

License Agreement

This agreement (the “**Agreement**”) is made effective as of March 9, 2021 by and between:

INNOVET ITALIA S.R.L. (hereinafter called “**Licensor**”)

Via Egadi 7 20144 Milano, Italy

– AND –

FSD PHARMA INC (hereinafter called “**Licensee**”)

100 King Street West, Suite 3400 – Toronto, Ontario M5X 1A4, Canada

(each referred to individually as “**Party**” and collectively as “**Parties**”)

WHEREAS:

- A. Licensor is in the business of developing, making, marketing and selling innovative, IP protected molecules of natural origin;
- B. Licensee is in the business of developing, making, marketing and selling novel prescription medical foods, FDA approved prescription products, and nutritional supplements;
- C. Licensor and Licensee desire to enter into this License Agreement to grant Licensee rights to Licensed IP to develop FDA (or other competent Regulatory Agency of the Territory) approved Veterinary drugs for the treatment of Canine and Feline Gastro-Intestinal Diseases (the Licensed Products).

NOW THEREFORE in consideration of the covenants and agreements contained in this Agreement and for other good and valuable consideration, the receipt and sufficiency of which the parties hereby acknowledge and agree as follows:

ARTICLE I

DEFINITIONS AND INTERPRETATION

1.1 Definitions

Terms which are defined in this Article when used in this Agreement shall be read in accordance with their definition in this Article:

- (a) “**Affiliate**” means, in relation to either Party, any person or entity that directly or indirectly controls, is controlled by, or is under common control with, such Party. For the purposes of this definition, “**Control**”

means a Party: (a) owns, directly or indirectly, fifty percent (50%) or more of (i) the voting stock or shares of a corporation, (ii) the partnership interests in a partnership, or (iii) the membership interests in a limited liability company; or (b) possesses, directly or indirectly, the power to direct or cause the direction of the management and policies of the entity or person, whether through the ownership of voting securities, by contract or in any other manner;

- (b) “**API**” means the active pharmaceutical ingredients listed in Schedule 2;
- (c) “**Applicable Laws**” means any local, state, or national rule, regulation, statute or law, or governmental agency regulation, in any jurisdiction in the Territory relevant to the activities undertaken pursuant to this Agreement, the Licensed Products, or applicable to either of the Parties with respect to any matters set forth herein;
- (d) “**Auditor**” shall have the meaning given in Clause 4.8;
- (e) “**Business Day**” means any day on which banks in each of Toronto, New York City and Rome are open for business (excluding Saturdays and Sundays);
- (f) “**Commercial Partner**” means a third party selected by Licensee, at its sole discretion as a sub-licensee in relation to the Licenses in any part of the Territory.
- (g) “**Commercially Reasonable Efforts**” means with respect to the efforts to be expended by a Party to accomplish a particular objective, efforts that are substantially equivalent to those efforts that similarly resourced companies in the Territory, that are either developing and/or selling products comparable to the Licensed Products in the Territory, would devote to one of their own products with similar commercial potential in the Territory, taking into account commercially relevant factors such as (as applicable) stage of development, product life, Patent position, market potential within the Territory (including availability of competitive products), costs of goods and sales, and regulatory issues;
- (h) “**Confidential Information**” shall have the meaning given in Clause 5.1;
- (i) “**Control**” or “**Controlled**” shall mean: (i) with respect to any Know-How and/or Patent, the possession by a Party of the ability to grant a license or sublicense of such Know-How and/or Patent as provided herein; and/or (ii) with respect to proprietary materials, the possession by a Party of the ability to supply such proprietary materials to the other Party as provided herein, in each case without violating the terms of any agreement or arrangement between such Party and any third party;
- (j) “**Effective Date**” means the date of this Agreement;

- (k) **“Europe”** means Albania, Andorra, Armenia, Austria, Azerbaijan, Belarus, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Georgia, Germany, Greece, Hungary, Iceland, Ireland, Italy, Kazakhstan, Kosovo, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Moldova, Monaco, Montenegro, Netherlands, North Macedonia, Norway, Poland, Portugal, Romania, Russia, San Marino, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey, Ukraine, United Kingdom and Vatican City.
 - (l) **“FDA”** means the United States Food and Drug Administration, or any successor entity that may be established hereafter which has substantially the same authority or responsibility currently vested in the United States Food and Drug Administration;
 - (m) **“Field”** means the use of Licensed Products for Gastro-Intestinal Diseases in Canines and Felines.
 - (n) **“Follow-On Product”** means any compound developed, discovered or identified by Licensor based on PEA, which may or may not comprise an Improvement of Licensed IP;
 - (o) **“Gastro-Intestinal Disease”** means any Gastro-intestinal indication in Canines and Felines including, but not limited to, inflammatory bowel disease (IBD), and chronic enteropathies.
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- (p) **“GCP”** means where relevant to the development of the Licensed Products in the Territory, the regulations and the good clinical practice guidelines of any Regulatory Agency and the current international ethical and scientific quality standards specified by the current International Conference on Harmonisation Guidelines, as amended from time to time (“ICH Guidelines”) for the design, conduct, performance, monitoring, auditing, recording, analysis and reporting of clinical studies that provide assurance that the data and reported results are credible and accurate, and that the rights, integrity and confidentiality of trial subjects are protected;
 - (q) **“GLP”** means where relevant to the development of the Licensed Products in the Territory the current standards and practices recommended by the ICH Guidelines regulating the non-human testing of pharmaceutical products as applicable to the development of the Licensed Products in the Territory from time to time;
 - (r) **“GMP”** means where relevant to the development of the Licensed Products in the Territory current good manufacturing practices for the methods to be used in, and the facilities and controls to be used for the manufacture and/or storage of Licensed Products, all as set forth from time to time by the FDA and by the relevant Regulatory Agency in such other countries within the Territory;

- (s) **“Improvements”** means any variations, updates, modifications, and enhancements to the Licensed IP, including but not limited to PEA; PEA combined with other drugs for treatment of Gastro-Intestinal Diseases in Canines and Felines; or other and any derivatives or sub-components of PEA alone or in combination with, any of the above, whether or not patentable and whether or not the subject of any Patent;
- (t) **“Joint Invention”** shall have the meaning given in Clause 6.1(b);
- (u) **“Know-How”** means any confidential scientific or technical knowledge, information and expertise in any tangible or intangible form whatsoever including discoveries, inventions, trade secrets, databases, practices, protocols, regulatory filings, including pharmacological, biological, chemical, toxicological and clinical information, whether or not patentable;
- (v) **“Liaison Person”** shall have the meaning given in Clause 2.4(a);
- (w) **“Licenses”** means the licenses granted to Licensee under Clauses 2.1 and 2.2;
- (x) **“Licensed IP”** means Licensed Patents and Licensed Know-How
- (y) **“Licensed Know-How”** means all Know-How and other information owned or Controlled by Licensor or its Affiliates that: (a) relates in any manner to: (i) the Licensed Patents; (ii) PEA; (iii) any Follow-on Product including PEA, and including but not limited to PEA combined with other drugs for treatment of Gastro-Intestinal Diseases in Canines and Felines; or any derivatives or sub-components of PEA; and/or (iv) any Improvement; and/or (b) which is necessary or useful for the discovery, development, manufacture, importation, use or sale of the Licensed Products;
- (z) **“Licensed Patents”** means all Patents Controlled by Licensor or its Affiliates as of the Effective Date and/or thereafter during the Term, and in each case, which is necessary or useful for the discovery, development, manufacture, importation, use or sale of the Licensed Products, together with all patents pertaining to any Improvements (whether solely or jointly owned but specifically excluding any Improvements solely owned by Licensee or jointly owned by Licensee and a third party). Licensed Patents as at the Effective Date are more particularly set out in Schedule 1 of this Agreement;
- (aa) **“Licensed Products”** means: (a) any and all Veterinary Prescription Drugs based on ultra-micro PEA developed in the Field using the Licensed Know-How; and/or (b) any Veterinary Prescription Drugs based on ultra-micro PEA developed in the Field which, except for the Licenses, would infringe the Valid Claims of a Licensed Patent;

