exceeds [***] Dollars ($[***]), Licensee shall pay to RVL [***] Dollars ($[***]);

(iii) in the event that the aggregate of all Net Sales of the Licensed Product made by Licensee or any of its Affiliates or its or their Sublicensees during the Royalty Term exceeds [***] Dollars ($[***]), Licensee shall pay to RVL [***] Dollars ($[***]); and

(iv) in the event that the aggregate of all Net Sales of the Licensed Product made by Licensee or any of its Affiliates or its or their Sublicensees during the Royalty Term exceeds [***] Dollars ($[***]), Licensee shall pay to RVL [***] ($[***]).

In the event that in a given Calendar Year more than one of the foregoing thresholds set forth in clauses (i) through (iv) of this Section 5.2.2. is exceeded, Licensee shall pay to RVL a separate milestone payment with respect to each such threshold that is exceeded in such Calendar Year. Each such milestone payment shall be due within forty-five (45) days of the end of the Calendar Year in which such milestone was achieved. Each milestone payment in this Section 5.2.2 shall be payable only upon the first achievement of such milestone in a given Calendar Year and no amounts shall be due for subsequent or repeated achievements of such milestone in subsequent Calendar Years. Each milestone payment shall be non-refundable and non-creditable against any other milestone payment or royalty payment obligation.

**5.2.3. Determination that Milestones Have Occurred.** Licensee shall notify RVL promptly of the achievement of each of the events identified as a milestone in Section 5.2.1 or Section 5.2.2. In the event that, notwithstanding the fact that Licensee has not provided RVL such a notice, RVL believes that any such milestone has been achieved, it shall so notify Licensee in writing and the Parties shall promptly meet and discuss in good faith whether such milestone has been achieved. Any dispute under this Section 5.2.3 regarding whether or not such a milestone has been achieved shall be subject to resolution in accordance with Section 11.5.

**5.3. Royalties.**

**5.3.1. Royalty Rates.** As further consideration for the rights granted to Licensee hereunder, during the Royalty Term, Licensee shall pay to RVL a royalty on Net Sales to Third Parties (including Distributors) of the Licensed Product in the Territory during each Calendar Year, at the following rates:

(i) for that portion of aggregate Net Sales of all Licensed Products in the Territory during a Calendar Year less than or equal to [***] ($[***]), a royalty rate of [***] percent ([***]%);

(ii) for that portion of aggregate Net Sales of all Licensed Products in the Territory during a Calendar Year greater than [***] Dollars ($[***]) but less than or equal to [***] Dollars ($[***]), a royalty rate of [***] percent ([***]%);

(iii) for that portion of aggregate Net Sales of all Licensed Products in the Territory during a Calendar Year greater than [***] Dollars ($[***]) but less than or equal to [***] Dollars ($[***]), a royalty rate of [***] percent ([***]%);

(iv) for that portion of aggregate Net Sales of all Licensed Products in the Territory during a Calendar Year greater than [***] Dollars ($[***]) but less than or equal to [***] Dollars ($[***]), a royalty rate of [***] percent ([***]%); and

(v) for that portion of aggregate Net Sales of all Licensed Products in the Territory during a Calendar Year greater than [***] Dollars ($[***]), a royalty rate of [***] percent ([***]%).

**5.3.2. Anti-stacking Reduction.** The royalty amount due under Section 5.3.1 shall be reduced by the amount that Licensee paid, during the same Calendar Year to any Third Party, as consideration for any Third Party Rights (i) that cover or are relevant to any aspect of the Licensee's Exploitation of the Licensed Product pursuant to the license under Section 2.1 including but not limited to [***] (ii) to which Licensee has obtained a license pursuant to Section 6.6; *provided* that (a) such reduction shall not exceed [***] percent ([***]%) of the royalty amount otherwise due and (b) no such reduction shall be available for any Third Party Rights that cover or are relevant to only those aspects of the Licensed Product that are developed solely by the Licensee and are not purported to be covered by the license under Section 2.1.

**5.3.3. Generic Reduction.** If in any country in the Territory during the Royalty Term for any Licensed Product, a Generic Product is launched in such country, Licensee shall, for such Licensed Product in such country, thereafter pay to RVL a royalty rate reduced by [***] percent ([***]%) with respect to Net Sales of such Licensed Product in such country (as compared to the rates set forth in Section 5.3.1); *provided* that if such Generic Product is no longer commercialized in such country during such Royalty Term for any reason, the foregoing reduction shall no longer apply and Licensee shall continue to pay the rates set forth in Section 5.3.1. "**Generic Product**" shall mean that the product is therapeutically equivalent to the Licensed Product, as determined by the applicable Regulatory Authority for a given country as is necessary to permit pharmacists or other individuals authorized to dispense pharmaceuticals under Applicable Law in such country to substitute one product for another product in the absence of specific instruction from a physician or other authorized prescriber under Applicable Law; *provided* that if pharmacists are not authorized to substitute Generic Products under Applicable Law in a given country without specific instruction from a physician or other authorized prescriber, "**Generic Product**" shall mean a product that has the same active ingredients, the same dosage form, the same route of administration, substantially the same strength, and the same indication as the Licensed Product.

**5.3.4. Blended Royalty.** Licensee acknowledges that (i) the RVL Know-How and the Information included in the RVL Regulatory Documentation licensed to Licensee are proprietary and valuable and that without the RVL Know-How and such Information, Licensee would not be able to obtain and maintain Regulatory Approvals with respect to the Licensed Products, (ii) access to the RVL Know-How and the rights with respect to the RVL Regulatory Documentation have provided Licensee with a competitive advantage in the marketplace beyond the exclusivity afforded by the RVL Patents and Joint Patents and any Regulatory Exclusivity Period and (iii) the milestone payments and royalties set forth in Sections 5.2.1 and 5.2.2 and Section 5.3.1, respectively, are, in part, intended to compensate RVL for such exclusivity and such competitive advantage. The Parties agree that the royalty rates set forth in Section 5.3.1 reflect an efficient and reasonable blended allocation of the value provided by RVL to Licensee.

**5.3.5. Royalty Term.** Licensee shall have no obligation to pay any royalty with respect to Net Sales of any Licensed Product in any country after the Royalty Term for such Licensed Product in such country has expired.

**5.4. Royalty Payments and Reports.** Licensee shall calculate all amounts payable to RVL pursuant to Section 5.3 at the end of each Calendar Quarter, which amounts shall be converted to Dollars, in accordance with Section 5.5. Within one month after the end of each Calendar Quarter, with respect to Licensed Products directly sold by Licensee or its Affiliates, and not through its Sublicensees or Distributors, Licensee shall furnish to RVL a written summary report (the "**Direct Net Sales Report**") setting forth, (i) for such Calendar Quarter, the gross sales and Net Sales of each Licensed Product (including the elements included in the calculation of gross sales and Net Sales for such Licensed Products) and (ii) for the immediately preceding Calendar Quarter, any adjustments to the Indirect Net Sales Report for such preceding Calendar Quarter. Within one month after the end of each Calendar Quarter, with respect to Licensed Products indirectly sold by Licensee or its Affiliates, through its Sublicensees or Distributors, Licensee shall furnish to RVL a written summary report (the "**Indirect Net Sales Report**") setting forth for such Calendar Quarter the estimated gross sales and Net Sales of each Licensed Product (including the elements included in the calculation of gross sales and Net Sales for such Licensed Products). The Net Sales Reports shall be subject to the audit provisions of Section 5.9. Upon submission of a Net Sales Report, Licensee shall pay to RVL the royalty amounts due with respect to a given Calendar Quarter (subject to adjustment as set forth in this Section 5.4). Each payment of royalties due to RVL shall be accompanied by the Net Sales Report (as outlined above) of the Licensed Products in each country in the Territory during the applicable Calendar Quarter (including such amounts expressed in local currency and as converted to Dollars) and a calculation of the amount of royalty payment due on such Net Sales for such Calendar Quarter. Without limiting the generality of the foregoing, Licensee shall require its Affiliates and Sublicensees to account for its Net Sales and to provide such reports with respect thereto as if such sales were made by Licensee.

**5.5. Mode of Payment; Offsets.** All payments to either Party under this Agreement shall be made by deposit of Dollars in the requisite amount to such bank account as the receiving Party may from time to time designate by notice to the paying Party. Until further notice, any payment to RVL shall be made to the following bank account:

[***]

For the purpose of calculating any sums due under, or otherwise reimbursable pursuant to, this Agreement (including the calculation of Net Sales expressed in currencies other than Dollars), Licensee shall convert any amount expressed in a foreign currency into Dollars by applying the TTM (Telegraphic Transfer Middle) rate published by the MUFG Bank, Ltd. on the last Tokyo Business Day in the Calendar Quarter with respect to the Net Sales in which royalties are paid. Notwithstanding anything contained herein to the contrary, a Party may convert any amount expressed in a foreign currency into Dollar equivalents using another standard conversion methodology consistent with GAAP; *provided* that the other Party consents to such methodology, such consent not to be unreasonably withheld. Other than as expressly permitted in Section 2.5.2, Licensee shall have no right to offset, set off or deduct any amounts from or against the amounts due to RVL hereunder.

**5.6. Taxes.**

**5.6.1. General.** Except as set forth below in Section 5.6.2 and Section 5.6.3, each Party shall be responsible for its own taxes, duties, levies, imposts, assessments, deductions, fees, withholdings or similar charges imposed on or measured by net income or overall gross income (including branch profits), gross receipts, capital, ability or right to do business, property, and franchise or similar taxes pursuant to Applicable Law.

**5.6.2. Withholding.** The upfront payment, milestones and royalties payable by Licensee to RVL pursuant to this Agreement (each, a "**Payment**") shall be paid free and clear of any and all taxes, except for any withholding taxes required to be deducted therefrom by Applicable Law. Licensee shall be authorized to deduct or withhold from any Payments any amount of withholding taxes in accordance with Applicable Law. Notwithstanding the foregoing, if RVL is entitled under any applicable tax treaty or other Applicable Law to a reduction of rate of, or the elimination of, applicable withholding tax, it may deliver to Licensee or the appropriate governmental authority (with the assistance of Licensee to the extent that this is reasonably required and is expressly requested in writing) the prescribed forms necessary to reduce the applicable rate of withholding or to relieve Licensee of its obligation to withhold such tax, and Licensee shall apply the reduced rate of withholding or dispense with withholding, as the case may be; *provided* that Licensee has received evidence, in a form reasonably satisfactory to Licensee, of RVL's delivery of all applicable forms (and, if necessary, its receipt of appropriate governmental authorization) at least fifteen (15) days prior to the time that the Payments are due. If, in accordance with the foregoing, Licensee withholds any amount, it shall pay to RVL the balance when due, make timely payment to the proper taxing authority of the withheld amount and send to RVL proof of such payment within thirty (30) days following such payment. Amounts withheld in accordance with this Section 5.6.2 shall be treated as paid to RVL pursuant to this Agreement. Licensee shall cooperate with RVL to enable RVL to recover any taxes withheld by Licensee in respect of any Payment if RVL is entitled to a lower rate of, or exemption from withholding, under any applicable tax treaty or other Applicable Law.

**5.6.3. Indirect Tax**. If any Indirect Taxes are chargeable in respect of any Payments, Licensee shall timely pay such Indirect Taxes at the applicable rate in respect of such Payments following the receipt of a valid invoice in the appropriate form issued by RVL in respect of such Payment, where applicable; *provided*, *however*, that RVL shall, upon written notification including an invoice provided by Licensee, promptly pay to Licensee one half (1/2) of the amount of any such Indirect Taxes that are not recoverable. Licensee shall pay the amount of any Indirect Taxes on the later of (i) the due date for making the relevant Payment to which such Indirect Taxes relate and (ii) forty-five (45) days after the receipt by Licensee of the applicable valid invoice specifying such Indirect Taxes. The Parties shall reasonably cooperate to issue valid invoices for all amounts due under this Agreement consistent with Applicable Law and to lawfully eliminate or minimize the amount of any Indirect Taxes imposed on or in connection with the transactions contemplated by this Agreement. For the purposes of this Section 5.6.3, "**Indirect Taxes**" means any value added, ad valorem, sales, use, goods and services, consumption, transaction and similar tax chargeable on the supply or deemed supply of goods or services under Applicable Law, regardless of whether such tax is recoverable or not, and including any interest, penalties or other additions to tax thereon. All Payments hereunder are exclusive of any Indirect Taxes.

**5.7. Interest on Late Payments.** If any payment due to either Party under this Agreement is not paid when due, then such paying Party shall pay interest thereon (before and after any judgment) at an annual rate (but with interest accruing on a daily basis) of [***] percent ([***]%) plus the Secured Overnight Financing Rate (SOFR) for Dollars (or the future prevailing standard overnight borrowing rate replacing SOFR) as published by the Federal Reserve Bank of New York on the first Business Day after the date on which the applicable payment was due, such interest to run from the date on which payment of such sum became due until payment thereof in full together with such interest.