- (bb) **“Material Adverse Change”** means for either party: any change, effect, event, occurrence or state of facts that, individually or in the aggregate, is, or would reasonably be expected to be, material and adverse to the business, operations, earnings, assets, and royalties payable to Licensor;
- (cc) **“Net Sales”** means the gross amount received per calendar year by Licensee or its Affiliates or sub-licensee for the sale of Licensed Products to a third party purchaser which is not an Affiliate or a sub-licensee of the selling party, less the following customary deductions: (i) sales taxes, value added taxes, duties, and other charges which may be imposed by any governmental body based upon the sale, transportation, delivery or use of the Licensed Products (other than income taxes); (ii) freight, transportation, shipping, postage, handling, insurance and other similar charges relating to the sale, transportation, delivery or return of the Licensed Products to or by a customer; (iii) quantity, cash, and other trade discounts, allowances, and credits actually allowed and taken; (iv) bad debts actually written-off; (v) provisions made for amounts repaid or credited by reason of rejections or returns including, without limitation, quality related recalls of previously sold Licensed Products; and (vi) compulsory payments and provisions made for rebates, price discounts, or reimbursements paid, made or credited to any governmental body or to any third party payor, administrators, or contractee, in relation to the sales of Licensed Products and in accordance with Applicable Laws whether taken at the time of sale or retroactively.

Sales of Licensed Products by and between Licensee and its Affiliates and sub-licensees are not sales to third parties and shall be excluded from Net Sales calculations for all purposes;

- (dd) **“Patent”** shall mean the rights and interests in and to issued patents and pending patent applications in the Territory, including, without limitation, all provisional applications, substitutions, continuations, continuations-in-part, divisionals and renewals, all letters patent granted thereon, if any, and all reissues, reexaminations, re-registrations and extensions thereof, and supplemental protection certificates of invention and utility models;
- (ee) **“PEA”** shall mean Palmitoylethanolamide, micronized Palmitoylethanolamide and ultramicronized Palmitoylethanolamide, and any derivatives or sub-components of Palmitoylethanolamide;
- (ff) **“Prescription Drug”** means an FDA Approved pharmaceutical drug that legally requires a medical prescription to be dispensed;
- (gg) **“Regulatory Agency”** means any body with authority to regulate the development and/or commercialization of any Licensed Product;
- (hh) **“Royalty Term”** shall have the meaning given in Clause 4.3;

- (ii) “**Term**” shall have the meaning given to it in Clause 8.1;
 - (jj) “**Territory**” means all countries worldwide, except (i) Italy; and (ii) subject to the first refusal right of Clause 2.1, any other country in the rest of Europe.
 - (kk) “**Valid Claim**” shall mean (i) a pending claim under a Patent application included within Licensed Patents for a period of five (5) years from the date of first examination on the merits of that patent application; or (ii) any claim of an issued Patent included within Licensed Patents, which in either case has not lapsed, been withdrawn, abandoned cancelled or disclaimed, nor held invalid or unenforceable by a court of competent jurisdiction in an appealed or unappealable decision, within the time allowed for appeal and which has not been disclaimed, denied or admitted to be invalid or unenforceable through reissue, reexamination or disclaimer or otherwise.
- 1.2 The clause headings in this Agreement are for convenience of reference only, will not be deemed to be a part of this Agreement, and will not be referred to in connection with the construction or interpretation of this Agreement. All references in this Agreement to “Clauses” are intended to refer to Clauses of this Agreement.
- 1.3 Any rule of construction to the effect that ambiguities are to be resolved against the drafting Party will not be applied in the construction or interpretation of this Agreement.
- 1.4 As used in this Agreement, the words “include” and “including” and variations thereof, will not be deemed to be terms of limitation, but rather will be deemed to be followed by the words “without limitation”.
- 1.5 The Schedules form part of this Agreement and shall have effect as if set out in full in the body of this Agreement. Any reference to this Agreement includes the Schedules.
- 1.6 Save where the contrary is indicated, any reference in this Agreement to:
- (a) words importing the singular shall include the plural and *vice versa*;
 - (b) a “person” includes any individual, company, corporation, unincorporated association or body (including a partnership, trust, fund, joint venture or consortium), government, state, agency, organisation or other entity whether or not having separate legal personality;
 - (c) any person (including the Parties) shall be construed so as to include its and any subsequent successors, transferees and assigns in accordance with their respective interests;

- (d) this Agreement or any other agreement or document shall be construed as a reference to this Agreement or, as the case may be, such other agreement or document as the same may have been, or may from time to time be, amended, varied, novated, replaced or supplemented;
- (e) a provision of law (including Applicable Law generally) is a reference to that provision as extended, applied, amended or re-enacted and includes any subordinate legislation; and
- (f) the “winding-up”, “dissolution”, “administration”, “insolvency” or reorganisation” of a company or corporation and references to the “liquidator”, “assignee”, “administrator”, “receiver”, “administrative receiver”, “manager” or “trustee” of a company or corporation shall be construed so as to include any equivalent or analogous proceedings or, as the case may be, insolvency representatives or officers under the law of the jurisdiction in which such company or corporation is incorporated or constituted or any jurisdiction in which such company or corporation or, as the case may be, insolvency representative or officer carries on business including without limitation, the seeking of liquidation, winding up, reorganisation, dissolution, administration, arrangement, adjustment, protection or relief of debtors.

ARTICLE II

LICENSES

2.1 Grant of Licenses

Licensor hereby grants to Licensee an irrevocable (except as provided in Clause 8), royalty-bearing, exclusive license for the Territory under the Licensed Patents, and during the Term, to: (i) itself or through Commercial Partners use, research, develop, make, have made, sell, offer to sell, import, export or otherwise dispose of or otherwise commercialize the Licensed Products in the Field; (ii) itself or through Commercial Partners commercialize the Licensed Products in the Field (such commercialization to include, but is not limited to, selling, marketing, distributing, pricing, reimbursing, manufacturing and any vigilance); and (iii) subject to section 4.6(a), itself or through Commercial Partners use any method, research or processor relating to (i) and (ii) above in manufacturing the Licensed Products in the Field.

Licensee will develop the Licensed Products in the United States with a view to filing an Investigational Animal Drug Application (IADA) with the FDA within thirty-six (36) months from the Effective Date. The 36-month period can be extended by an additional twelve (12) months by mutual consent, which will not be unreasonably withheld. Licensee shall provide Licensor annual reports of its progress towards the development of the Licensed Products in the United States.

Should Licensee not provide the first notification by FDA of the submission of a New Animal Drug Application within sixty (60) months following the Effective Date, or should the Licensee at any point following the Effective Date notify Licensor that it no longer intends to pursue the development of the Licensed Products in the United States, or should the FDA refuse the approval of the New Animal Drug Application for inactivity of FSD in pursuing the file or in complying with any request of FDA, Licensee shall be deemed to have issued a notice to terminate this Agreement for convenience under Clause 8.3.

Upon approval of a New Animal Drug Application (NADA) in the United States by FDA, Licensee will obtain regulatory approval in other countries of the Territory with a view to filing regulatory approval applications within thirty-six (36) months of the approval of the New Animal Drug Application in the United States. The 36-month period can be extended by an additional twelve (12) months by mutual consent, which will not be unreasonably withheld. Any country where Licensee fails to file a regulatory approval application within this time period will be excluded from the Territory.

Licensee is further given a first refusal right to expand the Territory to include any country in Europe except for Italy. To this effect, Licensor shall notify Licensee at least ninety (90) days prior to granting any license to any third party in any country of Europe, except for Italy and Licensee shall communicate in writing within the following ninety (90) days the decision to exercise its first refusal right. In this case the Parties shall amend this Agreement to expand the Territory hereunder to include any such countries, subject to such other reasonable terms and conditions as the Parties may negotiate and agree upon in good faith.

The Licensed Products shall be sold by Licensee, its Affiliates and sub-licensees with a label "under license of Innovet Italia S.r.l."

2.2 Know-How License Grant

Licensor hereby grants to Licensee an irrevocable (except as provided in Clause 8), non-exclusive license to use the Licensed Know-How itself or through Commercial Partners in the Territory in connection with any research, development, manufacture, sale, importation, exportation, disposal or any other commercialization of any Licensed Products in the Field subject to the limitation set forth in Section 2.1. above.

2.3 Sublicense

The Licenses include the right for Licensee to sublicense any and all of the Licensed IP to one or more tiers of sub-licensees, including without limitation Commercial Partners, without the prior written consent of Licensor on terms not materially inconsistent with the terms of this Agreement and with other terms as determined in Licensee's sole discretion. Licensee will deliver to Licensor the copy of any sublicenses granted within 14 days of the signing of the sublicense agreement or notification that a further sublicense has been granted.

2.4 Communications among the Parties

- (a) Each of Licensee and Licensor shall appoint a specific individual who shall be available and shall act as a “Liaison Person” to facilitate day-to-day communications among the Parties relating to the progress of the activities contemplated hereunder. Any changes to a Liaison Person shall be notified to the other Party in writing.
- (b) Licensee shall communicate to Licensor any key events in the research and development of the Licensed Products and in particular any adverse or serious adverse events occurring during any clinical study related to the Licensed Products.

ARTICLE III

Development and Commercialization

3.1 Development Efforts

Licensee shall use Commercially Reasonable efforts to develop the Licensed Products. Licensee shall use Commercially Reasonable Efforts to conduct such development in a good scientific manner, and in compliance in all material respects with the requirements of Applicable Laws and (if applicable) with applicable GLP, GCP and GMP (where relevant to the Licensed Product).

3.2 Technology Transfer

- (a) Technology. Upon written request by Licensee, and within thirty (30) days of receiving such request, Licensor shall transfer to Licensee all technology related to PEA and/or the Licensed Products, including, without limitation, all data, assays and Know-How (including without limitation Licensed Know-How). If necessary, the Licensee shall develop a plan for accomplishing such transfer, which Licensor shall make all Commercially Reasonable efforts to follow,
- (b) Manufacturing Information. Without limiting the generality of Clause 3.2(a) above, upon written request by Licensee, and within thirty (30) days of receiving such request, Licensor shall transfer to Licensee or such third party identified by Licensee, all technology related to the manufacture of PEA and/or the Licensed Products in the USA and Canada, and shall provide all necessary assistance and cooperation to effect such transfer.
- (c) Notwithstanding the above, Licensee, for itself, its Affiliates and sub-licensees, agrees to source PEA for use in Licensed Products from Licensor except in the circumstance where manufacturing in the US is mandatory according to a specific country’s regulations or where the Licensor accepts that there is a compelling commercial reason to use PEA

or Licensed Product manufactured in the US in a specific country or region.

- (d) Licensor agrees to supply Licensee with API at a price per kilogram as specified in Schedule 2 attached.

3.3 Regulatory

Licensee shall be responsible for ensuring compliance with Applicable Laws in relation to the use, research, development, manufacture, sale, offer to sell, import, export and other aspects of commercialization of the Licensed Products in the Territory including distributing, pricing, reimbursing, manufacturing and any vigilance provided that Licensor shall provide all reasonable assistance to Licensee in a timely manner in relation thereto.

3.4 Diligence

- (a) With respect to Licensed Products, Licensee shall, at its own cost, use Commercially Reasonable Efforts to: (a) subject to Clause 2.1, launch or have launched by a Commercial Partner the commercial sale of such Licensed Product as soon as reasonably practicable after obtaining the relevant regulatory approval and satisfactory reimbursement and pricing approvals in a country for such Licensed Products (if any); and (b) sell, promote and market the Licensed Product itself or through Commercial Partners on a continuing basis.
- (b) Licensee shall use Commercially Reasonable Efforts to enter into such commercially advantageous agreements with Commercial Partners in relation to the research, development, manufacture, sale or other disposal or commercialization of the Licensed Products in all or parts of the Territory as Licensee sees fit at its sole discretion and on such terms as it sees fit at its sole discretion.
- (c) Licensee shall in good faith notify Licensor in writing should it elect not to continue the development of Licensed Products. In such circumstance, Licensee shall be deemed to have issued a notice to terminate this Agreement for convenience whereupon the provisions of Clause 8.3 shall apply.

ARTICLE IV

Fees, Royalties, Reports, Audit and Taxes

4.1 Milestone Fees

The following fees are payable under this Agreement:

- (a) On or before the Effective Date of this Agreement, the non-refundable sum of USD 500,000 (five hundred thousand U.S. dollars) shall become due and payable by the Licensee to the Licensor as the first tranche of the consideration of Licensor's grant to Licensee of IP rights for Licensed Products for the treatment of Gastro-Intestinal Diseases in Canines and Felines. Payment of said amount will be due and payable no later than the above referenced date with an invoice issued by the Licensor to the Licensee for the said first tranche. A second tranche of the consideration of the Licensor's grant of the IP rights, being the nonrefundable sum of USD 250,000 (two hundred fifty thousand U.S. dollars), shall become due at the first anniversary of the Effective Date. A third tranche of the consideration of the Licensor's grant of the IP rights being the sum of USD 750,000 (seven hundred fifty thousand U.S. dollars) shall become due and payable by the Licensee to the Licensor within thirty (30) days from the first notification by the FDA of approval of a New Animal Drug Application (NADA) of the first Licensed Product hereunder to receive such approval in the United States.
- (b) Not later than thirty (30) days after the first notification of acceptance of a New Animal Drug Application (NADA) by the FDA, Licensee will supply to Licensor, without charge to Licensor, a copy of said Registration Dossier/NADA in respect of the Licensed Product for use by Licensor in territories in respect of which Licensee does not have exclusive rights, namely Italy, and, subject to the first refusal right of Clause 2.1, other countries in the rest of Europe.

4.2 Royalties and Payment

- (a) Subject to Clause 4.4, Licensee will pay to Licensor 14% of any one-off lump sum payments received by Licensee as consideration for granting a sub-license to a Commercial Partner specifically with respect to a Licensed Product.
- (b) Subject to Clause 4.4, Licensee will pay to Licensor a royalty throughout the Royalty Term of this Agreement of 5% of Net Sales of the Licensed Products.
- (c) Licensee will pay the amounts payable under this Clause 4.2 to Licensor on a quarterly basis within sixty (60) days after the end of each quarter for amounts received during such quarter. A quarter begins on each January 1, April 1, July 1, and October 1.