**5.8. Financial Records.** Licensee shall and shall cause its Affiliates and its and their Sublicensees to, keep complete and accurate financial books and records pertaining to the Commercialization of Licensed Products hereunder, including books and records of Invoiced Sales and Net Sales of Licensed Products, in sufficient detail to calculate and verify all amounts payable hereunder. Licensee shall and shall cause its Affiliates and its and their Sublicensees to, retain such books and records until the later of (i) three (3) years after the end of the period to which such books and records pertain and (ii) the expiration of the applicable tax statute of limitations (or any extensions thereof) or for such longer period as may be required by Applicable Law.

**5.9. Audit.** At the request of RVL, Licensee shall and shall cause its Affiliates and its and their Sublicensees to, permit RVL or an independent auditor designated by RVL, at reasonable times and upon advance notice of thirty (30) days, to audit the books and records maintained pursuant to Section 5.8 to ensure the accuracy of all reports and payments made hereunder. Except as provided below, the cost of this audit shall be borne by RVL, unless the audit reveals a variance of either (i) [***] percent ([***]%) or more from the reported amounts or (ii) [***] Dollars ($[***]) or more from the reported royalty amounts, in which case Licensee shall bear the cost of the audit. Unless disputed pursuant to Section 5.10 below, if such audit concludes that (a) additional amounts were owed by Licensee, Licensee shall pay the additional amounts, with interest from the date originally due as provided in Section 5.7 or (b) excess payments were made by Licensee, RVL shall reimburse such excess payments, in either case (clause (a) or (b)), within sixty (60) days after the date on which such audit is completed by RVL.

**5.10. Audit Dispute.** In the event of a dispute with respect to the auditor's conclusions of any audit under Section 5.9, RVL and Licensee shall work in good faith to resolve the disagreement. If the Parties are unable to reach a mutually acceptable resolution of any such dispute within thirty (30) days, the dispute shall be submitted for resolution to a certified public accounting firm jointly selected by each Party's certified public accountants or to such other Person as the Parties shall mutually agree (the "**Auditor**"). The decision of the Auditor shall be final and the costs of such arbitration as well as the initial audit shall be borne between the Parties in such manner as the Auditor shall determine. Not later than thirty (30) days after such decision and in accordance with such decision, Licensee shall pay the additional amounts, with interest from the date originally due as provided in Section 5.7 or RVL shall reimburse the excess payments, as applicable.

## ARTICLE 6
## INTELLECTUAL PROPERTY

**6.1. Ownership of Intellectual Property.**

**6.1.1. Ownership of Technology.** Subject to Section 3.2.1 and Section 6.1.2, as between the Parties, each Party shall own and retain all right, title and interest in and to any and all: (i) Information, and other inventions that are conceived, discovered, developed or otherwise made by or on behalf of RVL or its Affiliates or (sub)licensees, on the one hand and Licensee or its Affiliates or its or their Sublicensees, on the other hand, under or in connection with this Agreement, whether or not patented or patentable and any and all Patents and other intellectual property rights with respect thereto, except to the extent that any such Information or invention or any Patent or intellectual property rights with respect thereto, is Joint Know-How or Joint Patents; and (ii) other Information, inventions, Patents and other intellectual property rights that are owned or otherwise controlled (other than pursuant to the license grants set forth in Sections 2.1 and 2.2) by such Party or any of its Affiliates or its or their (sub)licensee or Sublicensees outside of this Agreement.

**6.1.2. Ownership of Joint Patents and Joint Know-How.** Subject to Section 3.2.1, as between the Parties, the Parties shall each own an equal, undivided interest in any and all: (i) Information, and other inventions that are conceived, discovered, developed or otherwise made jointly by or on behalf of RVL or its Affiliates or (sub)licensees, on the one hand and Licensee or its Affiliates or its or their Sublicensees, on the other hand, in connection with the work conducted under or in connection with this Agreement, whether or not patented or patentable (the "**Joint Know-How**"); and (ii) Patents (the "**Joint Patents**") and other intellectual property rights with respect to the Information, and other inventions described in clause (i) (together with Joint Know-How and Joint Patents, the "**Joint Intellectual Property Rights**"). Each Party shall promptly disclose to the other Party in writing and shall cause its Affiliates and its and their (sub)licensees and Sublicensees to so disclose, the development, making, conception or reduction to practice of any Joint Know-How or Joint Patents. Each Party shall, and does hereby, assign, and shall cause its Affiliates and its and their (sub)licensees and Sublicensees to so assign, without additional compensation, such right, title and interest in and to any Joint Intellectual Property Rights as well as any intellectual property rights with respect thereto, to the Parties as is necessary to fully effect the joint ownership provided for in clause (i) of this Section 6.1.2. Subject to the licenses and rights of reference granted under Sections 2.1 and 2.2 and restrictions and limitations of Territory provided thereunder, each Party shall have the right to Exploit the Joint Intellectual Property Rights without a duty of seeking consent or accounting to the other Party.

**6.1.3. United States Law.** The determination of whether Information**,** and other inventions are conceived, discovered, developed or otherwise made by a Party for the purpose of allocating proprietary rights (including Patent, copyright or other intellectual property rights) therein, shall, for purposes of this Agreement, be made in accordance with Applicable Law in the United States as such law exists as of the Effective Date irrespective of where or when such conception, discovery, development or making occurs. In the event that United States law does not apply to the conception, discovery, development or making of any Information, or other inventions hereunder, each Party shall, and does hereby, assign, and shall cause its Affiliates and its and their (sub)licensees and Sublicensees to so assign without additional compensation, such right, title and interest in and to any Information, and other inventions as well as any intellectual property rights with respect thereto, to the appropriate Party or Parties as is necessary to fully effect, as applicable, (i) the sole ownership provided for in Section 6.1.1 and (ii) the joint ownership provided for in Section 6.1.2.

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

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

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

**6.2. Maintenance and Prosecution of Patents.**

**6.2.1. Patent Prosecution and Maintenance of RVL Patents and Joint Patents.** RVL shall have the right, but not the obligation, through using counsel of its own choice, to prepare, file, prosecute and maintain the RVL Patents and Joint Patents in the Territory, which activities shall be at RVL's sole cost and expense. RVL shall periodically inform Licensee of all material steps with regard to the preparation, filing, prosecution and maintenance of the RVL Patents and Joint Patents in the Territory, including by providing Licensee with a copy of material communications to and from any Patent authority in the Territory regarding such RVL Patents and Joint Patents and by providing Licensee drafts of any material filings or responses to be made to such Patent authorities in the Territory sufficiently in advance of submitting such filings or responses so as to allow for a reasonable opportunity for Licensee to review and comment thereon. RVL shall consider in good faith the requests and suggestions of Licensee with respect to such drafts and with respect to strategies for filing and prosecuting the RVL Patents and Joint Patents in the Territory. If, as between the Parties, RVL decides not to prepare, file, prosecute or maintain an RVL Patent or a Joint Patent in a country in the Territory, RVL shall provide reasonable prior written notice to Licensee of such intention and, subject to any rights of any Third Parties under any In-License Agreement, Licensee shall thereupon have the option, in its sole discretion, to assume the control and direction of the preparation, filing, prosecution and maintenance of such RVL Patent or Joint Patent at its sole cost and expense in such country. RVL shall exercise its rights and interest and perform its obligations in accordance with the In-License Agreements to enable the Licensee to assume such control and direction of the preparation, filing, prosecution, and maintenance of such RVL Patent based on the terms of this Agreement.

**6.2.2. Patent Prosecution and Maintenance of Licensee Patents.** As between the Parties, Licensee shall have the sole right, but not the obligation, to prepare, file, prosecute and maintain the Licensee Patents worldwide, and to be responsible for any related interference, re-issuance, re-examination and opposition proceedings, in each case, at its sole cost and expense and using counsel of its own choice.

**6.2.3. Cooperation.** The non-prosecuting Party shall, and shall cause its Affiliates to, assist and cooperate with the prosecuting Party, as the prosecuting Party may reasonably request from time to time, in the preparation, filing, prosecution and maintenance of the RVL Patents, Joint Patents and the Licensee Patents under this Agreement, including that the non-prosecuting Party shall, and shall ensure that its Affiliates, (i) offer its comments, if any, promptly, and (ii) provide access to relevant documents and other evidence and make its employees available at reasonable business hours**.**

**6.2.4. Patent Term Extension and Supplementary Protection Certificate.** The Parties, through their representatives on the JSC, shall jointly make decisions regarding and (i) RVL shall have the right to apply for, patent term extensions, in the Territory, for the RVL Patents and Joint Patents with respect to the Licensed Products, and (ii) Licensee shall have the right to apply for, patent term extensions, in the Territory, for the Licensee Patents with respect to the Licensed Products, in each case including whether or not to do so.

**6.2.5. Common Ownership Under Joint Research Agreements.** Notwithstanding anything to the contrary in this Article 6, neither Party shall have the right to make an election under 35 U.S.C. 102(c) when exercising its rights under this Article 6 without the prior written consent of the other Party. With respect to any such permitted election, the Parties shall coordinate their activities with respect to any submissions, filings or other activities in support thereof. The Parties acknowledge and agree that this Agreement is a “joint research agreement” as defined in 35 U.S.C. 100(h).

**6.2.6. Patent Listings.** The Parties shall, through their representatives on the JSC, jointly make decisions regarding, and Licensee shall have the right to make, all filings with Regulatory Authorities in the Territory with respect to the RVL Patents and Joint Patents, including as required or allowed in the European Union, under the national implementations of Article 10.1(a)(iii) of Directive 2001/EC/83 or other international equivalents.

**6.3. Enforcement of Patents.**

**6.3.1. Notice.** Each Party shall promptly notify the other Party in writing of (i) any alleged or threatened infringement of the RVL Patents, Joint Patents or Licensee Patents in any jurisdiction in or outside the Territory or (ii) any certification filed under the Hatch-Waxman Act claiming that any RVL Patents, Joint Patents or Licensee Patents are invalid or unenforceable or claiming that any RVL Patents or Joint Patents would not be infringed by the making, use, offer for sale, sale or import of a product for which an application under the Hatch-Waxman Act is filed or any equivalent or similar certification or notice in any other jurisdiction in or outside the Territory, in each case (clauses (i) and (ii)) of which such Party becomes aware (an "**Infringement**").

**6.3.2. Enforcement of RVL Patents and Joint Patents.** As between the Parties, Licensee shall have the first right, but not the obligation, to prosecute any Infringement in the Field in the Territory with respect to the RVL Patents and Joint Patents, including as a defense or counterclaim in connection with any Infringement, at Licensee's sole cost and expense (*provided* that RVL cooperates pursuant to 6.3.4), using counsel of Licensee's choice. In the event Licensee prosecutes any such Infringement, RVL shall have the right to join as a party to such claim, suit or proceeding in the Territory and participate with its own counsel at its sole cost and expense; *provided* that Licensee shall retain control of the prosecution of such claim, suit or proceeding, including the response to any defense or defense of any counterclaim raised in connection therewith. RVL shall exercise its rights and interest and perform its obligations under the In-License Agreements in a manner that is sufficient to (i) enable Licensee to have the first right (before the licensor under the In-License Agreements) to prosecute any Infringement in the Field in the Territory with respect to the RVL Patents, or (ii) otherwise give full effect to this Section 6.3.2. If (a) Licensee or its designee does not use Commercially Reasonable Efforts to prosecute an Infringement (1) within ninety (90) days following the first notice provided above with respect to such Infringement or (2) provided such date occurs after the first such notice of such Infringement is provided, ten (10) Business Days before the time limit, if any, set forth in Applicable Laws for filing of such actions, whichever comes first or (b) Licensee communicates to RVL the intention of Licensee to abandon its efforts to prosecute an Infringement (which Licensee shall communicate promptly), then, in each case of clauses (a) and (b), RVL may prosecute such alleged or threatened infringement at its sole cost and expense upon written notification to Licensee. For purposes of satisfying the requirements and obligations and exercising the rights under the In-License Agreements only, and without prejudice to the Parties' rights and interests under this Agreement, such prosecution by RVL shall be deemed to be commenced and controlled on behalf of the Licensee, if and only to the extent required under the In-License Agreements to enable RVL to prosecute such infringement before the licensor under the In-License Agreements is entitled to prosecute such infringement. As between the Parties, RVL shall have the sole right, but not the obligation, to prosecute Infringement (A) outside the Field in the Territory, and (B) outside the Territory, in each case with respect to the RVL Patents and Joint Patents, including as a defense or counterclaim in connection with any Third Party Infringement Claim, at RVL's sole cost and expense, using counsel of its own choice.

**6.3.3. Enforcement of Licensee Patents.** As between the Parties, Licensee shall have the sole right, but not the obligation, to prosecute Infringement with respect to the Licensee Patents, including as a defense or counterclaim in connection with any Third Party Infringement Claim, at Licensee's sole cost and expense, using counsel of its own choice.

**6.3.4. Cooperation.** The Parties agree to cooperate fully in any Infringement action pursuant to this Section 6.3. Where a Party controls such an action, the other Party shall, and shall cause its Affiliates to, assist and cooperate with the controlling Party, as such controlling Party may reasonably request from time to time, in connection with its activities set forth in this Section 6.3, including where necessary, furnishing a power of attorney solely for such purpose or joining in, or being named as a necessary party to, such action, providing access to relevant documents and other evidence and making its employees available at reasonable business hours. Unless otherwise set forth herein, the Party entitled to bring any patent infringement litigation in accordance with this Section 6.3 shall have the right to settle such claim; *provided* that neither Party shall have the right to settle any Infringement litigation under this Section 6.3 in a manner that has a material adverse effect on the rights or interest of the other Party or in a manner that imposes any costs or liability on or involves any admission by, the other Party, without the express written consent of such other Party (which consent shall not be unreasonably withheld, conditioned or delayed).

**6.3.5. Recovery.** Except as otherwise agreed by the Parties in connection with a cost sharing arrangement, any recovery realized as a result of such litigation described above in this Section 6.3 (whether by way of settlement or otherwise) shall be first, allocated to reimburse the Parties for their costs and expenses in making such recovery (which amounts shall be allocated pro rata if insufficient to cover the totality of such expenses). Any remainder after such reimbursement is made shall be retained by the Party that has exercised its right to bring the enforcement action; *provided, however*, that to the extent that any award or settlement (whether by judgment or otherwise) with respect to an RVL Patent, Joint Patent or Licensee Patent is attributable to loss of sales or profits with respect to a Licensed Product in the Field, the Parties shall negotiate in good faith an appropriate allocation of such remainder to reflect the economic interests of the Parties under this Agreement with respect to such Licensed Product.

**6.4. Infringement Claims by Third Parties.** If the Exploitation of a Licensed Product in the Territory pursuant to this Agreement results in, or is reasonably expected to result in, any claim, suit or proceeding by a Third Party alleging infringement by Licensee or any of its Affiliates or its or their Sublicensees (a "**Third Party Infringement Claim**"), including any defense or counterclaim in connection with an Infringement action initiated pursuant to Section 6.3, the Party first becoming aware of such alleged infringement shall promptly notify the other Party thereof in writing. As between the Parties, Licensee shall have the first right, but not the obligation, to defend and control the defense of any such claim, suit or proceeding at its sole cost and expense, using counsel of Licensee's own choice. RVL may participate in any such claim, suit or proceeding with counsel of its choice at its sole cost and expense. If Licensee or its designee elects (in a written communication submitted to RVL within a reasonable amount of time after notice of the alleged patent infringement) not to defend or control the defense of, or otherwise fails to initiate and maintain the defense of, any such claim, suit or proceeding, within such time periods so that RVL is not prejudiced by any delays, RVL may conduct and control the defense of any such claim, suit or proceeding at its sole cost and expense. Where a Party controls such an action, the other Party shall, and shall cause its Affiliates to, assist and cooperate with the controlling Party, as such controlling Party may reasonably request from time to time, in connection with its activities set forth in this Section 6.4, including where necessary, furnishing a power of attorney solely for such purpose or joining in, or being named as a necessary party to, such action, providing access to relevant documents and other evidence and making its employees available at reasonable business hours; *provided* that the controlling Party shall reimburse such other Party for its reasonable and verifiable out-of-pocket costs and expenses incurred in connection therewith. Each Party shall keep the other Party reasonably informed of all material developments in connection with any such claim, suit or proceeding. Each Party agrees to provide the other Party with copies of all material pleadings filed in such action and to allow the other Party reasonable opportunity to participate in the defense of the claims. Any recoveries awarded to a Party in connection with any Third Party Infringement Claim defended under this Section 6.4 shall be applied first to reimburse such Party for its reasonable out-of-pocket costs of defending such claim, suit or proceeding, with the balance of any such recoveries being retained or provided to such Party and, in the case of Licensee, included in the calculation of Net Sales for the relevant Licensed Product.

**6.5. Invalidity or Unenforceability Defenses or Actions.** Each Party shall promptly notify the other Party in writing of any alleged or threatened assertion of invalidity or unenforceability of any of the RVL Patents, Joint Patents or Licensee Patents by a Third Party (including any request for, or any filing or declaration of, any reexamination, review, derivation, interference, opposition, or other patent office proceeding challenging, reviewing, or reexamining the validity or priority of the patent) and of which such Party becomes aware. As between the Parties, (i) RVL shall have the first right, but not the obligation, to defend and control the defense of the validity and enforceability of the RVL Patents and the Joint Patents at its sole cost and expense, using counsel of RVL's own choice, including when such invalidity or unenforceability is raised as a defense or counterclaim in connection with an Infringement action initiated pursuant to Section 6.3; *provided* that if RVL shall not unreasonably refuse to defend and control the defense if requested by Licensee, and (ii) Licensee shall have the first right, but not the obligation, to defend and control the defense of the validity and enforceability of the Licensee Patents at its sole cost and expense, using counsel of Licensee's own choice, including when such invalidity or unenforceability is raised as a defense or counterclaim in connection with an Infringement action initiated pursuant to Section 6.3. The non-controlling Party may participate in any such claim, suit or proceeding in the Territory with counsel of its choice at its sole cost and expense; *provided* that the controlling-Party shall retain control of the defense in such claim, suit or proceeding. If the controlling-Party or its designee elects not to defend or control the defense of the applicable Patents in the Territory or otherwise fails to initiate and maintain the defense of any such claim, suit or proceeding, then subject to any rights of Third Parties under any In-License Agreements, the non-controlling Party may conduct and control the defense of any such claim, suit or proceeding at its sole cost and expense. RVL shall exercise its rights and interest and perform its obligations under the In-License Agreements in a manner that is sufficient to (a) enable Licensee to have the right (before the licensor under the In-License Agreements) to defend and control the defense of the validity and enforceability of the RVL Patents, or (b) otherwise give full effect to this Section 6.5.

**6.6. Third Party Rights.** If in the reasonable opinion of Licensee, the Exploitation of the Licensed Product by Licensee, any of its Affiliates or any of its or their Sublicensees infringes or misappropriates or is reasonably expected to infringe or misappropriate any Patent, trade secret or other intellectual property right of a Third Party in any country in the Territory (such right, a "**Third Party Right**"), then, as between the Parties, Licensee shall have the first right, but not the obligation, to negotiate and obtain a license or other rights from such Third Party to such Third Party Right as necessary or desirable for Licensee or its Affiliates or its or their Sublicensees to Exploit the Licensed Compound and Licensed Products in such country; *provided* that Licensee shall obtain the written consent of RVL prior to entering into any such license, which consent shall not be unreasonably withheld, delayed or conditioned.

**6.7. Product Trademarks.**

**6.7.1. Notice.** Each Party shall provide to the other Party prompt written notice of any actual or threatened infringement of the Product Trademarks in the Territory and of any actual or threatened claim that the use of the Product Trademarks in the Territory violates the rights of any Third Party, in each case, of which such Party becomes aware.

**6.7.2. Prosecution of Product Trademarks.** Licensee shall be responsible for the registration, prosecution and maintenance of the Product Trademarks in the Territory using counsel of its own choice. All costs and expenses of registering, prosecuting and maintaining the Product Trademarks in the Territory shall be borne solely by Licensee. If Licensee decides not to prepare, file, prosecute or maintain a Product Trademark in a country in the Territory, Licensee shall provide reasonable prior written notice to RVL of such intention and, RVL shall thereupon have the option, in its sole discretion, to assume the control and direction of the preparation, filing, prosecution and maintenance of such Product Trademark at its sole cost and expense in such country. In the event RVL notifies Licensee that it intends to assume such control, Licensee shall promptly transfer all right, title and interest in and to such Product Trademark to RVL, and such Product Trademark shall cease to be a Product Trademark in such country.

**6.7.3. Enforcement of Product Trademarks.** Licensee shall have the sole right to take such action as Licensee deems necessary against a Third Party based on any alleged, threatened or actual infringement, dilution, misappropriation or other violation of or unfair trade practices or any other like offense relating to, the Product Trademarks by a Third Party in the Territory at its sole cost and expense and using counsel of its own choice. Licensee shall retain any damages or other amounts collected in connection therewith. Subject to the foregoing, RVL may elect at its sole cost and expense to participate in the enforcement of the Product Trademarks in the Territory.

**6.7.4. Third Party Claims**. Licensee shall have the sole right to defend against and settle any alleged, threatened or actual claim by a Third Party that the use or registration of the Product Trademarks in the Territory infringes, dilutes, misappropriates or otherwise violates any Trademark or other right of that Third Party or constitutes unfair trade practices or any other like offense or any other claims as may be brought by a Third Party against a Party in connection with the use of the Product Trademarks with respect to a Licensed Product in the Territory at its sole cost and expense and using counsel of its choice. Licensee shall retain any damages or other amounts collected in connection therewith.

**6.7.5. Cooperation**. RVL shall, and shall cause its Affiliates to, assist and cooperate with Licensee, as Licensee may reasonably request from time to time, in connection with its activities set forth in this Section 6.7, including where necessary, furnishing a power of attorney solely for such purpose or joining in, or being named as a necessary party to, such action, providing access to relevant documents and other evidence and making its employees available at reasonable business hours; *provided* that Licensee shall reimburse RVL for its reasonable and verifiable out-of-pocket costs and expenses incurred in connection therewith.

## ARTICLE 7
## CONFIDENTIALITY AND NON-DISCLOSURE

**7.1. Confidentiality Obligations.** At all times during the Term and for a period of ten (10) years following termination or expiration hereof in its entirety, each Party and its Affiliates shall and shall cause its officers, directors, employees and agents to, keep confidential and not publish or otherwise disclose to a Third Party and not use, directly or indirectly, for any purpose, any Confidential Information furnished or otherwise made known to it, directly or indirectly, by the other Party, except to the extent such disclosure or use is expressly permitted by the terms of this Agreement. "**Confidential Information**" means any technical, business or other information provided by or on behalf of one Party to the other Party in connection with this Agreement, whether prior to, on or after the Effective Date, including information relating to the terms of this Agreement (subject to Section 7.4 and Section 8.6.7), information relating to any Licensed Product (including the Regulatory Documentation), any Development or Commercialization of any Licensed Product, any know-how with respect thereto developed by or on behalf of the disclosing Party or its Affiliates (including Licensee Know-How and RVL Know-How, as applicable) or the scientific, regulatory or business affairs or other activities of either Party. Notwithstanding the foregoing, Joint Know-How and the terms of this Agreement shall be deemed to be the Confidential Information of both Parties and both Parties shall be deemed to be the receiving Party and the disclosing Party with respect thereto. Notwithstanding the foregoing, the confidentiality and non-use obligations under this Section 7.1 with respect to any Confidential Information shall not include any information that:

**7.1.1.** is or hereafter becomes part of the public domain by public use, publication, general knowledge or the like through no breach of this Agreement by the receiving Party;

**7.1.2.** can be demonstrated by documentation or other competent proof to have been in the receiving Party's possession prior to disclosure by the disclosing Party without any obligation of confidentiality with respect to such information; *provided* that the foregoing exception shall not apply with respect to Joint Know-How;

**7.1.3.** is subsequently received by the receiving Party from a Third Party who is not bound by any obligation of confidentiality with respect to such information;

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

**7.1.5.** can be demonstrated by documentation or other competent evidence to have been independently developed by or for the receiving Party without reference to the disclosing Party's Confidential Information; *provided* that the foregoing exception shall not apply with respect to Joint Know-How.

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

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

**7.2.1.** made in response to a valid order of a court of competent jurisdiction or other supra-national, federal, national, regional, state, provincial and local governmental or Regulatory Authority of competent jurisdiction or, if in the reasonable opinion of the receiving Party's legal counsel, such disclosure is otherwise required by Applicable Law, including by reason of filing with securities regulators; *provided, however*, to the extent practicable, that the receiving Party shall first have given notice to the disclosing Party and given the disclosing Party a reasonable opportunity to quash such order or to obtain a protective order or confidential treatment requiring that the Confidential Information and documents that are the subject of such order be held in confidence by such court or agency or, if disclosed, be used only for the purposes for which the order was issued; and *provided, further,* that the Confidential Information disclosed in response to such court or governmental order shall be limited to that information which is legally required to be disclosed in response to such court or governmental order;

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

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

**7.2.4.** made by or on behalf of the receiving Party to potential or actual Investors as may be necessary in connection with their evaluation of such potential or actual investment or acquisition; *provided, however*, that such Persons shall be subject to obligations of confidentiality and non-use with respect to such Confidential Information substantially similar to the obligations of confidentiality and non-use of the receiving Party pursuant to this Article 7 (with a duration of confidentiality and non-use obligations as appropriate that is no less than five (5) years from the date of disclosure); *provided, further*, that if either Party seeks to disclose the existence and terms of this Agreement to potential Investors, the Party seeking to disclose this Agreement must obtain the other Party's prior written consent before disclosing this Agreement (such consent not to be unreasonably withheld, delayed or conditioned).