4.3 Royalty Term

- (a) The obligation to pay any amounts under Clause 4.2(a), or any royalties under Clause 4.2(b), shall expire on a country-by-country basis on the

expiration of the last Valid Claim of the Licensed Patents covering the Licensed Products in that country (“Royalty Term”). For the avoidance of doubt, the approval of a substitutable, generic version of a Licensed Product in a country (e.g. a version that is deemed to be “therapeutically equivalent” by the FDA for purposes of a determination for the United States and/or any other Regulatory Agency in the Territory) will conclusively demonstrate that a Valid Claim does not cover the Licensed Products in that country.

- (b) Licensee acknowledges that, in the absence of Patents or pending patent applications covering the Licensed Products in a country, the obligation to pay any amount and royalties under Clause 4.2. are payable for the license of the Know-How granted with this agreement, until the expiration of the last-to expire of the Licensed Patents in the country where such patent is in full force.

4.4 Paid-Up License

If the Licenses are still in force with respect to Licensed Products at the end of the Royalty Term, such Licenses shall be automatically converted to fully paid-up, non-exclusive, royalty-free licenses, with the right to sublicense, under any Licensed IP necessary to make, have made, use, sell, offer to sell, and import Licensed Products on a country-by-country basis.

4.5 Exchange Rate; Manner and Place of Payment

All payments due under this Clause 4 shall be payable in United States dollars. With respect to each quarter, whenever conversion of payments from any foreign currency shall be required, such conversion shall be made at the rate of exchange reported in The Wall Street Journal, Western Edition, during the last day of the applicable quarter for which such rate is reported.

4.6 Third Party Patent Rights and Payments

- (a) In the event that, by mutual agreement of the Parties, it becomes necessary for Licensee or a Commercial Partner to license other intellectual property owned by a third party to use, develop, make, have made, sell, offer to sell, import, export, lease, or otherwise dispose of any Licensed Products, then Licensee or a Commercial Partner, as applicable, shall have the right to obtain a license from such third party and to credit fifty percent (50%) of any payment actually paid to such third party under such license against the royalties or other amounts payable to Licensor under Clause 4.2 up to a maximum of fifty percent (50%) of the royalty payable under Clause 4.2 in respect of sales in the countries in which it was necessary to obtain the license.

- (b) Licensor shall be responsible for any and all payments to third parties arising out of any licenses or sub-licenses that it has or may enter into relating to obtaining rights over Licensed IP.

4.7 Reports

Along with each royalty payment, Licensee will provide a statement showing the Net Sales during the preceding quarter and a calculation of the royalties accrued during such quarter. The statement will include on a regional and product-by-product basis (a) the aggregate gross revenues for Licensed Products itemizing the value of the sales made by Licensee and each of its Affiliates and sub-licensees in the same manner as used in the Licensee internal reports; (b) deduction from those gross revenues required to compute Net Sales of Licensed Products; (c) any other deduction made pursuant to this agreement; and (d) total royalties due pursuant to this agreement. Each statement shall be Confidential Information of Licensee and Licensor shall be bound by the obligations of confidentiality and non-use in Clause 5 in relation thereto.

4.8 Audit Rights

For a period of not less than three (3) years after the relevant period of sales, Licensee shall keep, and shall cause its Affiliates and sub-licensees to keep, full true, and accurate books of account sufficient to determine the royalties due hereunder. Licensor will have the right to request an audit of the books and records of Licensee and/or its Affiliates and/or sub-licensees, directly relating to the royalty payments for the sole purpose of ~~verifying the amounts due and payable under this Agreement, not more than once per~~ calendar year upon providing at least four (4) weeks' prior written notice to Licensee. All such audits will be conducted during reasonable business hours of Licensee and/or its Affiliates, and/or sub-licensees, in a manner that does not unreasonably interfere with such entity's normal business activities and will be conducted by a certified public accountant or equivalent acceptable to Licensee (the "Auditor"), such acceptance not to be unreasonably withheld or delayed. Except for the statement of royalty payments due, the Auditor will not disclose any information learned during the audit to Licensor. The audit will be conducted at Licensor's expense, except if the audit shows that amount of additional royalty payments due to Licensor is greater than five percent (5%) of the total ~~royalty paid to Licensor for the immediately preceding calendar year, Licensee will pay~~ for the cost and expense of such audit. If Licensee has overpaid royalties, Licensee may credit such overpayments against future royalties owed to Licensor or request immediate payment of the same.

4.9 Taxes

- (a) Subject to Clause 4.9(b), Licensor will be responsible for and will indemnify and hold Licensee harmless from payment of any taxes, fees, duties, and other governmental charges, and any related penalties and interests, arising from the payment of any fees and royalties under this Agreement.

- (b) If any taxes are required to be withheld by Licensee, Licensee will:
 - (i) deduct such taxes from the remitting payment;
 - (ii) timely pay the taxes to the proper taxing authority; and
 - (iii) send proof of payment to Licensor and certify its receipt by the taxing authority within sixty (60) days following such payment.

ARTICLE V

Confidentiality

5.1 Confidential Information

During the term of this Agreement, each Party (the "Receiving Party") may be provided with, have access to, or otherwise learn confidential and/or proprietary information of the other Party (the "Disclosing Party") (including certain information and materials concerning the Disclosing Party's business, plans, customers, technology, and products) that is identified as confidential at the time of disclosure or which should reasonably be considered, under the circumstances of its disclosure, to be confidential to the Disclosing Party ("Confidential Information").

5.2 Confidentiality Obligations

All Confidential Information remains the property of the Disclosing Party. The Receiving Party may disclose the Confidential Information of the Disclosing Party only to its employees and contractors who need to know the Confidential Information for purposes of performing under this Agreement and who are bound by the Receiving Party's standard employee or contractor (as applicable) confidentiality agreements that include terms at least as restrictive as those terms disclosed herein. Licensee may disclose the Confidential Information of Licensor to its Commercial Partners for use in accordance with the terms of this Agreement. The Receiving Party will not use the Confidential Information of the Disclosing Party without the Disclosing Party's prior written consent except in performance of its obligations and exercise of its rights under this Agreement. The Receiving Party will take measures to maintain the confidentiality of the Confidential Information equivalent to those measures the Receiving Party uses to maintain the confidentiality of its own confidential information of like importance but, in no event, are such measures to be less than reasonable measures. The Receiving Party will give immediate notice to the Disclosing Party of any unauthorized use or disclosure of the Confidential Information that comes to the attention of the Receiving Party and agrees to assist the Disclosing Party in remedying such unauthorized use or disclosure.

5.3 Exceptions

The confidentiality obligations do not extend to Confidential Information which: (i) becomes part of the public domain without the fault of the Receiving Party; (ii) is rightfully obtained by the Receiving Party from a third party with the right to transfer

such information without obligation of confidentiality; (iii) is independently developed by the Receiving Party without reference to or use of the Disclosing Party's Confidential Information, as evidenced by written records; or (iv) was lawfully in the possession of the Receiving Party at the time of disclosure, without restriction on disclosure, as evidenced by written records. In addition, the Receiving Party may disclose Confidential Information of the Disclosing Party as may be required by Applicable Laws, a court order, or a governmental agency with jurisdiction, provided that, where permitted, before making such a disclosure the Receiving Party first notifies the Disclosing Party promptly and in writing and cooperates with the Disclosing Party, at the Disclosing Party's reasonable request and expense, in any lawful action to contest or limit the scope of such required disclosure.

5.4 Return of Confidential Information

Upon termination or expiration of this Agreement, save as otherwise provided, the Receiving Party will return to the Disclosing Party or, at the request of the Disclosing Party, destroy all tangible copies of Confidential Information of the Disclosing Party including all copies thereof, which the Receiving Party no longer has the right to use, in the Receiving Party's possession or control and will erase from its computer systems all electronic copies thereof save that each Party will be entitled to retain for record keeping purposes only one copy of any such information and subject to the condition that such information is used for that purpose alone. The Receiving Party shall, upon request by the Disclosing Party, certify in writing that it has complied with this Clause 5.4.