**7.3. Use of Name.** Except as expressly provided herein, neither Party shall mention or otherwise use the name, logo or Trademark of the other Party or any of its Affiliates or any of its or their (sub)licensees or Sublicensees (or any abbreviation or adaptation thereof) in any publication, press release, marketing and promotional material or other form of publicity without the prior written approval of such other Party in each instance. The restrictions imposed by this Section 7.3 shall not prohibit (i) either Party from making any disclosure identifying the other Party to the extent required in connection with its exercise of its rights or obligations under this Agreement and (ii) either Party from making any disclosure identifying the other Party that is required by Applicable Law or the rules of a stock exchange on which the securities of the disclosing Party are listed (or to which an application for listing has been submitted).

**7.4. Public Announcements.** The Parties have agreed upon the content of one or more press releases which shall be issued substantially in the form(s) attached hereto as Schedule 7.4, the release of which the Parties shall coordinate in order to accomplish such release promptly upon execution of this Agreement. Neither Party shall issue any other public announcement, press release or other public disclosure regarding this Agreement or its subject matter without the other Party's prior written consent, except for any such disclosure that is, in the opinion of the disclosing Party's counsel, required by Applicable Law or the rules of a stock exchange on which the securities of the disclosing Party are listed (or to which an application for listing has been submitted). In the event a Party is, in the opinion of its counsel, required by Applicable Law or the rules of a stock exchange on which its securities are listed (or to which an application for listing has been submitted) to make such a public disclosure, such Party shall submit the proposed disclosure in writing to the other Party as far in advance as reasonably practicable (and in no event less than five (5) Business Days prior to the anticipated date of disclosure) so as to provide a reasonable opportunity to comment thereon. Neither Party shall be required to seek the permission of the other Party to repeat any information regarding the terms of this Agreement or any amendment hereto that has already been publicly disclosed by such Party or by the other Party, in accordance with this Section 7.4; *provided* that such information remains accurate as of such time and the frequency and form of such disclosure are reasonable.

**7.5. Publications.** The Parties recognize the desirability of publishing and publicly disclosing the results of and information regarding, activities under this Agreement. Accordingly, each Party shall be free to publicly disclose the results of, and information regarding, activities under this Agreement, subject to prior review by the other Party of any disclosure of such other Party's Confidential Information for issues of patentability and protection of such Confidential Information, in a manner consistent with Applicable Law and industry practices, as provided in this Section 7.5. Accordingly, prior to publishing or disclosing any Confidential Information of the other Party, the publishing Party shall provide the other Party with drafts of proposed abstracts, manuscripts or summaries of presentations that cover such Confidential Information. Such other Party shall respond promptly through its designated representative and in any event no later than fifteen (15) days after receipt of such proposed publication or presentation or such shorter period as may be required by the publication or presentation. The publishing Party agrees to allow a reasonable period (not to exceed thirty (30) days) to permit filings for patent protection and to otherwise address issues of Confidential Information or related competitive harm to the reasonable satisfaction of the other Party. In addition, the publishing Party shall give due regard to comments furnished by the other Party and such comments shall not be unreasonably rejected.

**7.6. Return of Confidential Information.** Upon the effective date of the termination of this Agreement for any reason, either Party may request in writing and the non-requesting Party shall either, with respect to Confidential Information to which such non-requesting Party does not retain rights under the surviving provisions of this Agreement: (i) promptly destroy all copies of such Confidential Information in the possession or control of the non-requesting Party and confirm such destruction in writing to the requesting Party; or (ii) promptly deliver to the requesting Party, at the non-requesting Party's sole cost and expense, all copies of such Confidential Information in the possession or control of the non-requesting Party. Notwithstanding the foregoing, the non-requesting Party shall be permitted to retain such Confidential Information (a) to the extent necessary or useful for purposes of performing any continuing obligations or exercising any ongoing rights hereunder and, in any event, a single copy of such Confidential Information for archival purposes and (b) any computer records or files containing such Confidential Information that have been created solely by such non-requesting Party's automatic archiving and back-up procedures, to the extent created and retained in a manner consistent with such non-requesting Party's standard archiving and back-up procedures, but not for any other uses or purposes. All Confidential Information shall continue to be subject to the terms of this Agreement for the period set forth in Section 7.1.

**7.7. Privileged Communications.** In furtherance of this Agreement, it is expected that the Parties will, from time to time, disclose to one another privileged communications with counsel, including opinions, memoranda, letters and other written, electronic and verbal communications. Such disclosures are made with the understanding that they shall remain confidential in accordance with this Article 7, that they will not be deemed to waive any applicable attorney-client or attorney work product or other privilege and that they are made in connection with the shared community of legal interests existing between RVL and Licensee, including the community of legal interests in avoiding infringement of any valid, enforceable patents of Third Parties and maintaining the validity of the RVL Patents, Licensee Patents and Joint Patents. In the event of any litigation (or potential litigation) with a Third Party related to this Agreement or the subject matter hereof, the Parties shall, upon either Party's request, enter into a reasonable and customary joint defense agreement. In any event, each Party shall consult in a timely manner with the other Party before engaging in any conduct (*e.g.*, producing information or documents) in connection with litigation or other proceedings that could conceivably implicate privileges maintained by the other Party. Notwithstanding anything contained in this Section 7.7, nothing in this Agreement shall prejudice a Party's ability to take discovery of the other Party in disputes between them relating to this Agreement and no information otherwise admissible or discoverable by a Party shall become inadmissible or immune from discovery solely by this Section 7.7.

## ARTICLE 8
## REPRESENTATIONS AND WARRANTIES

**8.1. Mutual Representations and Warranties.** RVL and Licensee each represents and warrants to the other, as of the Effective Date, and covenants, that:

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

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

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

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

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

**8.2. Additional Representations and Warranties of RVL.** RVL further represents and warrants to Licensee, as of the Effective Date, that:

**8.2.1.** RVL Controls the Existing Patents as of the Effective Date and has the right to grant the licenses and sublicenses specified herein;

**8.2.2.** RVL has not received any written claim or demand alleging that (i) the Existing Patents or the RVL Know-How are invalid or unenforceable or (ii) the Development or Commercialization of the Licensed Products as contemplated herein infringes any Patent owned by any Third Party, in each case of clauses (i) and (ii), in the Territory;

**8.2.3.** To RVL's knowledge, no Person is infringing or threatening to infringe the Existing Patents in the Field in the Territory;

**8.2.4.** Schedule 1.57 contains a true and complete list of all agreements under which RVL or any of its Affiliates is granted a right to Control Information, Regulatory Documentation, material, Patent or other intellectual property right that claims, covers, or is necessary for the Exploitation of the Licensed Product in the Field in the Territory;

**8.2.5.** RVL has provided Licensee with true and complete copies of all In-License Agreements, including all modifications, amendments and supplements thereto and waivers thereunder, that have been executed or are effective as of the Effective Date, except those terms and conditions that have been redacted as reasonably necessary to protect RVL's commercially sensitive information to the extent such redacted terms and conditions are not necessary for Licensee to understand and comply with its obligations under this Agreement;

**8.2.6.** The In-License Agreement and the Amendment to the In-License Agreement dated July 21, 2020 has been executed and delivered by the parties thereto in accordance with its terms;

**8.2.7.** Neither RVL nor, to RVL's knowledge, any other party to the In-License Agreement is, or is alleged to be, in breach of or default under, or has provided or received any notice of breach of, default under, or intention to terminate (including by non-renewal), any In-License Agreement;

**8.2.8.** The execution and delivery of this Agreement and the performance by RVL of the transactions contemplated hereby do not breach any In-License Agreement;

**8.2.9.** With respect to Schedule 8.2.9:

(i) Except as identified in Schedule 8.2.9, neither RVL nor any of its Affiliates has granted any interest to any party in any of the rights of RVL under, pursuant to, or in connection with, the In-License Agreement. To RVL's knowledge, no Third Party is asserting any claim or entitlement to the rights of RVL under, pursuant to, or in connection with, any In-License Agreement, whether arising under contract, by operation of law or equity, or otherwise;

(ii) Neither RVL nor any of its Affiliates is, or, to RVL's knowledge, is alleged to be, in breach of or default under any obligation owed to any party identified in Schedule 8.2.9;

(iii) The execution and delivery of this Agreement and the performance by RVL of the transactions contemplated hereby do not breach any agreement identified in Schedule 8.2.9; and

(iv) RVL covenants that it will promptly notify Licensee if (a) RVL receives a notice of default or breach under any agreement identified in Schedule 8.2.9; or (b) any party asserts in a writing received by RVL that such party holds an interest in, or claim under, any In-License Agreement such that, if such asserted rights or claims were recognized by a court of competent jurisdiction, would materially impair Licensee's ability to use, exploit, or otherwise enjoy the rights licensed by RVL under this Agreement; and

**8.2.10.** To the knowledge of RVL's Executive Vice President, Research & Development, and Vice President, Drug Safety and Regulatory Affairs, (i) RVL Regulatory Documentation submitted to the FDA and (ii) [***] disclosed to the Licensee are true and accurate in all respects.

**8.3. Additional Representations and Warranties of Licensee.** Licensee further represents and warrants to RVL, as of the Effective Date, that Licensee: (i) has conducted its own investigation and analysis of (a) the Patent and other proprietary rights of Third Parties as such rights relate to the Exploitation of the Licensed Compound and Licensed Products as contemplated hereunder and (b) the potential infringement thereof; (ii) understands the complexity and uncertainties associated with possible claims of infringement of Patent or other proprietary rights of Third Parties, particularly those relating to pharmaceutical products; and (iii) acknowledges and agrees that it is solely responsible for the risks of such claims.

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

**8.5. ADDITIONAL WAIVER.** LICENSEE AGREES THAT: (i) THE RVL PATENTS ARE LICENSED "AS IS," "WITH ALL FAULTS," AND "WITH ALL DEFECTS," AND LICENSEE EXPRESSLY WAIVES ALL RIGHTS TO MAKE ANY CLAIM WHATSOEVER AGAINST RVL FOR MISREPRESENTATION OR FOR BREACH OF PROMISE, GUARANTEE OR WARRANTY OF ANY KIND RELATING TO THE RVL PATENTS; (ii) LICENSEE AGREES THAT EXCEPT AS OTHERWISE EXPRESSLY PROVIDED IN THIS AGREEMENT RVL WILL HAVE NO LIABILITY TO LICENSEE FOR ANY ACT OR OMISSION IN THE PREPARATION, FILING, PROSECUTION, MAINTENANCE, ENFORCEMENT, DEFENCE OR OTHER HANDLING OF THE RVL PATENTS; AND (iii) LICENSEE IS SOLELY RESPONSIBLE FOR DETERMINING WHETHER THE RVL PATENTS HAVE APPLICABILITY OR UTILITY IN LICENSEE'S CONTEMPLATED EXPLOITATION OF THE LICENSED PRODUCTS AND LICENSEE ASSUMES ALL RISK AND LIABILITY IN CONNECTION WITH SUCH DETERMINATION. RVL AGREES THAT: (a) THE LICENSEE PATENTS ARE LICENSED "AS IS," "WITH ALL FAULTS," AND "WITH ALL DEFECTS," AND RVL EXPRESSLY WAIVES ALL RIGHTS TO MAKE ANY CLAIM WHATSOEVER AGAINST LICENSEE FOR MISREPRESENTATION OR FOR BREACH OF PROMISE, GUARANTEE OR WARRANTY OF ANY KIND RELATING TO THE LICENSEE PATENTS; (b) RVL AGREES THAT LICENSEE WILL HAVE NO LIABILITY TO RVL FOR ANY ACT OR OMISSION IN THE PREPARATION, FILING, PROSECUTION, MAINTENANCE, ENFORCEMENT, DEFENCE OR OTHER HANDLING OF THE LICENSEE PATENTS; AND (c) RVL IS SOLELY RESPONSIBLE FOR DETERMINING WHETHER THE LICENSEE PATENTS HAVE APPLICABILITY OR UTILITY IN RVL'S CONTEMPLATED EXPLOITATION OF THE LICENSED PRODUCTS AND RVL ASSUMES ALL RISK AND LIABILITY IN CONNECTION WITH SUCH DETERMINATION.