5.5 Confidentiality of the Agreement

Subject to Clause 13.11, neither Party will disclose any terms or conditions of this Agreement to any third party, without the prior written consent of the other Party, except: (i) to the extent that such disclosure is required by Applicable Laws or legal process, including without limitation the securities and antitrust laws of any country, including the United States or Italy, and the Parties acknowledge and agree that the determination that a disclosure is required by Applicable Laws shall be made in the sole, but reasonably exercised, discretion of the Party making such disclosure; (ii) to its attorneys, accountants, and other professional advisors under a duty of confidentiality; (iii) to assert or enforce such Party's rights under this Agreement; or (iv) if reasonably required in connection with the conduct of their respective businesses, each Party may disclose the existence or terms of this Agreement to bankers, other business associates and/or potential investors, provided that such persons and/or entities have agreed in writing to keep such information confidential subject to non-disclosure and non-use obligations at least as stringent as those set forth herein, and upon the request of either Party, the other Party shall identify those third parties to whom such disclosure has been made.

ARTICLE VI

Patents

6.1 Ownership and Prosecution

(a) Disclosure by Employees, Agents or Independent Contractors

Licensors agree that, as to any employees, agents, or independent contractors of Licensor presently in its employ or who are hired or retained by Licensor to perform, manage the performance of, or participate in any activities pursuant to this Agreement or otherwise in relation to the Licensed IP and/or Licensed Products, Licensor will ensure that such employees, agents, or independent contractors will promptly disclose and assign or exclusively license to Licensor any and all rights to inventions, developments, or improvements, including Improvements (whether patentable or not) conceived and/or, reduced to practice during the course of their duties. Licensor will further notify Licensee promptly of any Improvements and/or sole or Joint Inventions within the Licensed IP.

(b) Improvements

Any Improvement conceived jointly by Licensor and Licensee shall be owned jointly by the Parties (a "Joint Invention"), with each Party's ownership share being proportionate to the degree to which said Party contributed towards the development of the Improvement (as to be determined by the Parties through good faith negotiations), provided that Licensor's share of such Joint Invention shall automatically become part of Licensed IP and subject to the Licenses. The Parties shall reasonably cooperate with each other and each Party shall provide input in connection with the preparation, filing, prosecution and maintenance of patent rights in the Joint Inventions.

Any Improvement conceived solely by Licensor shall be solely owned by Licensor but shall automatically become part of Licensed IP and subject to the Licenses.

Any Improvement conceived solely by Licensee ("Licensee Improvement") shall be solely owned by Licensee. Licensee hereby grants to Licensor a worldwide, royalty-free, non-exclusive, non-transferrable license to use the Licensee Improvements during the Term to the extent necessary for the performance of the Licensor's obligations hereunder.

Except for patent filings, each Improvement shall be maintained in confidence by the Parties, unless and until a published patent application or an issued patent makes the content of such improvement public.

- (c) Prosecution. Licensor shall be obliged to prepare, file, prosecute and maintain in such countries as the Parties may agree acting reasonably and at its sole expense, and upon appropriate consultation with Licensee, Patents within the Licensed IP and all Improvements (sole or joint), and for conducting any interferences, reexaminations, reissues, oppositions or requests for patent term extension or governmental equivalents relating to such Licensed Patents, and Licensee shall give reasonable cooperation in connection therewith, at Licensor's reasonable request. If Licensor elects not to prepare, file, prosecute or maintain Patents in accordance with this Clause 6.1(c) Licensee may, in its sole discretion, elect to do so and Licensor shall give reasonable cooperation in connection therewith, at Licensee's reasonable request. In such cases, Licensor and Licensee shall be equally responsible for all associated costs.
- (d) Cooperation. Licensor shall keep Licensee fully informed as to the status of patent matters described in this Clause relating to Licensed Patents, and, upon request, shall provide Licensee with copies of any substantive documents that Licensor receives from such patent offices promptly after receipt, including notice of all interferences, reissues, re-examinations, oppositions or requests for patent term extensions. Licensee shall provide Licensor with all such co-operation as may be reasonably requested by Licensor in connection with the filing, prosecution and maintenance of Patents within the Licensed IP, including, without limitation, access to documentation and inventors.
-
- (e) Inventorship. Inventorship of all Patents shall be determined based upon U.S. Patent Laws.
- (f) Permitted Disclosures. Licensee shall be entitled to disclose in the specification of a Patent application filed by Licensee pursuant to this Agreement, any Licensed IP necessary to support and enable claims in such Patent applications.

6.2 Third Party Infringement Proceedings

- (a) Licensed IP. Licensee shall have the exclusive right, at its discretion, to initiate legal action to enforce the Patents within the Licensed IP against infringement or misappropriation by third parties or to defend any declaratory judgment action relating thereto. Licensee shall notify Licensor of its decision to bring proceedings or not, as the case may be, within sixty (60) days of the date that the infringement has come to its knowledge. Where Licensee elects not to bring proceedings, Licensor shall have the right either to do so, except where Licensee can demonstrate that such would have a material detrimental effect on commercialization of the Licensed Products, or to revoke the exclusivity granted hereto to the Licensee in any country where the said infringement or misappropriation

by third parties cause Material Adverse Change to the normal accruing of royalties payable to Licensor.

- (b) No Settlement Without Consent. Neither Party shall enter into any settlement of any claim, suit or proceeding under this Clause 6.2 which admits or concedes that any Licensed Patent is invalid or unenforceable without the prior written consent of the other Party, such consent not to be unreasonably withheld or delayed.
- (c) Cooperation. Each Party shall keep the other Party reasonably informed of the progress of any claim, suit or proceeding subject to this Clause 6.2 and the other Party shall cooperate reasonably in connection with such activities at the request and expense of the first Party in such claim, suit or proceeding.

6.3 Infringement Claims brought by Third Parties

If the development, manufacture, sale or use of Licensed Product pursuant to this Agreement results in any claim, suit or proceeding alleging Patent infringement against either Licensor or Licensee (or its Commercial Partners), the relevant Party shall promptly notify the other Party in writing setting forth the facts of such claim in reasonable detail. Licensee shall have the exclusive right to defend and control the defence of any such claim, suit or proceeding, at its own expense, using counsel of its own choice; provided, however, it shall not enter into any agreement or settlement which admits or concedes that any Licensed Patent is invalid, unenforceable or not infringed, without the prior written consent of Licensor, such consent not to be unreasonably withheld or delayed. Licensee shall keep Licensor reasonably informed of all material developments in connection with any such claim, suit or proceeding and Licensor shall cooperate reasonably in connection with such activities at the request of Licensee in such claim, suit or proceeding.

6.4 Division of Recoveries

- (a) Any recovery received in connection with a suit brought by Licensee pursuant to Clause 6.2(a) shall be used first to reimburse Licensee for expenses (including reasonable attorneys' fees) incurred by Licensee. Any recovery remaining after reimbursement of Licensee's expenses shall be retained by Licensee and deemed to be Net Sales, subject to the royalty fees set forth in Clause 4.2. Licensee shall pay the applicable royalty fees on such amount as if such amounts had been earned during such calendar quarter.
- (b) Any recovery received in connection with a suit brought by Licensor pursuant to Clause 6.2(a) shall be retained by Licensor.

6.5 Patent Term Restoration

The Parties shall give reasonable cooperation to each other in obtaining Patent term restoration or supplemental protection certificates or their equivalents in any country in the Territory where applicable to the Licensed IP.

ARTICLE VII

Representations and warranties

7.1 Mutual Representations and Warranties

Each party represents that

- (a) it is a corporation, duly incorporated and validly existing under the law of its jurisdiction of incorporation;
- (b) it and each of its subsidiaries has the power to own its assets and carry on its business as it is being conducted;
- (c) it has full right, power, and authority to enter into this Agreement and to perform its obligations and duties under this Agreement;
- (d) it has obtained all authorizations required or desirable:
 - (i) to enable it to lawfully enter into, exercise its rights and comply with its obligations in this Agreement; and
 - (ii) to make this Agreement admissible in evidence in its jurisdiction of incorporation;
- (e) the entry into and performance by it of, and the transactions contemplated by, this Agreement do not and will not conflict with:
 - (i) any law or regulation applicable to it;
 - (ii) its or any of its subsidiaries' constitutional documents; or
 - (iii) any agreement or instrument binding upon it or any of its subsidiaries or any of its or any of its subsidiaries' assets;
- (f) the performance of such obligations and duties does not and will not conflict with or result in a breach of any other agreements of such Party or any judgment, order, or decree by which such Party is bound; and
- (g) the choice of UNIDROIT Principles of International Commercial contracts as the governing law of this Agreement will be recognized and enforced in its jurisdiction of incorporation.

7.2 Representations and Warranties by Licensor

Licensor represents and warrants:

- (a) on each day during the Term hereof, that it has full right, power, and authority to license the Licensed IP to Licensee and to grant the Licenses;
- (b) on each day during the Term hereof, that if based on an invention made by an employee of Licensor, Licensed Products and Licensed Know-How have been effectively, unconditionally, irrevocably and fully transferred to Licensor pursuant to Applicable Laws;
- (c) on each day during the Term hereof, that it has not granted or will not grant during the term of this Agreement any security interest, option, lien, license, or encumbrance of any nature with respect to any Licensed Patent or Licensed Know-How which would conflict with the Licenses granted to Licensee under this Agreement;
- (d) on the Effective Date, that it is not aware of nor has Licensor received at any time written notice from any third party alleging that the Licensed IP and/or Licensee's development of the Licensed Products infringes the intellectual property rights of that third party. Furthermore Licensor is not currently involved in any court proceeding wherein a third party is claiming that Licensor's IP infringes the intellectual property rights of that third party nor has it ever been involved in such proceedings;
- (e) on the Effective Date, that no court, patent office or other proceeding is pending or threatened, nor has any written claim been received by Licensor, which challenges or challenged the legality, validity, or enforceability of the Licensed Patents or any of them; and
- (f) on the Effective Date, that to the best knowledge of Licensor, using, making, selling, or importing Licensed Products as permitted under this Agreement will not infringe, directly or indirectly, any Patent or other intellectual property right of a third party under the laws of any jurisdiction.

7.3 Undertakings

- (a) Licensor Undertakings. Licensor hereby undertakes:
 - (i) to comply with Applicable Laws in the performance of its obligations under this Agreement;
 - (ii) promptly to supply Licensee all necessary information concerning the hazards involved in using PEA and all safety instructions for use, storage and disposal of PEA;

- (iii) to provide progress reports in such form and at such frequency as the Parties may agree from time to time;
 - (iv) to the extent permitted by Applicable Laws, Licensor shall notify Licensee in writing of all information that comes to its attention concerning adverse events relating to PEA and/or the Licensed Products. Licensor will use its best efforts to provide such report to Licensee within forty-eight (48) hours after receipt of the information in the case of any experience coincident with the use of PEA and/or the Licensed Products, whether or not considered related to PEA and/or the Licensed Products, that suggests a hazard, contraindication, side effect or precaution or results in death, a life-threatening experience inpatient hospitalization, prolongation of an existing hospitalization, a persistent or significant disability or incapacity, or a congenital anomaly or birth defect; and
 - (v) as soon as possible upon receiving a written request by Licensee, to provide Licensee with any further information relating to PEA and/or the Licensed Products.
- (b) Licensee Undertakings. Licensee hereby undertakes to warn Licensee's freight handlers, Commercial Partners, and direct customers of any risks involved in using or handling the Licensed Products.
-
- (c) Licensor acknowledges that the development of the Licensed Products is experimental in nature and that Licensee makes no representation or warranty that it shall be successful.

ARTICLE VIII

Term and Termination

8.1 Term

This Agreement will take effect on the Effective Date and remain in effect for the Royalty Term unless terminated pursuant to Clauses 8.2 to 8.5 (inclusive) (the "Term").

8.2 Termination for Cause

If either Party materially breaches, or materially defaults in the performance of, or fails to be in material compliance with any warranty, representation, obligation or covenant of this Agreement, including any payment obligations, and such material default or noncompliance shall not have been substantially remedied, or steps initiated to substantially remedy the same to the other Party's reasonable satisfaction, within sixty (60) days after receipt by the defaulting Party of a written notice thereof and demand to cure such default from the other Party (or, in the case of a failure to pay any amount due

hereunder, within thirty (30) Business Days after receipt of such notice), the Party not in default or breach shall have the right to terminate this Agreement.

8.3 Termination for Convenience

Save as set forth in this Clause 8.3, at any time during the term of this Agreement, Licensee may terminate this Agreement by giving Licensor a written notice of termination. Termination will be effective ninety (90) days after the date of the notice of termination. The right of Licensee to terminate this Agreement pursuant to this Clause 8.3. may not be exercised within the first twelve (12) months following the Effective Date save in the event of concerns about the safety of the Licensed Product.

8.4 Insolvency

This Agreement shall automatically terminate if, at any time: (a) any action, proceedings, procedure or step is taken, or any petition filing is made in any court pursuant to any statute (and such petition is not dismissed within sixty (60) days after the filing thereof), for (i) the suspension of payments, winding up, dissolution, bankruptcy, administration or reorganisation (using a voluntary arrangement, scheme of arrangement or otherwise) of either Party, or (ii) the appointment of a liquidator, receiver, administrative receiver, administrator, trustee, compulsory manager or other similar officer in respect of either Party or any of either Party's assets; (b) either Party stops or suspends payment of any of its debts, or is unable to, or admits its inability to, pay its debts as they fall due; (c) either Party commences negotiations, or enters into or agrees to any composition or arrangement, with one or more of its creditors with a view to rescheduling any of its indebtedness (because of actual or anticipated financial difficulties); or (d) any event occurs in relation to a Party that is analogous to those set out in this Clause 8.4.

8.5 Effect of Termination

- (a) Accrued Obligations. Termination of this Agreement for any reason shall not release any Party hereto from any liability which, at the time of such termination, has already accrued to the other Party or which is attributable to a period prior to such termination.
- (b) Effect of Termination on Development. In the event of any termination of the Agreement, Licensee shall have no further obligation to conduct development activities after the effective date of such termination.
- (c) Effect on Licenses.
 - (i) In the event of termination: (i) due to Licensee insolvency under Clause 8.4; or (ii) by Licensee pursuant to Clause 8.3, all rights and licenses granted by Licensor with respect to Licensed Product hereunder shall terminate, save that Licensee may complete and sell any work-in-progress and inventory of the Licensed Products that exist as of the termination date for a period of twelve (12) months after the termination date, provided that Licensee pays

Licensors the applicable running royalty or other amounts due on such sales of Licensed Products in accordance with Clause 4.2.