**8.6. Anti-Bribery and Anti-Corruption Compliance.**

**8.6.1.** Licensee agrees, on behalf of itself, its officers, directors and employees and on behalf of its Affiliates, agents, representatives, consultants and subcontractors hired in connection with the subject matter of this Agreement (together with Licensee, the "**Licensee Representatives**") that for the performance of its obligations hereunder:

(i) The Licensee Representatives shall not directly or indirectly pay, offer or promise to pay or authorize the payment of any money or give, offer or promise to give or authorize the giving of anything else of value, to: (a) any Government Official in order to influence official action; (b) any Person (whether or not a Government Official) (1) to influence such Person to act in breach of a duty of good faith, impartiality or trust ("**acting improperly**"), (2) to reward such Person for acting improperly or (3) where such Person would be acting improperly by receiving the money or other thing of value; (c) any Person (whether or not a Government Official) while knowing or having reason to know that all or any portion of the money or other thing of value will be paid, offered, promised or given to or will otherwise benefit, a Government Official in order to influence official action for or against either Party in connection with the matters that are the subject of this Agreement; or (d) any Person (whether or not a Government Official) to reward that Person for acting improperly or to induce that Person to act improperly; and

(ii) The Licensee Representatives shall not, directly or indirectly, solicit, receive or agree to accept any payment of money or anything else of value in violation of the Anti-Corruption Laws.

**8.6.2.** Licensee shall promptly provide RVL with written notice of the following events: (i) upon becoming aware of any breach or violation by Licensee or other Licensee Representative of any representation, warranty or undertaking set forth in Section 8.6.1; or (ii) upon receiving a formal notification that it is the target of a formal investigation by a governmental authority for a Material Anti-Corruption Law Violation or upon receipt of information from any of the Licensee Representatives connected with this Agreement that any of them is the target of a formal investigation by a governmental authority for a Material Anti-Corruption Law Violation.

**8.6.3.** During the Term and six (6) years thereafter, Licensee shall for the purpose of auditing and monitoring the performance of its compliance with this Agreement and particularly this Section 8.6 permit RVL, its Affiliates, any auditors of any of them and any governmental authority to have access to any premises of Licensee or other Licensee Representatives used in connection with this Agreement, together with a right to access personnel and records that relate to this Agreement ("**Audit**").

**8.6.4.** On the occurrence of any of the following events: (i) RVL becomes aware of, whether or not through an Audit, that Licensee (or any other Licensee Representative) is in breach or violation of any representation, warranty or undertaking in Section 8.6.1 or of the Anti-Corruption Laws; or (ii) notification is received under Section 8.6.2 relating to any suspected or actual Material Anti-Corruption Law Violation by Licensee or any other Licensee Representative, in either case (clause (i) or (ii)), RVL shall have the right, in addition to any other rights or remedies under this Agreement or to which RVL may be entitled in law or equity, to take such steps as are reasonably necessary in order to avoid a potential violation or continuing violation by RVL or any of its Affiliates of the Anti-Corruption Laws, including by requiring that Licensee agrees to such additional measures, representations, warranties, undertakings and other provisions as RVL believes in good faith are reasonably necessary ("**Provisions**").

**8.6.5.** Any termination of this Agreement pursuant to Section 8.6.4 shall be treated as a termination by RVL for Licensee's breach and the consequences of termination set forth in Section 10.4.1 or 10.4.2, as applicable, shall apply and additionally: (i) subject to the accrued rights of the Parties prior to termination, RVL shall have no liability to Licensee for any fees, reimbursements or other compensation or for any loss, cost, claim or damage resulting, directly or indirectly, from such termination; and (ii) any amounts that would otherwise be payable to Licensee with respect to such terminated services or pursuant to this Agreement in its entirety, as applicable, including any then outstanding and unpaid claims for payment shall be null and void to the extent permissible under Applicable Law.

**8.6.6.** Licensee shall be responsible for any breach of any representation, warranty or undertaking in this Section 8.6 or of the Anti-Corruption Laws by any Licensee Representative.

**8.6.7.** RVL may disclose the terms of this Agreement or any action taken under this Section 8.6 to prevent a potential violation or continuing violation of applicable Anti-Corruption Laws, including the identity of Licensee and the payment terms, to any governmental authority if RVL determines, upon advice of counsel, that such disclosure is necessary.

## ARTICLE 9
## INDEMNITY

**9.1. Indemnification of RVL.** Licensee shall indemnify RVL, its Affiliates, its or their (sub)licensees and its and their respective directors, officers, employees and agents and defend and save each of them harmless, from and against any and all losses, damages, liabilities, costs and expenses (including reasonable attorneys' fees and expenses) (collectively, "**Losses**") in connection with any and all suits, investigations, claims or demands of Third Parties (collectively, "**Third Party Claims**") arising from or occurring as a result of: (i) the breach by Licensee of this Agreement; (ii) the gross negligence or willful misconduct on the part of Licensee or its Affiliates or its or their Sublicensees in performing its or their obligations under this Agreement; or (iii) the Exploitation by Licensee or any of its Affiliates or its or their Sublicensees of any Licensed Product or the Licensed Compound in or for the Territory (*provided*, *however*, that RVL's responsibility for any liabilities in respect of taxes arising from or occurring as a result of such Exploitation shall be determined in accordance with Section 5.6); except, in each case (clauses (i), (ii) and (iii)), for those Losses for which RVL has an obligation to indemnify Licensee pursuant to Section 9.2 hereof, as to which Losses each Party shall indemnify the other to the extent of their respective liability.

**9.2. Indemnification of Licensee.** RVL shall indemnify Licensee, its Affiliates and their respective directors, officers, employees and agents and defend and save each of them harmless, from and against any and all Losses in connection with any and all Third Party Claims arising from or occurring as a result of: (i) the breach by RVL of this Agreement, which, for avoidance of doubt, shall include RVL's breach of any representations and warranties in Article 8 of this Agreement; (ii) the gross negligence or willful misconduct on the part of RVL or its Affiliates in performing its obligations under this Agreement; or (iii) the Exploitation by RVL or any of its Affiliates or its or their sublicensees of any Licensed Product outside the Territory (*provided*, *however*, that Licensee's responsibility for any liabilities in respect of taxes arising from or occurring as a result of such Exploitation shall be determined in accordance with Section 5.6); except, in each case (clauses (i), (ii) and (iii)), for those Losses for which Licensee has an obligation to indemnify RVL pursuant to Section 9.1 hereof, as to which Losses each Party shall indemnify the other to the extent of their respective liability for the Losses.

**9.3. Indemnification Procedures.**

**9.3.1. Notice of Claim.** All indemnification claims in respect of a Party, its Affiliates or, in the case of RVL, its or their (sub)licensees or their respective directors, officers, employees and agents shall be made solely by such Party to this Agreement (the "**Indemnified Party**"). The Indemnified Party shall give the indemnifying Party prompt written notice (an "**Indemnification Claim Notice**") of any Losses or discovery of fact upon which such indemnified Party intends to base a request for indemnification under this Article 9, but in no event shall the indemnifying Party be liable for any Losses that result from any delay in providing such notice. Each Indemnification Claim Notice must contain a description of the claim and the nature and amount of such Loss (to the extent that the nature and amount of such Loss is known at such time). The Indemnified Party shall furnish promptly to the indemnifying Party copies of all papers and official documents received in respect of any Losses and Third Party Claims.

**9.3.2. Control of Defense.** At its option, the indemnifying Party may assume the defense of any Third Party Claim by giving written notice to the Indemnified Party within thirty (30) days after the indemnifying Party's receipt of an Indemnification Claim Notice. The assumption of the defense of a Third Party Claim by the indemnifying Party shall not be construed as an acknowledgment that the indemnifying Party is liable to indemnify the Indemnified Party in respect of the Third Party Claim, nor shall it constitute a waiver by the indemnifying Party of any defenses it may assert against the Indemnified Party's claim for indemnification. Upon assuming the defense of a Third Party Claim, the indemnifying Party may appoint as lead counsel in the defense of the Third Party Claim any legal counsel selected by the indemnifying Party; *provided* that it obtains the prior written consent of the Indemnified Party (which consent shall not be unreasonably withheld, conditioned or delayed). In the event the indemnifying Party assumes the defense of a Third Party Claim, the Indemnified Party shall immediately deliver to the indemnifying Party all original notices and documents (including court papers) received by the Indemnified Party in connection with the Third Party Claim. Should the indemnifying Party assume the defense of a Third Party Claim, except as provided in Section 9.3.3, the indemnifying Party shall not be liable to the Indemnified Party for any legal expenses subsequently incurred by such Indemnified Party in connection with the analysis, defense or settlement of the Third Party Claim unless specifically requested in writing by the indemnifying Party. In the event that it is ultimately determined that the indemnifying Party is not obligated to indemnify, defend or hold harmless the Indemnified Party from and against the Third Party Claim, the Indemnified Party shall reimburse the indemnifying Party for any and all costs and expenses (including attorneys' fees and costs of suit) and any Losses incurred by the indemnifying Party in its defense of the Third Party Claim.

**9.3.3. Right to Participate in Defense.** Any Indemnified Party shall be entitled to participate in, but not control, the defense of such Third Party Claim and to employ counsel of its choice for such purpose; *provided*, *however*, that such employment shall be at the Indemnified Party's sole cost and expense unless (i) the employment thereof has been specifically authorized in writing by the indemnifying Party in writing, (ii) the indemnifying Party has failed to assume the defense and employ counsel in accordance with Section 9.3.2 (in which case the Indemnified Party shall control the defense) or (iii) the interests of the indemnitee and the indemnifying Party with respect to such Third Party Claim are sufficiently adverse to prohibit the representation by the same counsel of both Parties under Applicable Law, ethical rules or equitable principles.

**9.3.4. Settlement.** With respect to any Losses relating solely to the payment of money damages in connection with a Third Party Claim and that shall not result in the applicable indemnitee's becoming subject to injunctive or other relief and as to which the indemnifying Party shall have acknowledged in writing the obligation to indemnify the applicable indemnitee hereunder, the indemnifying Party shall have the sole right to consent to the entry of any judgment, enter into any settlement or otherwise dispose of such Loss, on such terms as the indemnifying Party, in its sole discretion, shall deem appropriate. With respect to all other Losses in connection with Third Party Claims, where the indemnifying Party has assumed the defense of the Third Party Claim in accordance with Section 9.3.2, the indemnifying Party shall have authority to consent to the entry of any judgment, enter into any settlement or otherwise dispose of such Loss; *provided* it obtains the prior written consent of the Indemnified Party (which consent shall not be unreasonably withheld, conditioned or delayed). If the indemnifying Party does not assume and conduct the defense of a Third Party Claim as provided above, the Indemnified Party may defend against such Third Party Claim; *provided* that the Indemnified Party shall not settle any Third Party Claim without the prior written consent of the indemnifying Party (which consent shall not be unreasonably withheld, conditioned or delayed).

**9.3.5. Cooperation.** Regardless of whether the indemnifying Party chooses to defend or prosecute any Third Party Claim, the Indemnified Party shall, and shall cause each indemnitee to, cooperate in the defense or prosecution thereof and shall furnish such records, information and testimony, provide such witnesses and attend such conferences, discovery proceedings, hearings, trials and appeals as may be reasonably requested in connection therewith. Such cooperation shall include access during normal business hours afforded to the indemnifying Party to and reasonable retention by the Indemnified Party of, records and information that are reasonably relevant to such Third Party Claim and making Indemnified Parties and other employees and agents available on a mutually convenient basis to provide additional information and explanation of any material provided hereunder and the indemnifying Party shall reimburse the Indemnified Party for all its reasonable and verifiable out-of-pocket expenses in connection therewith.

**9.3.6. Expenses.** Except as provided above, the costs and expenses, including fees and disbursements of counsel, incurred by the Indemnified Party in connection with any claim shall be reimbursed on a Calendar Quarter basis by the indemnifying Party, without prejudice to the indemnifying Party's right to contest the Indemnified Party's right to indemnification and subject to refund in the event the indemnifying Party is ultimately held not to be obligated to indemnify the Indemnified Party.

**9.4. Special, Indirect and Other Losses.** EXCEPT (i) IN THE EVENT THE WILLFUL MISCONDUCT OR FRAUD OF A PARTY OR OF A PARTY'S BREACH OF ITS OBLIGATIONS UNDER ARTICLE 8 OR SECTION 2.6, (ii) AS PROVIDED UNDER SECTION 11.10, OR (iii) TO THE EXTENT ANY SUCH DAMAGES ARE REQUIRED TO BE PAID TO A THIRD PARTY AS PART OF A CLAIM FOR WHICH A PARTY PROVIDES INDEMNIFICATION UNDER THIS ARTICLE 9, NEITHER PARTY NOR ANY OF ITS AFFILIATES OR (SUB)LICENSEES SHALL BE LIABLE IN CONTRACT, TORT, NEGLIGENCE, BREACH OF STATUTORY DUTY OR OTHERWISE FOR ANY SPECIAL OR PUNITIVE DAMAGES OR FOR LOSS OF PROFITS SUFFERED BY THE OTHER PARTY.

## ARTICLE 10
## TERM AND TERMINATION

**10.1. Term and Expiration.** This Agreement shall commence on the Effective Date and, unless earlier terminated in accordance herewith, shall continue in force and effect until the date of expiration of the Royalty Term (such period, the "**Term**"). Following the expiration of the Royalty Term, the grants in Section 2.1 and Section 2.2 shall become non-exclusive, fully-paid, royalty-free, perpetual, and irrevocable for the Commercialization of the Licensed Product in the Territory.