- (ii) In the event of termination by Licensor pursuant to Clause 8.2, the Licensor shall be entitled to compensatory damages available at law, the amount of which shall not exceed in any case one hundred percent (100%) of the value of the royalties paid by Licensee in the year preceding the termination (with the exception that there will be no assessment for incidental, consequential, punitive, special or exemplary damages arising out of any breach of this Agreement). And where the Licensor is the breaching Party, the Licensee's licenses shall be converted to fully paid-up, royalty-free licenses, with the right to sublicense, under any Licensed IP, necessary to research, develop, make, have made, use, sell, offer to sell, and import the Licensed Product in the Territory for a period of three (3) years following the date of termination.
 - (iii) In the event of termination pursuant to Clause 8.4 (other than due to Licensee insolvency under Clause 8.4), all rights and licenses granted by Licensor with respect to Licensed Products shall remain in effect, so long as Licensee continues to comply in all material respects with its obligations under Clause 4, it being understood that in determining noncompliance, Licensee shall continue to have the benefit of the notice and cure provisions set forth herein.
-
- (iv) In the event of termination pursuant to Clause 8.3, then the Parties shall, from the period from the delivery of the termination notice until the effective date of the termination (the "Discussion Phase"), meet to discuss:
 - (A) the terms upon which Licensee would be agreeable to transfer to Licensor its know-how obtained in respect of the Licensed Product;
 - (B) the terms upon which Licensee would be agreeable to transfer any regulatory approval for Licensed Products held by Licensee to Licensor; or
 - (C) the terms of any press release for communication in respect of such termination.

Provided that, during the Discussion Phase, if an agreement in principle has been reached on future actions in respect of one of the issues listed in paragraphs (A) and (B) above, then following the expiry of the Discussion Phase, the Parties agree that they shall meet for a further period of sixty (60) days to negotiate in good faith for a binding agreement in respect of such matters. If,

following the Discussion Phase, or the following sixty (60) day period, if applicable, the Parties are unable to reach an agreement, neither Party shall have any further obligation under this Clause 8.5(c)(iv).

8.6 Survival

Upon termination or expiration of this Agreement, Articles 4.8, 5, 7.1, 7.2., 8, 9, 10, 11, and 13 will survive.

ARTICLE IX

Disclaimer

9.1 No Implicit Representations or Warranties

Except as provided above, neither Party makes any representations, extends any warranties of any kind, assumes any responsibility or obligations whatsoever, or confers any right by implication, estoppel, or otherwise, other than the licenses, rights, and warranties expressly granted herein.

ARTICLE X

Indemnification

10.1 Licensee Indemnification

Licensee shall indemnify and hold harmless, pursuant to the provisions of this Clause 10.1, Licensor and each of its officers, directors, employees, agents and Affiliates (collectively, the "Licensor Indemnitees"), from and against, and will reimburse each such Licensor Indemnitee with respect to, any and all third party claims, actions, demands, losses, damages, liabilities, costs and expenses to which such Licensor Indemnitee may become subject, including reasonable fees and disbursements of counsel and expenses of reasonable investigation (collectively, "Licensor Losses"), arising out of, based upon or caused by: (a) the inaccuracy of any representation or the material breach of any warranty, covenant or agreement of Licensee contained in this Agreement; (b) any failure by Licensee to conduct its development and other obligations arising hereunder in a diligent and professional manner and in accordance with Applicable Laws; or (c) any claim concerning the manufacture (by Licensee or by a third party on behalf of Licensee), sale or use of any Licensed Product and any side effects pertaining to such Licensed Product known by Licensee, but not disclosed to Licensor; or (d) any negligence or intentional wrongdoing by Licensee in the performance of its obligations (save to the extent covered by Licensor's indemnity under Clause 10.2).

10.2 Licensor indemnification

Licensor shall indemnify and hold harmless, pursuant to the provisions of this Clause 10, Licensee and each of its officers, directors, employees, agents and Affiliates (collectively,

the “Licensee Indemnitees”), from and against, and will reimburse each such Licensee Indemnitee with respect to, any and all third party claims, actions, demands, losses, damages, liabilities, costs and expenses to which such Licensee Indemnitee may become subject, including reasonable fees and disbursements of counsel and expenses of reasonable investigation (collectively, “Licensee Losses”), arising, out of, based upon or caused by: (a) the inaccuracy of any representation or the material breach of any warranty, covenant or agreement of Licensor contained in this Agreement; (b) any failure by Licensor to conduct its development and other obligations arising hereunder in a diligent and professional manner and in accordance, with Applicable Laws; (c) any claim concerning manufacture of any Licensed Product manufactured by or on behalf of Licensor and any known, but not disclosed, side effects pertaining to such Licensed Product; (d) any negligence or intentional wrongdoing by Licensor in the performance of its obligations (except in each case, and solely to the extent, that any Licensee Loss is due to the gross negligence or wilful misconduct of one or more Licensee Indemnitees); and (e) subject to the application of s. 11.1, any claim settled by Licensee with the prior written consent of Licensor, or assessed by a final decision of a competent court against Licensee alleging that the Licensed IP infringes on the intellectual property rights of such third party.

Further, Licensor hereby unconditionally and irrevocably agrees at all times, subject only to the applicable limitation periods imposed by law, to indemnify and hold harmless Licensee from, against and in respect of any and all charges, expenses, claims, suits, damages, costs, judgments, decrees, losses, reasonable legal fees and expenses, penalties, demands, liabilities and causes of action of any kind or nature whatsoever, by reason of, based upon, relating, or arising out of not having taken all necessary steps to be legally entitled to license the Licensed Patents and Licensed Know-How to Licensee in accordance with the terms of this Agreement.

10.3 Indemnification Procedures

Each Party, on behalf of itself and its respective Licensor Indemnitees or Licensee Indemnitees (each such person, an “Indemnitee”), agrees to provide the indemnifying Party prompt written notice of any action, claim, demand, discovery of fact, proceeding or suit (collectively, a “Claim”) for which such Indemnitee intends to assert a right to indemnification under this Agreement; provided, however, that failure to give such notification shall not affect each applicable Indemnitee’s entitlement to indemnification (or the corresponding indemnifying Party’s indemnification obligations) hereunder except to the extent that the indemnifying Party shall have been prejudiced as a result of such failure. The indemnifying Party shall have the initial right (but not obligation) to defend, settle or otherwise dispose of any Claim for which an Indemnitee intends to assert a right to indemnification under this Agreement as contemplated in the preceding sentence if, and for so long as, the indemnifying Party has recognized in a written notice to the Indemnitee provided within thirty (30) days of such written notice its obligation to indemnify the Indemnitee for any Licensor Losses or Licensee Losses (as the case may be) relating to such Claim; provided, however, that if the indemnifying Party assumes control of the defence, settlement or disposition of a Claim, the indemnifying Party shall obtain the written consent of each applicable Indemnitee prior to ceasing to defend,

settling or otherwise disposing of the Claim. If the indemnifying Party fails to state in a written notice during such thirty (30) day period its willingness to assume the defence of such a Claim, Licensor Indemnitee(s) or Licensee Indemnitee(s), as the case may be, shall have the right to defend, settle or otherwise dispose of such Claim, subject to the applicable provides of Clauses 10.1 and 10.2.

ARTICLE XI

Limitation of Liability

- 11.1** Except in the event of wilful misconduct, negligence or fraud of a Party, in no event will either Party be liable to the other Party or any third party for any consequential, indirect, punitive, exemplary, special or incidental damages, including any indirect lost data and indirect lost profits, arising from or relating to this Agreement or the Licensed Patents.
- 11.2** Except in the case of death or personal injury caused by Licensee's negligence or fraud of Licensee, Licensee's total liability in contract, tort (including negligence), misrepresentation, restitution or otherwise arising in connection with the performance, or contemplated performance, of this Agreement shall be limited to the fees and royalties paid to Licensor under this Agreement in the twelve (12) months preceding the event that gives rise to the claim.

ARTICLE XII

Insurance

- 12.1** Each Party shall maintain, for the term of this Agreement, with a reputable insurer commercially reasonable insurance to cover the risks associated with its business and the activities contemplated by this Agreement.

ARTICLE XIII

General

13.1 Notice

Any notice, approval, authorization, consent, or other communication required or permitted to be delivered to either Party under this Agreement must be in writing and will be deemed properly delivered, given, and received if: (i) delivered personally, at the time of delivery; (ii) sent by facsimile, upon receipt by the sender of a facsimile transmission report (or other appropriate evidence) that the facsimile has been transmitted to the addressee, provided that where transmission occurs after 6:00pm on a Business Day or at any time on a day which is not a Business Day, receipt shall be deemed to occur at 9:00am on the next following Business Day; (iii) sent by prepaid first class post (or by airmail from one country to another), on the second (or if by airmail the fourth) Business Date after the date of posting; or (iv) sent by international courier, on the date and at the time of signature of the courier's delivery receipt. All notices shall be sent to the fax

number or address set forth below (or to such other fax number or address as may be designated by a Party by giving written notice to the other Party pursuant to this Clause 13.1):

If to Licensor:

Via Einaudi 13
35030 SACCOLONGO (PD) Italy
Attn. Mr. Renato della Valle
[Redacted]

If to Licensee:

100 King Street West, Suite 3400
Toronto, Ontario M5X 1A4
Canada
Attn: Donal Carroll
[Redacted]

13.2 Governing Law

This Agreement will be construed in accordance with and governed in all respects by the UNIDROIT Principles of International Commercial Contracts.

13.3 Dispute Resolution; Jurisdiction

- (a) In the event that a dispute arises between the Parties as to (i) the interpretation or performance of any of the provisions of this Agreement; or (ii) matters related to but not covered by this Agreement, the Parties shall cause within fifteen (15) Business Days of the date of the dispute, a senior executive from each Party to meet to attempt to resolve the dispute. ~~Following such meeting (or such further meetings as may be agreed upon~~ by the Parties), if no agreement has been reached by such senior executives, then the matter may be submitted for litigation in accordance with Clause 13.3(b).
- (b) Any disputes, controversy or claim arising out of or in connection with this agreement (including any dispute concerning the validity or construction of this arbitration clause) will be finally settled in accordance with the Rules of Arbitration of the International Chamber of Commerce by three arbitrators appointed in accordance with said Rules, whose decision shall be final and legally binding upon each Party. The arbitration proceeding shall take place in Paris and shall be conducted in the English language.

13.4 Assignment

- (a) Licensee may assign this entire Agreement or any of its rights hereunder, without Licensor's consent (i) to any of Licensee's Affiliates; (ii) in connection with the sale of all or a material portion of any Licensee business unit, whether by merger, sale of assets, sale of shares, or otherwise; or (iii) to any other entity that agrees to abide by all terms of this Agreement.

- (b) Licensee may subcontract to any third party of its choice any of its obligations under this Agreement relating to the use, research, development, manufacture, sale, importation, exportation, disposal or commercialization of a Licensed Product; however, Licensee hereby acknowledges and agrees that Licensee will be and shall remain fully responsible for compliance by each of its subcontractors with all applicable terms and conditions of this Agreement and any breach of the terms of this Agreement by any subcontractor shall be treated as a breach by Licensee as if committed by Licensee.
- (c) This Agreement will be binding upon and shall inure to the benefit of the Parties hereto and their respective successors and assigns.

13.5 Remedies

The rights and remedies of the Parties will be cumulative (and not alternative). If any legal action is brought to enforce this Agreement, the prevailing Party will be entitled to receive its attorney's fees, arbitration costs, and other collection expenses, in addition to any other relief it may receive.

13.6 Waiver

All waivers must be in writing and signed by an authorized representative of the Party to be charged. Any waiver or failure to enforce any provision of this Agreement on one occasion will not be deemed a waiver of any other provision or of such provision on any other occasion.

13.7 Variation

This Agreement may not be amended, modified, altered, or supplemented other than by means of a written instrument duly executed and delivered on behalf of both Parties.

13.8 Severability

If any provision of this Agreement shall be held to be illegal or unenforceable, in whole or in part, under applicable law, that provision shall, to that extent, be deemed not to form part of this Agreement and the enforceability of the remainder of this Agreement shall not be affected.

13.9 Counterparts

This Agreement may be executed as two or more counterparts and execution by each of the Parties of any one of such counterparts will constitute due execution of this Agreement.

13.10 Force Majeure

If the performance of this Agreement or any obligation hereunder (except for the payment of money) is prevented, restricted or interfered with by reason of fire or other casualty or accident, strikes or labour disputes, inability to procure raw materials, power or supplies, war, invasion, civil commotion or other violence, compliance with any order of any governmental authorities or any other act or conditions whatsoever beyond the reasonable control of either Party hereto ("Force Majeure Event"), the Party so affected upon giving a prompt notice to the other Party shall be excused from such performance to the extent of such prevention, restriction or interference; provided, however, that the Party so affected shall use commercially reasonable efforts to avoid or remove such causes of non-performance and shall continue performance hereunder with the utmost dispatch whenever such causes are removed, to the extent commercially reasonable. The Party not seeking to rely on a Force Majeure Event shall have the right to terminate this Agreement with immediate effect if the Force Majeure Event continues for a period of ninety (90) days or more.

13.11 Publicity

The Parties agree to treat the existence of this Agreement, the terms and conditions hereof, the transactions contemplated hereby, and any proposed termination hereof as Confidential Information under Clause 5, provided, however, that each of the Parties may make a separate initial public announcement as to the Agreement. Prior to making any subsequent public announcements regarding this Agreement or the transactions contemplated herein, each Party agrees to provide the other Party with a reasonable opportunity to review and comment upon such proposed announcement.

13.12 Entire Agreement

This Agreement and the documents referred to herein constitute the entire understanding and only legally binding agreement between the Parties relating to its subject matter and supersedes all prior agreement or understandings between the Parties relating to all or any such matters. Each Party acknowledges that in entering into this Agreement it does not rely on any statement, representation, assurance or warranty (whether made innocently or negligently) that is not set out in this Agreement and further acknowledges that the development of the Licensed Products is experimental in nature and that Licensee makes no representation or warranty that it shall be successful.

13.13 Third Party Rights

A person who is not a Party has no right to enforce or to enjoy the benefit of any term of this Agreement. The consent of any person who is not a Party is not required to rescind or vary this Agreement at any time.

13.14 No Partnership

Nothing in this Agreement is intended to, or shall be deemed to, establish any partnership or joint venture between any of the Parties, constitute any Party the agent of another

Party, or authorize any Party to make or enter into any commitments for or on behalf of any other Party. Each Party confirms it is acting on its own behalf and not for the benefit of any other person.

13.15 Further Assurance

Each Party shall, and shall use all reasonable endeavours to procure that any necessary third party shall, promptly execute and deliver such documents and perform such acts as may reasonably be required for the purpose of giving full effect to this Agreement.

[Signature Page Follows]

IN WITNESS WHEREOF, the parties have executed this Agreement effective as of the Effective Date.

INNOVET ITALIA S.R.L

By: (signed) Renato della Valle
Name: Renato della Valle
Title: CEO

FSD PHARMA INC.

By: (signed) Raza Bokhari, MD
Name: Raza Bokhari, MD
Title: Executive Chairman & CEO

[Commercially sensitive information redacted]