**10.2. Termination.**

**10.2.1. Material Breach.** In the event that either Party (the "**Breaching Party**") shall be in material breach in the performance of any of its material obligations under this Agreement, in addition to any other right and remedy the other Party (the "**Non-Breaching Party**") may have, the Non-Breaching Party may terminate this Agreement by providing (i) ninety (90) days of advance written notice (if terminating before receiving Regulatory Approval in the relevant country or countries) or (ii) one hundred and eighty (180) days of advance written notice (if terminating after receiving Regulatory Approval in the relevant country or countries) (clauses (i) and (ii), the "**Notice Period**") (each such notice, the "**Termination Notice**") to the Breaching Party and specifying the breach and its claim of right to terminate; *provided* that (a) the termination shall not become effective at the end of the applicable Notice Period if the Breaching Party cures the breach specified in the Termination Notice during the applicable Notice Period (or, if such default cannot be cured within the applicable Notice Period, if the Breaching Party commences actions to cure such breach within the applicable Notice Period and thereafter diligently continues such actions) and (b) with respect to an uncured material breach consisting of Licensee's diligence obligations under Section 3.1.1 or Section 3.3.1, as applicable, with respect to any country in the Territory, RVL shall have the right to terminate this Agreement with respect to such country.

**10.2.2. Termination by RVL.** In the event that Licensee or any of its Affiliates or Sublicensees, anywhere in the Territory, institutes, prosecutes or otherwise participates in (or in any way aids any Third Party in instituting, prosecuting or participating in), at law or in equity or before any administrative or Regulatory Authority, including the U.S. Patent and Trademark Office or its foreign counterparts, any claim, demand, action or cause of action for declaratory relief, damages or any other remedy or for an enjoinment, injunction or any other equitable remedy, including any interference, re-examination, opposition or any similar proceeding, alleging that any claim in a RVL Patent is invalid, unenforceable or otherwise not patentable or would not be infringed by Licensee's activities absent the rights and licenses granted hereunder, RVL shall have the right to immediately terminate this Agreement in its entirety, including the rights of any Sublicensees, upon written notice to Licensee.

**10.2.3. Termination for Insolvency.** In the event that either Party (i) files for protection under bankruptcy or insolvency laws, (ii) makes an assignment for the benefit of creditors, (iii) appoints or suffers appointment of a receiver or trustee over substantially all of its property that is not discharged within ninety (90) days after such filing, (iv) proposes a written agreement of composition or extension of its debts, (v) proposes or is the subject of any dissolution or liquidation, (vi) files a petition under any bankruptcy or insolvency act or has any such petition filed against it that is not discharged within sixty (60) days of the filing thereof or (vii) admits in writing its inability generally to meet its obligations as they fall due in the general course, then the other Party may terminate this Agreement in its entirety effective immediately upon written notice to such Party.

**10.2.4. Termination at Will.** Licensee may terminate this Agreement in its entirety or for one or more countries in the Territory, without cause, upon no less than (i) ninety (90) days of advance written notice (if terminating before receiving Regulatory Approval in the relevant country or countries) or (ii) one hundred and eighty (180) days of advance written notice (if terminating after receiving Regulatory Approval in the relevant country or countries), unless a lesser time is mutually agreed upon by both Parties.

**10.2.5. Termination for Force Majeure.** Pursuant to Section 11.1, RVL shall have the right to terminate this Agreement upon written notice to Licensee with respect to the country or countries affected by a Force Majeure Termination Event.

**10.2.6. Termination by Licensee.** Licensee may terminate this Agreement in its entirety or for one or more countries in the Territory with immediate effect if the In-License Agreement is terminated by either party to the In-License Agreement.

**10.2.7. Termination for Competition.** The Non-Acquiring Party may terminate this Agreement in its entirety pursuant to Section 2.6.3 by providing one hundred and eighty (180) days prior written notice to the Acquiring Party.

**10.3. Rights in Bankruptcy.** All rights and licenses granted under or pursuant to this Agreement are and shall otherwise be deemed to be, for purposes of Section 365(n) of the U.S. Bankruptcy Code or any analogous provisions in any other country or jurisdiction, licenses of right to "intellectual property" as defined under Section 101 of the U.S. Bankruptcy Code. The Parties agree that the Parties, as licensees of such rights under this Agreement, shall retain and may fully exercise all of their rights and elections under the U.S. Bankruptcy Code or any analogous provisions in any other country or jurisdiction. The Parties further agree that, in the event of the commencement of a bankruptcy proceeding by or against either Party under the U.S. Bankruptcy Code or any analogous provisions in any other country or jurisdiction, the Party that is not a debtor in such proceeding shall be entitled to a complete duplicate of (or complete access to, as appropriate) any such intellectual property and all embodiments of such intellectual property, which, if not already in the non-debtor Party's possession, shall be promptly delivered to it (i) upon any such commencement of a bankruptcy proceeding upon the non-debtor Party's written request therefor, unless the debtor Party in such proceeding assumes this Agreement under Section 365(a) of the U.S. Bankruptcy Code, or otherwise elects to continue to perform all of its obligations under this Agreement under analogous provisions in any other country or jurisdiction, within sixty (60) days after the filing of the case or (ii) if not delivered under clause (i) above, following the rejection of this Agreement by or on behalf of the debtor Party in such proceeding upon written request therefor by the non-debtor Party.

**10.4. Consequences of Termination.**

**10.4.1. Termination in its Entirety.** In the event of a termination of this Agreement in its entirety for any reason:

(i) all rights and licenses granted by RVL hereunder shall immediately terminate, including, for clarity, (a) any sublicense granted by Licensee pursuant to Section 2.3 and (b) all rights granted under Section 2.4;

(ii) Licensee shall and hereby does, and shall cause its Affiliates and its and their Sublicensees to, effective as of the effective date of termination, assign to RVL all of its right, title and interest in and to (a) all Regulatory Documentation (including any Regulatory Approvals) applicable to any Licensed Compound or Licensed Product then owned or Controlled by Licensee or any of its Affiliates and (b) at RVL's request, each Product Trademark;

(iii) Licensee shall and hereby does, and shall cause its Affiliates and its and their Sublicensees to, effective as of the effective date of termination, grant RVL an exclusive, royalty-free license and right of reference, with the right to grant multiple tiers of sublicenses and further rights of reference, in and to (a) the Licensee Patents, (b) Licensee Know-How, (c) Licensee's rights in and to the Joint Patents and Joint Know-How and (d) all Regulatory Documentation (including any Regulatory Approvals) then owned or Controlled by Licensee or any of its Affiliates or its or their Sublicensees that are not assigned to RVL pursuant to clause (ii) above that are necessary or useful for RVL or any of its Affiliates or (sub)licensees to Exploit the Licensed Compound or any Licensed Product and any Improvement thereto, in each case (clauses (a) through (d)), to Exploit in the Territory any Licensed Compound or Licensed Product and any Improvement thereto;

(iv) unless expressly prohibited by any Regulatory Authority, at RVL's written request, Licensee shall and hereby does, and shall cause its Affiliates and its and their Sublicensees to, transfer control to RVL of all clinical studies involving Licensed Products being conducted by or on behalf of Licensee, an Affiliate or a Sublicensee as of the effective date of termination and continue to conduct such clinical studies, at Licensee's cost, for up to six (6) months to enable such transfer to be completed without interruption of any such clinical study; *provided* that (a) RVL shall not have any obligation to continue any clinical study unless required by Applicable Law and (b) with respect to each clinical study for which such transfer is expressly prohibited by the applicable Regulatory Authority, if any, Licensee shall continue to conduct such clinical study to completion, at Licensee's cost and expense if RVL terminates the Agreement due to reasons attributable to Licensee; and

(v) at RVL's written request, Licensee shall, and shall cause its Affiliates and its and their Sublicensees to, assign to RVL all Licensed Product Agreements, unless, with respect to any such Licensed Product Agreement, such Licensed Product Agreement expressly prohibits such assignment, in which case Licensee (or such Affiliate or Sublicensee, as applicable) shall cooperate with RVL in all reasonable respects to secure the consent of the applicable Third Party to such assignment and if any such consent cannot be obtained with respect to a Licensed Product Agreement, Licensee shall, and shall cause its Affiliates and its and their Sublicensees to, obtain for RVL substantially all of the practical benefit and burden under such Licensed Product Agreement, including by (a) entering into appropriate and reasonable alternative arrangements and (b) subject to the consent and control of RVL, enforcing, at RVL's cost and expense and for the account of RVL, any and all rights of Licensee (or such Affiliate or Sublicensee, as applicable) against the other party thereto arising out of the breach or cancellation thereof by such other party or otherwise.

**10.4.2. Termination in a Terminated Territory.** In the event of a termination of this Agreement with respect to a Terminated Territory pursuant to Section 10.2.1, 10.2.4, 10.2.5 or 10.2.6 (but not in the case of any termination of this Agreement in its entirety):

(i) all rights and licenses granted by RVL hereunder, including, for clarity, any sublicense granted by Licensee pursuant to Section 2.3 and all rights granted under Section 2.4, (a) shall automatically be deemed to be amended to exclude, if applicable, the right to market, promote, detail, distribute, import, sell for commercial use, offer for commercial sale, file any Drug Approval Application for or seek any Regulatory Approval for Licensed Products in such Terminated Territory and (b) shall otherwise survive and continue in effect in such Terminated Territory solely for the purpose of furthering any Commercialization of the Licensed Products in the Territory or any Development or Manufacturing in support thereof;

(ii) Licensee shall and hereby does, and shall cause its Affiliates and its and their Sublicensees to, effective as of the effective date of termination, assign to RVL all of its right, title and interest in and to (a) all Regulatory Documentation (including any Regulatory Approvals) applicable to the Exploitation of the Licensed Products solely in the Terminated Territory then owned or Controlled by Licensee or any of its Affiliates or its or their Sublicensees and (b) at RVL's request, each Product Trademark in such Terminated Territory;

(iii) Licensee shall and hereby does, and shall cause its Affiliates and its and their Sublicensees to, effective as of the effective date of termination, grant RVL an exclusive, royalty-free license and right of reference, with the right to grant multiple tiers of sublicenses and further rights of reference, in and to (a) the Licensee Patents, (b) Licensee Know-How, (c) Licensee's rights in and to the Joint Patents and Joint Know-How and (d) all Regulatory Documentation (including any Regulatory Approvals) then owned or Controlled by Licensee or any of its Affiliates or its or their Sublicensees that are not assigned to RVL pursuant to clause (ii) above that are necessary or useful for RVL or any of its Affiliates or (sub)licensees to Exploit the Licensed Compound or any Licensed Product and any Improvement thereto in the Terminated Territory, in each case (clauses (a) through (d)), to Exploit for commercial use in the Terminated Territory any Licensed Compound or Licensed Product and any Improvement thereto; and

(iv) at RVL's written request, Licensee shall, and cause its Affiliates and its and their Sublicensees to, assign to RVL or its designee all Licensed Product Agreements relating to the Terminated Territory, unless, with respect to any such Licensed Product Agreement, such Licensed Product Agreement (a) expressly prohibits such assignment (in which case, Licensee, or its Affiliate or Sublicensee, as applicable, shall cooperate with RVL in all reasonable respects to secure the consent of the applicable Third Party to such assignment), (b) relates both to (1) the Terminated Territory and the Territory or (2) Licensed Products and products other than Licensed Products (which, in either case (clauses (1) or (2)), at RVL's request, Licensee, or its Affiliate or Sublicensee, as applicable, shall cooperate with RVL in all reasonable respects to secure the written agreement of the applicable Third Party to a partial assignment of the applicable Licensed Product Agreement relating to the Terminated Territory or Licensed Products, as applicable) and, in either case (clause (a) or (b)) if any such consent or agreement, as applicable, cannot be obtained with respect to a Licensed Product Agreement, Licensee shall, and cause its Affiliates and its and their Sublicensees to, obtain for RVL substantially all of the practical benefit and burden under such Licensed Product Agreement to the extent applicable to the Terminated Territory and Licensed Products, as applicable, including by (A) entering into appropriate and reasonable alternative arrangements on terms mutually agreeable to RVL and Licensee, or such Affiliate or Sublicensee, as applicable, and (B) subject to the consent and control of RVL, enforcing, at RVL's cost and expense and for the account of RVL, any and all rights of Licensee, or such Affiliate or Sublicensee, as applicable, against the other party thereto arising out of the breach or cancellation thereof by such other party or otherwise.

**10.5. Remedies.** Except as otherwise expressly provided herein, termination of this Agreement (either in its entirety or with respect to one or more country(ies)) in accordance with the provisions hereof shall not limit remedies that may otherwise be available in law or equity.

**10.6. Accrued Rights; Surviving Obligations.** Termination or expiration of this Agreement (either in its entirety or with respect to one or more country(ies)) for any reason shall be without prejudice to any rights that shall have accrued to the benefit of a Party prior to such termination or expiration. Such termination or expiration shall not relieve a Party from obligations that are expressly indicated to survive the termination or expiration of this Agreement. Without limiting the foregoing, Sections 2.2, 3.2.4, 5.6, 5.7, 5.9, 5.10, 6.1, 8.4, 8.5, 10.4 and 10.5 (and Sections 6.2, 6.3 and 6.5 with respect to Joint Patents) and this Section 10.6 and Articles 1, 7, 9 and 11 of this Agreement shall survive the termination or expiration of this Agreement for any reason. If this Agreement is terminated with respect to the Terminated Territory but not in its entirety, then following such termination the foregoing provisions of this Agreement shall remain in effect with respect to the Terminated Territory (to the extent they would survive and apply in the event this Agreement expires or is terminated in its entirety or as otherwise necessary for any of RVL and its Affiliates and its and their (sub)licensees to exercise their rights in the Terminated Territory) and all provisions not surviving in accordance with the foregoing shall terminate upon termination of this Agreement with respect to the Terminated Territory and be of no further force and effect (and for the avoidance of doubt all provisions of this Agreement shall remain in effect with respect to all countries in the Territory other than the Terminated Territory).

## ARTICLE 11
## MISCELLANEOUS

**11.1. Force Majeure.** Neither Party shall be held liable or responsible to the other Party or be deemed to have defaulted under or breached this Agreement for failure or delay in fulfilling or performing any term of this Agreement (other than an obligation to make payments) when such failure or delay is caused by or results from events beyond the reasonable control of the non-performing Party, including fires, floods, earthquakes, hurricanes, embargoes, shortages, epidemics, quarantines, war, acts of war (whether war be declared or not), terrorist acts, insurrections, riots, civil commotion, strikes, lockouts or other labor disturbances (whether involving the workforce of the non-performing Party or of any other Person), acts of God or acts, omissions or delays in acting by any governmental authority (except to the extent such delay results from the breach by the non-performing Party or any of its Affiliates of any term or condition of this Agreement). The non-performing Party shall notify the other Party of such force majeure within thirty (30) days after such occurrence by giving written notice to the other Party stating the nature of the event, its anticipated duration and any action being taken to avoid or minimize its effect. The suspension of performance shall be of no greater scope and no longer duration than is necessary and the non-performing Party shall use commercially reasonable efforts to remedy its inability to perform. Without limitation to the foregoing, in the event that Licensee is the non-performing Party and the suspension of performance continues for one hundred eighty (180) days after the date of the occurrence, and an unaffected Third Party comparable to the Licensee can continue the Development and Commercialization of products comparable to the Licensed Product in the same country without suspension or delay despite the same force majeure event, RVL shall have the right to terminate this Agreement for such non-performance (a "**Force Majeure Termination Event**") pursuant to Section 10.2.5.

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

**11.3. Assignment.**

**11.3.1.** Neither Party may assign its rights or, except as provided in Article 8, delegate its obligations under this Agreement, whether by operation of law or otherwise, in whole or in part without the prior written consent of the other Party, which consent shall not be unreasonably withheld, conditioned or delayed, except that each Party shall have the right, without such consent, (i) to perform any or all of its obligations and exercise any or all of its rights under this Agreement through any of its Affiliates or its or their (sub)licensees or Sublicensees, and (ii) assign any or all of its rights and delegate any or all of its obligations hereunder to any of its Affiliates or to any successor in interest (whether by merger, acquisition, asset purchase or otherwise) to all or substantially all of such Party's business; *provided* that RVL shall provide written notice to Licensee within thirty (30) days after any such assignment or delegation. All validly assigned rights of a Party shall inure to the benefit of and be enforceable by, and all validly delegated obligations of such Party shall be binding on and be enforceable against, the permitted successors and assigns of such Party. Any attempted assignment or delegation in violation of this Section 11.3.1 shall be void and of no effect.

**11.3.2.** The rights to Information, materials and intellectual property: (i) controlled by a Third Party permitted assignee of a Party that immediately prior to such assignment (other than as a result of a license or other grant of rights, covenant or assignment by such Party or its Affiliates to, or for the benefit of, such Third Party); or (ii) controlled by an Affiliate of a Party that becomes an Affiliate through any Change of Control of such Party that were controlled by such Affiliate (and not such Party) immediately prior to such Change of Control (other than as a result of a license or other grant of rights, covenant or assignment by such Party or its other Affiliates to, or for the benefit of, such Affiliate), in each case (clauses (i) and (ii)), shall be automatically excluded from the rights licensed or granted to the other Party under this Agreement.

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

**11.5. Dispute Resolution.**

**11.5.1.** Except as provided in Section 5.10 or 11.10, if a dispute arises (i) within the JSC with respect to any decision under the jurisdiction of the JSC that remains unresolved pursuant to Section 4.2.3 (a "**JSC Dispute**") or (ii) otherwise between the Parties in connection with or relating to this Agreement or any document or instrument delivered in connection herewith (collectively, clauses (i) and (ii), a "**Dispute**"), then either Party shall have the right to refer such Dispute to the Alliance Managers and Senior Officers for attempted resolution by good faith negotiations during a period of ten (10) Business Days. Any final decision mutually agreed to by the Senior Officers shall be conclusive and binding on the Parties.

**11.5.2.** If such Senior Officers are unable to resolve any such Dispute within such ten (10)-Business Day period and such Dispute is a JSC Dispute, Licensee shall have final decision-making authority.

**11.5.3.** If such Senior Officers are unable to resolve any such Dispute within such ten (10)-Business Day period and provided such Dispute is not a JSC Dispute, either Party shall be free to institute binding arbitration in accordance with this Section 11.5.3 by final and binding arbitration administered by the International Chamber of Commerce ("**ICC**") in accordance with its Rule of Arbitration in force at the time the Request of Arbitration is submitted ("**ICC Rules**"). The arbitration shall be before a panel of three (3) arbitrators with relevant industry experience (the "**Arbitrators**" or "**Tribunal**"). Each of Licensee and RVL shall promptly select one (1) Arbitrator each, which selections shall in no event be made later than thirty (30) days after the respondent receives the Request of Arbitration. If either party fails to appoint an Arbitrator within such thirty (30)-day time limit, such Arbitrator(s) shall be appointed by ICC in accordance with ICC Rules. The two (2) Arbitrators so appointed shall choose, promptly (in no event later than thirty (30) days after both of them are appointed) by mutual agreement, the third Arbitrator, who shall be the presiding Arbitrator. If the two Arbitrators to be appointed by the Parties fail to agree upon a presiding Arbitrator within such thirty (30)-day time limit, ICC shall appoint the presiding Arbitrator in accordance with ICC Rules. The presiding Arbitrator shall be a person who is free of conflict of interest and is not a citizen, national, or permanent resident of the United States or Japan. The Tribunal shall follow the IBA Rules on the Taking of Evidence in International Commercial Arbitration to determine what discovery will be permitted. The seat of arbitration shall be in New York, New York, with final hearings to be held in New York, New York and other proceedings to be held remotely or at places to be determined by the Tribunal. The Parties shall use reasonable efforts to expedite the arbitration if requested by either Party. The Arbitrators shall, within fifteen (15) days after the conclusion of the final arbitration hearing, issue a written award and statement of decision describing the essential findings and conclusions on which the award is based, including the calculation of any damages awarded. The decision or award rendered by the Arbitrators shall be final and non-appealable, and judgment may be entered upon it in accordance with Applicable Law in the State of New York or any other court of competent jurisdiction. The Arbitrators shall be authorized to award compensatory damages, but shall not be authorized to reform, modify or materially change this Agreement or any other agreements contemplated hereunder. This arbitration clause shall be governed by the laws of the State of New York.

**11.5.4.** Each Party shall bear its own counsel fees, costs, and disbursements arising out of the dispute resolution procedures described in this Section 11.5, and shall pay an equal share of the fees and costs of the Arbitrators, as applicable, and all other general fees related to any arbitration described in Section 11.5.3; *provided*, *however*, the Arbitrators shall be authorized to determine whether a Party is the prevailing Party, and if so, to award to that prevailing Party reimbursement for its reasonable counsel fees, costs and disbursements (including expert witness fees and expenses, photocopy charges, or travel expenses), or the fees and costs of the Arbitrators. Unless the Parties otherwise agree in writing, during the period of time that any arbitration proceeding described in Section 11.5.3 is pending under this Agreement, the Parties shall continue to comply with all those terms and provisions of this Agreement that are not the subject of such pending arbitration proceeding. Nothing contained in this Agreement shall deny any Party the right to seek injunctive or other equitable relief from a court of competent jurisdiction in the context of a bona fide emergency or prospective irreparable harm, and such an action may be filed and maintained notwithstanding any ongoing arbitration proceeding. All arbitration proceedings and decisions of the Arbitrators under Section 11.5.3 or 11.5.4, as applicable, shall be deemed Confidential Information of both Parties under Article 7.

**11.6. Governing Law.** This Agreement shall be governed by and construed in accordance with the laws of the State of New York, excluding any conflicts or choice of law rule or principle that might otherwise refer construction or interpretation of this Agreement to the substantive law of another jurisdiction. The Parties agree to exclude the application to this Agreement of the United Nations Convention on Contracts for the International Sale of Goods.

**11.7. Notices.**

**11.7.1. Notice Requirements.** Any notice, request, demand, waiver, consent, approval or other communication permitted or required under this Agreement shall be in writing, shall refer specifically to this Agreement and shall be deemed given only if delivered by hand or sent by facsimile transmission (with transmission confirmed) or by internationally recognized overnight delivery service that maintains records of delivery, addressed to the Parties at their respective addresses specified in Section 11.7.2 or to such other address as the Party to whom notice is to be given may have provided to the other Party in accordance with this Section 11.7.1. Such notice shall be deemed to have been given as of the date delivered by hand or transmitted by facsimile (with transmission confirmed) or on the second Business Day (at the place of delivery) after deposit with an internationally recognized overnight delivery service. Any notice delivered by facsimile shall be confirmed by a hard copy delivered as soon as practicable thereafter. This Section 11.7.1 is not intended to govern the day-to-day business communications necessary between the Parties in performing their obligations under the terms of this Agreement.

**11.7.2. Address for Notice.**

If to Licensee, to:

Santen Pharmaceutical Co, Ltd.
4-20 Ofuka-cho, Kita-ku
Osaka 530-8552
Japan
Attention: Head, Global Business Development
E-mail: [***]

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

Santen Pharmaceutical Co, Ltd.
4-20 Ofuka-cho, Kita-ku
Osaka 530-8552
Attention: General manager, Intellectual Property Group
E-mail: [***]

If to RVL, to:

RVL Pharmaceuticals, Inc.
400 Crossing Boulevard
Bridgewater, NJ 08807 USA
Attention: General Counsel
Facsimile: 1-908-809-1301

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

Covington & Burling LLP
One CityCenter
850 Tenth Street, NW
Washington, D.C. 20001
Attention: Van W. Ellis
Email: [***]

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

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

**11.10. Equitable Relief.** Each Party acknowledges and agrees that the restrictions set forth in Section 2.6 and Articles 6 and 7 are reasonable and necessary to protect the legitimate interests of the other Party and that such other Party would not have entered into this Agreement in the absence of such restrictions and that any breach or threatened breach of any provision of such Section or Articles may result in irreparable injury to such other Party for which there will be no adequate remedy at law. In the event of a breach or threatened breach of any provision of such Section or Articles, the non-breaching Party shall be authorized and entitled to seek from any court of competent jurisdiction injunctive relief, whether preliminary or permanent, specific performance and an equitable accounting of all earnings, profits and other benefits arising from such breach, which rights shall be cumulative and in addition to any other rights or remedies to which such non-breaching Party may be entitled in law or equity. Both Parties agree to waive any requirement that the other (i) post a bond or other security as a condition for obtaining any such relief and (ii) show irreparable harm, balancing of harms, consideration of the public interest or inadequacy of monetary damages as a remedy. Nothing in this Section 11.10 is intended or should be construed, to limit either Party’s right to equitable relief or any other remedy for a breach of any other provision of this Agreement.

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

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

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

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

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

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

**11.17. 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 and the same instrument. This Agreement may be executed by facsimile, PDF format via email or other electronically transmitted signatures and such signatures shall be deemed to bind each Party as if they were original signatures.

[SIGNATURE PAGE FOLLOWS.]

THIS AGREEMENT IS EXECUTED by the authorized representatives of the Parties as of the date first written above.

| **RVL PHARMACEUTICALS, INC.** | **SANTEN PHARMACEUTICAL CO. LTD.** |
| --- | --- |
| By: /s/ Brian Markison | By: /s/ Shigeo Taniuchi |
| Name: Brian Markison | Name: Shigeo Taniuchi |
| Title: Chief Executive Officer | Title: President and Chief Executive Officer |

*[Signature Page to the License Agreement]*

Schedule 1.24

Corporate Names

RVL Pharmaceuticals, Inc.

Osmotica Pharmaceutical US LLC

Osmotica Pharmaceuticals plc

Schedule 1.35

Existing Patents

[***]

Schedule 1.57

1. License Agreement dated August 31, 2011 by and between VOOM, LLC and RevitaLid, Inc.

2. Letter Amendment dated July 21, 2020, to the License Agreement dated August 31, 2011 between VOOM, LLC and RVL Pharmaceuticals. Inc. (formerly named RevitaLid, Inc.).

Schedule 1.66

Licensed Product

[***]

Schedule 1.101

RVL Trademark

- UPNEEQ

Schedule 1.108

Territory

1. Europe
    a. EU (as of January 1, 2020)
        i. Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, The Netherlands, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, Sweden, United Kingdom of Great Britain and Northern Ireland
    b. Other European Countries
        i. Albania, Andorra, Bosnia & Herzegovina, Faroe Islands, Iceland, Kosovo, Liechtenstein, Monaco, Montenegro, North Macedonia, Norway, San Marino, Serbia, Switzerland, Turkey, Vatican City
    c. CIS
        i. Azerbaijan, Armenia, Belarus, Georgia, Kazakhstan, Kyrgyzstan, Moldova, Tajikistan, Turkmenistan, Uzbekistan, Ukraine
2. North Africa and Middle East
    a. Algeria, Kingdom of Saudi-Arabia, Kuwait, Morocco, Turkey
3. Asia and Japan
    a. East Asia
        i. People’s Republic of China, Macau, Hong Kong, Japan, South Korea, Taiwan
    b. ASEAN
        i. Brunei, Cambodia, Indonesia, Laos, Malaysia, Myanmar, Philippines, Singapore, Thailand, Vietnam

Schedule 3.1.2

Development Plan

[***]

Schedule 3.6

Protection of Territorial Integrity

[***]

Schedule 5.2.1

Approval Letter and Invoice

[***]

Schedule 7.4

Press Release

**DRAFT Not for Immediate Release**

**Santen and RVL Pharmaceuticals, Inc., an Osmotica Company, Enter into an Exclusive License Agreement in Japan, Asia, and EMEA for RVL-1201, a First-in-Class Treatment for Acquired Blepharoptosis**

Osaka, Japan and Bridgewater NJ, July 28, 2020, Santen Pharmaceutical Co., Ltd (hereinafter, Santen) and RVL Pharmaceuticals, Inc., a subsidiary of Osmotica Pharmaceuticals plc (Nasdaq: OSMT) (hereinafter, Osmotica), announced today an exclusive license agreement covering the development, registration, and commercialization rights in Japan, China, and other Asian countries as well as EMEA countries to RVL-1201, oxymetazoline hydrochloride ophthalmic solution 0.1%, which is the first and only ophthalmic formulation approved by the U.S. Food and Drug Administration (FDA) for the treatment of acquired blepharoptosis or ptosis in adults. Santen will be responsible for further development of RVL-1201 and regulatory approvals as well as commercialization in its licensed territories under the agreement.

RVL-1201 is a novel, once-daily ophthalmic formulation of oxymetazoline, a direct-acting alpha adrenergic receptor agonist, which when administered to the eye, is believed to selectively target Müller's muscle and elevate the upper eyelid. RVL-1201, was approved on July 8, 2020 under the brand name UPNEEQ™ in the United States.
Acquired blepharoptosis, also known as ptosis or droopy eyelid, is a unilateral or bilateral drooping of the upper eyelid that usually occurs from a partial or complete dysfunction of the muscles that elevate the upper eyelid. It can lead to loss of visual field and cosmetic concerns for patients. While precise prevalence of the condition is unknown, tens of millions of adults are believed to suffer from ptosis globally[1,2]. The companies believe that there are no approved pharmacologic treatments for acquired ptosis anywhere outside the United States.

Shigeo Taniuchi, Santen President and CEO said, "Our mission is to try our hand at resolving eye health-related social challenges that patients worldwide are facing and, in turn, contributing to improving eye health. As a specialized ophthalmic company, we are very pleased to be entering into this license agreement with Osmotica. Ptosis is said to cause conditions such as tight shoulders, cephalalgia, and asthenopia, and is a disease that lowers the Quality of Life (QoL). To better the QoL of patients across the world through eye health and wellness, thus to achieve our WORLD VISION, "Happiness with VISION" that we have set in the new long-term vision, Santen proactively engages in collaborative and open innovation endeavors with various external institutions. We hope that our agreement with Osmotica enables us to serve to people's eyecare."

“We are delighted to have formed a partnership with Santen, a leading multi-national ophthalmology company, to develop and commercialize RVL-1201 across Japan, China, and other Asian countries as well as EMEA. RVL-1201 is the first-in-class, non-invasive therapy for ptosis in US, and if successfully approved in other countries, it will similarly address a significant unmet need for patients and providers across the world,” stated Brian Markison, Osmotica Chief Executive Officer. “With its preeminent position in eye care and its established sales organization, Santen is an ideal partner to address the large treatment gap in ptosis and ensure that patients across its broad global footprint will have access to this therapeutic. This is a meaningful advancement and value-driver for our organization,” concluded Markison.

Under the terms of the licensing agreement, Osmotica will receive up to $89 million in upfront and milestone payments, not including future royalties on sales in Santen’s territories. Osmotica will receive an upfront cash payment of $25 million and up to an additional $64 million in cash milestone payments based on regulatory and sales achievements in Santen’s territories. Osmotica is also entitled to royalty payments on sales of RVL-1201 in Japan, China, and other Asian countries as well as EMEA.

[1] Source: A Community Survey of Ptosis of the Eyelid and Pupil Size of Elderly People. G. V. SRIDHARAN, R. C. TALLIS, B. LEATHERBARROW, W. M. FORMAN.

[2] Source: Eye The Scientific Journal of The Royal College of Ophthalmologists. 2017 Jun; 31(6): 940–946. Prevalence and associated factors of blepharoptosis in Korean adult population: The Korea National Health and Nutrition Examination Survey 2008–2011 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5518839/

**About RVL-1201**

In U.S. clinical studies, RVL-1201 demonstrated statistically significant improvements compared to placebo in both superior visual field, as measured by the Leicester Peripheral Field Test (LPFT), and eyelid lift, as measured by the Marginal Reflex Distance Test (MRD-1) in two pivotal double-masked efficacy studies. A third pivotal safety study successfully showed that RVL-1201 was well tolerated when administered once daily in the morning (to both eyes) over a 12-week period. The majority of adverse events were mild and self-limited. Adverse reactions that occurred in 1-5% of subjects treated with UPNEEQ were punctate keratitis, conjunctival hyperemia, dry eye, blurred vision, instillation site pain, eye irritation and headache.

**About Santen**

As a specialized company dedicated to ophthalmology, Santen carries out research, development, marketing, and sales of pharmaceuticals, over-the-counter products, and medical devices. Santen is the market leader for prescription ophthalmic pharmaceuticals in Japan and its products now reach patients in over 60 countries. With scientific knowledge and organizational capabilities nurtured over a 130-year history, Santen provides products and services to contribute to the well-being of patients, their loved ones and consequently to society. For more information, please visit Santen’s website (www.santen.com).

**About Osmotica Pharmaceuticals plc**

Osmotica Pharmaceuticals plc (Nasdaq: OSMT) is a fully integrated biopharmaceutical company focused on the development and commercialization of specialty products that target markets with underserved patient populations. The company has a diverse portfolio consisting of four promoted products and approximately 30 non-promoted products, several of which incorporate Osmotica's proprietary Osmodex® drug delivery system. RVL Pharmaceuticals, Inc. is the Company's ophthalmic subsidiary supporting UPNEEQ. Vertical Pharmaceuticals, LLC represents the Company's diversified branded portfolio and Trigen Laboratories, LLC represents the Company's non-promoted products, including complex generic formulations. Osmotica has operations in the United States, Argentina, and Hungary.

**IMPORTANT SAFETY INFORMATION**

UPNEEQ™ (oxymetazoline hydrochloride ophthalmic solution), 0.1% was approved for treatment of acquired blepharoptosis in adults by the US FDA on July 8, 2020.As of July 28, 2020, the product is not approved for use in any other countries.

**WARNINGS AND PRECAUTIONS**

- Alpha-adrenergic agonists as a class may impact blood pressure. Advise UPNEEQ patients with cardiovascular disease, orthostatic hypotension, and/or uncontrolled hypertension or hypotension to seek medical care if their condition worsens.
- Use UPNEEQ with caution in patients with cerebral or coronary insufficiency or Sjögren's syndrome. Advise patients to seek medical care if signs and symptoms of potentiation of vascular insufficiency develop.
- UPNEEQ may increase the risk of angle closure glaucoma in patients with untreated narrow-angle glaucoma. Advise patients to seek immediate medical care if signs and symptoms of acute narrow-angle glaucoma develop.
- Patients should not to touch the tip of the single patient-use container to their eye or to any surface, in order to avoid eye injury or contamination of the solution.

**ADVERSE REACTIONS**

Adverse reactions that occurred in 1-5% of subjects treated with UPNEEQ were punctate keratitis, conjunctival hyperemia, dry eye, blurred vision, instillation site pain, eye irritation and headache.

**DRUG INTERACTIONS**

- Alpha-adrenergic agonists, as a class, may impact blood pressure. Caution in using drugs such as beta-blockers, anti-hypertensives, and/or cardiac glycosides is advised. Caution should also be exercised in patients receiving alpha adrenergic receptor antagonists such as in the treatment of cardiovascular disease, or benign prostatic hypertrophy.
- Caution is advised in patients taking monoamine oxidase inhibitors which can affect the metabolism and uptake of circulating amines.

**Santen Forward-looking Statements**

Information provided in this press release contains forward-looking statements. The achievement of these forecasts is subject to risk and uncertainty from various sources. Therefore, please note that the actual results may differ significantly from the forecasts. Business performance and financial conditions are subject to the effects of changes in regulations made by the governments of Japan and other nations concerning medical insurance, drug pricing and other systems, and to fluctuations in market variables such as interest rates and foreign exchange rates.

**Osmotica Forward-looking Statements**

This press release includes statements that express Osmotica's opinions, expectations, beliefs, plans, objectives, assumptions or projections regarding future events or future results and therefore are, or may be deemed to be, "forward-looking statements." Osmotica's actual results may vary significantly from the results anticipated in these forward-looking statements, which can generally be identified by the use of forward-looking terminology, including the terms "believes," "expects," "may," "will," "should," "seeks," "projects," "approximately," "intends," "plans," "estimates" or "anticipates," or, in each case, their negatives or other variations or comparable terminology. These forward-looking statements include all matters that are not historical facts. They include statements regarding Osmotica's intentions, beliefs or current expectations concerning, among other things, our growth plan, strategies, trends and other events, particularly relating to the development, approval and introduction of new products, FDA and other regulatory applications, approvals and actions. By their nature, forward-looking statements involve risks and uncertainties because they relate to events and depend on circumstances that may or may not occur in the future. We may not achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place significant reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. Important factors that could cause actual results and events to differ materially from those indicated in the forward-looking statements include the following: our ability to successfully develop or commercialize new products, or do so on a timely or cost effective basis; failures of or delays in clinical trials or other delays in obtaining regulatory approval or commencing product sales for new products; the impact of competition from both brand and generic companies; any interruption at our manufacturing facility, our warehouses or at facilities operated by third parties that we rely on for our products; our ability to develop and maintain our sales capabilities; the impact of any litigation related to allegations of infringement of intellectual property; any changes to the coverage and reimbursement levels for our products by governmental authorities and other third-party payors as a result of healthcare reform or otherwise; the impact of any changes in the extensive governmental regulation that we face; manufacturing or quality control issues that we may face; and other risks and uncertainties more fully described in the "Risk Factors" section of our Annual Report on Form 10-K for the year ended December 31, 2019 and other filings that the Company makes with the Securities and Exchange Commission. These forward-looking statements speak only as of the time of this release and we do not undertake to publicly update or revise them, whether as a result of new information, future events or otherwise, except as required by law.

CONTACT
Akiko Yoshikawa
Corporate Communications Group
Santen Pharmaceutical Co., Ltd.
E-mail: ir@santen.com Tel : +81-6-4802-9360

Investor and Media Relations for Osmotica Pharmaceuticals plc
Lisa M. Wilson
In-Site Communications, Inc.
T: 212-452-2793
E: lwilson@insitecony.com

Schedule 8.2.9

Credit Agreement

1. Credit Agreement, dated as of February 3, 2016, by and among Osmotica Pharmaceutical Corp., a Delaware corporation, Orbit Blocker I LLC, a Delaware limited liability company, Orbit Blocker II LLC, a Delaware limited liability company, Valkyrie Group Holdings, Inc., a Delaware corporation, Osmotica Holdings US LLC, a Delaware limited liability company, the other Loan Parties thereto, the Lenders thereto and CIT Bank, N.A., as amended by the First Amendment dated as of November 10, 2016, the Second Amendment dated as of April 28, 2017 and the Third Amendment dated as of December 21, 2017.